we connect

Operational Excellence: High Quality in Production
Quality – Key Challenge of the Future

The debate about the quality of medicines is not new. In recent years, however, since the Food and Drug Administration (FDA) launched its "Pharmaceutical cGMPs for the 21st Century" initiative in 2002, it has gained considerable momentum. In addition to the FDA, a second international regulatory body, the European Medicines Agency (EMA), has become active in this field – also in joint projects such as a pilot program on Quality by Design. The International Society for Pharmaceutical Engineering (ISPE) has launched two projects that focus on the quality of pharmaceutical production with its initiatives on the subjects of “Drug Shortages” and “Quality Metrics”. The time line below lists selected milestones in this development and demonstrates that quality is one of the key challenges of the future for pharmaceutical production.

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**FUTURE**

Food and Drug Administration Amendments Act (FDAAA)
Legislation to increase the powers of the FDA and its resources

FDA Sentinel Initiative
Introduction of a monitoring system for the safety of medicines, biopharmaceuticals and medical equipment

FDA Healthy People Initiative
Initiative on health promotion and disease prevention to improve people’s health

FDA-EMA Pilot
Pilot program for the parallel evaluation of Quality by Design (QbD) submissions

ISPE’s Drug Shortages Initiative
Initiative to support global efforts to prevent drug shortages


FDA Critical Path Initiative
Initiative to introduce quality guidelines for the development and manufacture of medical products

FDA Unapproved Drugs Initiative
Initiative for drug safety (prohibition of unapproved medicines)

FDA Safe Use Initiative
Cooperation to reduce avoidable damage by drugs

FDA Medical Countermeasures Initiative (MCMI)
Initiative for measures against chemical, biological and infectious hazards

FDA Global Initiative
Development of a community for a global public safety net in the health sector
DEAR READER,

Quality has become one of the key challenges of the future for the pharmaceutical industry. The more people worldwide have access to basic healthcare, the more important it becomes that drugs and medical products satisfy the highest standards – no matter where they are manufactured.

As manufacturers of specialized machines we play an important role in this sector. The global supply of medicines would not be possible without industrial production. In order to be able to produce medicines efficiently and safely, pharmaceutical manufacturers demand the highest quality technology and processes. It is precisely this aspiration to deliver the best quality that unites the companies of Excellence United and led us to create a binding framework for our cooperation in 2011. We encountered one another again and again in countless projects long before the foundation of this alliance. Our customers told us the reason: They wanted to invest in best-in-class technology.

Excellence United enables us to satisfy this demand and combines leading-edge technological solutions to cover the entire value chain ranging from product development via manufacturing to packaging and service. The name of our magazine reflects this aspiration: “we connect”. We bring together people, technologies and processes. Working with you, we will develop the best possible solutions for your needs.

The members of Excellence United cordially invite you to find out more about our products and services in this magazine.

Yours sincerely,

Thomas Weller

Spokesman of Excellence United
Towards a New Culture of Quality

Pharmaceutical companies have recently experienced problems in their production processes, leading to bottlenecks and shortages. Another result has been intense scrutiny of industry procedures that for years were considered tried and true. Government authorities in the US and Europe have now taken the initiative and are working with manufacturers to establish a new culture of quality in the pharmaceutical industry.

It’s an eye-catching statistic: Between 2010 and 2013, the number of warning letters issued by the US Food and Drug Administration (FDA) for noncompliance with pharmaceutical industry regulations increased tenfold.

