Researchers establish a biotechnological process to produce bacterial alginate for use as the raw material for fibre-based medical products

Wound dressings made from bacterial alginate

Fig. 1: Alginate-viscose fibres produced us-ing bacterial alginate. © Hohenstein Institute

In a joint project called „AlBioTex“, researchers at the Hohenstein Institute, B.R.A.I.N AG („BRAIN AG“; ISIN DE0005203947 / WKN 520394) and Kelheim Fibres GmbH have successfully developed wound dressings made from bacterial alginate. The aim of the project (sponsorship ID 031A126, in the Federal Ministry of Education and Research (BMBF) BioIndustrie 2021 programme) was to develop a biotechnological process to produce alginate and then process it into fibre-based products for use in wound dressings. The soil bacterium Azotobacter vinelandii was used as a natural alginate resource. This means that the conventional, time-consuming process of obtaining the biopolymer from brown algae can be avoided and replaced by a sustainable biotechnological process.

The organisations involved in the research partnership were the Hohenstein Institut für Textilinnovation gGmbH in Boennigheim (William-Küster-Institut for Hygiene, Environment and Medicine), the bioeconomy company BRAIN AG in Zwingenberg, the world's leading manufacturer of special viscose fibres Kelheim Fibres GmbH, and the producer of highly specialised materials for medical engineering, rökona Textilwerk GmbH in Tübingen. Thanks to the interdisciplinary collaboration between the research partners, they have succeeded in mapping out for the first time a complete production and treatment process, from using biotechnology to produce bacterial alginate, right through to producing fibres and manufacturing textile materials.

Alginate is a biopolymer (polysaccharide) that consists of the glycosidically bonded monomers, guluronic and mannuronic acid. The range of industrial applications for the biopolymer is determined by the sequence and ratio of these two sugar components. Alginate is particularly suitable for use in wound dressings because of its excellent biocompatibility, enormous liquid-absorption capacity and good healing properties.

The conventional alginate that is obtained from algae varies greatly in the composition of its sugar components, because of environmental factors. A time-consuming preparation process is required to obtain the ultrapure and biochemically defined alginate that is needed for medical applications, for example. Using biotechnology to produce alginate, on the other hand, offers the option of synthesising biopolymers which have defined properties and are of consistent quality for use in medical products.

Research work that began in 2013 has been able to establish, optimise and standardise the cultivation of the soil bacterium and the biotechnological process for producing and isolating bacterial alginates.

Wound dressings made from bacterial alginate

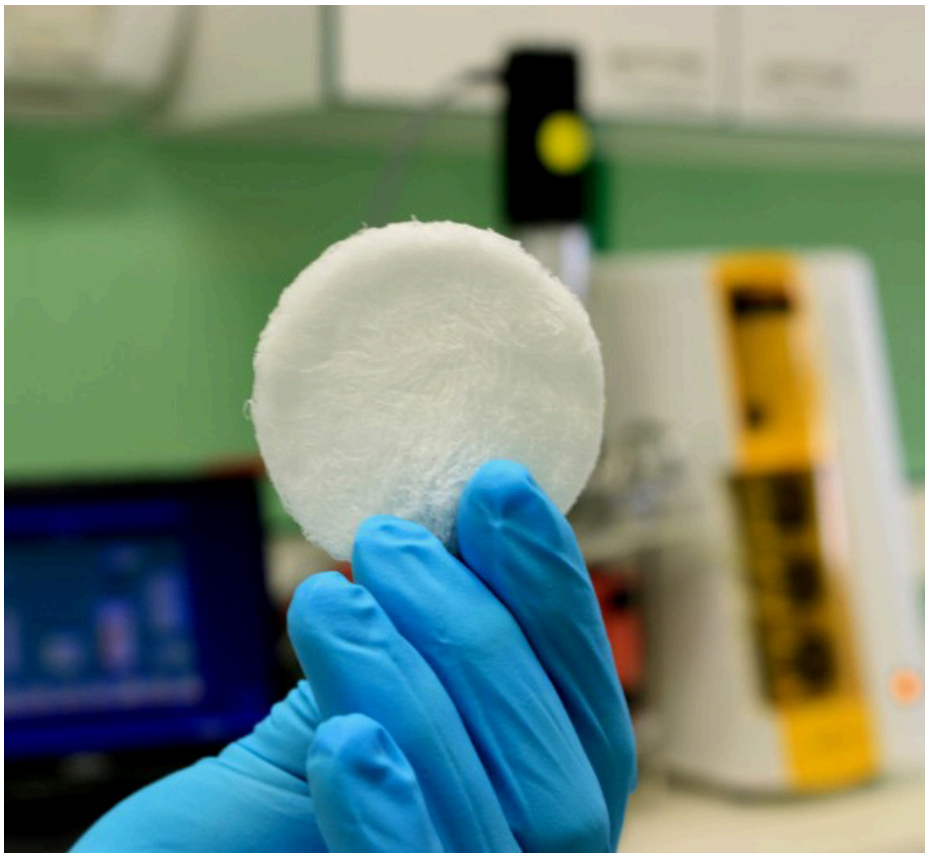

Fig. 2: Wound dressing (nonwoven/fleece) made from alginate fibres derived from bac-teria. Bacterial alginate nonwoven materials absorb up to 70% more liquid than marine alginate nonwovens. © Hohenstein Institute

By working specifically on optimising the bacterium's alginate biosynthesis, the researchers succeeded in improving the composition, and therefore the properties and yield of the alginate. This meant that they could make customised alginates that are particularly suitable for producing fibres for use in medical products. In a pilot production facility, the research partners were able to spin fibres from alginate and alginate-viscose, and turn them into innovative nonwoven materials and wound dressings within the established process. When the new wound dressings were tested in use, the alginate product that had been made using biotechnology was impressive for its liquid absorption capacity, which was significantly better than that of commercially available marine alginate-based wound dressings. The bacterial wound dressings absorbed up to 70% more liquid than marine-based dressings.

