



Hans J. Michael GmbH

MT-Messtechnik



Are You Dressed For Success?

Autor: Franck Bureth

Increasing productivity while maintaining environmental quality and regulatory compliance is an important challenge for cleanroom teams and requires solutions that address the root causes of contamination events. In this article the human causes and resulting impacts of cleanroom contamination are discussed, along with approaches that pharmaceutical managers can take to mitigate them, while also building a more productive cleanroom operation.

Cleanroom Contamination – The Human Element

Studies show that the behaviour and preparation of personnel is responsible for a large proportion of contamination issues in cleanrooms. Human error is responsible for over 80% of process deviations in pharmaceutical manufacturing environments(1).

Such contamination issues come in many forms. For example, 30% of all microbial detections in parenteral drug manufacturing are found on the surface of operator clothing, which is regularly contaminated during complex donning(2) procedures.

Contamination risks from the body, undergarments or degraded garment fibres are possible when there is a gap in the barrier. Cleanroom operators are trained to minimise unnecessary movement or talking to reduce such issues, but this is a difficult challenge in even

basic manual operations – there are over a billion microbes per droplet of saliva(3) and thousands of shed skin particles can be ground to as small as a micron during simple movements such as walking.

The results of such contaminations are significant and lead to billions of dollars being wasted each year in write-offs, shutdowns and lost productivity(4). In 2012 nearly a third of the US sterile injectable drug industry's manufacturing capacity was off-line due to quality issues, according to a Congressional report(5), with knock-on effects on patient safety worldwide. It is time the industry implemented more effective approaches to mitigate contamination.

Design over training

In the majority of cases further training is often

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prescribed when human error is identified as the cause of a contamination event or GMP deviation(1), possibly along with removing the operator until they are re-qualified in aseptic gowning. Such training can take up a significant amount of time and resources, with an average site spending over six hours a week performing ongoing aseptic gowning training, adding up to thousands of hours across the industry(2).

However, studies have shown that training is responsible for less than 10% percent of the deviations related to performance(1). Therefore, although training can reduce the risk of human error during gowning, alternative solutions for reducing contamination associated with people may produce better results without affecting productivity to the same extent.

One such solution is better garment design. Cleanroom apparel with more intuitive folding and donning mechanism between areas such as the coverall, hood and over boot, along with an optimised donning process can reduce both contamination risk and the potential for human error. Real-time observation of personnel gowning techniques are required during GMP inspections(6); a clear sign that it's a critical point to consider when selecting a preferred cleanroom apparel solution.

Better design can also lead to an increase in cleanroom productivity; reducing the time it takes to perform compliant aseptic gowning by just two minutes can free up over a thousand hours a year(7), as well as lead to a reduction in training time. In addition, better design results in more comfortable cleanroom clothing, which has been shown to result in fewer operator errors(8).

Protect processes and people confidently with single-use clothing

Although better designed cleanroom gowns results in fewer gaps between individual garments through which contamination may pass, microscopic damage of fabric can also cause contamination events. Such decline in the barrier occurs over time due to damage and through regular usage cycles of wearing/washing/sterilisation(9).

Kimberly-Clark Professional™ has found that this decline in barrier performance occurs more often in reusable clothing than in single-use alternatives when single-use coveralls are assessed against laundered garments by measuring their bacterial filtration efficiency (BFE). BFE is a common measure of filtration efficiency that can be correlated to contamination risk and takes into account the actual wear and tear of garments in the cleanroom.

In addition, a recent public study has started to provide guidance on how to consider the decline of performance throughout the lifetime of a reusable garment(10). Of course, the selection criteria may vary upon specific needs but the single-use solution removes variability, ensuring consistent performance every time.

Disposable cleanroom garments can also be more cost-effective. The McIlvaine report(11) shows that disposable clothing can have a lower 'cost-per-use' than reusable garments. 'Cost-per-use' takes into account apparel purchase price, as well as the average number of laundering cycles and laundering cost per item, per use (which are both zero for single-use garments).

When disposable cleanroom clothing's cost-per-use is combined with the productivity increases and cost-savings resulting from reduced contamination events, it is clear that such clothing is extremely attractive from a financial standpoint. However, the cost of disposal should also be considered, and this can be minimised through effective recycling programs.

Improving sustainability through material reuse

Ensuring garment sustainability is vital to the acceptance of disposable clothing, and requires an analysis of energy and material used throughout the product lifecycle (from manufacturing, through re-processing, to eventual disposal). Several studies on sustainability, such as the McIlvaine report(11) have found that reusable cleanroom garments can have a larger overall impact on environmental resources than single-use garments, consuming up to 4.5 times more resources.

Modern materials offer new opportunities for reducing waste through recycling, such as in Kimberly-Clark Professional's Right-Cycle* program. This initiative helps pharmaceutical companies to improve sustainability by collecting used apparel and gloves and upcycling them into eco-friendly products such as furniture and bike racks (that can in turn be recycled again).

A comprehensive solution to cleanroom contamination control

The wide range of issues resulting from contamination control that have been explored in this article are multi-faceted, and require a mitigation approach that addresses all aspects of clothing use and disposal. Documented and enforced training programs, verified ongoing adherence to the latest regulatory compliance, and effective disposal and recycling procedures can all be combined to create

Reference & bibliography:

- (1) Ginette Collazo. "Reducing Human Error on the Manufacturing Floor." MasterControl, 2010.
- (2) Damon Larkin. "Donning by design." Cleanroom Technology, 2010.
- (3) <http://www.rdhmag.com/articles/print/volume-29/issue-7/columns/the-landers-file/oral-bacteria-how-many-how-fast.html>
- (4) Katie Thomas. "Lapses at Big Drug Factories Add to Shortages and Danger." The New York Times, 2012.
- (5) 2012 Report FDA's Contribution to the Drug Shortage Crisis.
- (6) FDA Compliance program guidance manual, Nov 2015.
- (7) A 2 minute reduction in gowning time for a site with 100 cleanroom entries a day equates to a saving of 1,117 hours/year (2 minutes/entry x 100 entries/day x 335 days/year = 67,000 minutes/year = 1,117 hours/year).
- (8) How our clothing affects our work, Hohenstein Institute, March 2011.
- (9) Romano, F.; Ljungqvist, B.; Reinmüller, B. et al. (2016). Performance test of technical cleanroom clothing systems, Proceedings of Indoor Air 2016, 14th International Conference on Indoor Air Quality and Climate, paer#990, Ghent, Belgium, 2016. [Nr. 245692] <http://www.isiaq.org/docs/Papers/Paper990.pdf>.
- (10) A life cycle assessment of reusable garment properties, Cleanroom Technology June 2017.
- (11) McIlvaine Company. „A White Paper on Performance, Cost Per Use, and Environmental Impact of Single-Use and Reusable Surgical Gowns & Drapes.” 2009.

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a safer, more productive and sustainable operation. High quality clothing design plays a vital role in this.

Kimtech™ A5 Sterile Cleanroom Apparel has been designed to provide this solution. The Kimtech™ SMS (Spunbond/Melt-blown/Spunbond) fabric provides strength, cloth-like comfort and a strong barrier for fine particles and liquids. Its middle layer acts like a filter which traps particles while maximising airflow to keep the wearer cool and comfortable. In addition, the sterilisation process, involving gamma irradiation of the polymers, occur on only a single garment at a time, so the apparel's protective properties are consistently maintained.

Proprietary CLEAN-DON™ technology ensures gowning is simple to learn and minimises contamination during the donning process(2). The garments are uniquely configured with inside-out folding, and with arms and legs pre-drawn and snapped in position, reducing the risk of touching the outside of the suit(2), or any other surface while gowning. In addition, the vacuum packaging is not

only a way to extend the sterile validity but also acts as a visual sterility breach indicator.

By demonstrating how optimised cleanroom clothing can reduce contamination and form part of a system that produces better results at a lower cost, Kimtech™ aims to support continuous improvement across the Pharmaceutical industry. Well-designed disposable cleanroom garments have been shown to be cost-effective and sustainable, while also providing improved contamination protection and greater comfort for pharmaceutical cleanroom operators. Cutting down on the human based causes of contamination leveraging disposable apparel leads to increased productivity and a reduction in operator training requirements, cleanroom downtime and drug shortages – truly assisting modern cleanrooms to dress for success.

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June 2019

Dear subscribers,

for the current issue of our newsletter we have again compiled some interesting articles, among them:

Are You Dressed For Success?

Pharmaceutical Cleanroom Monitoring Software Solution

Spotless – The new certified cleanrooms at the maxon headquarters in Switzerland ...

Manufacturing and commercialisation of components for high purity stainless steel tube systems

Development of biologics: The market requires short development times and high productivity

**Hermetically tight design:
Aseptic diaphragm pump technology ensures maximum production safety in food industries**

ISPE's 2019 Facility of the Year Award for Operational Excellence

...

I wish you interesting reading.

Yours sincerely,


Reinhold Schuster



Pharmaceutical Cleanroom Monitoring Software Solution



Particle Measuring Systems releases the new Pharmaceutical Net® Pro Environmental Monitoring Software for FacilityPro® Environmental Monitoring Systems.

Particle Measuring Systems® (PMS) introduces the new Pharmaceutical Net® Pro cleanroom monitoring software for data and collection management, reporting and automation built on an industrial automation architecture. The software is used with FacilityPro® Processors which connect directly to environmental sensors, including viable air samplers and non-viable particle counters, temperature/humidity sensors, HMI stations, as well as light towers for visual alarm indication.

Pharmaceutical Net Pro software meets all relevant regulatory requirements including 21CFR Part 11 for data integrity. As a GAMP 5 Category 4 software, it is easy to install with reduced validation time. Pharmaceutical Pro software offers flexible integration options to handle a variety of sensors. It can be used in cleanrooms for filling lines, isolators, RABs, lyophilizers, biosafety cabinets and flow hoods, as well as general cleanroom and overall facility monitoring. The software offers intelligent features such as facility mapping, alarming, reporting, and recipe-driven sampling. Up to five clients can be used for remote access and viewing of data.

“Pharmaceutical Net Pro software is the next generation in cleanroom data management. This new software builds on the long-term success of our original Pharmaceutical Net solution while providing the flexibility for long term growth,” said Paul Hartigan,

PMS Global Product Line Manager for Systems and Software.

About Particle Measuring Systems

Particle Measuring Systems Inc. (PMS), a subsidiary of Spectris plc, is a global technology leader in contamination monitoring, the inventor of laser particle counting, and is now the leading provider of solutions for monitoring and controlling many forms of contamination that impact companies that manufacture in ultra-clean environments.



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The screenshot displays the 'Particles counter 1' software interface. It features a grid of eight monitoring panels (PC01-PC08). Each panel shows a 'State' and 'Edit' section with a table of particle counts for different sizes (0.5, 5.0, 5.0, 5.0 micrometers). Below this, there are sections for 'Sampling Mode', 'Clean Time', and 'Flow Alms', 'Core Alms', and 'Laser Alms'. The interface includes a navigation panel at the bottom left and a status bar at the bottom right with options like 'Log In', 'Log Out', 'Sampling', 'Recipes', 'User Event', 'Alarms', 'Report', 'Limits', 'Analog Limits', 'RT Trend', and 'System'. The top right corner shows the date and time '19/10/2018 23:53:45' and user information 'Logged user: asctec Group: Installer'.



Spotless

Autor: Adrian Venetz, maxon

The new certified cleanrooms at the maxon headquarters in Switzerland, before and after setting up the first assembly stations. Medical technology has no tolerance for error. This is why maxon micromotors are made in certified cleanrooms. This kind of special facility takes significant effort to build.

Cleanrooms are needed in all kinds of industries — e.g., medicine, food technology, and the semiconductor industry. Using cleanrooms to make electric motors seems a little odd at first. However, that's exactly what maxon has been doing since early 2019 in its new Innovation Center in Switzerland. In more than 1200 square meters of cleanrooms, drives can be made under strict hygiene standards. However, to what end?

Making a powerful motor, for example to be used in industrial automation, takes engineering skill, good workmanship, and a clean environment — but not a cleanroom. The new cleanrooms are used for making maxon's miniature drives: Motors with diameters of only a few millimeters. This type of drive is used especially in medical technology. maxon is already a strong partner when it comes to drives for medical applications, such as insulin pumps or hand-held surgical tools. With the new cleanrooms however, the Swiss drive specialist is getting ready for even more finicky and delicate applications, such as implantable drive systems for heart pumps.

Months of planning

"Planning a certified cleanroom was a new and exciting challenge for us," says Christian Kunde, project manager at maxon medical. It was a lot of effort. "The planning took about 15 months and was done in cooperation with external experts." Indeed: At first glance, it's just a series of clean areas with lots of assembly stations and microscopes, separated by glass windows. The technology is literally hidden behind the scenes: In the partitions and in the ceiling, there are whole arrays of pipes and kilometers of cables.

The equipment is necessary, among other things, to generate a higher air pressure in the cleanrooms. How does this work? When the airlock to a cleanroom opens, then clean air flows to the outside and prevents contaminated air from coming in. Leaving all the doors open would be the equivalent of a deadly sin. In order to prevent this from happening in the first place, cleanrooms have airlocks in which the air pressure is slightly lower than inside but still

Spotless

higher than normal. Other equipment prevents that the two doors of an airlock are open at the same time. “So you won’t be able to shout at me from the other room here,” Christian Kunde chuckles.

The particle concentration in the air is measured every minute. In addition to cleanrooms, maxon now also has what’s called a GMP area (good manufacturing practice). In this area, not only the particle concentration is measured, but also the microbiological contamination of surfaces and the air with germs, bacteria, and fungi — again with an eye on future applications in medical technology with implantable micro drives.

Air is “diluted” continuously

Cleanrooms come in several certification classes. The maxon cleanrooms are among the more “pleasant” ones. While the employees need to take a variety of measures before and during work,

such as wearing a hair net and special clothes, they are not in a completely different world. This is different in nanotechnology, the pharmaceutical industry, or semiconductor production. Workers in these industries sometimes look like they’re on a different planet. The equipment for keeping the particle concentration low is also different: In the maxon cleanrooms, there is a constant flow of filtered air coming in. This air disturbs the air in the room, which in turn is extracted and filtered. This continuous exchange effectively “dilutes” the air with respect to particle concentration. A different type of technology, one that is used in operating rooms, is called “laminar flow.” In this technology, filtered air flows from the ceiling to the floor. The goal is not to disturb the air, but instead to prevent particles from “floating” in the room altogether.

maxon motor gmbh
D 81825 München



These windings in the cleanroom of maxon in Switzerland are ready for use. They will soon serve in brushless micromotors with a diameter of 6 millimeters. These midgets are in high demand, especially in medical technology. The enameled copper wire has a diameter of less than 0.07 millimeters, about the thickness of a fine human hair.



Fig.1: Working in a clean room environment

Manufacturing and commercialisation of components for high purity stainless steel tube systems

Assurance of quality even for welds created by the customers

Weldability as significant product feature

As manufacturer of components for high quality stainless steel tube systems the family-owned German company Dockweiler has got a worldwide leading position in the field of tubing for semicon-

ductor, pharmaceutical, biotechnological, and photovoltaic applications. A major proportion of the manufactured products has to be assembled from individual parts which must be joined by welding, so welding competence is a vital objective of its corporate philosophy.