Consequently, by April 2013 there were significant shortages of some 300 drugs in the US alone, with the cost of compensating for the shortfalls estimated at 400 million dollars. According to the European Medicines Agency (EMA), disruptions in the production of critical medicines in Europe have also increased dramatically in recent years. A study published in June 2013 by the International Society for Pharmaceutical Engineering (ISPE) shows that the problem often stems from quality assurance difficulties during production, a phenomenon that has caught the attention of

ALARMING INCREASE IN FDA WARNING LETTERS

In 2013 the number of letters issued by the US Food and Drug Administration (FDA) was more than 15 times greater than in 2008. The government agency sends out the warnings when production procedures or facilities do not meet the relevant good manufacturing practice (GMP) standards.

government authorities. At the end of 2012, the EMA therefore launched an initiative to reduce the number of cases where compliance with good manufacturing practices (GMPs) is not met. Similarly, the FDA initiative Pharmaceutical cGMPs for the 21st Century, begun in 2002, has moved into its next phase with the creation of a new “super agency”, the Office of Pharmaceutical Quality. The OPQ will pool regulatory expertise on quality-related issues in pharmaceutical production processes. It will also cooperate with other agencies and with drug makers to further develop the international framework in this area.

**More demanding production requirements**
A number of factors are forcing pharmaceutical manufacturers to change their production processes, such as cost pressures resulting from new competitors based in emerging countries, patents on blockbuster drugs that are now expiring and the globalization of production networks. Innovations in pharmaceutical research are also having an impact on production – in the form of “personalized medicine”, for example. In the future, drug-based therapy will not only depend on the standard diagnosis for an illness, but also on a patient’s individual characteristics such as genetic factors. Pharmaceutical companies will therefore need to have a range of individual, precisely formulated medicines available. At the same time, the growing use of highly potent active ingredients will require that production systems meet even more stringent safety standards. All of this means that drug makers will need production processes and machines that are highly efficient and reliable. Manufacturers of pharmaceutical production machines therefore have a key role to play in improving quality.

**Excellence United offers outstanding production tools**
Numerous elements must come together seamlessly if production processes are to be efficient; processing equipment and facilities must run smoothly, maintenance and other services must be available as needed, and operating personnel must be properly trained. Above all, there can be no disruptions where processes overlap, and quality levels at all points in the production chain must meet current – and coming – requirements. Excellence United therefore provides state-of-the-art production technology for the entire value chain, from product development to packaging. It also offers a comprehensive service portfolio, including consulting and training. Here, too, quality plays a key role. The alliance members pool their expertise in workgroups in order to develop uniform standards and processes. That allows them to help customers upgrade existing production processes and create new facilities that meet tomorrow’s standards today.
Excellence United Opens First Sales and Service Hub

Making medicines is a highly complex process. Disruptions, delays and, above all, downtime can quickly result in additional costs and reduced quality. That means the services offered by manufacturers of pharmaceutical production machines are of critical importance. As a result, Excellence United continues to expand its sales and service network – to the benefit of its customers.

Time is of the essence when production processes are disrupted. That’s why a good service team will prevent problems and downtime from occurring in the first place – thereby increasing efficiency levels over the long term. One of Excellence United’s key goals is to establish centralized hubs with highly qualified sales and service teams. On 1 March 2014 the alliance’s first sales and service hub of this kind opened in Istanbul. Others will follow soon.

Excellence United’s global service network already includes a sales and service office operated jointly by Fette Compacting, Glatt and Harro Höfliger in Mumbai, India, and an office run by Bausch+Ströbel, Fette Compacting and Uhlmann in France. Moreover, Akhnaton has become the alliance’s first representative in Egypt. “These facilities allow us to ensure the quality of service that Excellence United customers expect – on the spot,” explains Thomas Weller, Excellence United spokesman. “Our network will continue to grow in coming years.”

Excellence United’s innovative Service Portal is now setting new standards in comprehensive remote service provision for pharmaceutical production processes. Alliance members are equipping their machines with standardized server architecture, giving machine operators access to a full range of services directly from the control panel.

It’s simple. Operators can use the video communications channel to speak directly with engineering specialists.

It’s secure. The system offers TÜV-certified point-to-point connectivity.

It’s comprehensive. Operators can access documentation for machines and spare parts, along with OEE data, maintenance information and much more.
Built-In Troubleshooting: Excellence United Service Portal

Pharmaceutical production machines are similar to the movements of precision timepieces: all of the processes need to interlock perfectly and their fault tolerance is low. That’s why the Excellence United Service Portal installed at Pfizer in Illertissen, Germany provides the highest possible level of production reliability. This technology offers process optimization across the board.