„The results that were achieved from this successful research project will form the basis for incorporating bacterial alginate in industrial production," declared Dr. Guido Meurer, a member of the Management Board of BRAIN AG. „Now our next goal for the future is to identify other areas of application for bacterial alginate and so open up new sales markets for customised ‚special alginates'," added Dr. Daniela Beck from Kelheim Fibres. „Until now it has been impossible, or very difficult, to vary and optimise the material properties of alginate. Thanks to biotechnology, there is now nothing to prevent the targeted use of alginate in specialist textiles," said a delighted Prof. Dirk Höfer of the Hohenstein Institute.

Companies interested in alginate products made using this biotechnological process are invited to share in the success of the research partnership. There are a range of possible areas of application for which the technology could be licensed.

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Dear readers, dear subscribers,

now it's the beginning of September 2016, holidays are over and we have a lot of interessting news and a lot of interesting events for your appointment calendar.

So the amount of the German and the International newsletters is constantly growing. We hope, we can give you with this information a good help for your daily work and your planning tasks.

Yours sincerely

Reinhold Schuster

The map shows where the readers of the cleanroom online newsletter are coming from: if you want to get in contact with these readers please contact us.

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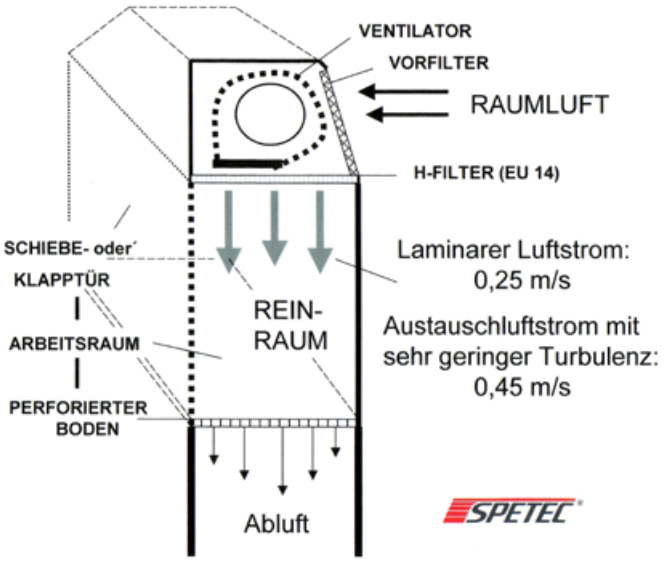
Suspended module

Example showing an inexpensive way of creating partial sterile clean air areas

For some 15 years now, Erding-based SPETEC Gesellschaft für Labor- und Reinraumtechnik mbH have been designing and building clean rooms of various sizes that allow flexible design, manufacture and installation to meet customer requirements and needs. To date, these products have been used in a whole range of different areas of application. They are installed in all kinds of industrial buildings, wherever there is a need for especially clean working conditions and where an extremely sterile environment is needed or recommended.

The characteristic design feature is a laminar flow module equipped with a high quality fan and a filter system made up of a pre-filter and a high-performance filter (EU 14). The filter classification EU 14 indicates that this filter is capable of filtering out 99.995 % of all particles with a diameter ≥ 0.5 µm. The size of the module is variable, depending on the precise application. The tried-and-tested approach to creating high quality clean air workplaces, located either in an enclosed clean room or in air-conditioned rooms, is to suspend a module above the workplace.



Example showing a module

The laminar flow of clean air creates a restricted zone that is sterile and free of particles. If larger clean air zones (clean room cells) are needed, it is also possible to install and connect several modules alongside each other. If the intended clean room contains equipment or furniture, SPETEC recommends a low-turbulence flow of clean air to ensure that air is exchanged throughout the space. SPETEC manufactures the modules and all accessories in compliance with GMP (good manufacturing practice) standards and is accredited accordingly. In addition to the standard sizes shown in the company's catalog, a number of options are available.

In-house fabrication facilities allow custom sizes to be manufactured to meet specific customer needs. SPETEC's experience shows that the clean air area can be any size up to 250 m². Today's modern modules can be suspended at any height or secured to the ceiling. They are quiet in operation and feature a filter change indicator. The filter is easy to replace. The period for which the filter remains sufficiently effective depends on the quality of the air in the room. In some cases, a service life of four years and more has been recorded in practice.

With new builds and renovation projects, modules like this can also be recessed in the ceiling. This method of producing clean air represents an inexpensive alternative to complex, fully enclosed clean rooms. If entrances and windows are well sealed, a similar level of air cleanliness can be produced if the systems run permanently.

The characteristics and quality categories for clean rooms are laid down in the following standards: DIN EN ISO 14644, Part 1 (classes

Example showing an inexpensive way of creating partial sterile clean air areas

Hängendes Modul

1 – 9), DIN EN ISO 14698, Parts 1-3 and VDI 2083, Parts 1-18 (classes 0 – 7); US Federal Standard 209E (classes 1 – 100 000) or in the EC GMP Guidelines (classes A – D).