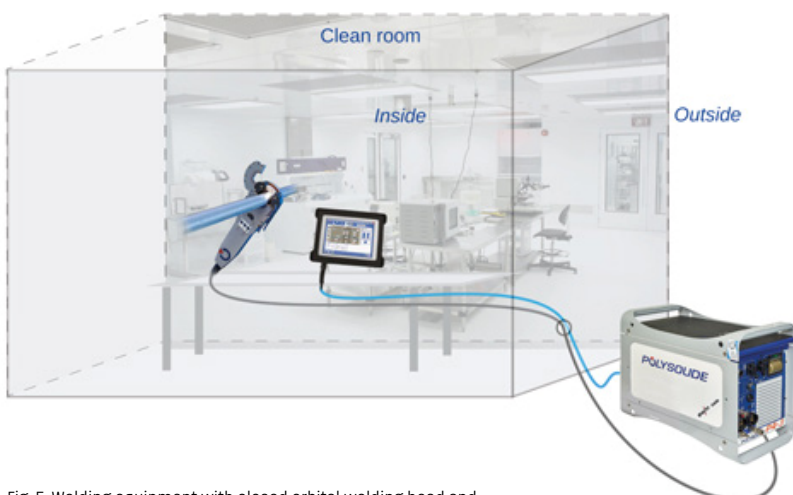


Fig. 5: Welding equipment with closed orbital welding head and touch screen inside the clean room and the power source outside in the service area.

Like other companies which depend on the soundness of their welding technology Dockweiler has implemented a system of efficient quality assurance procedures, but additionally to its proper joining activities it is primordial for this manufacturer to care about an at least sufficient quality level of the welds created by their customers.

No matter whether components with simple geometries like tubes, elbows, T-pieces, reducers or caps are demanded or complex units, e.g. manifolds or valves, have to be supplied, all of them are designed to become an integral part of a tube system for the distribution of high purity liquid and gas media at a high-tech production site.

Comprehensive inspection of incoming shipments

At Dockweiler's a comprehensive inspection for all incoming shipments is obligatory. Semi-finished products

Manufacturing and commercialisation of components for high purity stainless steel tube systems

are only accepted if accompanied by valid in-shop testing certificates, the chemical composition of the materials is analyzed in a systematic manner and must comply with the standards or agreed limits, the geometry of the parts must not exceed the specified tolerances, and the mechanical properties and corrosion resistance must meet at least the expected values.

All parts which have passed these tests successfully are then reviewed for their weldability. After a visual examination of a few preliminary welds the experts are generally able to ascertain the parameters which have to be programmed for orbital welding of test coupons. The welds of these coupons are analyzed thoroughly: general visual impression of the weld seam, geometry at the inside and outside on the entire circumference of the specimen, surface appearance, presence of discoloration etc. Furthermore, cross-sections of the welded tubes are prepared for macrographic exploration: uniform and satisfying penetration in all positions, dimension of the heat affected zone, tendency to form coarse grains, and possible occurrence of segregation. Completed by determinations of the mechanical properties of the welded zones and their corrosion resistance the results are used for a final improvement of the welding parameters. Differently to the joining of tubes or pipes with more important diameters the arc time of these small parts is quite short and a possible increase of the welding speed would not cause substantial economic advantages, so the optimization can be concentrated exclusively on the tangible quality of the welds. An example of a completed form indicating the resulting welding parameters for a particular heat and batch of a certain material is

shown in Fig. 2.

Internal specifications merge the most stringent requirements

Now it can be checked whether some or even all of the input materials qualify for Dockweiler's in-house regulations. These regulations are laid down exclusively for internal use and consist of a compilation of the most stringent requirements of all applicable codes and standards. Components which are manufactured in accordance with these regulations can be supplied to any customer, independently of the specific codes which have to be respected in the particular case.

Otherwise, the materials are ranked according to a more extensive system within a range of marks from 1 to 5. Based on this ranking the best subsequent use for each of the batches is decided. Due to their individual properties some batches may suit better for pharmaceutical purposes, whereas others fit perhaps perfectly for semiconductor processing. According to Dockweiler's experience a classification of 3 or better is absolutely necessary if the parts shall be provided for semiconductor applications.

Sophisticated welding technique

The proper material quality and geometry of the workpieces to be joined are essential prerequisites to obtain best welding results, but the process, the equipment, the consumables, the environmental conditions etc. must meet the same strict requirements.

Welding Parameters
GTA Orbital Welding

466

DOCKWEILER
Fm. 7.5.1-60 E
2015-02-06

Reference / Customer AA 8.2.4 - 47	Drawing no.	Weld ID
WPS # 3810165-wAr		

Welding Parameters					
Programparameter					
N °	0	31	52	53	54
T10 - sek	35				
T30 - sek	4.5				
N30 (D) - °	0				
D - mm	18.1				
V32 (D) - mm/min	85	85	85	85	
I22 - A	68	66	54	62	
I23 - A	23	23	23	23	
T22 (D) - ms	119	119	119	119	
T23 (D) - ms	218	218	218	218	
T11 - sek					30
N20 (D) - °					370
T25 - sek					10

Work Piece	Strip	<input type="checkbox"/>
Tube	<input checked="" type="checkbox"/>	
Diameter	38.10	mm
Wall	1.65	mm
Material	S31603	
Heat No.	851.819	
Batch No.	1230 263501	
DW No.	K4 6555	
MTR attached	<input checked="" type="checkbox"/>	

Type of Weld	buttjoint
Welding Machine	Type Polykoude P4-2
Weld Head	460 40
Filler Metal	Type <input checked="" type="checkbox"/>
Material	<input checked="" type="checkbox"/>
Electrode as per DIN EN ISO 8848	Length <input checked="" type="checkbox"/> mm
Distance	1.0
2% ThO ₂	<input type="checkbox"/>
W52	<input checked="" type="checkbox"/>
Welding Gases	Shielding Gas Argon 5.0
Flow Rate	20 l/min
Backing Gas Argon 5.0	Flow Rate 15 l/min

Welder	Name R. Linder Hvy
Date	20.11.2017
Welding Supervisor	Name Robert B. B. B. B.
Date	24.11.2017

8-Ferrite	Mean	Min. value	Max. value
(%)	5.3	4.7	6.5

Q/Qualitätswesen/ QM-System_ ISO9001

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Fig. 2: Optimized welding parameters for a particular batch of material.

Welding Procedure Specification

DOCKWEILER

WPS No.	WPS-3810165-wAr	Rev. no.	1	Supporting PQR No.	PQR-5082165-wAr	by	Robert Rossmann
Date	21.06.2016	Signature	<i>R. Rossmann</i>	Welding process	GTAW		
Standard	ASME IX and DIN EN ISO 15614-1						

Joint design	see drawing
Backing	No
Backing material	No
Root spacing [mm]	0 - 0.2
Non fusion retainers	No
Wall thickness t or t _h [mm]	1,65
Diameter D [mm]	38,10

Base Metal	ASME P-No. / Group	8	ASME P-No. / Group	8
Sub-Group	1	to Sub-Group	1	
T Limits [mm]	ISO: 1.14 - 3.14 ASME: 1.50 - 3.30	T Qualified [mm]	1,65	
Pipe diameter range [mm]	ISO: 25.4 - unlimited ASME: unlimited	Group No. Qualified	8	

Filler Metal	Filler	without	Filler metal product form	-
Ø of Filler metal [mm]	-	Flux	-	
F-No / Material number	-	Consumable insert	-	
A-No / Denotation	-	Classification	-	
Spec. No. SFA	-	Position of Filler	-	

Positions	Position(s) of groove	5G / PK	Welding progression	rotating
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Preheat	PWHT
Temperature min. [°C]	RT
Temperature max. [°C]	RT
Temperature range [°C]	without
Time range [min]	without
T Limits [min]	No

Gas	Shielding gas	Argon (industrial pure)	Flow rate [l/min]	15 - 30
Backing gas	Argon (industrial pure)	Flow rate [l/min]	5 - 20	
Tacking gas (shielding/backing)	No	Flow rate [l/min]	No	

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Fig. 3: Welding Procedure Specification for the production of a specific component.

Manufacturing and commercialisation of components for high purity stainless steel tube systems

TIG welding is probably the best choice if delicate materials like stainless steel or nickel base alloys have to be joined. No fumes or spatter are generated by the process, the welds are smooth and uniform and the welding parameters can be optimized within a wide range to preserve the required characteristics of the sensitive base materials.

As every welder knows, joining of thin-walled tubes with small diameters by manual TIG welding always turns out to be a tedious task. Only well-trained and highly-motivated staff members with extraordinary skills are able to obtain the expected results; the lack of reproducibility and the extremely low productivity are some of the reasons why this method is avoided whenever possible.

Orbital TIG welding of tubes is an efficient way to gain productivity and to improve the quality of the obtained welds substantially. The TIG torch travels around the circumference of the tubes to be joined, guided by a mechanical system. The optimized welding parameters are programmed in advance and stored in the memory of the control device. Generally, the operator follows the instructions of the particular Welding Procedure Specification (a completed WPS for the assembly of a T-piece is shown in Fig. 3) of the respective component. When it comes to the joining process, he has to position the orbital welding head on the workpiece and start the welding cycle. The weld itself is carried out automatically without any need for the operator to intervene; after the end of the cycle it is up to him to release the properly joined workpiece.

Thin-walled tubes can be joined by autogenous welding, i.e. the

welds are completed without wire addition solely by melting and unifying the base material of both tube ends. This task can be accomplished perfectly by means of a closed orbital welding head as shown in Fig. 4. The entire welding zone remains inside the closed chamber of the welding head. Before, during, and after the welding operation the chamber is flooded with shielding gas, thus an accurate protection of the hot metal can be obtained. The torch is reduced to a tungsten electrode which is directly fixed on a gear inside the chamber and rotates around the tubes.

Acceptable welding equipment for clean room fabrication

To obtain the requested quality, Dockweiler's components for high purity applications are joined in a clean room environment as shown in Fig. 1. The atmosphere in such a clean room is controlled, i.e. the amount and size of floating particles are limited to specified values. A continuous flow of filtered air leaves the outlets under the ceiling and passes the clean room as laminar stream. Light particles are taken away by the stream and disappear together with the discharged air.

Human beings constitute an important source of particle emission in a clean room environment, therefore their skin and hair have to be covered as much as possible, and additionally they are instructed to move slowly. Many technical devices are banned from the inside of a clean room for the same reasons, especially if they disturb the laminar flow by hot surfaces or fans with powerful air

WPS No.	Rev. No.	DOCKWEILER	
WPS-3810/165-woAr	4		
Electrical Characteristics			
Tungsten electrode [Ø mm]	1,6 - 2,4	Amps (+/- 10%)	25 / 65
Welding current, Type/Polarity	DECN	Volts (+/- 10%)	not specified
Pulsing	yes	Tungsten type	WT20WS2
Heat input [kJ/mm] (+/- 10%)	not specified	Weld program	3810/165-woAr
Technique			
Gas cup size [Ø mm]	N/A	String or weave bead	string
Oscillation	No	Peening	not allowed
Electrode spacing [mm] (+/- 10%)	1	Type of chamber	N/A
Travel speed [mm/min] (+/- 10%)	90	Multiple or single pass	single
Multiple or single electrodes	single	Method of back gouging	None
Manual or machine	machine		
Method of cleaning	pickling, electropolishing or mechanical grinding		
Use of thermal processes	N/A		
Adjustment and tacking			
Heat input [kJ/mm] (+/- 10%)	if necessary, must be adapted to the wall thickness		
Manual adjustment and tacking	if necessary, see table (must be adapted to the component)		
Wall thickness	Distance between the tack points		
Up to 1,5 mm	10 - 30 mm, but min. 3 tack points		
1,5 - 2,5 mm	25 - 60 mm, but min. 4 tack points		
From 2,5 mm	50 - 80 mm, if necessary tack welds		
Remarks / Details			
Acceptance criteria for direct or remote visual examination of weld face and root as per Doc. 8.2.4-60. If either the weld face or the weld root cannot be visually examined by any means the welder/operator shall note "VT N/A" on the relevant manufacturing drawing. In such case, it is the responsibility of the welding supervisor to decide on an alternative and appropriate test method.			

Fig. 3: Welding Procedure Specification for the production of a specific component.

Weldability Complaint Report

DOCKWEILER
Fr. 8.5.2-3
2006.09.27

Date	Distributor	Contact distributor	COMPLAINT No.
Customer		Contact at Customer	
Customers site (location)		Direct phone number (cell phone) + eMail	
Type of product, e.g. tube, elbow, ...	Dimension [OD - wall]	Quality grade	
Purchase order / line item number	Delivery note / line item number	Delivery date	
Dockweiler no.	Job no.	Heat no.	
Description of complaint			
Brand of Equipment <input type="checkbox"/> AMI <input type="checkbox"/> Orbitec <input type="checkbox"/> Polysoude <input type="checkbox"/> Other			
Weld head <input type="checkbox"/> Type			
Type of gas inside <input type="checkbox"/> Argon <input type="checkbox"/> Argon + <input type="checkbox"/> % Hydrogen (H ₂) <input type="checkbox"/> N ₂ /H ₂ <input type="checkbox"/> Gas purity			
Type of gas outside <input type="checkbox"/> Argon <input type="checkbox"/> Argon + <input type="checkbox"/> % Hydrogen (H ₂) <input type="checkbox"/> N ₂ /H ₂ <input type="checkbox"/> Gas purity			
Liters per minutes inside	Liters per minute		
Diameter of the exit opening	mm		
Liters per minute outside	Liters per minute		
Tungsten electrode diameter	mm		
Gap electrode / work	mm		
Tungsten electrode	<input type="checkbox"/> ground by hand <input type="checkbox"/> ground by machine		
Tungsten electrode	* angle of tip <input type="checkbox"/> sharp tip <input type="checkbox"/> top flattened		
Tube ends faced?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Tube ends are cleaned?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
If yes, which solvent was used?	<input type="checkbox"/> Ethanol <input type="checkbox"/> Aceton <input type="checkbox"/> Isopropanol		
Welds are done	<input type="checkbox"/> in house <input type="checkbox"/> outside		
Corrective actions		Responsible	Due date
Preventive actions		Responsible	Due date
Report closed		Date	

Fig. 6: Dockweiler's Weldability Complaint Report.

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streams.

However, closed orbital welding heads are tolerated in clean rooms. Generally, an electric arc has always to be regarded as efficient particle generator, but in this case the released particles remain enclosed within the chamber of the welding head and can not contaminate the surrounding atmosphere.

Power sources for TIG welding generate waste heat which is dissipated by strong fans, so they are not at all acceptable within a clean room environment. On the occasion of a change of the welding equipment in Dockweiler's production line the French company Polysoude supplied power sources of the P4 family which have been especially adapted for this type of clean room application. The power source itself has been separated from the rest of the welding equipment and moved into the service area outside the border of the clean environment, only the operating panel and the closed welding head (Fig. 5) remain in the clean room.

The surfaces of the control panel with the integrated display are flat and easy to clean, no mechanical switches or other moving parts allow dust and dirt to be accumulated. Wearing of protective clothing presents no problem for the staff, as the soft buttons on the touch screen can be operated even with gloves. A graphic interface is used to indicate the progress of the current welding cycle, all important welding data is continuously monitored by a real-time data acquisition system.



Fig. 4: Closed orbital welding head

Programmable and non-programmable welding parameters

A finished weld is always the result of a vast number of influencing factors. Generally, these factors are referred to as welding parameters. When it comes to orbital TIG welding Dockweiler's experts talk about a total of several thousand parameters which contribute in a more or less important manner to a successful welding operation.

Some of the welding parameters affect the joining process so obviously that their setting is always carried out as a matter of course. In case of manual welding the operators are used to adjust or check these parameters routinely by means of the control elements of the power source, when automated TIG welding is applied the parameters have to be determined in advance and stored as a welding program. The corresponding parameters are also recognized as programmable welding parameters.