It’s only a small detail: a servomotor that drives a feed belt between two machines has a fault during certain processes and it won’t restart. "In order to troubleshoot the issue, a technician would need to come on-site – but then the machine would be out of production until they arrived. To get around this, the operators would shut down the line and restart it to clear the fault," explains René Heyn of Pfizer. As a result, several periods of downtime occurred over eight months – an avoidable cost factor.

Because the fault could only be identified when it was actually occurring, the Excellence United Service Portal played an important role, as Thorsten Heidrich of Excellence United explains: "When the problem happened again, we were able to respond directly. We quickly identified the ‘bug’ using remote analysis and were finally able to permanently resolve the issue. Since then the transport belt has been running without any problems." The fact that Excellence United experts equipped five production lines at Pfizer with the Excellence United Service Portal in January 2014 has really paid off. The networked machines now have special software and access to a secure server so that if they need servicing the operator only needs to press a button on the HMI. An equipment specialist will soon make contact – for example, via a videoconference or a chat message. This saves an enormous amount of time.

Operators can also request spare parts via the HMI. Maintenance intervals can also be managed by the Excellence United Service Portal. "We have been impressed by this technology and have had very good experiences with it. It greatly simplifies our service management. Our Excellence United partners have a highly competent team. They know what needs to be done when something goes wrong," explains Dominikus Pöchmann of Pfizer.
There can be no compromises on the quality of medicines

Where is the pharmaceutical industry heading? Five questions to Birgit Fischer, Chief Executive of the Association of Research-Based Pharmaceutical Companies (VFA).

In your opinion, what role will research play in coming years? Birgit Fischer: Research and development are at the center of the work of research-based pharmaceutical companies. Today, however, the development of a new drug already costs an average of between 1.0 and 1.6 billion dollars and is threatening to become even more expensive in the future. That’s why it is an important industry goal to increase success rates while keeping R&D expenditure stable. More and more often today firms work together in research groups or with academic researchers. Open access to industrial research findings and research resources is no longer an alien concept.

Which overall trends are discernible? Research-based pharmaceutical companies are prioritizing the areas where the need is greatest: for example, serious and life-threatening diseases. Accordingly, one third of all projects aim to improve cancer therapy and 20% of projects focus on the treatment of inflammatory diseases, such as MS and rheumatism. Another important advance is personalized medicine, in which there is direct interaction between diagnostics and drugs. In this therapeutic approach the most suitable medicine is chosen on the basis of the results of genetic and other tests.

Which products are now set to enter the market? In the next few years we anticipate additional improvements in therapy – for example, for people with hepatitis C, pulmonary diseases and coagulation disorders. In many of these cases, too, Germany is likely to benefit as the production location.

In which countries do you expect to see the highest growth rates over the next few years? Until a few years ago, the industrialized countries were by far the most important sales markets for medicinal drugs. Today this position is shared with the emerging economies of China, India, Latin America and Eastern Europe. What does that mean for the pharma industry? Now that production has already become strongly globalized, R&D and sales will increasingly also use the new growth markets. But, of course, the industry will not give up its activities in developed markets.

How important, in your view, is quality in production? There can be no compromises on the technical quality of medicines. And because that is the case, production plants in Germany can be competitive in the globalized world economy: they verifiably create the required quality assurance for highly complex products (for example, biopharmaceuticals and vaccines as well as for challenging synthetic chemical medicines). The key to this is intelligently controlled, highly automated machines combined with well-trained and highly motivated personnel.