The things that have the greatest impact on keeping objects clean are the ambient air and people. Clean rooms are also contaminated as a result of particles being transported through the air, the introduction of particles on technical surfaces and the production of particles by equipment, staff and running processes. In a class 8 clean room, more than 600 million particles (> 0.5 µm Ø) per cubic meter are given off per person per shift by the skin and clothing alone. This figure, along with other counts of particles of the same size given off when staff in protective clothing move (when sitting with gentle movement of the lower arm: 20,000; when standing up: 50,000 and as a result of slow walking: 80,000 per person) is based on data from the Fraunhofer Institute for Manufacturing Engineering and Automation (IPA) in Stuttgart. In addition to microdroplets, dust and smoke particles, the ambient air mainly contains bacteria (~ 0.5 – 50 µm Ø) and viruses (~ 0.005 – 0.1 µm Ø). Bacteria that are resistant to antibiotics can be extremely dangerous for humans, particularly in medical environments. Most of these particles, however, are not hazardous to healthy people. The situation is different for sick people, particularly those with an acute immune deficiency or with open wounds, and who must be treated in the ambient air or in air-conditioned rooms with air circulation systems.

To achieve an even more favorable air cleanliness classification, SPETEC recommends separating the room with a strip curtain: Within this space, it is then possible to work in a particle-free, sterile environment. Sensitive equipment or tools can be used and stored there. All this can be achieved without the need for any significant building work.

Suspended module with strip curtain

In summary, it can be seen that an expensive, fully enclosed clean room may not always be needed, particularly when operators need to move around in the room. The inexpensive, flexible SPETEC modules can also be fitted or suspended as required.

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Decentralized Compressed Air Dryer Integrated in Centralized Control System

Bespoke Compressed Air Dryers for Clean Room Production

The Dortmund-based German company Boehringer Ingelheim microParts GmbH has set up a new clean room manufacturing area for the production of small and extremely small PEEK moulded parts as part of a recent product expansion project. Because of the parts' low throughputs, installing a central compressed air drying system was out of the question. Hence, Motan-Colortronic developed and supplied a bespoke material conveying system with twelve specially-designed compressed air dryers that are integrated into a centralized conveyor control unit with a centralized process visualization system.

Boehringer Ingelheim microParts produces its Respimat inhaler, a special atomizer for delivering liquid medication, at its Dortmund production site. The inhaler is composed of about 30 individual parts, the smallest of which weighs around 1 mg. All parts that come into contact with the agent, which includes five that are made of plastic, are manufactured by the company itself. These parts are produced under GMP and FDA-compliant conditions in GMP Grade D clean rooms.

Boehringer Ingelheim microParts' latest product expansion project revolved around the production of small and extremely small parts at its own production site in Dortmund. To do so, the company commissioned Motan-Colortronic with the design, production and installation of a new material supply system. This material supply system was to be designed for the production of small and extremely small PEEK parts with shot weights of between 0.7 and 5.5 g. In designing this system, it was important to take into account the system's low throughputs of between 200g/h and 1.2 kg/h. Further, the material drying system had to be designed such as to account for the fact that PEEK, which is a high-performance polymer, is hygroscopic and, in line with the latest processing recommendations, needs to be dried to a residual moisture content of about 0.05% at a temperature of 150 to 160 °C. Further, there was the additional requirement that the material had to stay dry while in the conical pile and right up to the point of discharge including while the machine is idle. Failure to do so would have meant that the moist material would have had to be removed and discarded under controlled conditions every time the machine was stopped. This would have been extremely expensive, as this highly special production process does not permit any of the rejects or sprue to be recycled.

Every compressed air dryer has its own control unit, which communicates with the centralized control system through the Profibus'. (Photo: motan-colortronic)

The entire system can be operated and monitored using the LINKnet 2 visualisation system installed in the clean room or from the central control unit. (Photo: motan-colortronic)

As a result, the only viable option was the use of a decentralized compressed air dryer system. The dryers that were subsequently installed were modified LUXOR CA compressed air dryers manufactured by Motan-Colortronic. The dryers depressurize ultrapure compressed air from 6 bar to atmospheric pressure. This produces dry process air with a low dew point that is subsequently supplied to the drying hopper via a temperature-controlled heater, absorbs the moisture and exits the hopper via an outlet leading into a special clean room air extraction system.

In order to ensure that the compressed air dryers will work reliably even when working with low throughputs, Motan-Colortronic performed a wide range of tests and analyses at its own technical centre in Friedrichsdorf. The data from these tests were used to develop the process specifications and subsequent validation.

The average residence of the material inside the dryer is about three to four hours, with respect to which the processes are operated around the critical ranges' mean. The drying temperatures for the compressed air dryers are selected at the central operating panel. The temperature sensors are tested once a year and calibrated if necessary. The same applies for the ultrapure compressed air system in order to ensure that the compressed air is of consistent quality.

The injection moulding machines are supplied with material by Motan-Colortronic medical range CSK conveyors.

Material supply system with batch tracking

The material supply system contains two octabin stations and is located inside a separate room outside the injection moulding area. As soon as one of the bins is empty, a signal is sent to the central control unit and the two-component valve between the two octabins automatically switches from one

Bespoke Compressed Air Dryers for Clean Room Production

bin to the other. However, this is only possible if the two bins contain the same batch. If this is not the case, the conveying system is disabled and a corresponding signal sent.

The process for changing the octabins is subject to a strict set of rules. Once the empty container has been removed, the machine operator has to log into the system and authenticate himself. Next, the station at which the container is to be changed has to be identified using a scanner, after which the material and batch codes of the new octabin also have to be entered into the system with the scanner. If the material code is correct, the new octabin can be fitted. Both the removal of the empty container and the fitting of a new octabin are monitored with a light barrier. The system records every deviation from these rules as an error, at which point it records the name, date and time and disables the material supply system.