Within a typical program of an orbital welding cycle the following steps and their related parameters are specified:

- Pregas: Duration of flooding and purging the chamber of the closed welding head with shielding gas before the ignition of the arc.
- Ignition: Commonly carried out by a high frequency discharge.
- Welding current: As welding current serves usually pulsed DC, so the pulse time as well as peak and background current intensities have to be determined.
- Rotation: The linear welding speed is associated to the programmed rotational speed and the tube diameter.
- Sectors: To compensate the dissimilar influence of gravity in the different welding positions and the increasing temperature of the workpiece during the progress of the weld cycle, the creation of sectors may be useful. In a new sector a reduction of energy input can be achieved e.g. by an extended time span of the lower background current.
- Downslope: To avoid crater formation or cracks due to an abrupt turn off of the welding current the slowly decreasing current intensity at the end of the weld seam is known as downslope.
- Postgas: Duration of flooding the chamber of the closed welding head with shielding gas after the loss of the arc.

After a pertinent set-up of the welding equipment the programmed welding cycle can be executed as scheduled. The set-up of the equipment comprises its connection to the electrical power, shielding and backing gas supplies; the tungsten electrode to be mounted must consist of the specified alloy and have the proper geometry and exact length; and the clamping inserts of the welding head must match with the O.D. of the tubes to be welded.

Once the equipment is switched on the power source needs some time to warm up for an accurate control of the welding current intensities; shielding and backing gas flow have to be adjusted manually and a sufficient interval has to pass for the hoses and valves to be purged from humidity and oxygen. A reasonable number of test welds should be carried out to heat up the welding head and ensure that any remaining impurities can disappear from the inside of the device.

Now the equipment is ready and the production welds can be executed.

In summary, the set-up of orbital welding equipment is a rather

Manufacturing and commercialisation of components for high purity stainless steel tube systems

complex procedure. The programmable parameters and their values are stipulated in the welding program, whereas the instructions for putting the devices into operation and adjusting or checking the rest of the remaining non-programmable parameters should be documented as precise as possible in the WPS.

Orbital welding in the factory or on site

Automated welding equipment is designed to repeat a programmed welding cycle as often as desired. A good welding result is reproducible as long as the surrounding conditions can be kept sufficiently constant. Dockweiler's experts profit from their excellent knowledge of the welding production line in the factory and care thoroughly to avoid any deliberately caused modifications or changes. Additionally mounted devices support a constantly high quality level of the produced welds: a drying and cleaning unit prior to the consumption point improves the purity of the supplied shielding and backing gas substantially; a measuring instrument indicates the remaining oxygen content of the backing gas at the outlet vent, so the purging efficiency can be assessed and any waste of gas and time can be prevented.

Finally it's not surprising that as a result of these efforts a constantly high quality level of the produced welds can be preserved. But, as mentioned in the beginning, up to now only half of the expert's mission has been accomplished.

To accomplish their task, the experts are challenged to make certain that Dockweiler's components are welded perfectly by the customers as well.

Arc welding on a construction site is always a difficult endeavour. Differently to a production line in a factory a lot of conditions can not or rarely be controlled. The only available electrical power supply is often interrupted, instable or with a too much shifted phase angle. Environmental conditions may be subject to strong fluctuations, differences in temperature and high atmospheric humidity can cause detrimental effects to equipment and consumables, sufficient protection against dirt and dust is not always possible.

As consequence of such unsatisfactory situations the whole range of weld defects can occur: lacking or excessive fusion, inadmissible weld seam geometry, porosity and heat tint, just to name some of them. Unnecessary to mention that due to those defects the mechanical characteristics and the corrosion resistance of the joints become irrecoverably corrupted.

But poor welding results of the customers can also have other causes: wrong set-up or unprofessional handling of the equipment, error in the welding program, inferior quality of tubes and/or consumables, defective equipment, etc.

If a customer calls for support he will be asked to provide detailed technical information about the application, the employed equipment and the specific problem and to fill out Dockweiler's questionnaire "Weldability Complaint Report" (Fig. 6). The experts have to figure out whether the involved staff of the customer is sufficient familiar with the equipment and experienced enough in the field of the particular welding task so that wrong set-up, inadvertent connections, erroneously loaded programs, mistakenly selected materials, inadequate positioned workpieces and other typical beginner's mistakes can be excluded.

Another important question is whether the problem occurred

from the very beginning of the work or if the customer arrived to finish some joints successfully before the campaign failed. Most fundamental programming errors can be easily revealed by the experts – if the program is available. Companies with established welding expertise have often invested considerable amounts of time and money to develop their own reliable procedures and to get the necessary experience, so they consider their know-how as corporate secret which is not allowed to be published to anyone. However, although this point of view is understandable it does not really contribute to a quick and efficient solution of a specific joining problem.

At the first attempt, the Dockweiler experts try their best to deal with the welding problems remotely, but improper operation of electronic components, leakages in the gas supply, temporarily occurring failures and other serious incidents can hardly be analysed without being present on site. In these cases, in agreement with the customer, an on-the-spot support will be organised. Sometimes, rather complex difficulties can only be solved with assistance from the equipment manufacturer. The Dockweiler experts are used to cooperate closely with the service technicians of the respective producer, especially the Polysoude After Sales Service enjoys an excellent reputation concerning targeted advice and immediate action.

Regardless of whether a customer had been bothered by a slight inconsistency of his welding results or faced serious quality problems with his joining technique, in the past the Dockweiler experts always succeeded to find a satisfying solution, and they are firmly decided to do their utmost in the future as well.

Conclusion

Manufacturing of components for high grade stainless steel tube systems in the field of hygienic applications requires a rigorous inspection of all incoming semi-finished products, a distinctive classification concerning the weldability of the used materials and, last but not least, sophisticated production methods. Autogenous orbital TIG welding is considered to be the most appropriate process to ensure a constantly excellent joint quality of the thin-walled tubes. Polysoude, a French company and worldwide leader if it comes to automated TIG welding systems, offers reliable equipment which is customized to be operated in the particular clean room environment.

The unrivalled standard of the produced components is an essential precondition to meet the strict criteria of hygienic pipework, but a sustainable commercialisation of these parts can only be maintained if the customers obtain extensive advice and technical support. Especially the joints made by the customers in their factory or on a construction site deserve close attention. Therefore Dockweiler makes available the related data, e.g. proofed welding parameters, but in case of serious problems the customers are also invited to consult the renowned welding experts of the company. Due to their experience or in close cooperation with the specialists of the equipment manufacturer they arrived in the past to find always an acceptable solution for each problem and they are confident to continue in the same way.

Exyte honored 'Excellent Supplier of the Year' by HLMC



Exyte, the global leader in the design, engineering and construction of high-tech facilities, plants and factories, received the "Excellent Supplier of the Year" Award from Shanghai Huali Microelectronics Corporation (HLMC) on March 19, 2019.

The award is in recognition of Exyte's exceptional performance in the delivery of HLMC's new 300mm wafer fab manufacturing facility in Shanghai, China. The wafer fab will provide HLMC, a pure-play foundry with their most advanced 300mm manufacturing capability for semiconductor ICs including new products based on 14nm FinFET process technology.

Exyte served HLMC as the key contractor delivering high tech cleanroom and related sub-systems, as well as process-critical facility systems. As the global leader in the design & build of

semiconductor facilities, Exyte successfully contributed its vast experience to this project and fully met customer's needs. One of the most important factors here is to ensure that the sensitive silicon wafers being processed are continuously maintained in an ultra-clean and controlled environment and supplied with high purity/process-critical media at the process equipment.

Through more than a decade of partnership, Exyte has realized several semiconductor projects for HLMC in Shanghai, China.

Junjun Tang, President of HLMC, said: "HLMC is developing very quickly. The support of our vendors and contractors is important to contribute to our growth. This award to Exyte is significant as it is the first time HLMC has presented an excellent performance award to a construction contractor."

Herbert Blaschitz, President of Exyte's Global Business Unit Advanced Technology Facilities, received this award on behalf of Exyte. "We are very proud to receive this award from our customer HLMC. It highlights Exyte's focus on delivering engineering excellence as well as the commitment to our customers for high-quality project delivery that is on time and on budget."

"The Asia Pacific region is the most important market for Exyte. This award by HLMC is an acknowledgement of Exyte's leadership in the design and construction of highly controlled clean-room environments. We strive to expand and bring our field of expertise to support the requirements of customers in the semiconductor, pharmaceutical, biotechnology, chemicals and data center industries," states Mark Garvey, President of Exyte Asia-Pacific.

Exyte was awarded the contract by HLMC to design and build its new facility in Shanghai, China. The 300mm advanced production line project with a capacity of 40K wafers per month is the biggest integrated circuit investment project in Shanghai. The new facility works by Exyte include a 34,000m² cleanroom, mechanical, electrical and process distribution and plant systems. As a result of the close cooperation between HLMC and Exyte China, the project was completed in 16.5 months, 45 days ahead of its planned schedule.



From left to right: Junjun Tang (President of HLMC) and Herbert Blaschitz (President of Exyte's Global Business Unit Advanced Technology Facilities)



Award winners: Excellent Supplier of the Year by HLMC.



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Development of biologics: The market requires short development times and high productivity

Using a high-speed workflow to generate a production cell line



"It is our aim for all biologics to be manufactured to the same level of quality at their designated destination as they are in our laboratory. This not only includes a stable monoclonal cell line but also the First CHOice cell culture medium and the manufacturing and purification process," explains Dr Lars Kober, Managing Director of UGA Biopharma GmbH. (Source: UGA Biopharma GmbH)

Biologics offer new therapy options for numerous diseases: They are already used to treat cancer and autoimmune diseases such as rheumatoid arthritis as useful alternatives to standard therapies. The extent of their market potential is revealed by the fact that the number of patent applications has been on the rise for decades now. However, the route from the lab to mass production is much more complicated for biologics than for conventional drugs. The desired biomolecules (biologics) are manufactured using living systems, consequently a careful development and selection process of the cell line to be used, as well as thorough checks, are absolutely essential in order to ensure straightforward production later. For this reason, contract developer UGA Biopharma GmbH has developed a high-speed cell line development workflow including analytics, purification and bioprocess development in bioreactors. Using an optimised expression vector means that highly productive clones can be generated. In this way, monoclonal and highly productive cell lines can be developed within just four months, and an optimised bioprocess within a further three.

Traditionally, drugs used in chemotherapy or antibiotics were produced using chemical synthesis. By contrast, biologics are manufactured using genetically modified, living cells in bioreactors. Many factors can significantly influence the quality of biologics manufactured in this way, including process conditions during manufacturing, such as temperature during fermentation, pH, dissolved oxygen concentration and nutrient supply and, of course, the cell line used. If the cell line is contaminated or the isolated monoclonal cell lines (clones) are unstable, the drug may end up being unusable – with correspondingly high financial losses for the manufacturer. For this reason, UGA Biopharma GmbH pays particularly close attention to the productivity, stability and quality of the clones when developing new cell lines. As a result of its specially optimised processes and many years of experience, the company only requires seven months for the development of a cell line, including bioprocess development and the

development of a purification process, in addition to providing of all necessary analytical data.

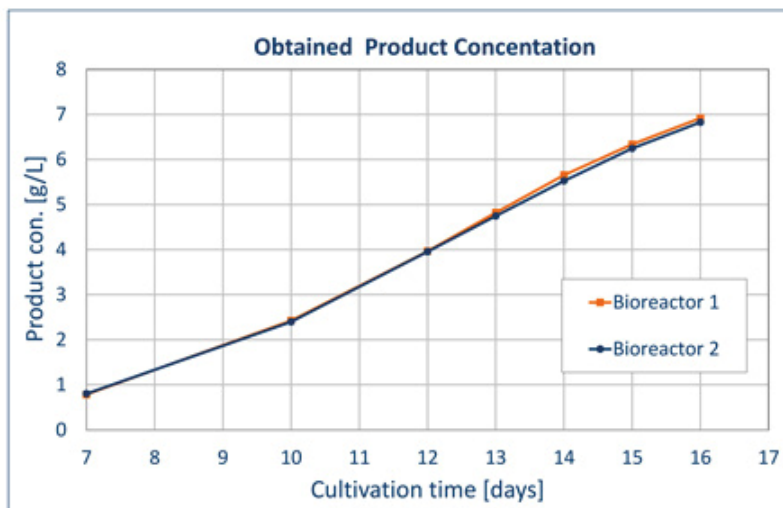
From concept to production cell line

UGA Biopharma's work starts with a biomolecule: "If a biomolecule with a potential therapeutic effect is identified during the course of research at a university or a company, this may be an interesting discovery but it is still a long way from becoming a product. Often, research institutions and companies do not have the necessary expertise or capacities to quickly turn interesting discoveries into biotherapeutic products, or biologics," explains Dr Lars Kober, Managing Director of UGA Biopharma GmbH. "This is where contract developers like us come in: We develop highly productive cell lines which are able to produce the desired biologics with high yields." To do this, the molecule first needs to be characterised in order to determine the desired quality attributes and the gene of interest (GOI), which will then be transferred into the company's own expression vector. "In recent years, we have optimised the expression vector and cell line generation work flow to such an extent that we are able to create highly productive stable production cell lines within a very short period of time, achieving product concentrations of up to 7 g/L," Kober adds.

In recent years, a Chinese hamster ovary (CHO) cell has proven particularly well suited. During cell line development, the expression vector is introduced into this CHO cell, creating a mixture of cells with different characteristics. Using single-cell cloning, highly productive monoclonal cell lines (clones) can then be isolated, cultivated and used to create cell banks for long-term storage at 196°C.

Searching for a suitable clone

"Generally speaking, pharmaceutical companies



Testing highly productive cell lines in bioreactors. (Source: UGA Biopharma GmbH)

Development of biologics: The market requires short development times and high productivity

have many requirements of the isolated cell lines, such as scalability, monoclonality and, of course, high productivity and clone stability,” Kober explains. “In addition, the biologics should neither trigger immunogenic reactions in patients nor should the production cell lines be contaminated with viruses or mycoplasma.” For this reason, the company acts in accordance with the requirements of the European Medicines Agency (EMA), which is responsible for the evaluation and monitoring of drugs. During the development process, the company also conducts glycan analyses in order to obtain useful information about the selection of promising clones early on in the process.

The isolated clones are then expanded in the next step: “Usually, therefore cells are cultivated at lab-scale in shake flasks. Many contract developers leave it at that.” However, in order to guarantee the scalability of the cell lines, the laboratory staff then carry out a process transfer into bioreactors and derive a suitable bioprocess from this.

“But even the ‘best’ cell line is of no use to the pharmaceutical company if it cannot be cultivated and the manufactured biological drug cannot be purified,” Kober notes. As a result, UGA Biopharma does not restrict itself to the optimisation of the manufacturing process in bioreactors. Furthermore, the right purification process

is also developed and the potency of the purified biologics is tested via various binding assays and in different cell culture models. If necessary, an optimised cell culture medium can also be provided for the cell lines and the developed manufacturing process. Normally the company’s own culture medium, First CHOice, is used, which was developed by UGA Biopharma. With the aid of this medium and the relevant feeds, both the product concentration and thus the cost of goods achieved in the final manufacturing process, as well as the product quality of the manufactured biologics, can be influenced advantageously.

Short development time is a prerequisite

In total, it only takes seven months until the developed cell line can be supplied: four months are required for the cell line development and three for the bioprocess development, the development of the purification process and for analyses to be carried out. “Short development times are essential in the pharmaceutical industry because patent protection for pharmaceuticals generally expires after 20 years,” Kober emphasises. “In this time, all phases of the technological development, various clinical trials including the marketing authorisation procedure has to be completed as quickly as possible because the profit margins for the drugs developed generally drop sharply once the patent protection has expired. Every month counts here because short development times facilitate early market entry and thus the profit is secured before the patent expires.”

