Bosch expands pharmaceutical portfolio

- Flexible Sigpack VPF for powder filling
- Compact horizontal flow wrapping machine for hermetic packaging
- Solutions for complete lines from a single source

Bosch Packaging Technology, a leading supplier of processing and packaging technology, expands its expertise in the non-aseptic packaging process for pharmaceuticals. Following the introduction of the Sigpack TTMP topload cartoner for pharmaceutical products, the company now adds two further machines to its portfolio: the Sigpack VPF vertical flat pouch machine and the horizontal flow wrapping machine Sigpack HML. “Our new machines ideally complement the portfolio of Bosch Packaging Technology. We offer our customers from the pharmaceutical industry reliable and efficient solutions from a single source that can cover the entire production and packaging process,” says Dr Christian Walti, general manager at the Bosch Packaging Technology site in Beringen.

Pain killers in powder form are amongst the products typically filled into sachets. Thanks to the innovative sealing technology from Bosch, the machine produces hermetically sealed packages, which safely protect the product. The VPF allows manufacturers to flexibly expand their sachet production by up to twelve lanes. The pouch size can also be quickly and easily adapted according to customer requirements. Thanks to the high dosing accuracy and excellent sealing properties, the machine can produce and fill up to 1,500 sachets per minute precisely and at the highest quality.

In September 2016, the Sigpack VPF received the German Packaging Award from the German Packaging Institute (DVI) in the category packaging machinery.

Compact horizontal flow wrapping machine for hermetic packaging

Bosch further extends its portfolio by a compact horizontal flow wrapping machine, which can either
Dear subscribers,

the cleanroom-online team
and I wish you a healthy
and successful 2017

Looking forward seeing you at the LOUNGES in Stuttgart

Your
Reinhold Schuster
Minimizing risk potentials by the qualification of compressed air

Being prepared for the new VDMA guidelines

The impairments, caused by using compressed air of insufficient quality for operations in cleanrooms should not be underestimated. Seasonal influences (pollen count etc.), temperature and humidity, fine dust pollution at the point of origin, or impurities, e.g. of compressors can impair the quality of the cleanroom air and thus also the quality of the product.

**Compressed air is an important process medium and develops a far-reaching effect on the air quality**

Compressed air is among the essential process media and therefore indispensable for the medical and pharmaceutical industry. As compressed air is efficient, quickly available and easy to store, it is frequently used for transporting granulates, checking tightness or blowing out plastic blanks.

In practice, compressed air is, in contrast to cleanroom air, not sufficiently monitored. Therefore, a potential contamination risk exists during the manufacturing process, as compressed air often gets into contact with the product itself, but also indirect contact with the product, for instance via packaging material, can lead to a transmission of impurities. As a consequence of this, a negative effect on durability and sterility of the product is possible. There are contamination risks from different sources.

The good news is that risk potentials, in principle, are easy to identify and to minimize.

For the generation of compressed air, atmospheric air is aspirated from the surrounding and compressed by a compressor. Thus, within the compressed air there are all possible impurities such as particles, dust, humidity and steams, which exist in the surrounding. All these impurities occur then in compressed form. There is also an additional danger during the generation of compressed air: it is possible that impurities such as rust, dust, abrasion and oil, caused by the compressed air net itself, get into the compressed air out of the compressor or the medium lines.

Using compressed air of insufficient quality in sensitive production areas might result in a significant decrease of the product quality. It is therefore crucial to treat the compressed air in sensitive production areas for achieving the required purity. That is possible by a certain treatment in removing impurities from the compressed air.
Qualified compressed air enables the evidence of technical purity

The qualification of compressed air serves as evidence of the required purity. Basis for this is the international ISO 8573 series of standards. This series of standards enables the classification in purity classes based on specified parameters; particles, oil and humidity. Dust, airborne particles and pollen are counted among other things to these particles.

Within the compressed air system, water occurs in form of steam, water aerosol or water droplets and enters the system, especially via the atmospheric air. This humidity can cause rust in the pipes and lines. Furthermore there is a serious danger with regard to the growth of bacteria and moulds. Microbiological contamination as moulds and bacteria can enter the compressed air in this way. The usual lubrication of the compressors with oil may also lead to a permanent contamination of the compressed air system.