Batch changes care closely linked to lot changes, which are subject to yet another strict procedure. In order to remove any pellets from the material lines when changing lots, the system has been equipped with a suction-based return line that allows the system to be completely emptied of all residues. While this process is active, the conveyor units at the injection moulding machines are disabled. Each dryer is furthermore fitted with an additional slide valve at the bottom. To ensure that the new material is completely dry, this slide valve will only open once the preset residence time has expired when the machine is restarted.

The parts are produced under GMP and FDA-compliant conditions in GMP Grade D clean rooms. (Photo: motan-colortronic)

Networked control with two bus systems

Safety is critical to the manufacture of medical products. This is why is was vital to Boehringer Ingelheim microParts to employ a comprehensive system capable of enabling reliable compliance with documentation requirements and of protecting the system from incorrect and misuse.

The entire material supply system and all of the control components for the dryers and conveyors as well as the material supply scanner is consequently integrated in a centralized control unit with a LINKnet 2 visualisation system from Motan-Colortronic. This system in turn is connected to the company's Ethernet and hence the PDA system through the visualisation system. The system records and stores all data together with a time stamp, amendments, new and old values and user name.

The entire system can be operated and monitored using the LINKnet 2 visualisation system installed in the clean room or the central control unit. Each of the system's units is furthermore equipped with a decentralized operating panel that displays important data such as the unit's operating temperature and pressure.

The scanner is used to record bin changes and for entering the material and batch codes of the new octabins. (Photo: motan-colortronic)

In line with current regulations, all of the components of the material supply system are GMP/FDA compliant. The material lines and return line, including the elbows and Y-pieces, are made of borosilicate glass, and the vacuum line of V2A stainless steel. The dryers, drying hoppers and separators are made of electropolished stainless steel with specific surface roughness'. All of the above is documented in material certificates.

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EcoCCompact from Dürr Ecoclean: a new space-saving system for cleaning and preservation with hydrocarbons and modified alcohols

Versatility for maximum efficiency and targeted cost reduction in industrial part cleaning

With the EcoCCompact, Dürr Ecoclean has developed a versatile full-vacuum system for parts cleaning and corrosion protection with non-halogenated hydrocarbons and modified alcohols. The successor to Compact 80 C/P offers a wide range of options, from rapid degreasing right through to sophisticated cleaning tasks conforming to exacting cleanliness specifications. Innovative technologies guarantee maximum cleaning efficiency and a targeted reduction in per-unit costs. Besides being extremely compact and easy to operate, the new EcoCCompact also looks good and is excellent value for money.

The EcoCCompact system can be operated under a full vacuum with non-halogenated hydrocarbons or modified alcohols (polar solvents) and it is easy to change from one solvent to another.

Small and medium-sized enterprises, in particular, are often faced with the challenge of having to meet different cleaning demands reliably and cost-effectively with a single cleaning system. Fast processing times, high machine availability and user-friendliness are also essential, as well as short delivery times and environmental compatibility. With this in mind, Dürr Ecoclean has designed the versatile EcoCCompact which supersedes the Compact 80 C/P model. The system is operated under a full vacuum with non-halogenated hydrocarbons or modified alcohols (polar solvents) and it is easy to change from one solvent to the next.

A new approach to versatile part cleaning

A well-thought-out concept and a multitude of standard options make EcoCCompact easy to adapt to a company's specific requirements, for example, from degreasing through pre-washing and intermediate washing right up to fine cleaning. With a footprint of just 4,000 x 1,600 x 2,700 mm (L x W x H), the space-saving housing can hold one, two or three fluid tanks for cleaning and corrosion protection processes. Tank two and/or three can also be retrofitted at a later date - for example, if cleanliness requirements rise or if parts require corrosion protection. Each fluid tank has its own energy-efficient flood pump with variable-frequency drive unit, as well as a separate filter circuit. Designed as a combined filter system, bag or cartridge filters can be used as required without having to change the housing.

Furthermore, the EcoCCompact can be adapted to different batch sizes. The work chamber is designed to hold batches up to 530 x 320

Thanks to three flood tanks and numerous standard options, the EcoCCompact can be perfectly adapted to specific user requirements. It can be used for anything from pre-washing and intermediate washing right through to final cleaning and corrosion protection.

Versatility for maximum efficiency and targeted cost reduction in industrial part cleaning

x 200 mm (L x W x H) in size. Alternatively, with the same footprint, a larger work chamber can be installed to hold part containers with a height of 250 mm. This not only increases throughput but also cuts part cleaning costs.

In addition, the new system is remarkably adaptable in operation. Via the modern HMI control panel with touchscreen and self-explanatory pictographs for quick and safe operation, the operating mode can easily be switched from cleaning to corrosion protection and vice versa as required. Thanks to the integrated part visualization unit, process tracking becomes intuitive and much easier.

Maximum cleaning efficiency at lower per-unit costs

To improve the quality of cleaning or degreasing processes and cut costs at the same time, a wealth of experience and innovative technologies from other Dürr Ecoclean systems have found their way into the EcoCCompact. Rotation of the part container, for example, is controlled by a variable-frequency drive unit. This enables the movement of the basket to be adapted to the parts to be cleaned, thus optimizing the process. Moreover, parts can be specifically positioned in the work chamber to ensure that critical areas are reached, or to allow fluid to drain off before vacuum drying. The advanced vapour degreasing respectively rinsing option also serves to optimize the process. With this function, the oil-laden solvent is fed directly to the distillation unit. This minimizes the accumulation of oil in the solvent, or dirt in the flood tank, and thus improves the quality of the processing fluid.