Once development is complete, the company supports its customers where necessary with the process transfer to the manufacturing facility and is always on hand if there are any problems. “It is our aim for all biologics to be manufactured to the same level of quality at their designated destination as they are in our laboratory. This not only includes a stable monoclonal cell line but also the First CHOice cell culture medium and the manufacturing and purification process,” Kober confirms.



Developing purification processes for biologics. (Source: UGA Biopharma GmbH)

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Cultivation of clones in 96-well plates during cell line development. (Source: UGA Biopharma GmbH)

Hermetically tight design: Aseptic diaphragm pump technology ensures maximum production safety in food industries

Best technology for high-pressure homogenization

Author: Dr.-Ing. Hans-Joachim Johl

Short-term thermal treatment is used in the food industry for a wide range of products such as milk, mixed drinks or liquid foods. This treatment kills off any pathogenic micro-organisms and extends the shelf life of the products. Since high-pressure homogenization may not re-contaminate food products after thermal treatment, it must be ensured that all components being used have a hygienic or – even better – aseptic design, material selection and integration. To date, packed plunger pumps have primarily been relied upon as the type of pump technology installed in these applications. However, in terms of aseptic production safety, using these pumps is only the second-best choice. This is because, despite a design that accounts for plunger packing components with sterile barriers and flushing systems, there is a risk of recontamination after in-process CIP/SIP cleaning. Furthermore, the thermal load created here results in increased wear on the plunger and its sealing system. The consequence is a significantly reduced service life, especially when the food product being treated contains abrasive ingredients. One alternative is to use process diaphragm pumps. They feature a hermetically tight liquid end, which is hermetically separated from the hydraulic chamber and process environment by a diaphragm. This prevents the inside of the fluid chamber from becoming contaminated, ruling out any contamination of the process space—including the food product.



Dr.-Ing. Hans-Joachim Johl,
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at LEWA. (Source: LEWA
GmbH)

Listeria in cheese, E. Coli bacteria in meat and salmonella in baby formula—food scandals and recall campaigns by major manufacturers have become all too frequent in recent times, damaging the reputations of the manufacturers responsible. This phenomenon has been increasing customer awareness and putting more pressure on the industry. Especially for sensitive products and products with high hygienic standards, it is absolutely imperative to ensure hygienic production through flawless hygienic process steps, as this guarantees microbiological integrity. In doing so, the following points must be kept in mind: Safe and reliable aseptic manufacturing processes are necessary in achieving high microbiological quality and lasting stability while still meeting the customers' high expectations for aspects such as high taste quality, healthiness and sustainability of the product. Short-term thermal treatment (UHT processes) and consistent downstream aseptic technology present a possible solution to this problem using reliable food-processing technology.

New trends in the food and beverage sector such as unprocessed and innovative ready-to-eat products pose certain challenges to the food industry supply chain with regard to food safety. This applies to both increasing expectations for freshness and the additives and preservatives put into food, which make it necessary to invest in different technologies than those used in previous production processes. The production chain is further affected by crossover-products between the food and pharmaceutical sectors such as ready-to-drink

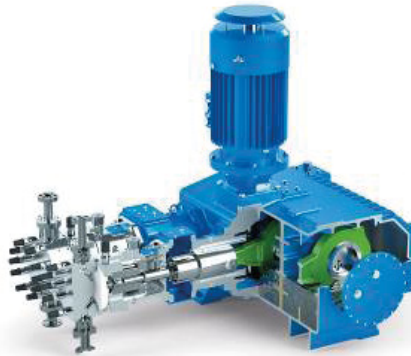
„nutritional beverages,“ as they are called, which sometimes contain high proportions of abrasive solids (e.g. due to calcium and nuts) or ingredients with microbiological sensitivity. In producing such crossover products, empirical knowledge from the pharmaceutical GMP environment is advantageous. Here, nutritional supplements with functional milk protein sources, fruits and flavors are combined to form new beverages, which may require special attention during production depending on their acidity and pH values. These high requirements must be adhered to specifically when formulating baby foods and high-calorie clinical nutrition (liquid enteral/parenteral foods). During processing, there are key tasks that must be handled by the pump technology specifically, e.g. for feeding raw materials and creating formulations that match the recipe, including metering and mixing ingredients at the correct proportions. Since the end products are ideally stored at room temperature and are supposed to last for an extended time in shelf, short-term thermal treatment is recommended here as well. It is the optimal technology for killing off foreign germs at a high rate and should be followed by aseptic high-pressure homogenization using diaphragm pump technology. This prevents re-contamination and ensures gentle product treatment.

Freedom from residue and microbial safety in high-pressure homogenization

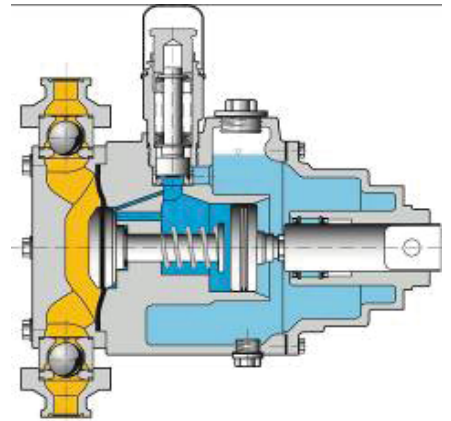
Hermetically tight design



The purpose of the pump is to generate the energy for dispersion in the homogenization valve, to convey the fluid being dispersed and to ensure the exact flow rate in the process. (Source: LEWA GmbH)



Process diaphragm pumps stand out for their robust mono-block design, for their smooth running thanks to the integrated worm gear with high hydraulic output and for having flow rates that are independent of the discharge pressure. (Source: LEWA GmbH)



In homogenization applications, you benefit tremendously from the fact that diaphragm pumps are designed for robust 24/7 continuous operation without significant wear. A hermetically tight working space allows for a continuous cleaning process (CIP/SIP) followed by interruption-free production processes. (Source: LEWA GmbH)

High-pressure homogenization is an application field that poses particular challenges to pump technology. The systems used in this field consist of a high-pressure pump used as a pressure generator in addition to a hydraulic consumer, which is called the homogenization valve. The purpose of the pump is to generate the energy for dispersion in the valve, to convey the fluid being dispersed and to ensure the exact flow rate in the process. In general, homogenizers can be roughly sorted into the following tiers:

- 1) Low/medium-pressure homogenization: 50 - 500 bar (typically in the food industry, e.g. at approx. 400 bar but trending upward)
- 2) Medium-pressure homogenization: 500 - 700 bar (in chemical, cosmetic and other industries)
- 3) High-pressure homogenization: 700 - 2,000 bar (e.g. for cell rupture for the release of metabolites in the biotechnology industry or pyrogen-free liposome production in pharmaceutical formulation)
- 4) Ultra-high-pressure homogenization: 2,000 - 40,000 bar (for killing off germs/preserving foods)

High-pressure homogenization is primarily used for breaking components down into fragments and mixing them as part of emulsion or dispersion. Milk homogenization serves as a known example of this. In this application, fat agglomeration (creaming) is to be prevented. The technology being used must not have a negative impact on the quality of the products. This is especially true

for baby formula. The objective here is to recreate the properties of breast milk as close as possible by selecting the right production components. This product fundamentally requires absolute absence of residues and maximum microbial safety. The aseptic systems and the process-related devices installed in them (such as the pumps) must meet these standards with respect to material selection and design. Any compromise made or installation error may later turn out to be a source of contamination.

Working principles of high-pressure pumps for homogenization applications

The reciprocating high-pressure pumps that the high-pressure homogenization machines are equipped with are necessary for pumping the fluid from the suction side through a feed pump (usually a centrifugal pump) by increasing pressure on the homogenization unit (single-stage or two-stage valve). Homogenizer pumps are equipped with three to six pump heads. Process diaphragm pumps stand out for their robust mono-block design and because of the integrated worm gear with high hydraulic output thanks to very smooth running. Fluid valves with application-specific designs that have been optimized for wear and hygiene ensure reliable pumping on both the intake and discharge sides of the pump. Automated homogenization valves are controlled pneumatically and hydraulically. The droplet size during homogenization is determined mainly by the cavitation in the chamber of the second stage and is dependent on the pressure-drop there. As-

suming incompressible fluids are handled, the flow rate of a reciprocating diaphragm process pump is reduced by a small amount as pressure increases and can be treated as a nearly constant value. Pressure fluctuations between a reciprocating pump and the homogenizer valve can be countered using pulsation-smoothing measures. This includes selecting suitable operating points for the pump and damping measures on the piping. Here, very specific dynamic simulation programs carried out within the scope of a pulsation analysis can provide support in the design.

For homogenization tasks following UHT treatment, the homogenization pump and the homogenization valve must consistently meet aseptic requirements so that the integrity of the products being treated remains ensured. However, many pumps still in use today are packed plunger pumps. For this type of unit, note that plunger packing components with sterile barriers and flushing systems must be incorporated into the design as a measure of preventing recontamination after in-process CIP/SIP cleaning. Moreover, contaminations caused by plunger abrasion in the packing area cannot be ruled out for this pump class. The preferable option for aseptic processes is thus to equip the homogenization steps with hermetically tight process diaphragm pumps.

Diaphragm pump technology eliminates fluid contamination

The diaphragm pump can be viewed as a successful evolution of the packed plun-

Hermetically tight design

ger pump. The diaphragm pump reaches an efficiency of up to 95 percent (in reference to what are called triplex diaphragm pumps, i.e. featuring three pump heads). The pump is set apart thanks to its low amount of wear and thanks to flow rates that are nearly independent of the discharge pressure. In homogenization applications, you benefit tremendously from the fact that diaphragm pumps are designed to operate without dynamic sealing systems. This guarantees a hermetically tight pump head, meaning zero emissions or substrate leaks from inside the system as well as zero ingress of germs from the outside. As a result, fluid contamination can be ruled out. This means that the diaphragm pump is the perfect solution for demanding applications. It is suitable for media that, for instance, have to be pumped with zero leaks and absolute operating reliability because they are hazardous or abrasive and must under no circumstances be released into the production environment, or media such as baby formula that have to remain sterile and free of contamination.

A hygienic or aseptic application requires additional special adjustments to the diaphragm pump head: A suitable pump head material such as stainless steel 1.4404 or, as an alternative, particularly corrosion-resistant austenitic materials such as 1.4439 or 1.4462 (Duplex), polished surfaces with an RA value $< 0.8 \mu\text{m}$ and fluid chambers with minimal dead space and no gaps may make it possible to carry out CIP/SIP cleaning steps repeatedly and efficiently, thus ensuring sterile operation without dismantling. The design and installation of the pump should, however, allow for the cleaning results to be checked periodically while still minimizing the sterile interfaces in the pipe routing. Directives such as those of the European Hygienic Engineering Design Group (EHEDG) – specifically Document 17 („Hygienic Design of Pumps, Homogenizers and Dampening Devices“) – or the 3-A Sanitary Standards 44-03 („Sanitary Standards for Diaphragm Pumps“) and 04-05 („Sanitary Standards for Homogenizers and Reciprocating Pumps“) provide information on how pumps for the food industry are to be designed and installed. Hygienic design aspects regarding cleaning and drainability of the pumps, valves and piping of sterile systems for the design of aseptic process connections of diaphragm pumps can also



Because the homogenizers downstream of the UHT processes must not re-contaminate the food, high-pressure diaphragm pumps should be used. It must be ensured that the attachments have a hygienic design and are installed in a way that allows them to be cleaned. (Source: LEWA GmbH)

be found in the ASME BPE Standard in the version that is valid for the specific application.

Depending on the process requirement and the necessary pressure rating, process diaphragm pumps can be equipped with an EU 10/2011-compliant, multi-layered PTFE diaphragm (up to 700 bar). In the case of milk products, going from packed plunger to diaphragm pump technology is a crucial step in making it possible to keep a process free of unwanted micro-organisms over the required process time and until the next time CIP/SIP cleaning is carried out. In maintaining an aseptic process chain down the line, hermetically tight high-pressure diaphragm pumps are also suitable for feeding spray towers with the aseptic and very hygienically sensitive milk concentrates.



Homogenization pumps are equipped with three to six pump heads. Aseptic processes are equipped with homogenization steps and spray towers with hermetically tight process diaphragm pumps. Their designs stand out for the fact that they function without dynamic seals. (Source: LEWA GmbH)

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High-pressure homogenizers consist of both a pump acting as a pressure generator and a hydraulic consumer, which is called the homogenization valve. (Source: LEWA GmbH)

Optimum results due to part specific workpiece holders

Correct use of part-specific cleaning containers

Parts cleaning applications that require part specific designed workpiece holders are steadily increasing for various reasons. For these uses, Metallform develops and manufactures technically and economically ideal solutions as standalone and insert workpiece holders.

Increasing requirements on the cleanliness of workpiece surfaces, a higher automation level in production, workpieces with critical to clean areas and increasingly complex part geometries are leading to growing demands in parts cleaning. Therefore, part specific designed workpiece holders are becoming more and more important. Due to their optimal design as standalone or insert workpiece holder they make an important contribution to fulfill cleaning requirements needs-based, efficiently and ergonomically.

Standalone workpiece holders – ideal for massive and heavy parts

Standalone workpiece holders are used without an outer cleaning basket. The main application area is the cleaning of massive and heavy parts and components which are manufactured in high volume quantities. The weight of these batches is usually too high for manual handling. The loaded workpiece holder is therefore hoisted with a lifting device directly to the cleaning machine's loading device. As another advantage of this solution, the positioning of parts in the workpiece holder can be optimally adapted to the requirement of cleaning. This includes, on the one hand, the all-around accessibility for the cleaning medium and washing mechanics such as ultrasonics or spray jet. On the other hand, the workpiece can be placed in the holder in such a way that critical to clean areas can be specifically be treated. Additionally, a good automation of parts handling with robots and thus the integration into a networked production environment speak for this solution. The measures of standalone workpiece holders are typically adapted to the batch size of the cleaning machine, which ideally corresponds to the dimensions of a standard cleaning basket. This allows for

using the cleaning machine with standalone workpiece holders as well as with cleaning baskets.

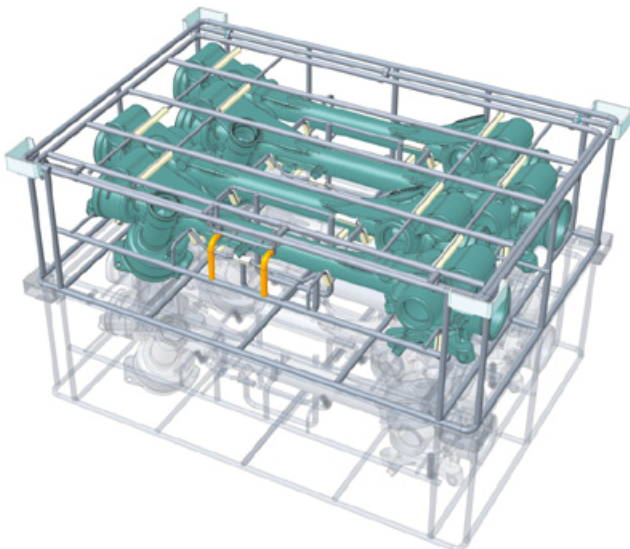
Insert workpiece holders – the more flexible alternative

Characteristic for this solution is that the loaded workpiece holder can be handled manually. For using the full capacity of the cleaning machine, several workpiece holders are combined to one batch and placed into an outer basket. In addition, for gentle parts cleaning the basked allows for building different compartments by using compartment rods. The basket, therefore, can be used for different part specific workpiece holders and compartments as well as for cleaning bulk parts. The higher flexibility is a major advantage of this solution.