However, even with oil-free compressors small quantities of hydrocarbons in aerosol or gas form may enter the compressed air. So, escaping compressed air can have a negative effect on the quality of the clean room air.

Conclusion

Product-contacting compressed air needs to be equal or better than the room air, in which the product is manufactured.

The German Engineering Federation (VDMA) currently works on a draft concerning the purity of compressed air for defined applications in the food technology and pharmaceutical engineering. The estimated publication date of this work is 2017.

Apart from the prescribed period, companies, using compressed air in their cleanrooms, should think about a qualification. The quality of compressed air is an important factor for the quality assurance.

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Fig. 5: Generation of compressed air

Fig. 6: Visual inspection of low trace gases via oil impactor

Fig. 4: Test of the microbiological contamination
Phillips-Medisize Builds New 80,000 Square Foot Facility in Menomonie, WI

Phillips-Medisize Corporation announced plans to open a new 80,000 square foot manufacturing facility on its Menomonee Falls, Wisconsin campus. The state-of-the-art facility manufactures high volume prefilled drug delivery systems, and is planned to be complete in 2017. Investment in the new facility is driven by the signing of a new supply contract with a major biopharmaceutical company and is expected to employ more than 100 people at full production.

Matt Jennings, CEO and President of Phillips-Medisize, a Molex company, commented, “This expansion illustrates our continued commitment and investment in the design and manufacturing of drug delivery devices for biopharmaceutical companies, globally. Expanding in Menomonee helps us to further our manufacturing capacity to produce fully assembled and packaged drug delivery devices. We are proud of this leading-edge manufacturing campus featuring advanced molding and assembly, cold-chain drug handling, serialization technologies and FDA-registered dedicated clinical and pilot build facilities for drug delivery and finished combination products.”

The new facility allows for continued expansion. Business growth continues to accelerate as customers turn to Phillips-Medisize for complete design, development and manufacturing of combination products. Jennings continues, “The recent acquisition of Phillips-Medisize by Molex bolsters our ability to provide comprehensive end-to-end electronics solutions as part of our drug delivery device capabilities. Customer response to our addition of Molex electronics capabilities has been tremendous.”

The expansion is the latest in a series over the last four years, reflecting continued growth of contract design, development and manufacturing capabilities to serve the drug delivery, consumable diagnostics, and medical/surgical customers. Phillips-Medisize has also been dedicated to investing in its people through a strong collaboration with the University of Wisconsin-Stout, located in Menomonee, which provides technical resources and an educated workforce prepared to meet the growing demand of the drug delivery industry.

This past summer Phillips-Medisize acquired Medicom Innovation Partner, in Denmark, who focuses on the design and development of connected health drug delivery systems and combination devices. Earlier in 2016, Phillips-Medisize opened a 17,000 square foot dedicated clinical and pilot build facility for drug delivery and combination devices in Menomonee, Wisconsin. Last November, the Company doubled the size of the New Richmond, Wisconsin medical device facility and in late 2014 expanded its Finland facility. These investments demonstrate ongoing support for biopharmaceutical customers by providing design, development and manufacturing solutions.

Phillips-Medisize Corporation
CH 8309 Nürensdorf

Modular Cleanroom Technology – Serie CleanCell 2017

The newest generation of the cleanroom systems CleanCell4.0®, CleanMediCell® and CleanSteriCell® from SCHILLING ENGINEERING. Featuring state of the art technique and highest functionality:

- ISO Cleanroom classes 5-9 and GMP Cleanroom classes B,C,D,E
- Flexible modular design
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- Bus-compatible, whisper-quiet UF5 ULPa laminar flow modules

- Freely configurable Cleanroom-Control-System with integrated ISO-compliant monitoring, mobile operation from tablets and smartphones
- Low maintenance costs

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Dr. Stefan König (51) will become president of Bosch Packaging Technology on January 1, 2017. Dr. König holds a PhD in data mining and has been a member of the executive management since 2011. He oversees Technology (comprising Engineering, Manufacturing, and Quality), the Confectionery & Food and Liquid Food business units, as well as Assembly Systems and Special Machinery. Dr. König succeeds Friedbert Klefenz (61), who is set to retire from Bosch Packaging Technology on June 30, 2017. Mr. Klefenz will provide consulting to Bosch until his retirement.