MAIN AREAS OF PHARMA INDUSTRY RESEARCH

The member companies of the Association of Research-Based Pharmaceutical Companies (VFA) could put medicines for more than 110 diseases on the market by 2017. Almost one third of all projects are focusing on improving cancer treatments, a complex field that benefits strongly from flexible medication. Specialized quality and flexibility in pharmaceutical production will become even more important in these areas.
Excellence United aims to provide best-in-class engineering for the entire value chain in pharmaceutical production. Although it is a highly ambitious goal, this focus on quality is clearly paying off. Excellence United partners currently have more than 40,000 of their plants in use around the world and their growth prospects are good.

Three years after its foundation, Excellence United can look back on a positive interim result: the small and medium-sized privately owned engineering companies that make up the alliance have successfully continued to grow. The alliance’s total turnover increased from roughly 800 million euros in 2011 to 965 million euros in the last business year. In 2014, Excellence United companies will achieve a turnover of over one billion euros for the first time. Since 2011, the number of people working for Excellence United companies worldwide has grown from 4,800 to almost 6,000, including more than 600 service employees.

Foundation of Excellence United Marketing GmbH
In 2014 the alliance will realize another milestone in its strategy with the foundation of Excellence United Marketing GmbH. In addition to overarching marketing activities, the new company is currently coordinating eight project workgroups. Among others, key areas here are technical cooperation, service, sales and integrated quality management.

MINIMIZING INTERFACE PROBLEMS – PRODUCTION LINE PROJECTS FROM A SINGLE SOURCE
Should the new production line guarantee efficient processes from the very start? Of course. That’s why integrated project management is so important.

The key to success in production line projects with different equipment manufacturers is coordination between the companies involved. Cost, quality and date targets can only be met if all the participants work hand in hand. Unified project management enables Excellence United to reduce typical interface problems and offer customers the reliable completion of ambitious production line projects. Among other things, the business offering includes:

- Integrated project management with established processes and communication within the alliance based on an industry-specific pool of knowledge.
- Best-in-class equipment and service as well as outstanding problem-solving expertise.
- Transparency and cost certainty because Excellence United partners work together without any mark-up. Furthermore, the guarantee for all components of the complete installation only begins when the entire production line is in place at the customer’s plant.
- Compatibility of all sub-systems and machines.
- Coordinated after-sales packages for hotline/support, spare parts, maintenance, training, updates, upgrades and a joint Service Portal.

Contact: info@excellence-united.com

Excellence United milestones:
Highlights from the last three years show how fast the alliance has developed. The partner companies have expanded their German sites and developed their presence in international markets.

2011
Five specialist engineering companies working in the field of pharmaceutical production come together in a strategic alliance to form EXCELLENCE UNITED. Ever since the network has offered its customers technologically advanced production solutions of the highest quality and comprehensive service around the globe.

2014
The foundation of Excellence United Marketing GmbH enables the alliance to offer its customers a COMPREHENSIVE SERVICE from a single source in the future.
How can extremely diverse products and batches be processed in one isolator – with very short changeover times? Bausch+Ströbel answered this question for the pharmaceutical company Boehringer Ingelheim. It created an intelligent production system in conjunction with the isolator specialists Skan.

Tailor-made compounds and individual packaging are just two signs of the current pharma industry trend towards greater variance between batches. In order to be able to guarantee a completely new level of flexibility in aseptic production, specialists at Bausch+Ströbel have developed an innovative modular design: individual production modules in a clean-room class A isolator can easily be changed using the lock-and-key principle. Diverse laboratory equipment, semi-automatic machines, dosing systems, inspection stations and more are available here.

**Potential production modules include:**

- A production module that can be very specifically equipped with the most varied kinds of laboratory equipment or semi-automatic machines as required.
- A fully automatic machine for filling and closing (KSF 4105) or closing (KS 4105) bottles or vials with a maximum throughput of 2,000 units per hour.
- A fully automatic machine for filling and closing ready-to-fill single-use syringes, vials or cartridges in nests or tubs that achieves a maximum throughput of 4,200 units per hour (SFM 5105).