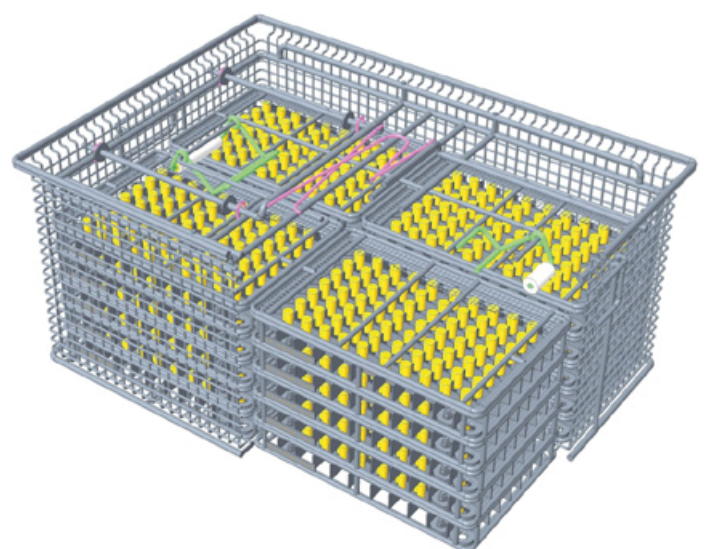
Stainless steel in careful workmanship

Metallform manufactures both, workpiece holders and cleaning baskets from stainless steel rounds with electrolytic-polished surfaces. Therefore, the products can be used with all cleaning media, and offer an all-around accessibility due to their open design. Additionally, the high-quality material enables a long service life. The rods of the workpiece holders, as well as the outer structure of cleaning baskets, are butt welded which prevents injury hazardous edges.

Metallform Wächter GmbH
D 75004 Bretten



Standalone workpiece holders are an ideal solution for massive and heavy parts. (Image source: Metallform Wächter GmbH)



For insert workpiece holders, several smaller units are manually placed into an outer basket. (Image source: Metallform Wächter GmbH)



ISPE's 2019 Facility of the Year Award for Operational Excellence won by partners Exyte and Kantonsapotheke Zurich



The award was announced on 2 April 2019 at the ISPE Europe Annual Conference in Dublin, Ireland. Exyte sincerely congratulates its client on this success. The facility Kantonsapotheke Zurich (KAZ) is a true shift forward, as a confluence of ideas, leadership, technology, finance and marketplace. It leads the very concept of hospital pharmacies into the future and establishes benchmarks of operational excellence never seen before in patient focused facilities.



ISPE's annual FOYA Awards identify the best projects around the world in Life Science, recognizing innovation and creativity in technology, regulatory compliance, operations and business practices. Exyte is pleased to have been the design-build partner bringing this project from concept to startup.

"Working in concert with the leadership team of Kantonapotheke Zurich, Exyte provided engineering, procurement, construction management and validation that led to the development of this technologically-advanced facility", outlines François Abiven, President Life Sciences & Chemicals at Exyte.

Life Sciences & Chemicals is the second largest strategic business segment of Exyte measured by sales revenue. Exyte is a provider and integrator of technology advanced solutions, including design, construction and commissioning to deliver complex processing plants. For this segment Exyte provides a full range of services: consulting & planning, engineering, project management, construction, commissioning and qualification for customers in the pharmaceuticals & biotechnology, food & nutrition, consumer care and specialty chemicals industries.

Operational excellence benchmark sets a new standard

The KAZ has replaced and integrated two outdated hospital pharmacies that had been unable to continue

serving the progressive needs of the community. Today, the facility provides the Canton of Zurich hospital system a range of oral, dermal and parenteral formulations, often with patient-specific recipes. It is highly flexible, adaptable and expandable to easily and quickly accommodate new functions, such as the rapidly emerging field of personalized medicine. All products are manufactured under industrial cGMP conditions, a major step change that is new to hospital pharmacies and their workers.

According to Armin Uwira, Head of Engineering at Exyte in Switzerland: "KAZ is the first of a kind, a technically, financially and operationally superior facility serving hospital patients. It has achieved an astonishing performance record of 60 to 90 minutes turnaround from diagnostic test and prescription to patient injection for cytotoxic compounds used oncology. The facility raises the bar of quality and drives the use of cGMP protocols and behavior into hospital pharmacies."

About ISPE

The International Society for Pharmaceutical Engineering (ISPE) is the world's largest not-for-profit association serving its members through leading scientific, technical, and regulatory advancement across the entire pharmaceutical lifecycle. The 18,500 members of

ISPE's 2019 Facility of the Year Award for Operational Excellence

ISPE are building solutions in the development and manufacture of safe, effective pharmaceutical and biologic medicines, and medical delivery devices in more than 90 countries around the world. Founded in 1980, ISPE has its worldwide headquarters and training center in North Bethesda, Maryland USA, and its operations center in Tampa, Florida USA.

About Exyte

Exyte is a global leader in design, engineering and construction delivering high-tech facilities, plants and factories. With a history of more than 100 years, the company has developed a special expertise in controlled and regulated environments. It serves the most technically demanding clients in growth markets such as semiconductors, life sciences, and data center across the full spectrum of services from consulting and design to managing turnkey solutions. Operating in more than 20 countries, Exyte is uniquely positioned

to support clients locally and globally. In 2017, Exyte generated sales of 2.4 billion euros, up from 2.1 billion euros in 2016 on a like-for-like basis, with over 4,800 highly experienced and motivated employees (by the end of the year 2017). Exyte emerged from a regrouping of the M+W Group in 2018. Exyte is a member of the Stumpf Group.

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New Raumedic leadership duo to intensify market focus

The medical technology manufacturer Raumedic has re-assigned responsibilities among its top management team. Executive Board member Stefan Seuferling has been named Chairman of the Executive Board of Raumedic AG by the company's Board of Directors in a decision that took effect March 15. Martin Bayer, the former Chairman of the Executive Board of the Raumedic Group, will focus on his function as CEO and President of the U.S. associated company Raumedic Inc. in order to develop business in North America, the world's largest medical technology market.

Think globally, act locally

Jürgen Werner, the Chairman of the Board of Directors, said the decision was designed to improve the position of the company in the respective markets. "Medical technology and the pharmaceutical industry face different requirements in each economic region," Werner said. "In addition, customers are approaching Raumedic with highly individual product requests. With the new management structure, we want to enable both companies to retain their

flexibility and to be highly responsive to their respective markets."

As the highest oversight authority for both companies, the Board of Directors works closely with the management team to ensure that the principle of "One Raumedic" is systematically applied, Werner said in describing the new structure.

Executive Board under new leadership

Stefan Seuferling joined Raumedic AG in September 2018 as the Executive Board member responsible for strategy, from which position he leads sales activities in Europe and Asia. He also oversees the departments of Marketing Communication, Quality Management, Regulatory Affairs, as well as Projects & Services. Together with his Executive Board colleagues, Seuferling will lead the business activities of Raumedic AG as Chairman of the Executive Board.

Closer to the world's largest medical technology market

As part of the efforts of Raumedic to enter the world's largest medical technology and pharmaceutical market, Martin Bayer moved his office to Mills River, North Carolina, in spring of 2018. Bayer, who has extensive experience in the medical technology market, intends to generate the same success in the USA that he produced for the global organization: Under his leadership, both sales and staffing nearly doubled from 2008 to 2018.

"The new leadership team is the next logical step in our efforts to make Raumedic increasingly agile and market-centric," Chairman of the Board of Directors Jürgen Werner said. "We have the utmost confidence in Stefan Seuferling and Martin Bayer. We are certain that they can help the entire company continue generating sustainable and profitable growth. With this goal in mind, they will remain in close dialogue in the future."



Vetter's Skokie Facility Expansion nears Completion

Facility growth is necessary to help meet customer demands and new product requirements

- **Demonstration of consistent strategy to stay at the forefront in the market**
- **Expansions will help meet an increase in customer projects**
- **A second extension is in the final planning stage**

Vetter, a global operating Contract Development and Manufacturing Organization (CDMO) announced today that a significant level of expansion activities are nearing completion at its US clinical manufacturing facility located at the Illinois Science & Technology Park in suburban Chicago. The ongoing growth of the facility will help satisfy existing and ever-increasing future customer requirements as well enable meet the complex needs of newer drug molecules like peptides or antibodies, many which need refrigeration or freezing. New offices with 45 work stations, conference rooms and an archive room are also included. To support the increase in customer projects, a permanent second work shift will be added in Visual Inspection over the next months. A second shift in Quality Oversight is also planned. "This variety of activities is a further proof point of Vetter's consistent strategic approach to stay ahead of the market by focusing on the important service needs of our customers during their drug development journey; promptness; flexibility; high yield of their valuable API and, of course high quality," explains Dr. Claus Feussner, Senior Vice President of Vetter Development Service.

Since beginning full operations in late 2011, Vetter's US ear-

ly-stage development site has been expanding to help meet growing customer demands. As recently as 2016, the site expanded its storage capacity by 150 percent to 3,700 sq. ft. With the new additions, most of which are expected to be completed by April, the site will increase its storage space by an additional 3,100 sq. ft. The new storage includes a 2,500 sq. ft. freezer farm as well as a planned 600 sq. ft. walk-in refrigerator. In total, 6,800 sq. ft. of storage space will result. A second extension, now in the final planning stage, will include an additional 1,500 sq. ft. of room temperature and freezer space. "When completed, the facility will have more than double the overall storage space we have currently available. This extensive expansion of freezer and refrigeration storage space represents the ongoing evolution in our Chicago business," summarizes Dr. Susanne Lemaine, Vice President Vetter Development Service Chicago.

Vetter Pharma International GmbH
D 88212 Ravensburg



Inside the new freezer farm at Vetter's US Development Service site. (Source: Vetter Pharma International GmbH)

Diversity in the management team

Velina Allerkamp takes over the Corporate Development division of the CWS Group

The CWS-boco Group focuses on diversity: Velina Allerkamp joined the management team of the service provider as Head of Corporate Development at the beginning of March. She has extensive international experience and is now the fourth female member of the international management team of the CWS Group.

Most recently, Velina Allerkamp held the position of Head of Strategy at GEA Group,



Velina Allerkamp takes over the Corporate Development division of the CWS Group.

an MDAX-listed global mechanical engineering company. In this position she was responsible, among other things, for the strategic development of the company.

Velina Allerkamp was born in Bulgaria and studied International Business at Reutlingen University of Applied Sciences. She began her career in 2005 in the M&A department of the Investment Bank Dresdner Kleinwort Wasserstein. Afterwards, Allerkamp joined the Boston Consulting Group, where she worked from 2009 to 2012 as a project manager in the Corporate Development & Corporate Finance Practice.

„We are pleased that we were able to win

Velina Allerkamp to head the Strategy and M&A departments of the CWS Group. The company will benefit from her extensive experience in all aspects of strategic development,” reports Thomas Schmidt, CEO of the CWS Group.

„I also welcome the increasing diversity of our management team. By networking different qualifications, gender, cultural and professional backgrounds, we promote innovation and thus the further development of the CWS Group,” explains Schmidt.



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Finding the Optimum Configuration for Injection Molds

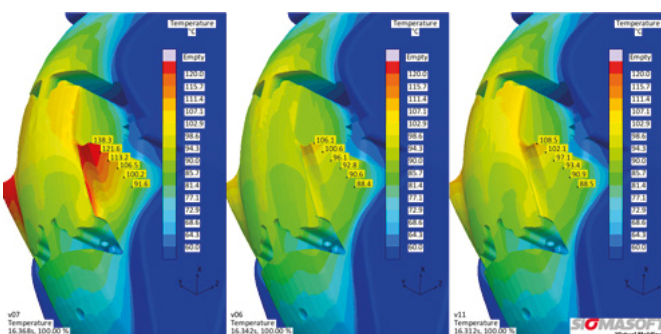
SIGMASOFT® helps mold makers to identify the right tool alloy during the design stage

For highly technical parts the optimum mold configuration is paramount to produce high quality parts in robust processes. With the help of SIGMASOFT® Virtual Molding mold makers test their mold concepts upfront on a virtual injection molding machine. In this way, they identify the ideal mold configuration before machining the steel.

At Moulding Expo 2019 (May 21st to 24th, 2019, in Stuttgart, Germany) SIGMA Engineering GmbH from Aachen, Germany, exhibits their SIGMASOFT® Virtual Molding technology. In hall 7 at booth 7E15 SIGMA showcases how the software helps to analyze and evaluate injection molds and their tempering concepts from the early design stage. It supports the user in identifying the ideal combination of mold alloys and tempering layout. Thus, the software allows mold makers to built molds that produce good parts from the first trial on the machine.

In an example case for an automotive application the mold initially was planned with a common mold steel. To avoid costly iterations of the mold, the whole configuration – including all mold components and their respective alloys – was set-up in SIGMASOFT®. Working as a virtual injection molding machine the software calculated an initial heating-up phase as well as several injection cycles to reach a thermal steady state. The analysis of the thermal steady mold revealed hot spots in some of the mold cores (Fig. 1, left), where the temperature got up to 30 °C higher than in the rest of the cavity. To reach a more homogenous distribution, different possible solutions were discussed and evaluated with the help of SIGMASOFT® Virtual Molding.

Due to the overall configuration of the mold the preferred solution was to exchange the common mold steel with a high conductivity alloy instead of introducing additional cooling channels. Therefore, virtual trials were conducted with mold inserts out of CuBe B2 and Moldmax HH. As in the initial analysis, these virtual trials were calculated with a heating-up phase followed by several molding cycles to reach a thermal steady state. In the end, the temperature distribution on the cores with all three materials was compared. Both high conductivity alloys showed a significantly improved and more homogenous temperature distribution (Fig. 1, middle and right). As the achieved temperatures of both high con-



Temperature distribution on the mold core for the initially planned common mold steel (left), as well as the core inserts out of CuBe B2 (middle) and Moldmax HH (right).

Finding the Optimum Configuration for Injection Molds

ductivity alloys were in the same range, both provided a sufficient solution for avoiding the hot spots. Based on the simulation results, the mold could immediately be built with high conductivity cores to supply the base for a robust process.

SIGMASOFT® allows its users to easily test and evaluate their planned mold configuration before the mold is built. With its help they identify critical temperature behavior and test solutions to

improve the mold and make the injection molding process more robust. Thus, they save costs and avoid iterations on the mold during the trial-and-error on the machine.

SIGMA Engineering GmbH
D 52072 Aachen

Vaisala Widens Its Product Offering for Demanding HVAC and Light Industrial Applications



Vaisala, a global leader in weather, environmental and industrial measurements, introduced today three new duct-mounted product models for demanding HVAC and light industrial applications such as museums, cleanrooms, data centers, and laboratories. The new products complement the previously launched HMD60 Series products with new features and enhanced usability.

The new Vaisala HMD60 and Vaisala TMD60 are broadening the HMD60 Series product portfolio. The HMD60 measures humidity and temperature and the TMD60 is dedicated to temperature measurements only. Both models come with two optional probe lengths: a long or a short probe, which is optimized specifically for small ducts. The transmitters are fully configurable and scalable, which enables users to get precisely the needed parameter and scale without having to know the exact application requirements when placing the order.

The third new model, Vaisala HMD65, will replace two current products, Vaisala HMD70U and Vaisala HMD70Y. The HMD65 has a long probe suitable for larger ducts and in addition to Modbus RTU, the transmitter features a standardized BAC-

net protocol enabling easy installation.

All the newly introduced transmitters are based on leading thin-film capacitive humidity sensor technology, HUMICAP®. The transmitters incorporate the latest HUMICAP® R2 sensor for improved stability, accuracy, and long-term reliability.