Upon joining the Bosch Group in 1998, Mr. Klefenz assumed leadership of the Pharma Liquid product group at Bosch Packaging Technology. He has been president of Bosch Packaging Technology since April 2002. “Friedbert Klefenz has played a key role for years in advancing Bosch Packaging Technology as a leading provider of packaging and process technology. He has also helped make the division more international. We want to thank Mr. Klefenz for his years of commitment to the company. We also wish Dr. König great success in continuing his predecessor’s great work,” said Dr. Werner Struth, member of the board of management of Robert Bosch GmbH.

Dr. König has worked at Bosch since 1997. He has held various positions, including a stint in the Bosch Mobility Solutions business sector. In 2009, Dr. König transferred to the Bosch Packaging Technology division, where he initially oversaw the Assembly Systems and Special Machinery business unit.

Uwe Harbauer (52) will join the executive management of Bosch Packaging Technology on January 1, 2017. He will be in charge of sales. A mechanical engineer, Mr. Harbauer will retain his current position as management spokesman for Bosch Packaging Technology’s Pharma business unit.

Meanwhile, Klaus Albeck (57) will continue to be the member of the executive management responsible for finance and administration as well as IT coordination.

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Cleanroom Technology, Maintenance and Equipment Exhibition

Cleanroom Exhibition Istanbul

Facility managers and “Cleanroom professionals” who design and engineer “extraordinary spaces” for facilities will come together at the “one and only” Cleanroom Exhibition of Turkey in Istanbul on 20-22 April 2017.

Cleanroom 2017 Exhibition will be an appropriate business platform for all concerned sectors to present the materials, products, technology and services for the increasing demand of the facility managers and professionals who require “Cleanrooms” in their facilities.

In its capacity as a trade event aimed in particular at facility managers, system administrators, engineers, designers and laboratory professionals, the fair is primarily regarded as a communication and information platform of the industry where networking contacts can be established in addition to the presentation of new trends.

Cleanroom Istanbul 2017 Exhibition offers ideal business opportunities to make new business contacts and to meet the expanding industrial market of Turkey.

Advanced technologies, special knowhow and industrial equipment will meet the professional visitors from all around concerned industries of Turkey and the neighbouring countries of Eastern Mediterranean Area as well as the Middle East.

Aside from the extensive range of products and solutions to be presented by the exhibitors in the areas of maintenance and facility management, Cleanroom Exhibition will also offer an interesting accompanying programme to the professionals, to give important information, developments, recent news and trends from the concerned fields.

Cleanroom 2017 is going to be much more fruitful since the exhibition will be organised at the same time, at the same venue with Biotech Eurasia, Biotechnology an Life Sciences Exhibition and Expo Analytec, Analytic Technology and Laboratory Equipment Exhibition under the title of “CBA High Technology Show”.

All kind of technological solution providers and cleanroom equipment manufacturers come together at Cleanroom 2017 Istanbul Exhibition. Take this opportunity and meet the market!

**Cleanroom Exhibition 2016 with numbers:**

- The exhibition was visited by 4714 distinguished professional visitors who were active in the field of cleanroom in different sectors,
- 52% of the visitors were engineers and technicians, 4%4 of the trade visitors were facility managers and investors, 4% of the total visitors were academic personnel,
- 80% of the trade visitors were real professionals who actually and directly do business in the cleanroom industry, 75% of the visitors were decision-makers,
- 80% of the trade visitors visited the exhibition to find new products, technology and solutions for their projects and were all satisfied by the wide product range of Cleanroom Exhibition.
**Interplastica 2017: Arburg heralds a „golden“ electric era**

- **Golden Electric machine series**: cost-effective entry-level electric injection moulding production
- **Standardised**: high-quality technology at an attractive price/performance ratio
- **Quality parts**: Allrounder Golden Electric produces moulded part for the medical technology sector

At the Interplastica 2017, to be held in Moscow (Russia) from January 24 to 27 2017, Arburg will present the cost-efficient automatic manufacturing of quality parts. At Arburg Stand 1B25 in Hall 2.1, an Allrounder 520 E Golden Electric from the new entry-level electric machine series will produce syringe barrels for the medical technology sector using an 8-cavity mould. Thanks to its consistent standardisation, the machine offers an excellent price/performance ratio.