To reduce non-productive times, the EcoCCompact has efficient pumps and large-diameter piping. Operating costs are reduced also by using frequency-controlled flood pumps and recycling heat from the distillation process to warm the fluid. A further advantage of the new compact system is the option to cool either with water or air. The EcoCCompact is convincing also by its attractive price/performance ratio and its high level of standardization ensuring short delivery times.

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Cherwell to offer expert insight in environmental monitoring and process validation to both NHS and industrial pharmaceutical manufacturers

Microbiological Environmental Monitoring Features in two National Conferences supported by Cherwell Laboratories

Cherwell Laboratories, will be offering expert knowledge and demonstrating their comprehensive range of specialist environmental monitoring and process validation products at two events in September 2016, organised by the Pharmaceutical & Healthcare Sciences Society and the NHS. Whether pharmaceutical manufacturing facilities are located in an industrial or NHS setting, the issues of microbiology, regulation and patient safety must be addressed whatever the location. From 45 years of experience, Cherwell fully understands the challenges faced in differing manufacturing settings and can advise accordingly at both events.

The first event on 6th September is the PHSS Annual Conference 2016, which will be held at the School of Pharmacy, UCL, London. The one day conference, which is free-to-attend for PHSS members, will provide an important insight into the impact of EU GMP regulation and ISO standard changes, together with applied best practice guidance, on risk based environmental control.

The second event, the NHS Pharmaceutical QA Symposium for Technical Services, will be held on 20th & 21st September at the Crowne Plaza Hotel in Chester. Aimed at pharmacy professionals working in pharmaceutical production and quality assurance environments within both the NHS and commercial sectors, the event offers a variety of presentations and workshops to educate and update delegates on current issues. Topics covered will include: Pragmatic approaches to eliminating spores and How to set action and alert limits for environmental microbiology.

Cherwell, who will be celebrating their 45 year anniversary this year, have built a reputation for providing high-quality products, expert advice and excellent customer service to meet the specific requirements of environmental monitoring and process validation. Members of the Cherwell team will be attending both events to demonstrate Cherwell's product range, offer practical advice and discuss customer-specific requirements. Items from the following ranges will be on display: Redipor® prepared media - such as petri dishes, settle plates, bottled media, broth bags, vials and ampoules; SAS microbial air samplers for environmental monitoring and Mar Cor bio- decontamination solutions.

Andrew Barrow, Sales Manager, Cherwell Laboratories, who will be attending both events, commented, "Microbiology, regulation and patient safety are similar for all pharmaceutical manufacturers, but the individual challenges to satisfy them differ between industrial and NHS and from one site to another. We work with our customers to provide them with the most appropriate solution for their specific needs. These events allow us keep up to date with regulatory changes and the challenges they present to our customers, so ensuring that we can continue to offer the best possible advice and solutions".

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Statement by Joachim Schäfer, managing director of Messe Düsseldorf GmbH on MEDICA 2016 in Düsseldorf (14 - 17 November)

Medical technology continues to be a fascinating growth market. There was a very strong phase, particularly at the beginning of the millennium, with enterprises achieving two-digit increases with regard to the sector-wide average over a period of several years in a row. This phase seems to have ended. However, the medical technology business continues to be described as promising throughout the course of numerous market reports. The innovative power of the suppliers is a strong indication of continuing good market perspectives. The share of expenditures for research and development in relation to sales, for example, is at nine percent with respect to German medical technology companies, significantly higher than those in the chemical industry or the processing industry. In addition, according to the European Patent Office, in 2015, there was no other technological sector where as many patent applications had been submitted on a world-wide scale than in the field of medical technology.

For the companies, access to their customers has changed, a development once more characterised as a market-trend barometer this year, thereby significantly influencing the world's leading medical trade fair, the MEDICA in Düsseldorf (scheduled date: 14 – 17 November 2016/ Monday - Thursday). While medical technology suppliers have been dealing with physicians and the directors of individual hospitals for decades, in today's age, investments take place through co-operations within purchasing networks or in large corporate hospital operator groups through higher-ranking, centrally acting entities. Furthermore, a strong position is due to trade, via which suppliers are able realise their market presence in preferred countries in a relatively simple way, particularly in the export business. With all of these developments, suppliers see themselves as being confronted with tougher competition and a stronger level of price pressure.

The concentration of purchasing power is reflected at the MEDICA by the visitors' high level of decision-making competence as well as an increase of visitor numbers from non-medical fields, such as the hospital management and trade on a national and international level. More than 80 percent of MEDICA visitors (2015: 130,000) are significantly involved in or provide professional consultation for purchasing decisions.

Suppliers in top form – digitalisation continues to make progress

For suppliers, any MEDICA trade fair provides the opportunity to present themselves in top form to an audience with decision-making power and involved in sales. This seems more necessary than ever because the medical technology is encountering the outlined market developments with value-oriented sales techniques. Thereby, the focus is not just on the price of medical-technology products, equipment and systems, but on a cost-benefit consideration throughout the complete product life cycle. After-sales services such as unit maintenance, for example, as well as user trainings or also suitable financing are being taken into consideration here.

With regard to new products, the MEDICA 2016, with once again around 5,000 exhibitors from approx. 70 countries, will be of particular interest to the global health business. This is because the market is characterised by the dynamics of important supplier trends. Therefore, a visit to Düsseldorf at the middle of November is an absolute must for anyone who wants to stay up-to-date.

For example, the digitalisation of healthcare is progressing at an unstoppable rate, and this concerns all fields, outpatient and clinical care, as well as patients and physicians alike. With reference to Germany, the latest enacted E-health Act should ensure that the networking of stakeholders within the scope of the healthcare process is considerably optimised by means of a more effective collection and utilization of patient data – at least this has been stated as its clear goal. The predominant „digital patchwork" up until now pertaining to intrinsically sophisticated, but poorly compatible solutions could now be woven into a better overall system using consistent data integration.