The three products have a wide range of humidity parameters available, including relative humidity (RH), absolute humidity, dew point, enthalpy, wet bulb temperature, and mixing ratio. They also have enhanced measurement accuracy up to ± 1.5 %RH and ± 0.1 °C (± 0.18 °F). The transmitters' all-metal bodies are IP66 rated, corrosion resistant and they withstand water jets (NEMA4X). The probes enable easy maintenance, when the electronics can be accessed without removing the units from the duct.

“The combination of the HMD60 Series transmitters' high accuracy, stability and reliable operation makes the product series an ideal choice for demanding HVAC applications. The newly launched transmitters' two probe lengths, wide range of humidity parameters and easy configuration with improved stability enriches the product portfolio for our customers and widens the installation possibilities,” says Product Manager Lars Stormbom from Vaisala's Industrial Measurements.

The HMD60 Series transmitters can be configured and adjusted by using the complementary Vaisala Insight PC Software. The field calibration is easy with trimmers or with the Vaisala Handheld Humidity Meter HM70 when needed. All the launched product models come with a traceable (ISO9001) calibration certificates. Accredited (ISO17025) calibration is also available.

Vaisala HUMICAP® HMD60, TMD60 and HMD65 are available on April 29, 2019.



VAISALA

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Exyte concludes financial year 2018 with record results and expects further growth



- Record sales of € 3.5 billion (+48%)
- Rise in order intake to € 4.4 billion (+35%)
- Adj. EBIT at € 170 million (+57%)
- Outlook for 2019: rising sales and sustained development of adj. EBIT

Exyte AG (“Exyte”), a global leader in the design, engineering and construction of high-tech facilities, continued on its profitable growth path and clearly achieved its objectives in the financial year 2018.

The company generated sales of € 3.5 billion in 2018, resulting in a growth of more than 48% compared to the previous year (2017: € 2.4 billion). Order intake at Exyte increased by 35% to € 4.4 billion in 2018 (2017: € 3.2 billion). Adjusted EBIT improved more than forecasted and rose to € 170 million in the past year (2017: € 108 million), which corresponds to an adjusted EBIT margin of 4.8%.

“We generated a record result in 2018 and will continue on our path for sustained profitable growth. This positive development is confirmation that our strategic realignment and focus on clearly defined target markets and core regions is paying off, and that we are on the right track with our customer-oriented approach,” Dr. Wolfgang Büchele (CEO) said. “Exyte’s key growth driver remains our Advanced Technology Facilities (ATF) segment, in which we serve customers in the semiconductor industry. Meanwhile, we are also benefiting from the continued growth in demand for highly efficient manufacturing environments for semiconductor production. A key driver of our business is the volume development of produced wafers and chips, which has been growing steadily by 7% to 8% per year over the course of the past years.”

While the Advanced Technology Facilities segment (semiconductors specifically) remains Exyte’s strongest business segment, with total sales of € 2.8 billion, sales also developed well in the two other strategic business segments, Life Sciences and Chemicals (pharmaceuticals and biotechnology in particular) and Data Center.

Exyte was once again able to grow at a regional level, with a 59% year-on-year increase in sales in the Asia-Pacific (APAC) region, which made up over half of the company’s total sales. At the same time, Exyte was also able to generate a substantial year-on-year increase in sales in Europe (EMEA) (+78%).

Significant increase in workforce

The total number of employees at the Exyte Group increased from 4,846 in 2017 to 5,561 in reporting year 2018, corresponding to a growth of 15%. The strongest growth was recorded in the APAC region. Overall, Exyte continues to aim to provide the highest quality of services to companies of the technologically most demanding industries around the world and is therefore focusing on specialists with engineering skills and technical expertise.

Exyte continues to benefit from key global trends

The Exyte Group designs and constructs high-tech production

facilities and plants around the world. Exyte’s growth in all three strategic business segments is decisively driven by various key global trends on a sustained basis. As a result of digitalisation, in particular developments such as the Internet of Things (IoT) and Artificial Intelligence (AI), demand in the semiconductor industry continues to increase.

With regard to the market segments for semiconductors, food, consumer goods and consumer care, Exyte also benefits from other key trends, such as Industry 4.0. The growth in the world’s population is also positively impacting the battery, pharmaceutical, biotechnology, food and nutrition markets. In addition, Exyte’s growth is made possible by the rise in general prosperity and regulatory initiatives in specific industries, such as the market for batteries for electromobility and renewable energies. Exyte’s semiconductor and batteries business also benefits from state funding of specific industries by various nations, such as the People’s Republic of China.

Outlook for 2019: Exyte expects strong demand

In light of the key global trends mentioned above, Exyte expects the positive development experienced in the previous year to continue. With its strategic “upside” program, the company will be focusing in the years ahead on actively developing its core markets. Sustained profitable growth will be supported by operational excellence and the further development of digital solutions. Overall, Exyte expects the current financial year 2019 to generate more sales than the previous year, an order intake slightly below the record level of 2018 (due to a major order in the previous year) and a moderate rise in adjusted EBIT.

Exyte’s CEO, Dr. Wolfgang Büchele, had this to say on the goals for the 2019 financial year: “Overall, we believe we are well-positioned in our core business segments and target markets, which are marked by global growth trends. Our focus for 2019 is to further expand our strong market position in all of our core business segments.”



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Additive manufacturing in medical technology

Arburg seminar at the University of Bologna

- **In practice: Experts reporting on trends and plastics processing in medical technology**
- **Comprehensive: Medical plastic products – from high-volume production to individualised single parts**
- **Innovative: University of Bologna uses Freeformer for research and development**

On 23 May 2019, Arburg Italy hold its first seminar on „Additive manufacturing in medical technology“ at the „Alma Mater Studiorum“ University in Bologna. Prof. Maurizio Fiorini, Mattia Mele and Prof. Luca Tomesani from the University of Bologna spoke about their experience using the Freeformer and presented applications as well as the new Expertise Centre for Industry 4.0. On behalf of Arburg, experts Dr. Didier von Zeppelin and Martin Manka talked about news regarding Arburg Plastic Freeforming (APF) and current applications and trends in medical technology.

„Arburg has decades of experience in medical technology. We offer innovative injection moulding technology and tailor-made clean room and turnkey solutions for efficient plastics processing. In addition, we have the Freeformer, which is capable of additively processing medically approved original materials to create functional components, thereby opening up completely new applications“, emphasises Raffaele Abbruzzetti, Managing Director at Arburg Italy. „This potential has also been recognised by the renowned University of Bologna which uses the Freeformer for material development. The seminar allows us to combine know-how from industry and research so that participants are able to obtain comprehensive information on trends and additive manufacturing in medical technology from various perspectives.“

Arburg demonstrates the potential of additive manufacturing

Dr. Didier von Zeppelin, Manager Additive Manufacturing at Arburg, and Ivan Panfiglio from Arburg Italy supported the University of Bologna in putting the Freeformer into operation and provided technical training. During the seminar, Dr. Didier von Zeppelin will present the APF process, available original materials and the ability to specifically influence process parameters and thus part properties. Furthermore, he will present functional components made of resorbable and FDA-approved materials and will also discuss how the Freeformer can be automatically integrated into IT-networked manufacturing lines in order to realise „on demand“ production in single-unit batches. Dr. Didier von Zeppelin

will also talk about the experience that customers such as Aesculap and Samaplast have already gained using the APF process.

Martin Manka, Senior Sales Manager Medical at Arburg, will present an overview of the market, industry trends and Arburg's full range of medical technology products. This includes clean room concepts, multi-component technology, e.g. for injection moulding of ready-to-use labs-on-a-chip, processing of resorbable materials and the Arburg ALS host computer system for GMP-compliant documentation of process data. In addition, Martin Manka will demonstrate the potential offered by the Freeformer with regard to the EU-wide „Medical Device Regulation“ which requires traceability down to the individual parts.

University of Bologna presents current R&D results

Prof. Maurizio Fiorini and Mattia Mele, who primarily works on the Freeformer in the university laboratory, presented the first results for industrial additive manufacturing. Finally, Prof. Luca Tomesani gave a lecture on the newly opened „BI-REX“ (Big Data Innovation & Research Excellence) Expertise Center, a pilot factory for Industry 4.0 in which new technologies are to be developed starting at the end of the year. In addition, participants had the opportunity to take a „live“ look at the premises of the department and its resident Freeformer and to exchange ideas directly with the speakers.

ARBURG GmbH + Co KG D 72290 Loßburg



During the Arburg seminar at the University of Bologna, the experts also presented application examples for the Freeformer in medical technology. (Photo: ARBURG)



Arburg offers a wide range of products for medical technology – from high-volume production on Allrounders in clean rooms through to additive manufacturing of individual parts using the Freeformer. (Photo: ARBURG)

Investments at record level and outstanding success stories

Swiss biotechnology

The Swiss biotech industry continues to be buoyant and once again managed to increase its sales, exports and research investments in 2018. As a result, it is laying the foundations for further growth and forward-looking development. Capital investment in listed biotech companies saw an especially striking increase: Polyphor boasted one of Europe's most successful flotations in recent years.

The Swiss biotech industry can once again look back on a record year. Industry sales increased by 6 percent compared to 2017, reaching CHF 4 billion. The number of people employed within the 249 biotech companies and 63 suppliers rose by around 4 percent to over 14,300. Capital investment in listed biotech companies has been booming.

Investment in research as the foundation of success

The industry has been laying the foundations for this impressive, sustained growth spanning a number of years with investment in research and development, which has been increasing for years and which rose by a further 32 percent from 2017 to 2018. Swiss biotech companies also invested the lion's share of resources generated by profits and financing transactions in research and development in 2018. The results include a valuable patent portfolio (53 percent of Swiss biotech patents are „world-class patents“) and a pipeline filled with promising drug candidates in the preclinical and clinical research phase. The Swiss biotech industry is predominantly made up of small to medium-sized enterprises, and is bolstered by capital investment, major interest from global companies in collaborations, and success in national and international project support programs (Innosuisse, Horizon 2020, international trusts and foundations).

Fit for the future

With the focus this year on „Shaping change“, the Swiss Biotech Report 2019 – which is published today – tells the story of this success and uses comprehensive figures to substantiate its claims. The report thus provides proof that the Swiss biotech industry is optimally placed to meet global challenges. An outstanding example of the industry's promising future is the flotation of Polyphor in spring 2018. Having raised around CHF 155 million, this was the largest biotech IPO in Switzerland in over 10 years, and one of the three largest in Europe in the last three years.

Awards for outstanding achievements

The secret to the Swiss biotech industry's success lies not in individual leading-edge companies, but in its diversity. Each year, the Swiss Biotech Association presents companies with the „Swiss Biotech Success Stories Awards“ in recognition of outstanding achievements. Biogen, Okairos, Roche Glycart, Selexis and Vifor Fresenius Medical Care Renal Pharma received the award at this year's Swiss Biotech Day after being nominated in 2018.

The companies nominated for the coming 2019/2020 period were also announced. For the first time, the nominees include an individual: Prof. Dr. Werner Arber, who was awarded the 1978 Nobel Prize in Physiology or Medicine. With his groundbreaking research in the field of molecular genetics, he was instrumental in the development of biotechnology in many ways over several decades.

Furthermore, three foundations have been nominated that have been supporting biotech startups with great success for more than 10 years, thereby making a significant contribution to the growth of the industry: Venture Foundation, Venturelab and Venture Kick.

Three outstanding and commercially successful biotech companies additionally made it onto the independent jury's list: Actelion, Debiopharm and Helsinn.

Actelion, a Janssen pharmaceutical company of Johnson & Johnson, is an industry leader in pulmonary hypertension. Debiopharm, known for oncological therapies and antibiotics, has developed a business model whereby promising product candidates are optimized, tested in clinical development and finally licensed to pharmaceutical partners. Helsinn has a broad portfolio of marketed cancer care products and a deep development pipeline. It has built significant R&D and manufacturing capacities and is an important employer in Ticino.

The Swiss Biotech Association will be working closely with these laureates over the coming 12 months to highlight the diversity and innovative strength of the Swiss biotech industry based on these successes.

Winners of the Swiss Biotech Success Stories Awards 2018/19 (in alphabetical order):

Biogen is a biotech pioneer and is being recognized for the many Swiss elements in its success story. Founded in Switzerland, Biogen is now one of the world's leading biotech companies with over 7,000 employees.

Glycart (now Roche Glycart) is a pioneer in antibody engineering for cancer immunotherapy. The first drug to be based on this technology was approved in 2013 for the treatment of chronic lymphocytic leukemia.

Okairos (now GlaxoSmithKline) has developed innovative vaccines based on T cells for the treatment of major infectious diseases like malaria, hepatitis C, HIV and Ebola. GSK acquired the company in 2013 for EUR 250 million.

Selexis has been at the forefront of the development of protein expression for more than a decade and is setting new standards in bioproduction. Selexis's cutting-edge technology is used by over 100 partners worldwide.

Vifor Fresenius Medical Care Renal Pharma is a transformational joint venture between Vifor Pharma and Fresenius: a partnership that established a leading global company offering therapies for the treatment of kidney diseases.



parts2clean 2019: Future-proofing the cleaning of industrial parts

22nd - 24th Oct. 2019: parts2clean, Stuttgart (D)

- The trade fair that showcases the latest technology and trends in industrial parts cleaning
- Virtually all the market and technology leaders now on board

In light of global trends such as electromobility, autonomous vehicles, lightweight construction, miniaturization, automation and digitization, the industrial parts and surface cleaning sector is facing new challenges. parts2clean 2019 shows how these challenges can be met. The 17th International Trade Fair for Industrial Parts and Surface Cleaning will be held from 22 to 24 October 2019 at the Stuttgart Exhibition Center.

Areas of current interest include new and modified production technologies, such as the growing use of adhesive bonding, laser welding and coating processes, as well as the additive manufacturing of components. At the same time, there is increased demand for the cleaning of workpieces made from new materials or material combinations, as well as complete assemblies. And then there are the tougher regulatory requirements, such as those contained in the new European Medical Device Regulation (MDR).

These changes are forcing business enterprises to review existing processes and question old ways of doing things. "parts2clean is the perfect place for businesses to gather the information they need for positive changes," says Olaf Daebler, Global Director of parts2clean at Deutsche Messe. "As a global meeting place for industry, the event and its exhibitors not only showcase the very latest technological advances in industrial parts and surface cleaning, but also highlight key trends and offer best-fit solutions." A glance at the exhibitor lineup proves the point, for it already includes virtually every market and technology leader from each of the show's display categories, all of whom traditionally use parts2clean as a prime opportunity to unveil their latest new products and innovations.

Meeting specific requirements reliably

The range of leading-edge exhibits allows visitors from many different sectors such as the car and component supply industry, medical technology, mechanical engineering, the aerospace industry, precision engineering and micro-engineering, optics, electro-

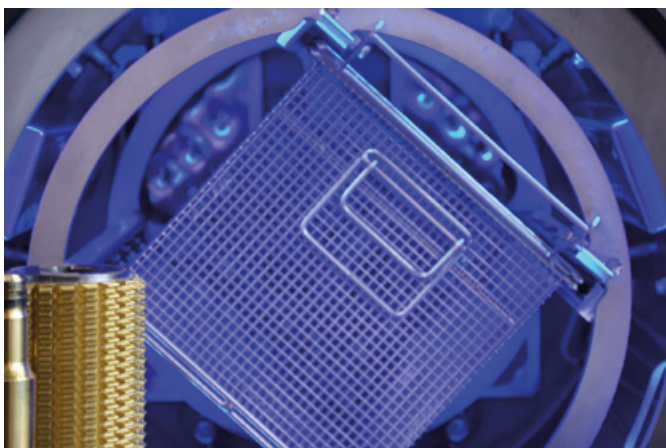
ronics, semi-conductors and coating technology – to find the information they need quickly and easily. Some will be looking for the right process engineering and plant to remove particulates or film-type contaminants efficiently and with consistent results in order to comply with new, tougher standards. Others will be more interested in technology for cleaning parts made from new materials, or parts with highly complex geometries. Also popular with visitors will be solutions for the control and monitoring of cleaning, rinsing and drying processes, as well as systems for checking and quantifying the degree of cleanliness achieved. Another major interest is the automation of cleaning operations and associated parts handling, e.g. using robots and suitably designed workpiece carriers. And yet another matter of growing importance is the intelligent integration of cleaning processes in networked manufacturing environments and cloud solutions, which make it possible to retrieve large quantities of information at any time, and from any location. Rounding off the coverage of this theme is the special QSREIN 4.0 display, the main focus of which will be on the future of process management in water-based parts cleaning.