Arburg launched the „Golden Electric“ machine series onto the market in spring 2016 to facilitate the cost-effective entry into electric injection moulding production. Like their successful „Golden Edition“ hydraulic counterparts, the new electric machines offer an excellent price/performance ratio thanks to consistent standardisation, e.g. a fixed combination of distance between tie-bars, clamping force and injection unit size.

**High-performance, precise, energy efficient**

The Allrounder Golden Electric is available in four machine sizes with clamping forces from 600 to 2,000 kN. The double five-point toggle system ensures fast, high-performance cycles. The play-free spindle drives operate with high precision. The position-regulated screw ensures high moulded part quality.

The new electric machine series also features liquid-cooled motors and servo inverters and offers benefits in terms of energy efficiency, short dry cycle times and high reproducibility. Compared to hydraulic standard machines, the high efficiency of the servo motors, continuous power adaptation and energy recovery during braking provide for energy savings of up to 55 percent. The machines are also easy to maintain thanks to swivelling injection units, plug-in cylinder modules and further improved lubrication and cooling.

**Ideally suited to high-quality technical parts**

The entry-level electric machines are mainly used in the cost-efficient and reproducible manufacturing of high-quality technical parts. At the Interplastica 2017, Arburg will demonstrate the manufacture of syringe barrels with Luer lock threads for the medical technology sector: An Allrounder 520 E Golden Electric with a clamping force of 1,500 kN and a size 400 injection unit will produce eight moulded parts from PP in a cycle time of approximately ten seconds. The 8-cavity mould from Tim Plastik is equipped with hot runner technology.

**Allrounders for the medical sector**

In addition to the standard range, Arburg offers special clean room solutions. The modular product range enables Allrounder injection moulding machines and production cells to be very precisely tailored to customer requirements and the application at hand. This includes the high-performance electric Alldrive series, which is optionally available in a clean room version and in a stainless steel version with a clamping unit.

A clean-air module with air ionisation above the clamping unit provides for low-particle air in the working area. Thanks to preliminary and HEPA filters, it ensures a high level of air circulation and neutralises electrically charged moulded parts. Liquid-cooled drives, which are standard at Arburg, also contribute to low-emission production. Moreover, FDA/NSF H1-compliant lubricants are exclusively used.
Arburg medical technology experts at the Pharmapack Europe 2017

On 1 and 2 February 2017, Arburg will be represented at the Pharmapack Europe 2017 in Paris (France) at Stand D81 in Hall 4. The experts will be available there for discussions with customers and prospects who want to find out more about the extensive range of machines and solutions for plastic part production in the medical technology and packaging sectors. These range from high-speed, high-performance machines and clean-room Allrounders in stainless steel versions to the Freeformer for additive manufacturing, as well as automation and complex turnkey solutions.

“At the Pharmapack Europe 2017, we will be informing trade visitors about our broad range of products for the pharmaceuticals industry and the medical technology sector – from efficient standard machines to customised solutions tailored to specific requirements,” says Marc Schuh, Managing Director of Arburg France.

Sven Kitzlinger, Application Technology Consulting, Medical Technology at Arburg, adds: „We’re aware of the increasing automation of manufacturing processes and ever greater integration of downstream processing steps. For example, we have already implemented applications that are precisely tailored to the production of medical implants or pre-filled COP syringe barrels. Other trends he mentions include high-speed, high-performance machines for pharmaceuticals packaging and the use of complex moulds, including cube mould technology. „There is evidence of increasing synergies with the packaging sector, where we also have a high level of expertise and special machine technology,” says Sven Kitzlinger.