**PARTNERS**

Bausch+Ströbel acquires Swiss company Wilco AG, thereby expanding its range of filling and packaging equipment to include high-precision **FULLY AUTOMATIC INSPECTION MACHINES** for leak detection and visual control as well as spectroscopic systems.
THE LARGEST BUILDING PROJECT in the company’s 47-year history results in a new assembly shop, a spacious commissioning store, additional rooms for seminars and customer meetings, offices and a works canteen with roof terrace.

SPECIALIZED MACHINES FOR THE PHARMACEUTICAL INDUSTRY

Bausch+Ströbel has been manufacturing specialized machines for the pharmaceutical industry for over 45 years. Its technology offers massive benefits for the industrial processing of medicines in liquid and powder form.

The machines made by this specialist company ranges from semi-automatic machines for the laboratory to fully automatic stand-alone units and even highly complex installations for processing items such as vials, bottles, syringes, ampoules and cartridges. A large number of individual work steps have to be carried out here, such as unpacking, cleaning and sterilizing the items before they are filled, closed, inspected and labelled.

Bausch+Ströbel has steadily grown over recent decades, so that approximately 1,100 employees now work at its Ilshofen site alone, while its global workforce already exceeds 1,400. The company maintains production sites in north Germany and the USA as well as over 50 sales and service facilities worldwide.

In 2013 the company bought Wilco AG in Switzerland. Its fully automatic high-precision inspection machines for leak detection and visual control and its spectroscopic systems complement the Bausch+Ströbel range perfectly.

SPECIALIZED MACHINES FOR THE PHARMACEUTICAL INDUSTRY

From cleaning to filling and closing – a complete high-performance machine processes ampoules at extremely high speed.

The FVF 5063 filling and closing machine fills up to 24,000 vials per hour and closes them with stoppers – including in-process control at full speed.

The KCP 5060 is a specialized filling and closing machine for small batch production. Clean-room robots transport the vials, syringes or cartridges.

This highly flexible isolator production solution for processing different products and batches uses various production modules for filling, dosing and closing. The system enables swift changeovers.

INNOVATIONS
Setting New Dimensions in Tableting Efficiency

The pharmaceutical industry is currently facing many challenges: expiring patent protection for blockbuster drugs, shorter product life cycles, dynamic growth in new markets, increasingly stringent regulations and greater price pressures. Fette Compacting has answered these by setting new standards in tableting efficiency with its latest generation of tablet presses.

How do you increase the efficiency of tablet production? Although a machine’s performance data was long considered the most important factor, now people are beginning to reconsider this idea. What really counts in the compression area is the perfect interplay between human and machine. This was the principle Fette Compacting had in mind when it developed its latest generation of tablet presses. The machines in the FE series combine the very highest performance with a unique form of operation.

TRI.EASY design – simple operation is the key to efficiency
The Fette Compacting TRI.EASY design facilitates simple and safe operation. The underlying idea is straightforward: equipment can only be efficient if it is equally simple to use in the three important areas of operation, changeover and maintenance. That is why the TRI.EASY design was consistently devised to meet the needs of users, offering them extensive support in all tasks that practically rules out operating errors. Short training periods and significantly improved handling safety for operators ensure the highest standard of product quality in even the most demanding jobs.

The FE series has already won several prestigious prizes for this comprehensive design concept, including the Achema Innovation Award, Red Dot Design Award, the iF Design Award and the German Design Award.

2011 Fette Compacting celebrates the world launch of the first tablet press in a new MACHINE GENERATION. Offering an unprecedented number of stations in a very small floor space, the FE55 sets new standards for efficiency in tableting. At the same time, Fette Compacting presents its new TRI.EASY design with the FE55.

2011 A new COMPETENCE CENTER opens in Goa, India. As a result, Fette Compacting is the first manufacturer of tableting technology to offer its customers in India comprehensive service and training on the spot.
Fette Compacting has tailored its products and services to meet these requirements. In addition to a range of tablet presses and process equipment for wide-ranging applications from galenics to high-volume production to WIP and containment solutions, the company also offers extensive support, consulting and training services.