For the all-over or selective cleaning of surfaces in various situations, there is now a growing trend towards the use of dry cleaning processes. parts2clean reflects this development with a broad range of offerings, which include systems for CO2 snow blasting, plasma cleaning, laser cleaning, vibratory finishing and cleaning with compressed air.

parts2clean Industry Forum and Guided Tours add value for visitors

"The three-day Industry Forum is a favorite destination, and therefore a must for visitors," Daebler reports. "The program of talks, available in simultaneous translation (German <> English), offers a wealth of valuable information about current trends and innovations." Organized in association with the Fraunhofer Cleaning Technology Alliance and the German Industrial Parts Cleaning Association (FiT), this knowledge-sharing event offers lecture-style talks and discussions on technology basics, strategies for optimizing processes and costs, quality assurance, best-practice applications, and the latest trends and developments.

The Guided Tours will be offered in English on all three days of the show. Focusing on selected exhibitor stands, they give visitors the opportunity to gather information about specific areas of interest in industrial parts and surface cleaning at every stage of the process chain. For them it is a quick and easy way to discover relevant solutions and innovations and identify likely suppliers who can solve their problems. The Guided Tours are also an excellent business opportunity for participating exhibitors, who can present their products and innovations directly to a pre-selected target audience at their stands, resulting in additional contacts and sales prospects.



(Source: parts2clean)

A country report in the run-up to K 2019



Southeast Asia: a wild card in the global plastics industry

The Asian region is buckling down on major trends and issues to achieve a future “perfect” economic growth, which will have a ripple effect on the plastics industry. In the run-up to K 2019, The World’s No. 1 Trade Fair Plastics and Rubber, which will take place in Düsseldorf from 16 to 23 October 2019, we will first take a look at the Asian economy, broken down into various areas, in order to then identify the plastics industry, market growth and challenges in the region.

With the world economies on a roller coaster ride, sluggish trade growth is expected on the heels of further trade restrictions and policy uncertainties. According to the OECD (Organisation for Economic Cooperation and Development), the global economy is likely to expand from 3.3% in 2019 to 3.4% in 2020, down from the 3.5% it had projected for both years last year.

Meanwhile, in China, while new policy measures have offset weak trade developments, OECD’s forecast for the country remains close to 2018, with a forecast growth of 6.2% in 2019 from 6.3%. And while India’s growth wound down to 7.1% in the third quarter of 2018, it is expected to grow at 7.3% in the fiscal year 2018-19, and 7.5% in the following two years, says the World Bank.

Bracing for further headwinds in the months to come, mature economies are pointing their compasses towards Southeast Asian countries, even against the Bank of America Merrill Lynch forecast of a slowdown in five countries – Indonesia, Malaysia, the Philippines, Singapore and Thailand – with growth falling slightly to 4.8% in 2019, from 5% in 2018.

As a single market, Southeast Asia is very attractive for key industries, including automotive, packaging, construction and medical devices. The region is also embracing salient issues relating to fuel efficiency, through development of its electric vehicle industry; plastics waste reduction through a recycling infrastructure; and adoption of smart manufacturing via Industry 4.0 initiatives. Southeast Asia’s plastics market is expected to register a CAGR of 5.5% from 2018-2023, according to a report by Mordor Intelligence. Construction and packaging industries are the major consumers of plastics in the region, as are film/sheet applications.

Meanwhile, Mordor Intelligence also says that the market for engineering plastics in Asia-Pacific was 25.37 million tonnes in 2017. The market is expected to portray a healthy growth rate over the forecast period of 2018-2023, at a CAGR of 5.7%. PET (Polyethylene terephthalate) resins are expected to dominate the segment, with a 51% share in the engineering plastics’ product share and a growth of 6.6% over the next five years.

Flaunting its automotive base assets

To remain competitive, Southeast Asia needs to measure up with the global automotive demand. The region produced over 4 million vehicles in 2018, and averaged a 7.6% growth in production and sales, from January-November 2018, according to the ASEAN Automotive Federation (AAF).

Thailand the region’s largest producer of vehicles (commercial and passenger vehicles), takes the lead, having produced 2.16 million units in 2018, up by 9% from the previous year. For 2018, full year vehicle sales in Thailand increased 19.2% year-on-year to 1 million units. However, the Federation of Thai Industries (FTI) fore-

casts that vehicle production in Thailand is expected to decrease slightly to 2.15 million units in 2019. The country, dubbed as the Detroit of Asia, remains a manufacturing haven for global automobile makers including Toyota, Ford, Honda, BMW, Mercedes and more, which have set up factories in Thailand.

Second in rank in production is Indonesia, which produced over 1.24 million units, up 9.9% from 1.13 million units a year ago, according to the AAF data. As well, Indonesia remains the largest market for vehicles in 2018, having sold 1.06 million units in the 11 months to November, up 6.9% from 994,436 units over the same period a year ago.

Meanwhile car producing Malaysia, saw a 23.7% dip in sales following three months of a windfall from June-August; and capped the month of November 2018 with a sales growth of 5.5%, according to the Malaysian Automotive Association (MAA).

Plugging into electric vehicles or EVs

Sales of electric cars are increasing around the world, surpassing 1.2 million for the first time in 2018, and more than 1.6 million EVs expected to be sold worldwide by the end of the year, according to the Frost & Sullivan Global Electric Vehicle Market Outlook for 2018. While China, the US and Europe account for around 90% of all electric car sales in the world, Japan and South Korea are also major players, with China cornering half of global production in 2017, followed by Europe and the US with 21%, and 17%, respectively; and Japan and South Korea representing 8% and 3%, respectively.

Southeast Asia, where vehicle, industrial and biomass burning are main reasons for degrading air quality, is also progressing towards low carbon transport. A 2018 study by Frost & Sullivan and Nissan, covering Singapore, Indonesia, Thailand, Malaysia, Vietnam and the Philippines, says though EV uptake remains comparatively low, consumers are aware of the differences in various EV technologies such as battery electric vehicles (BEVs), plug-in hybrid vehicles (PHEVs) and full hybrid. It also said EVs are gaining popularity among young individuals below the age of 40.

When British technology firm Dyson picked Singapore as the location for its multi-billion dollar electric car project, to roll out its first EVs by 2021, it came as a surprise since almost 90% of vehicles are petrol-based in Singapore. According to the Land Transport Authority (LTA), as of last year, 357 cars were petrol-electric plug-ins while 466 were pure electric, of the 614,937 cars registered in Singapore. Nevertheless, the country is one of a few in the world with both an electric car-sharing scheme and an electric taxi fleet and it is also expected that 60 electric buses will ply public bus routes by 2020, according to the LTA.

Elsewhere, the “Big 3” – Thailand, Malaysia, and Indonesia, have formed respective EV roadmaps to build an integrated EV ecosys-

A country report in the run-up to K 2019

tem to support private investments across the value chain. Under its “Electric Vehicle Promotion Plan”, part of the Thailand Alternative Energy Development Plan 2012-2021, Thailand has progressed from having 60,000 hybrid passenger cars and 8,000 battery electric motorcycles in 2014 to 102,000 hybrid cars and 1,400 battery electric vehicles in 2018, according to the Land Transport Department.

Indonesia has delved deeper into the issue of adoption, pushing its goal for 20% of all locally manufactured cars to be electric by 2025. It is targeting 2.1 million units of two-wheeler EVs like e-motorcycles and 2,200 units of four-wheeler vehicles by 2025. Investments are rife and recent developments include South Korea’s Hyundai setting up a 250,000-unit/year EV plant in Cikarang Industrial Complex; and a consortium of investors from South Korea, Japan and China building a US\$4 billion EV battery plant in Morowali to tap into Indonesia’s abundant nickel laterite reserves, a key ingredient in lithium ion batteries. The country is also finalising a policy that offers fiscal incentives to EV battery producers and car makers, as well as tariff agreements with countries that have high EV demand.

Under its National Green Technology Master Plan and the Electric Mobility Blueprint (EMB), Malaysia envisages by 2030, it will have 100,000 electric cars on the road, along with 2,000 electric buses and 125,000 charging stations, says the Malaysian Investment Development Authority.

In the Philippines, the Electric Vehicle Association of the Philippines (EVAP) set a target in 2014 to have 1 million EVs on roads by 2020, while the Philippine Department of Energy (DOE) collaborated with the Asian Development Bank (ADB) to introduce e-tricycles (e-trikes) powered by lithium-ion battery technology. As of 2018, around 1,400 e-jeepneys and e-trikes ply the roads, according to the Department of Trade and Industry’s Board of Investments, along with charging stations in 19 locations. EVAP envisions 200 of these in place by 2022. In predominantly two-wheeler Vietnam, its first car manufacturer Vinfast expects to produce 250,000 e-motorcycles/year and is planning to release its own electric car in the near future.

Still, the region has to tackle the slow take-up rate of EVs due to unattractive incentives, higher prices of EVs, compared to petrol engine equivalents, and lack of availability of charging infrastructure, with the Frost & Sullivan findings indicating that governments have a critical role to play in promoting EV usage.

Top scorers in packaging

The Asian flexible packaging market is poised to reach a CAGR of 5.7% to US\$6.7 billion from 2016-2024, according to a Transparency Market Research sector forecast, driven by growth and increasing disposable incomes. Thailand, touted as the “Kitchen of the World” for drawing importance on its food and agriculture sectors, has one of Asia’s most advanced food processing segment, with more than 10,000 food-and-beverage processing factories. Its third largest sector, it accounts for over 20% of the country’s GDP.

The Thai packaging industry is expected to grow to 63.1 trillion units in 2020 from 51.3 trillion units in 2017, registering a CAGR of 4.2%, says Global Data research. Packaging that offers greater functionality such as on-the-go, sustainable or personalised packs are forecast to rake in higher demand in the longer term, as is rigid plastics with the highest market share gainer and growth of 4.5%

during 2017-2022.

Indonesia is, likewise, predicted to lead in the flexible packaging market in the region, with food packaging accounting for 70% of plastic consumption, according to Transparency Market Research. Food and beverage sales are among key drivers to Indonesia’s strong retail sales growth averaging 3.7% year-on-year based on the December 2018 data of Bank Indonesia. This backs the growth of the Indonesian plastics market, forecast to witness a CAGR of 6.23% in a Mordor Intelligence report spanning 2018-2023.

The emerging trend of busy, fast-paced lifestyles in Indonesia’s flourishing urbanisation is driving the demand for smaller, convenient, on-the-go packs, and other packaging types, according to Global Data, which also alludes to rising environment awareness among consumers as a key factor in thriving demand for eco-friendly packaging formats. Flexible packaging holds a broad usage in Indonesia’s food industry, owing to its low cost, flexibility to suit multiple shapes and sizes, convenience, and low-carbon foot print. Flexible packaging occupied a market share of 42% in 2016, accounting for 42 billion units in 2016, and is forecast to reach 52 billion units in 2021, at a CAGR of 4.3% during 2016-2021. Nevertheless, rigid packaging snapped up a sizeable market share in Indonesia in 2016, accounting for nearly 25% of the market, and is expected to grow at a CAGR of 7.7% by 2021.

With over 1,500 plastic production companies, Malaysia’s plastics market is driven by packaging. Citing data from Statista, Malaysia’s food and beverage segment is predicted to earn US\$268 million in 2019; and is expected to grow annually at a CAGR of 18% to US\$520 million by 2023. In the same trajectory, the pharmaceutical industry is propelling the growth of packaging.

Looming waste problem – going full circle for sustainability

The booming plastics and packaging sectors in Southeast Asia have resulted in a growing waste problem. According to the Ocean Conservancy environmental advocacy group, and based on the findings of the Science journal, more than half of plastics that end up in the oceans come from five countries – China, Indonesia, the Philippines, Thailand, and Vietnam.

Meanwhile, with China’s ban on the import of most global recyclable plastics last year, to develop its own domestic recycling capacity, Southeast Asia has become a dumping ground for plastic waste from other countries. And while Thailand, Vietnam and Malaysia have started to enforce import bans on plastic waste, further legislation is required to stem the tide, since illegal plastics recycling factories rise up even with the enforcement.

As the second largest contributor to the plastic waste crisis in the oceans, trailing only behind China, Indonesia has a monumental task to tackle. The 250 million-populated country used 9.8 billion plastic bags in 2016 alone, according to the Ministry of Environment and Forestry. Against a failed plastic bag tax on single-use bags, which would have had an “impact on small and medium enterprises”, according to Indonesian Olefin, Aromatic and Plastic Industry Association (Inaplas), the country has now pledged US\$1 billion, including a US\$100 million loan from the World Bank. It expects to reduce the amount of plastic it leaks into the oceans by 70% by 2025, according to the Coordinating Ministry for Maritime Affairs, through product packaging redesign, use of recyclable materials, and adequate waste management. Of the latter, the country has a “sizeable” recycling industry, with about 1.1 million tonnes/

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year of plastic waste recycled, yet the recycling rate remains low at 20%, says the newly formed Indonesia Plastics Recyclers (IPR).

With Thailand producing around 3 million tonnes/year of plastic waste, the country has established a 20-year strategy, which includes banning the use of thin single-use plastic bags by 2022, followed by single-use plastic cups and straws in 2025, according to plans drafted by the Pollution Control Department.

Neighbouring country Malaysia has charted a zero-waste plan that aims to abolish single-use plastics by 2030. With incineration high on its agenda, Singapore has held off on introducing policies that either ban or tax single-use plastic, to the chagrin of environmentalists since even Cambodia has introduced a levy on plastic bags in shopping centres and supermarkets. In the Philippines, a ban on single-use plastic also came into effect in government offices, with plastic utensils, bags and straws banned. Local governments have also enforced zero-plastic policies in their cities.

Conclusions and outlook for the Southeast Asian plastics industry

As Southeast Asia moves on a trajectory path, in its plastics sector growth, sustainability in the industry cannot be achieved without altering the current systems of plastics management and consumption. Already, the five Asian countries of Indonesia, the Philippines, Vietnam, Thailand and Malaysia collectively produce 8.9 million tonnes/year of mismanaged plastic waste. Addressing the environmental impact of handling waste build-up through plastic bag bans, and similar tax-based actions, which are predominantly the first line of defence for many countries to manage waste, may no longer be as efficient as anticipated. Today, a more expansive approach is sought to incorporate design and enable technologies to maximise the value of materials. Bringing into the fold is the circular economy model that aims to curb wastage through reuse of materials as well as recyclability of materials in major sectors (automotive, construction, packaging and others).

Meanwhile, targets have been set in the newly formed sustainable framework led by Malaysia-based NGO, Circular Economy Asia (CEA), to consolidate efforts for Asia to tackle its waste leading to a circular economy. CEA's model includes providing a regular, convenient and efficient collection service, support of informal recycling collectors and utilising the tiers they operate within because it is a system that already works well; as well as licensing informal recycling collectors for technology-connected geographical areas, providing the information and data for a range of key solutions. CEA is also lauding the Asian Plastics & Packaging Agreement (APPA), a programme that seeks to establish a common recycling labelling system, a certifiable supply chain and advocates each country in Asia to establish a sustainable, circular plastics and packaging industry.