Innovations in focus and great prominence "waiting in the wings"

MEDICA 2016 visitors will be able to see for themselves what the digital future in the healthcare sector will be like via the exhibitors' many innovations as well as the lectures and presentations at the MEDICA CONNECTED HEALTHCARE FORUM (with the MEDICA App COMPETITION) or the MEDICA HEALTH IT FORUM (each in hall 15).

In particular, "wearables" and smartphones in combination with special health apps, which can also be used by patients themselves, have the potential of becoming an indispensable element of networked health in the future. Numerous new products relating to this topic have been already presented at the MEDICA 2015, such as a mobile 22-channel ECG system for tablet PCs and smartphones as well as an analysis tool for recording sleeping activity – delivering a quality level virtually equal to that of sleep

Statement by Joachim Schäfer, managing director of Messe Düsseldorf GmbH

laboratories. Countless other mobile health applications are currently under development, whereby many focus on cardiovascular diseases, diabetes as well as the remote monitoring of therapies. Here a particularly high level of user potential can be expected in the future with regard to patient numbers.

The topic of big data is not any less exciting, whereby it would be probably better called smart data. At its core, it has to do with compiling and evaluating enormous amounts of patient data in order to be able to gain knowledge with regard to the development of and effective therapy for certain diseases. The best future prospects can be expected due to big players in the digital economy such as Google, Apple, Microsoft or IBM also becoming active in the healthcare sector in addition to many startups. These players are currently investing enormous sums, for example, in the development of artificial intelligence. The results entail innovative software, which, in part, offers sensational options. This applies, for example, to the research and development of algorithms for automated image analysis. In the field of stroke, there is already a very promising solution with the goal of making the professional expertise of neurologists generally available via the software-based assessment of CT images. In this way, faster decisions with regard to suspected cases of stroke can be made in the accident and emergency departments without a neurologist necessarily being present.

The MEDICA ECON FORUM will also be dealing with the opportunities and consequences of healthcare digitalisation. The forum (in hall 15), organised as a joint effort between the Techniker Krankenkasse (a German statutory health insurance company) and Messe Düsseldorf, has been firmly established as a platform for health policy dialogue, shown by the confirmations of prominent guests to again attend this year's event. Those who have already confirmed their participation include, among others: The Federal Minister of Health, Hermann Gröhe, the NRW Minister of Health, Barbara Steffens, or also Maria Klein-Schmeink, health policy spokeswoman of the Bundestag parliamentary group Alliance 90/The Green Party (Bündnis 90/Die Grünen).

The third dimension is finding its way into operating theatres

Not only bits and bytes are affecting the healthcare business, however. Medical technology also has exciting topics to offer. At the moment, innovations for interventional procedures are seen as particularly important. In the case of modern surgery procedures, an „integrated" approach is in demand. Data deriving from medical imaging flows into the controls of surgical assistance systems. They can even be generated during surgery by imaging systems directly available in the operating theatre, ensuring that the intervention can take place in a precise and gentle manner. Here, above all, progress in the field of endoscopy and instruments for minimally invasive surgery translate into great benefit.

Currently, the third dimension is increasingly finding its way into operating theatres. In the case of so-called 3D laparoscopy systems, there are two image sensors that are precisely aligned with each other at the end of the endoscope, providing the surgeon with a lifelike endoscopic 3D image during the course of minimally invasive surgery. The spatial depiction makes it easier for the surgeon to make an assessment with regard to anatomy and the use of instruments. Thereby, for example, needles can be better perceived during suturation, which enables a more precise and quick procedure.

Conferences directly integrated into the specialist trade fair

Such important medical technology trends will not only be represented by exhibitor innovations at the MEDICA, but will also be reflected within the scope of the programmes of the accompanying conferences.

For example, these include the MEDICA MEDICINE & SPORTS CONFERENCE, dealing with the use of applications in close proximity to the body and „wearables" for monitoring vital signs, or the MEDICA EDUCATION CONFERENCE.

This conference is being organised this year for the third time by the German Society for Internal Medicine (DGIM) and offers participants an excellent opportunity to gather and exchange information on new technologies and their medical use as part of a scientific training event held in parallel to the world's largest medical trade fair. Of the four conference days, each individual day offers a particular thematic focus. Along with the innovations already mentioned in the field of 3D laparoscopy, among other things, the event will be started off with „New operative techniques during surgery".

On the other days, the MEDICA EDUCATION CONFERENCE will be dedicated to imaging and interventional procedures (e.g. magnetic resonance tomography and sonography), future technologies for internal medicine (e.g. remote monitoring in the case of chronic disease) as well as, on the event's last day, diagnostics in the fields of internal medicine, laboratory medicine, toxicology and hygiene.

With reference to the MEDICA conference programme, furthermore, the 39th German Hospital Conference as a leading event for the directors and management of German hospitals, the international DiMiMED conference for specialists from the field of disaster and military medicine as well as the MEDICA PHYSIO CONFERENCE will be forming a close content-oriented link to the topics of the specialist trade fair – aimed toward the specific interests of their respective participant target groups.

Complete range of outpatient and hospital care

Now, and in the future, a central strength of the MEDICA continues to be that it does not just deal with solutions for one individual medical specialist discipline at a time, but that it offers solutions for the complete "workflow" of patient treatment.

Almost 5,000 exhibitors will use the MEDICA 2016 in order to present a full range of new products, services and processes for use within the scope of outpatient and clinical care on over 116,000 square meters of booked floor space.