The company has developed a manual for its products and services in the shape of the Fette Compacting Efficiency Guide. It covers the three areas of Technology, Service and Competence.

**INNOVATIONS**

**Pmax Turret with FS12 Tools – High Performance for Tablet Production**
Pmax turrets with FS12 significantly boost productivity: they enable users to increase tableting output by up to 40% – without increasing production time. The turrets with 45, 66 and 110 punch stations are also available for retrofitting.

**OEE Consulting – Maximum Productivity for Existing Machines**
Fette Compacting OEE analysis covers the core areas of tablet production: tool use, service and maintenance processes, standards of operator training and the production process itself. Experience from countless projects indicates that most users are able to increase their OEE levels by an average of at least 30%.

**eShop – Perfect Inventory with OEM Spare Parts**
- Fette Compacting's eShop provides a swift and convenient way to order supplies of spare and wear parts.
- Short delivery times
- Standard spare and wear parts according to machine type
- Direct placement of orders and automated quotation submittal
- Filling cam calculator

**2012**
Fette Compacting launches the **FE35** at the Achema fair. The second tablet press in its FE series offers fast product changeovers. A new **COMPETENCE CENTER** opens in Campinas, Brazil.

**2014**
Major project is launched in Schwarzenbek near Hamburg. By 2016 the LMT Group plans to invest roughly 30 million euros in a **NEW CUSTOMER AND INSPECTION CENTER** as well as Fette Compacting’s future business development.
In the future many pharmaceutical products will be manufactured using continuous processes that offer enormous savings potentials. The production experts at Glatt are now demonstrating the opportunities this approach offers with the MODCOS continuous production line. One innovation is central to this.

Scaling up batch processes – moving from laboratory to pilot production and on to the smallest full-scale production – involves time and expense. Many manual handling steps are required in a changeover. In continuous processes, however, the procedure runs fully automatically. Against this background, the MODCOS production line offers enormous savings potentials.

Easily adapt existing machines
The decisive innovation here for many users is Glatt’s new process unit. Why? Because it makes it easy to convert existing batch units in the GPCG2 and GPCG 10 series into continuous fluid bed machines. Afterwards it is possible to precisely control the time products spend in the machine. Investment in a new machine is no longer required.

High-safety integrated system
The integrated continuous process begins with the micro-twin-screw dosing unit for powders and microgranules. Then the necessary granules are manufactured by twin-screw extrusion (or alternatively a binding agent is added using the Glatt high-shear mixer). Drying is carried out in a Glatt fluid-bed machine with the new rotary chamber before final tablet production begins after further mixing processes. The entire system offers a high level of safety and each step of the process is precisely monitored by PAT systems.
Glatt is one of the world’s leading suppliers of fluid bed systems, high-shear granulators, granulating lines and tablet coaters. Additionally, the company also offers a wide range of services and technological solutions.

Werner Glatt built his very first fluid bed system for the pharmaceutical industry with a dozen employees in 1959. Today, the company employs more than 1,500 people at facilities in Germany, the USA, Switzerland, India, Russia, the UK, China and the Czech Republic. The goal of the specialists who work for the Binzen-based company has remained unchanged over the years: continuously improving the standard of technology and developing highly efficient production solutions.

Glatt is organized in four divisions:

• **Pharmaceutical Services** develops and produces solid dosage forms as a service provider. Key areas here are multiple unit dosage systems such as pellets and micropellets as well as granules.

• **Process Technology Pharma** develops fluid bed systems, high-shear granulators, granulation lines and tablet coaters. Glatt developed its original core business in a targeted way, expanding it to include important processes in the production of pharmaceutical solids – from weighing materials to the transfer to packaging and associated product handling steps in the production chain.

• **Process Technology Food, Feed & Fine Chemicals** develops, plans and markets fluid bed and spouted bed systems for the food, animal feed and chemical industries.

• **Process & Plant Engineering** plans and realizes plant engineering projects worldwide. Its range of expertise covers the expansion and conversion of existing facilities to the partial or total construction of newbuild plants.