Finally, CEA says that if policy makers embrace the circular economy now, it is expected to come full circle for Asia in 2050, through the elimination of landfilling with the diversion of recyclable resources for reprocessing and with the production of 100% of recyclable plastics.

At K 2019, both raw material producers and mechanical engineers want to make their experience and knowledge of recycling, sustainable development and circular economy with plastics available internationally. Against this background in particular, the „Circular Economy“ will be at the centre of K 2019, which as the leading global trade fair for the sector offers optimum conditions for deepening discussions on this important topic with experts from many countries around the world and for intensifying cooperation.

16th - 23rd October 2019: K2019, Duesseldorf (D)

Messe Düsseldorf GmbH
D 40001 Düsseldorf

pacprocess MEA 2019 comes under the auspices of the Egyptian President

Premiere of Arab Star Pack Pro Award

Egyptian President H.E. Abdel Fattah Al Sisi will sponsor the first pacprocess MEA, which will take place from 9 to 11 December 2019 at the Egypt International Exhibition Centre in Cairo, in parallel with Food Africa, and will be organised by Messe Düsseldorf, IFP Egypt and Konzept. Support from the highest political level underscores the importance attached to pacprocess MEA by government organisations and ensures that the fair is highly attractive to potential visitors. The political leaders in Egypt are relying on sustainable trade fair concepts to attract investors to the country on the Nile and develop markets accordingly. The country is also striving to play a key role in the MEA region as a gateway to the African world. The premiere of the "Arab Star Pack Pro" Award also has the aim of promoting the sector with a focus on Arab companies. Winners of the competition will take part in the World Packaging Organisation's (WPO) international awards.

The Arab Star Pack Pro Award is aimed at companies from the packaging industry in the region. The competition seeks to find the best in Arab design for packaging of consumer and industrial goods. The concept was recently presented at an event of the German-Arab Chamber of Foreign Trade, Printing Industry Division, which cooperates with the Industrial Modernisation Centre (IMC)

and the Regional Office of the United Nations Industrial Development Organisation (UNIDO).

The "Arab Star Pack" award for students was already being organised by UNIDO and the Lebanese association LibanPak in the past. At pacprocess MEA, this award with "Pro" added to its name will now focus on companies that are proving themselves interna-



pacprocess MEA 2019 comes under the auspices of the Egyptian President

tionally in the industry with ideas relating to trending topics and the latest developments on the technical side and in marketing. The focus here will be on the added value and attractiveness for potential customers of good product packaging.



The award is specifically targeted at Arab companies and projects from the packaging industry with the application areas of agricultural products, food and beverages, pharmaceuticals and cosmetics, as well as cleaning products for the household, in addition to industrial goods and non-food articles. The evaluation criteria for the award include functionality, ergonomics, sustainability, packaging design and information, general execution, innovation and creativity. The jury is made up of representatives from international organisations and designers as well as experts from the food and consumer goods industries.

The Arab Star Pack Pro Award serves as the national qualifying round for the international WPO award. It provides local companies with an excellent platform for attracting attention worldwide.

09th - 11th Dec. 2019: pacprocess, Kairo (Egypt)

Messe Düsseldorf GmbH
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U.S. Market Launch: B. Braun Medical Inc. Uses Needle-Trap from Schreiner MediPharm for New Prefilled Heparin Syringe

FDA Approval for Prefilled Syringe with Needle Protection System

B. Braun Medical Inc., located in Bethlehem, PA, recently launched its prefilled syringe of Heparin Sodium Injection, USP (United States Pharmacopeia; compendium of drug information) which utilizes Schreiner MediPharm's label-integrated Needle-Trap system to the U.S. market. According to B. Braun, this is the first prefilled heparin syringe with an integrated needle protection device approved by the U.S. Food and Drug Administration (FDA).

In the United States, syringes should be used with safety devices to protect healthcare staff against the risk of needlestick injuries. B. Braun Medical was looking for an efficient and safe needle protection solution for its prefilled Heparin Sodium Injection and found it in Needle-Trap from Schreiner MediPharm.

The Needle-Trap system is internationally established. It complies with the US NIOSH requirements for safe instruments, among

other things, and has been awarded 510(k) Pre-Market Notification by the FDA for marketing in the United States. "Clinical staff benefit from reliable protection against needlestick injuries because Needle-Trap's activation is easy and irreversible. It is intuitive to use and requires no change in injection technique," says Gene Dul, President of Schreiner MediPharm in the United States.

Needle-Trap is the only label-based needle protection system on the market: The plastic needle trap is an integral component of the marking label and serves to secure the needle after the injection has been performed. Due to its special construction, Needle-Trap can easily and cost-efficiently be integrated into existing pharmaceutical production processes. It requires only minor modifications of the application systems, no changes to secondary packaging, and minimal space during shipping, storage and disposal.

"Our products are designed to increase patient and clinician safety, while reducing medication errors and improving dosage accuracy and workflows. Obviously, efficient and economical manufacturing are equally important. Collaborating with Schreiner MediPharm allowed us to meet those needs," says Leigh Nickens, Director of Marketing, Fluid Therapy and Injectables at B. Braun.



The prefilled syringes from B. Braun with Schreiner MediPharm's Needle-Trap are the first prefilled heparin syringes with an attached needle protection system approved in the US market.

Schreiner MediPharm D 85764 Oberschleissheim

Gerresheimer to launch a new packaging solution for effervescent vitamin C tablets

At FCE Pharma in São Paulo, Gerresheimer was showcasing a complete solution for packaging effervescent vitamin C tablets, which are currently seeing strong demand. A leading manufacturer of specialty plastic packaging solutions for pharmaceuticals, Gerresheimer is further expanding its newest plant in Anápolis in the Brazilian state of Goiás.

Complete solution for effervescent vitamin C tablets

The packaging solution comprises a small tube made from polypropylene (PP) with capacity for 10 or 16 tablets and a lid made from low-density polyethylene (LDPE) and filled with desiccant. Versions of the lid with or without a flat coil spring are available. The state-of-the-art offset printing press enables the plastic tubes to be printed in up to six colors, while the shock- and waterproof decoration ensures a long useful life. Strong brand identities can thus be shaped in an eye-catching way and in line with corporate design guidelines.

Anápolis plant being expanded

Gerresheimer Anápolis enjoys a favorable strategic location in Goiás state, home to many Latin American generics manufacturers. The factory, which opened its doors last year, is set to house an entire production line for plastic products, assembly and decoration operations, and a logistics center in the future. To this end, the premises are being expanded to over 29,500 square meters this year. The plant will also supply customers all over Brazil with high-quality packaging products and solutions going forward. By the end of 2020, it will be kitted out with machinery capable of manufacturing most products in Gerresheimer's portfolio for Brazil such as plastic bottles, caps, syringes, beakers, and droppers.



Complete solution for effervescent vitamin C tablets

Gerresheimer in Latin America

With its new factory, Gerresheimer now has a presence in two Brazilian states. Alongside Goiás, the company is also represented in the São Paulo region, where several plants provide the full range of pharmaceutical primary packaging made from plastic. Gerresheimer makes insulin pens for the South American market in Indaítuba, near to the state capital São Paulo. The company also has another factory for plastic products in the Argentinian city of Buenos Aires and manufactures pharmaceutical ampoules and vials from glass in Querétaro, Mexico.

Gerresheimer AG
D 40468 Düsseldorf

Robust CO₂ Sensor with RS485 Interface

The EE820 CO₂ sensor, particularly resistant to pollution, is now available also with digital interface.

The well proven EE820 sensor from E+E Elektronik is appropriate for reliable monitoring the CO₂ concentration in harsh and polluted applications such as agriculture and life stock barns. Beside voltage and current output, the sensor is now also available with RS485 interface with Modbus RTU or BACnet MS/TP protocol.

Long-Term Stable CO₂ Measurement

The operation of the EE820 is based on the long-term stable E+E dual-wavelength NDIR principle, which is highly insensitive to contamination and automatically compensates for ageing effects. The multi-point CO₂ and temperature factory adjustment procedure ensures high CO₂ measurement



The EE820 CO₂ sensor from E+E Elektronik can be used in harsh environment. (Photo: E+E Elektronik GmbH)

accuracy over the entire temperature range -20...60 °C (-4...140 °F).

Suitable for Demanding Applications

The EE820 features a robust IP54 enclosure with a special filter, which offers best protection of the measurement electronics in harsh and polluted environment.

The functional enclosure facilitates mounting the sensor with closed cover. Thus, the electronics is safe from mechanical damage and construction site pollution during installation.

Fast Response Time due to Active Ventilation

For fast response time to changes in CO₂, the EE820 is optionally available with a forced air circulation module installed behind the filter.

Analogue Output, Modbus RTU and BACnet MS/TP

The measured data with range up to 10000 ppm CO₂ is available on the analogue output (voltage / current) or on the RS485 interface with Modbus RTU or BACnet MS/TP protocol.

An optional adapter and the free EE-PCS Product Configuration Software facilitate the configuration and adjustment of the EE820.



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Vaisala Introduces CAB100 Industrial Cabinet for Cleanrooms

Vaisala, a global leader in weather, environmental, and industrial measurements, launches its newest offering for centralized environmental monitoring in cleanrooms: The CAB100 integrates Vaisala's world-class instruments for monitoring parameters into a simple, pre-configured enclosure.

Vaisala CAB100 Industrial Cabinet for Continuous Monitoring System (CMS) is ideal for data collection specifically in cleanrooms, and in other demanding industrial environments. It integrates Vaisala's data loggers, analog signal data collection and differential pressure transmitters in a single enclosure with a high IP-rating and easy-to-use design.

The CAB100 is an add-on part of Vaisala viewLinc Continuous Monitoring System. The monitoring system integrates data loggers, transmitters and monitoring software



to monitor several parameters, and provides real-time and historical measurement data, customizable reporting, and reliable alarming to email, SMS, and local or PC display.

"The Vaisala viewLinc Continuous Monitoring System is used globally in pharmaceutical and biotechnical companies to fulfill their Good Manufacturing Practice, also known as the GMP-requirements," says Vaisala's Product Manager Steven Bell. "The CAB100 cabinet is a great addition to the viewLinc monitoring system, as it makes the installation of the application-optimized instrumentation much easier. This is essential for example in cleanrooms where the cleanliness is important and installation of any equipment inside the clean area has limitations."

The CAB100 cabinets are configurable according to the application requirements, with various options for measurement in-

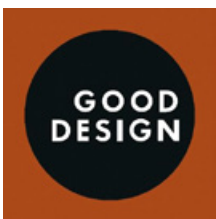
puts and safety barriers to instrumentation used in hazardous areas. The powering options include integrated power supply for mains powering or Power over Ethernet (PoE).

The CAB100 Industrial Cabinet for CMS will be available in two sizes. The first deliveries of the product are taking place in April 2019.

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Good Design Award for the design of Drug Delivery Devices by Sensile Medical



Die Drug Delivery Devices mit Mikropumpe von Sensile Medical, einem Unternehmen der Gerresheimer Gruppe, haben ein unverwechselbares Design. Es wurde von der in England ansässigen Agentur Team Consulting entwickelt. Diese erhielt dafür 2018 den renommierten amerikanischen Good Design Award in der Kategorie „Medical 2018“. Auf der CPhI North America stellte Sensile Medical seine elektronischen und digitalen Lösungen für Drug Delivery Devices vor.

"We are continuously working on improving quality of life for patients who rely on injection aids," said Sandra de Haan, CBO at Sensile Medical. With SenseCore micro pump technology, Sensile Medical ensures the safe, simple, and precise administration of liquid drugs by the patient themselves at home or on the move, and always with absolute reliability. This injection aid is impressively simple and discreet to use and the patient does not see the needle, making it suitable for all manner of different applications.

In 2017, Sensile Medical commissioned the British agency Team Consulting, which specializes in medical devices, to package

these requirements and attributes of its drug delivery devices in a patient-friendly design. The Chicago Athenaeum Museum of Architecture and Design Good Design Award is the world's oldest and most presti-



The modular structure of the device reduces waste.

gious design award, open to manufacturers, companies and emerging start-up businesses.

This is what the jury at the Good Design Awards based their decision on

The Sensile Medical Design Language provides a unified look across a range of injection devices. Different product varieties can be clearly identified as belonging to a single family with key attributes of the Sensile technology – the flexible modular approach and low-cost disposable component.

The Sensile family of products addresses many of the key user and commercial concerns that surround wearable injection devices; namely ease of use, comfort, discretion, reduction of waste, flexibility and ease of customization.

By creating a uniform product family range from a coherent design language, Sensile's range is significantly strengthened. Its customers in particular rely on the devices offering a consistent user experience, independent of the primary packaging for medication.

Gerresheimer AG
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Stainless steel oldham couplings

New from Ruland

Ruland now makes oldham coupling hubs from 303 stainless steel. This addition gives designers an off-the-shelf coupling to choose from when designing systems in corrosive, vacuum or cleanroom environments. Stainless steel oldham couplings are zero-backlash, can accommodate all forms of misalignment and have a balanced design, making them suitable for a wide variety of servo driven applications.

Oldham couplings are comprised of two hubs that mate to a center disk. This three-piece design allows users to easily customize oldham couplings with clamp or set screw hubs with inch, metric, keyed and keyless bores. They have a balanced design for reduced vibration at high speeds of up to 6,000 rpm and operate with low bearing loads, protecting sensitive system components such as bearings from premature failure. Ruland uses a proprietary hub machining process that leaves a smoother surface for interaction between the hub and disk, resulting in longer life and reduced downtime.

The oldham disk is available in acetal for zero-backlash and high torque capacity, PEEK for high temperature and low outgas-

sing, and nylon for dampening and noise reduction. In the event of failure or wear the disk can be replaced, restoring the original performance characteristics of the coupling. Oldham couplings may also act as a mechanical fuse during torque overload situations, with the disk breaking cleanly and stopping power transmission.

The use of 303 stainless steel when combined with a PEEK disk now allows designers to use standard oldham couplings in a wider variety of servo driven applications such as those found in scientific instruments, food processing, packaging and medical. Stainless steel hubs are provided with hardware of like material to maintain consistent corrosion resistance. Ruland adds a proprietary surface treatment to hardware to prevent galling. While the treatment is advantageous for most operating environments, they do outgas and may not be suitable for cleanrooms or vacuum. Users can request untreated hardware as a non-standard or replace it themselves with commercially available hardware.

Ruland stainless steel oldham couplings are available in bore sizes from 3 mm to 20 mm and 1/8 inch to 3/4 inch. Disks can be manufactured with a center hole to allow further shaft penetration or slots for retention hardware to attach the disk to a hub so it can stay in place during disassembly.

Stainless steel oldham couplings are carefully manufactured in Ruland's factory in Marlborough, Massachusetts, under strict controls using proprietary processes. 3D CAD files, full product specifications and additional technical information are available on www.ruland.com.

Summary:

- Stainless steel oldham coupling hubs have high corrosion resistance and are suited to cleanroom and vacuum applications.
- Oldham couplings are zero-backlash, have a balanced design and can accommodate all forms of misalignment.
- Oldham couplings are highly customizable, allowing the user to tailor the coupling's performance to their application.
- Disks are available in acetal for high torque, PEEK for corrosion resistance and low outgassing, and Nylon for dampening.
- RoHS3 and REACH compliant .
- Carefully made in Ruland's Marlborough, MA factory and available for immediate delivery.



Stainless steel oldham couplings are well suited for corrosive, cleanroom, and vacuum applications that require high misalignment capabilities.

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