Efficient manufacturing of personal care products

Cost pressures are high in the personal care segment. For this reason, the focus here is on the production-efficient manufacturing of mass-produced items. The Packaging versions of hybrid Allrounder injection moulding machines are designed for this type of high-speed, high-quality and high-volume production and are therefore ideally suited to the production of thin-walled mass-produced items, closures, pipette tips or syringe barrels. They feature short cycle times, reproducibility, reduced energy requirements, as well as process stability and a long service life.

Micro production cell for tiny parts

Arburg offers a complete micro-production cell that can be flexibly used for the reproducible production of extremely small parts and micro implants, as required in minimally invasive interventions. This comprises a small electric Allrounder 270 A injection moulding machine equipped with a Euromap size 5 micro injection unit and a horizontal dual arm robot for the reliable separation of micro components and sprues. The micro injection unit combines an 18 or 15-millimetre screw for melting the material with an 8-millimetre screw for injection. This enables problem-free processing of normal granule sizes and therefore all common materials.

Additive manufacturing in medical technology

Arburg offers the Freeformer for additive manufacturing of one-off parts and multi-variant small-volume batches. The associated geometric freedom, combined with material freedom enables completely new applications to be achieved, including use within the human body. Arburg recently demonstrated that the Freeformer can in principle also process medical PLA, based on the example of facial and cranial bones, at the formnext 2016 trade fair. Further applications options include individually adapted implants and aids or orthotics. Another interesting option in this context is the possibility of combining injection moulding and additive manufacturing to individualise mass-produced parts as single-unit batches.

Complex turnkey systems

The modular product range from Arburg offers clear advantages to exactly meet the requirements of OEMs and users, as turnkey solutions are individually configurable and can therefore be precisely tailored to specific customer requirements. This is complemented by the various clean room concepts and extensive know-how of the Arburg expert team, as well as collaborations with expert cooperation partners.

One high-end medical technology application is the manufacture of syringe barrels made from COP (Cyclic Olefin Polymer), an alternative to glass, using a GMP-compliant stainless steel version of the Allrounder 370 A. A clean-room module above the clamping unit ensures clean production conditions. The electric injection moulding machine produces two syringe barrels weighing 2.25 grams each in a cycle time of around nine seconds. This is achieved by lateral injection with a needle-type shut-off nozzle. In a downstream step, the syringe barrels can be pre-filled, assembled and packaged ready for use.

Plastic products that perform functions within the body in the form of medical implants also have huge potential. One example of this is the production of a vaginal ring for HIV prevention. In this case, Arburg acted as primary contractor for the entire production cell. An encapsulated stainless steel clamping unit was used to adapt the machine to the highest hygiene requirements in accordance with ISO 13485, as well as the specifications of the FDA and GMP directives.

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The Swiss Medtech Expo is now up for round two following a promising premiere in 2015: Switzerland’s medtech industry will convene at Messe Luzern from 19 to 20 September 2017. The trade fair will focus on advanced manufacturing.

**The Swiss Medtech Expo contributes towards innovation**

The Swiss Medtech Expo in Lucerne offers developers and engineers from manufacturing companies and SMEs an opportunity to network with leading system providers and innovation enablers. Around 200 national and international exhibitors from many different sub-sectors of the medtech industry will present their expert knowledge and portfolios of special technologies. Swiss Medtech Expo will once again provide a compelling mix of exhibition, knowledge transfer and networking.

**“Advanced manufacturing” as the focal point**

The integration and development of new, innovative applications is at the heart of the Swiss Medtech Expo. Various competence partners of the trade fair will present application-oriented new designs, materials, technologies and processes. “We want the Swiss Medtech Expo to demonstrate in practice how advanced manufacturing leads to innovations in the medtech industry”, explains trade fair director Fabrizio Raffa. “The success of this industry depends decisively on the ability to develop innovative products quickly and reliably”. This is exactly where the Swiss Medtech Expo delivers.

**Innovation Symposium: lectures by competence partners**

The Innovation Symposium is very much in keeping with the topic of advanced manufacturing. Each competence partner will present their respective area of advanced manufacturing in detail at one half of a presentation point.