The Glatt rotary process unit makes it easy to move from stepped batch manufacturing to integrated continuous production: GPCG 2 and CPCG 10 series batch fluid bed machines can be converted into continuous fluid bed granulators. Afterwards it is possible to precisely control the time the product spends in the machine – and that guarantees high quality. An ingenious automatic discharge system provides additional process reliability.

Glatt takes over a modern production operation in Pune, India. The facility will help its sales and service organization to develop **BUSINESS IN INDIA**. An additional office, which is maintained jointly with Fette Compacting and Harro Höfliger in Mumbai, helps provide optimum customer support.

The first Glatt **ROTARY CHAMBER** is ready for the market.
Reaching New Dimensions of Productivity and Flexibility

Is it possible to increase pharmaceutical production output while maintaining the required high level of safety? One answer to this question is currently offered by Harro Höfliger. The Modu-C High Speed capsule filling machine is setting new speed records and with it the developers at the Swabian pharmaceutical machine manufacturer are entering a new dimension.

Frank Naseband, product manager at Harro Höfliger, makes this clear: “The new machine processes up to 200,000 capsules an hour. That is currently the highest output available for filling capsules.” This leap in performance was made possible by the expert knowledge of the specialists at Harro Höfliger. Harro Höfliger has spent decades specifically developing machines for filling and checking pharmaceutical capsules as part of the overall production process.

The Modu-C High Speed now represents an additional, highly efficient solution for capsule filling. Its patented trolley system ensures flexibility in production. The trolleys can be quickly changed to allow different substances to be processed. At the same time, GMP-appropriate design and optimum accessibility facilitate efficient cleaning. “The system offers a high level of safety and simultaneously guarantees maximum output. We are sure this achievement will win over the market,” explains Frank Naseband.

In November, during the Frost & Sullivan Congress for “Growth, Innovation and Leadership” in Frankfurt, Harro Höfliger was honoured for Technology Innovation Leadership as a result of its development of the MICROVIBE DOSING SYSTEM.

The NEW ASSEMBLY HALL for pharmaceutical production in Allmersbach im Tal is put into operation. Large-scale projects are realized on roughly 7,000 m² of space. The integrated offices allow a direct and market specific assignment of equipment specialists from the various business units.
[ALL YOU NEED] – WHAT HARRO HÖFLIGER OFFERS

From a one-man show to a technology leader in many fields – Harro Höfliger, a specialist in pharmaceutical production and packaging machines, is continuing its expansion course.

Over 800 employees achieved a turnover of 150 million Euro in 2013. The export quota was 75%. On one hand, the international success of the company with sites in Canada, China, France, Russia, Switzerland, Singapore and the USA is based on growth in the core business of developing customized solutions. On the other hand, it is the result of Harro Höfliger’s ongoing specialization: The company excels with specialist knowledge, technical support and production assistance. Assembly automation, web converting processes and inhalation technology are areas where Harro Höfliger has long since become the technology leader.

Guaranteeing safety with pharma services
Materials and substances containing active agents are tested for their process capability as part of the company’s extensive service offering. Harro Höfliger has a wide variety of testing machines and units available for this purpose at its headquarters. These can be used to investigate the original product under actual production conditions – including test runs with customer’s machines in a pharmaceutical production environment. This guarantees safety and reliability. The motto “ALL YOU NEED” says everything about Harro Höfliger. This means that Harro Höfliger stands by their customers with technological support to ensure that the solutions are 100% tailored to meet their requirements. The fundamental qualities “Inventive. Qualified. Reliable.” reflect the values that distinguish Harro Höfliger in realizing customer-specific system solutions.

WORKING TOGETHER FOR A SECURE FUTURE

One of the goals of the establishment of the Harro Höfliger Foundation was to preserving the partnership with customers. Company founder Harro Höfliger transferred his shares in the business to the family foundation on 1 January 2013. This step successfully concluded the strategically organized handover to the next generation and enables the company to preserve its independence.