The individual focuses of the MEDICA trade fair, which are clearly structured according to hall, include: Electromedicine/medical technology (more than 2,500 exhibitors), laboratory technology/diagnostics, physiotherapy/orthopaedic technology, commodities and consumables, information and communication technology, medical furniture and specialist furnishings for hospitals and doctors' offices.

COMPAMED – hotspot for complex high-tech solutions

This year, once more in parallel to the MEDICA, the COMPAMED will be taking place for the 25th time. Always scoring top annual results with reference to the number of exhibitors and visitors, it has long since developed into the leading international marketing communication platform for suppliers of the medical technology industry. And it is not just the numbers that are right with almost 800 exhibitors. Also the quality of the range of offers has changed through the years, continuously improving in stride with the changes on the medical technology market itself. Where, at one time, simple parts, components and equipment for technical devices and medical products had primarily been presented, today, COMPAMED is a hotspot for complex high-tech solutions.

Here, the microsystem technology solu-

Statement by Joachim Schäfer, managing director of Messe Düsseldorf GmbH

tions for mobile diagnosis, monitoring and therapy systems are particularly in line with the current trend. These include, among others, smart sensors and energy storage systems for use in „wearables“, microtechnology applications for intelligent implants or printed electronics. In addition, the subcontracting and outsourcing of services for all elements of the process chain (R&D, production, supply chain management, quality management, spare parts handling, etc.) are continuing to gain in importance. Irrespective of whether a customer from the medical technology industry is a large corporation or a small family-run business: Suppliers present themselves as competent partners to all of them. This enables them to focus on their respective core competencies and to improve efficiency by outsourcing processes which are not within the scope thereof.

With 18,800 visitors last year, the COMPAMED broke its best record so far. One of the reasons for this: Extending the trade fair to four days. This year, the event will also take place from Monday to Thursday, being held fully in parallel to the MEDICA (in halls 8a and 8b). This grants suppliers and their customers - primarily product developers, responsible for production or purchasing decision-makers of the MEDICA exhibitors - valuable extra time for discussions concerning joint projects.

This unique combination allows MEDICA and COMPAMED to represent the entire process chain and full range of medical products, devices and instruments. Together, they keep the Düsseldorf trade fair complex (19 halls) fully booked.

As in previous years, it will be possible to visit both events with a single ticket.

14 th - 17 th Nov. 2016: MEDICA 2016 + COMPAMED 2016, Duesseldorf (D)

Messe Düsseldorf GmbH
D 40001 Düsseldorf

Fakuma 2017 Represents the Plastics Industry from 30 Countries

Fakuma Celebrates 25th Birthday in the Fall of 2017

15 months still remain until opening day, but attention will once again be focused entirely on plastics technology from 17 to 21 October 2017 on Lake Constance where Germany, Austria and Switzerland meet! At the premiere event there was really no way of foreseeing that Fakuma would evolve into a “Mecca for plastics processing companies” at the Friedrichshafen Exhibition Centre – in particular for injection moulding. The Fakuma international trade fair for plastics processing is now able to celebrate its 25th birthday and in all probability will once again host 1700 exhibitors from 30 nations as the information, communication and procurement platform for plastics processing.

Although the product and service portfolios of the manufacturers and distributors (i.e. Fakuma’s exhibitors) have changed during the course of the years, injection moulding, extrusion and thermoforming technologies still make up the great majority of the exhibition offerings. From well-established and new materials, continuously optimised production processes and increasing functions integration, right on up to the portrayal of consistent processes or alternative 3D printing in industrial quality– Fakuma has often paved the way to new approaches for innovative solutions in plastics processing, and has thus repeatedly created new markets during its 24 sessions to date!

Challenges such as lightweight design, substitution of aluminium and steel and reduced consumption of materials and energy have lead, and are leading, to new developments in the field of plastics, entirely new material combinations, unconventional manufacturing process mixes, new tooling designs and much more – and they’re making their way from theory to practice, or from the developmental stage to industrial use, at trade fairs like Fakuma. Not excluding the possibility of going astray, developers, manufacturers and distributors at Fakuma explore the opportunities for their products and solutions, and alone that and nothing else is the primary concern, and thus the purpose of a trade fair!

And thus it’s no wonder that “market and marketing-oriented” companies and institutions have once again decided to participate at Fakuma, which is currently the case to a very great extent. Already at a very early registration stage, Fakuma project manager Annemarie Schur is announcing strong booking and reservation activity. “More than 65% of the exhibitors who participated at Fakuma 2015 have already made firm bookings for the event in 2017, and the list is growing every day. This is a valuable indicator for us with which we are of course quite pleased, and it also shows the great importance placed on this technical event by the manufacturers and distributors. The fact that participation of foreign exhibitors is also once again increasing and that we’re already able to welcome companies from 30 countries is noteworthy as well!”

In light of these prospects, the Fakuma international trade fair for plastics processing is headed for record-breaking participation and a full house once again in its anniversary year!

17th - 21th Oct. 2017: Fakuma 2017, Friedrichshafen (D)

P. E. Schall GmbH & Co. KG
D 72636 Frickenhausen

Gx RTF ClearJect syringe is manufactured in Germany

Gerresheimer at CPhI 2016 - innovative solutions for sensitive pharmaceutical drugs

The first Gx RTF ClearJect syringe in COP to be made in Germany is one of the innovations on show at CPhI from October 4-6 in Barcelona. Gerresheimer's international team of experts will be presenting them to visitors at stand 2H28 in the Fira de Barcelona Gran Via exhibition center. Two of those experts will also be making presentations on multilayer tablet containers and the use of tungsten in syringe production.