19th - 20th Sept. 2017: SWISS MEDTECH EXPO, Luzern (CH)

Messe Luzern AG
CH 6005 Luzern

**Steven Brimble appointed as new Quality Manager for Cherwell**

Steven Brimble, Quality Manager, Cherwell Laboratories

Cherwell Laboratories, specialists in cleanroom microbiology solutions, are pleased to announce the appointment of former National Quality Manager for Public Health England Food Water & Environmental microbiology, Steven Brimble, as Quality Manager. The appointment of Steven, to head up Cherwell’s well established quality team, demonstrates Cherwell’s dedication to delivering high quality prepared media, environmental monitoring and bio-decontamination products that customers can be 100% confident in. Quality is critical at Cherwell and, under quality management systems, the Company’s quality team continually develops and enhances processes to meet and surpass the rigorous expectations of its customers within the pharmaceutical and related industries.

Steven holds a Master’s degree in biomedical science, with 25 years’ experience in microbiology and over 10 years’ experience in Quality Management. He is also a member of the Chartered Quality Institute which further endorses his expertise. Most recently Steven worked as the National Quality Manager for Public Health England, Food, Water and Environmental laboratories, whose main function is to protect the public from significant health threats associated with food, water and environmental hazards.

Andy Whittard, Managing Director of Cherwell, commented, “We are delighted to welcome Steven as our new Quality Manager and to secure someone with his extensive experience and knowledge of quality systems and microbiology. Steven will oversee a great quality team at Cherwell, and his leadership and development skills only strengthen that team further so that we can offer a great service to our customers. Steven joins us at a key point as we migrate to the 2015 version of ISO9001 and plan additional projects to continually enhance our quality offering to our customers.”

Commenting on his new role Steven said, “I am thrilled to be part of Cherwell Laboratories, and look forward to working with the highly professional and experienced team. A key focus for me is to build on and strengthen the existing quality system to further enhance what we do, which in turn ensures we don’t just meet, but exceed our customers’ expectations.”

Steven’s experience and qualifications will enable Cherwell to continue to strive to deliver high quality products and service to their customers at all times. There is a growing need within the pharmaceutical and related industries for high quality environmental monitoring and cleanroom microbiology products, from reputable suppliers who can demonstrate credibility with robust systems. By maintaining a strong focus on quality, Cherwell are demonstrating that they are determined and very able to meet that need.
The EE800 room transmitter for CO2, temperature and relative humidity is now also available in „anthracite grey“ and „white aluminum“.

CO2, T and RH room transmitter with new housing colours

The EE800 room transmitter from E+E Elektronik combines CO2, temperature (T) and relative humidity (RH) measurement in a single device. It is ideal for use in demand-controlled ventilation and indoor climate control. In addition to the standard housing colour “signal white”, the EE800 is now also available in „anthracite grey“ and „white aluminum“, which are the most common colours of light switches and power sockets.

Besides modern design and new housing colours, the EE800 impresses by its technical features. The dual wavelength NDIR CO2 measuring principle with auto-calibration is highly insensitive to contamination, compensates for ageing effects and leads to outstanding long-term stability. Additionally, the multi-point CO2 and temperature factory adjustment ensures excellent CO2 measurement accuracy across the entire temperature working range.

Out of the RH and T measured values, EE800 calculates the dew point temperature. The versions with Modbus RTU or BACnet MS/TP interface calculate also further physical quantities, such as absolute humidity, mixing ratio or specific enthalpy. The digital interfaces allow for easy integration into a modern bus system for building automation.

The EE800 versions with analogue outputs (current or voltage) also feature an optional passive temperature output. An optional USB configuration adapter facilitates easy setup and adjustment of the device.

Further room transmitters

In addition to the EE800, the E+E portfolio also includes room transmitters for combined RH and T measurement (EE10), T measurement only (EE10-T) and a CO2 switch (EE80).

All E+E room transmitters are available in the new colours and with optional display. The innovative snap-on enclosure facilitates mounting of the device, which saves time and minimizes installation costs. The enclosure is available in two sizes corresponding to the EU and US standards.

Figure 1: EE800 room transmitters from E+E Elektronik. (Photo: E+E Elektronik GmbH)