2013
In Aspach, ten kilometers from the company headquarters, a modern LOGISTICS AND PRODUCTION CENTER was built on an area of 5,000 square meters to supply the surrounding assembly facilities. A fleet of state-of-the-art CNC machines makes it possible to supply components for high-volume systems engineering projects.

2014
The takeover of a practically new production facility in Backnang is enabling the company to refocus its business areas. In future, the site will be home to MACHINES FOR THE MANUFACTURE OF PRODUCTS MADE OF WEB CONVERTING MATERIALS and MACHINES FOR HORIZONTAL CASE-PACKING on a further 3,500 square meters.
Flexibility is especially important in the field of pharmaceutical packaging technology. A large number of different products often have to be processed on a single line – swiftly, economically and flexibly. One Uhlmann solution sets new standards.

A total of 72 different packaging combinations and a large number of secondary variants form the impressive packaging solution for one hormone drug. At the German plant of an Uhlmann customer there are two identical production lines, consisting of a blister machine, pillow pack machine, cartoner and stretch-banding machine. The lines are configured in such a way that the pharmaceutical manufacturer can respond flexibly and cost-effectively to the needs of its customers. “In addition, we have developed the lines so that a changeover of product variants from one line to the other is possible without any problem,” explains Christian Link, Head of Customized Packaging Systems. “Depending on the packaging variant, the blister machine processes up to 400 blisters per minute.”

300 cartons per minute
Even at high speeds, the two lines guarantee production reliability. Feeders accurately place the tablets in the individual blister pockets. A camera inspection system then checks correct filling. The integrated downstream cartoner processes the individual blisters using a dancer magazine or the finished pillow packs using a double-lane stacking belt feeder.

Assisted start of production
Uhlmann experts not only configured the production line, but also accompanied start of production and trained the operating personnel. “We ensure that the customer production processes run smoothly from the very start,” explains Christian Link.
Top: Blister Express Center 300 – a flexible containment solution for the packaging of highly active medicines, such as cytostatic drugs. The area where the open product is processed is fully encapsulated.

Center: Blister Express Center 500 processes up to 500 blisters and a maximum of 450 folded cartons per minute. A Case packer E 4012 then packs 500 cartons into 12 transport cases per minute. All the modules in the line are optimally coordinated.

Bottom: From the bottle to the pallet – a line incorporating an Integrated Bottle Center 120, Labeler L 180 and Case Packaging Center 10 combining a case packer and a palletizer.

AUTOMATED PACKAGING PIONEER

For over six decades, Uhlmann has been advancing the development of packaging technology in the pharmaceutical industry with highly innovative solutions – and is ideally equipped to master with the challenges of globalization.

Uhlmann packaging specialists have repeatedly demonstrated their innovative strength over the years: the world’s first universal strip packaging machine (1956), the world’s first pharmaceutically compliant bottle filler for tablets (2008) and the Blister Express Center 500 as a complete system consisting of blister and cartoner module (2012) are just three of numerous examples. Approximately 8,000 packaging machines and production lines from Laupheim, not far from Ulm, are currently in use worldwide. The export ratio is roughly 80%.

Proximity to customers, proximity to the market

The experts also offer an extensive range of services. Uhlmann Customer Service ensures smooth machine operation over many years. Against this background, the experts have subsidiaries in the USA, Brazil, the UK, Sweden, Spain, Russia, Switzerland, France, Singapore and China. Furthermore, Uhlmann maintains a competence center at its headquarters in Laupheim, which guarantees maximum reliability and productivity in the pharmaceutical manufacturing and packaging process with innovative inspection and printing systems.

Uhlmann is investing a double-digit million euro sum in new buildings at its HEADQUARTERS in Laupheim over the next few years.
Excellence United
The Community of Experts

The Community of Experts
Excellence United is a strategic alliance of leading manufacturers of specialized machinery for pharmaceutical production.

www.excellence-united.com