Gerresheimer is now manufacturing the first Gx RTF ClearJect plastic syringe made of COP in Germany

COP does not leach any metal ions into the liquid pharmaceutical drug. The entire syringe, including the needle overmould, is produced in one single step and the product is also tungsten and adhesive-free. COP has a high pH tolerance and, unlike glass, there is no change in pH value over time during storage. Another key argument in favor of the Gx RTF ClearJect syringe is excellent user safety. COP is extremely inert and break resistant, so it is an excellent choice as a packaging material for sensitive or toxic active ingredients. High elasticity in comparison to similar materials also enhances the Dupont impact strength of COP syringes.The use of a high-viscosity silicon oil to coat the inside of the syringe barrel reduces the level of syringe content contamination with silicon particles, and the integration of standardized closure components also offers the pharmaceutical manufacturer flexibility. The application of a concept to create the entire innovative COP syringe out of standard components ensures its cost-efficiency. It has standard needles, plungers, plunger heads, backstops and closures.

COP is an interesting alternative to the traditional glass syringe as a result of the new demands on primary packaging posed by innovative active ingredients. Oncological drugs can be extremely aggressive, so syringe break resistance is an important criteria in the selection of their primary packaging. Innovative biotech drugs, on the other hand, are often administered in tiny dosages and many of them are very expensive. With this type of drug, it is important to rule out any interaction between the syringe material and its content. COP meets all these requirements.

Presentation on the use of tungsten in the glass syringe moulding process

"A few liquid dose pharmaceuticals react to the traces of tungsten that are left behind during the drilling part of the syringe manufacturing process," said Bernd Zeiss, Biologist and Technical Support Manager at Gerresheimer Medical Systems in Bünde. He explains why this is the case and talks about low-tungsten and tungsten-free syringe alternatives for sensitive applications in his presentation.

Presentation on DUMA Twist-Off Protect – the new generation

"Pharmaceutical drugs are often sensitive to moisture vapor and oxygen. As a result, they need more effective protection from suitable packaging," said Dr. Wolfgang Dirk, Product Management and Innovation at Gerresheimer. "That's why we've extended our established range of Duma-family products to include an additional model with improved barrier properties for enhanced air-tightness and more reliable content protection." He will be explaining the key aspects, potential pitfalls and applications for multilayer containers and their closures.

Ampoules and vials are top sellers

Vials are one of Gerresheimer's most popular and top-selling products. There is high demand for them because they are one of the most frequently used pharmaceutical packaging products in the world. Gerresheimer manufactures them in the USA, Asia and Europe with filling volumes of between 1 and 50 ml.

Gerresheimer AG
D 40468 Düsseldorf

All the strengths of the new Gx RTF ClearJect syringe at a glance.

Phillips-Medisize strengthens its presence in Europe through integration of Medicom A/S, Denmark

INNOVATIVE SOLUTIONS: Phillips-Medisize will present solutions for development and manufacture of medical devices in drug delivery, consumable diagnostics, and medical/surgical consumable technologies at COMPAMED in Dusseldorf, Germany, 14-17 November 2016 (hall 8a, stand H15). The wide variety of contract services featured include device strategy, product development and manufacture across specialty drug delivery devices, dosing systems, disposables and consumables for diagnose components, disposable insulin pens, blood glucose meters, inhalators, multi-component dosing units, spray applicators, IV sets, peristaltic pumps, titration plates, mixing injectors, right up to complete MDD application sets. Phillips-Medisize offers its customers a complete service chain, from first ideas to finished solutions, from the design stage all the way to the ready-to-use sterile-wrapped medical products. The company's strong point in the market is represented in particular by complex disposables, controlled across all processes through highly prioritized quality assurance measures compliant with ISO 13485 as well as FDA standards and GMP (Good Manufacturing Practice). Highlights among the showcased examples of developments are wearable drug delivery devices which considerably ease insulin dosing and delivery.

Phillips-Medisize is always focused on quality, innovation and service. Successful and prosperous partnership with customers is based on process know-how, state-of-the art hardware and, last but not least, investment in qualified personnel. As the worldwide leading outsource partner for the design and production of medical and pharmaceutical devices Phillips-Medisize has once again extended its presence in Europe considerably in order to take account of the rising demand for biopharmaceutical and medical drug delivery systems. On June 1st, 2016, Phillips-Medisize announced the acquisition of Medicom Innovation Partner A/S, Struer, Denmark, including Medicom's subsidiary in Cambridge, UK. This leading provider of medical devices with a focus on product strategy and development of personal connected health drug delivery devices has grown continuously and employs a staff of 90 specialists in Denmark and the UK. Philipp-Medisize now employs about 500 engineers throughout its global design and development network with hubs in Struer, Denmark and Hudson, WI, USA to develop injectable and inhalation device innovations for global market.

The fundamental motives for acquisitions are deeply rooted in Phillips-Medisize's corporate strategy:

- to incorporate companies with high competence, culture and reputation in the medical device and pharmaceutical markets,
- to partner small and medium-sized expert firms with comparable engineering know-how – both for their qualified personnel, as well as their comprehensive plastics processing machinery
- to expand together with partners whose product program is a valuable complement to Phillips-Medisize's portfolio, and
- to enlarge the company's footprint in the respective markets.

For Phillips-Medisize, this transaction of acquiring Medicom is completely in line with the company's strategic focus on serving the rapidly growing market segments of diabetes and biologics treatments, as well as pharmacological and personalized oncology solutions. These markets need advanced products. Furthermore, the increased volume and wider program significantly reinforces its leading position in the segment of drug delivery devices. Customers of both companies will benefit from the comprehensive portfolio of integrated end-to-end services and obtain the expected prime quality supported by a worldwide service network.

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