BÖHLE

TOPICS

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Dear readers,

We are looking back at a very chaotic year. The COVID-19 pandemic is keeping the whole world, the global economy and, of course, us as a company in suspense.

First of all, we hope that you have come through this time well and in good health so far. Thankfully, we have not yet had an infection with the coronavirus in our company. We would therefore like to take this opportunity to compliment our employees. Everybody has helped develop and accept the comprehensive pandemic precautionary measures and hygiene rules. During these difficult times, they have acted with prudence and understanding.

Within a very short time, we had to change our company processes and adapt them to the new conditions. Important trade fairs were postponed or cancelled entirely, and our field service and sales representatives worldwide could no longer visit our customers and interested parties. At the same time, we introduced a prophylactic multi-shift work model in order to ensure the continuation of our business operations in the event of an infection with the coronavirus.

After a good six months under these changed conditions, we hope that we will all continue to get through these difficult times healthy and well. We all had to adapt to the new situation: instead of holding discussions on site, we now mainly communicate via video conferences. Instead of an FAT on site with us in Ennigerloh or Sassenberg, we now conduct acceptance tests of machines and systems with our customers via live streams.

Start of Plant 4

At L.B. Bohle Maschinen und Verfahren GmbH, countercyclical acting is definitely part of the company's history. Once again, we are boldly setting the course for the future, just like we did during the financial crisis after the Lehman bankruptcy when we consistently invested in innovations.

Not far from the headquarters in Ennigerloh, Plant 4 is being built on an area of 12,000 m^2. Starting at the end of 2021, processing machines for the continuous manufacturing of tablets will be produced on a surface area of around 2,000 m^2. With Plant 4, we are increasing our capacity, thus meeting the increased demand for systems for continuous manufacturing.

We are taking major development steps, especially in the area of machines for continuous manufacturing. In October, a multinational company accepted the new continuous wet granulator and fluid bed dryer QbCon® WG from us. In contrast to systems by our competitors, QbCon® WG is the first system that enables truly continuous drying of the granules without interruptions.

Adapted corporate design and new website

As you may have already noticed, the current issue of our corporate magazine Innovativ appears in a new design. Our marketing team used the time without trade fairs creatively to give our company a new and fresh corporate design. In addition, our company's website has been redesigned. Soon the website will also be available in Spanish, French and Russian. This will increase the user-friendliness, and you will be able to obtain comprehensive information about our products and services.

Dear readers, we hope that you will get through the "corona phase" well so that we can resume our exceptional business activities as they have always been prior to this pandemic.

We look forward to a continued trusting cooperation in numerous projects so that we can continue to contribute to your success with our machines, processes and innovations.

Sincerely,
Tim Remmert & Thorsten Wesselmann
Executive Directors

L.B. BOHLE BUILDS PLANT 4 *in Ennigerloh*

Production will start in the anniversary year 2021

With the world premiere of the QbCon® continuous manufacturing system at the ACHEMA trade fair in 2015, L.B. Bohle laid the foundation for a new generation of machines. 5 years later, the technology company is planning to build a new plant at the site in Ennigerloh. "2021 will see the 40th anniversary of the founding of our company. We want to celebrate this in autumn at the new production site. Production will launch before the end of the year," says founder and owner Lorenz Bohle setting out the ambitious timetable.

The focus of the new plant which will be located in close proximity to Plant 3 will be exclusively on the production of machines and systems for continuous manufacturing. On an area of 12,000 m^2, a production complex with a surface area of around 2,000 m^2 will be built according to latest technological standards. "The ground preparations on the premises are completed, and the building application will be submitted in the fall. We are expecting the building permit to be issued before the end of this year so that we will have the new plant completed in late summer 2021," explains Lorenz Bohle outlining the tight schedule.

L.B. Bohle recognizes the significance of continuous manufacturing processes

It is clear that the proportion of continuous processes is increasing in the pharmaceutical industry. Traditional batch production is often the production method of choice. However, the trend is clearly towards implementing continuous manufacturing processes. Continuous manufacturing systems offer clear advantages in terms of quality, cost savings, flexibility and operator safety, and they optimize research and development.

With the Technology Center as a research and test center, which was inaugurated in 2015, and the continuous manufacturing system QbCon®, which enables the production of tablets, from powder to coated tablets, via direct compression, dry or wet granulation, L.B. Bohle set highlights for continuous manufacturing processes early on.

> **"The demand for systems from the QbCon® series is increasing. Most recently, mainly large multi-national corporations have placed orders. With Plant 4, we will be prepared for further demands," says Tim Remmert (Executive Director).**

Continuous manufacturing systems in the focus of customers

In our previous manufacturing facilities, this production cannot be integrated easily because of the long service life. "Continuous manufacturing systems place significantly higher demands on the software and more extensive documentation is required, thus considerably prolonging the production time," Remmert explains.

He describes the added value for potential customers as follows: "In the new Plant 4, we will create prerequisites to offer our customers test and acceptance options under optimized conditions. This applies in particular to systems in the high-containment area. We will already be able to conduct particle measurements during the factory acceptance test in order to carry out a risk assessment for the use of highly active substances. This enables our customers to evaluate the system's safety at an early stage with regard to operator and drug protection."

Start of construction amid the COVID-19 pandemic

L.B. Bohle will invest four million euros in the new production facility including the equipment. The start of construction in the midst of the COVID-19 pandemic and the associated countercyclical acting is part of the company's history of turning challenges into opportunities. Even during the last financial crisis, L.B. Bohle invested in innovations and thus set signals for the growth in recent years. "We anticipate a further leap in sales through Plant 4 in the next few years and are securing our independent position in the market," says Lorenz Bohle with an optimistic look into the future.

L.B. BOHLE SETS MILESTONE WITH CONTINUOUS GRANULATION AND DRYING

German generics manufacturer uses QbCon® WG

In mid-October the time had come: After eleven months of project time a German manufacturer of generic products has successfully accepted the FAT (Factory Acceptance Test) of the QbCon® WG - a continuous wet granulator and dryer.

“The new unit allows a throughput of 25 kg/h and is designed for continuous production,“ reports Tim Remmert, Executive Director of L.B. Bohle Maschinen und Verfahren GmbH. “This means that the unit can produce without interruption and generate a high throughput,“ continues Remmert.

Trend towards continuous manufacturing

The proportion of continuously operating systems in pharmaceutical production is currently still low, with production running mainly in batch production. In recent years, however, the demand for continuously operating systems has increased immensely.

“With our various solutions for continuous dry and wet granulation as well as continuous drying and tablet coating, we are top of the market.“

THORSTEN WESSELMANN
EXECUTIVE DIRECTOR

“In addition to the individual components, our solutions for the production of coated tablets via dry or wet granulation or direct compression offer cutting-edge technology,“ states Wesselmann as he emphasizes the exceptional position of the Ennigerloh-based technology company.

The recently accepted QbCon® WG system revolutionizes pharmaceutical technology. “The dryer has been successfully patented,“ Remmert proudly states. With this innovation, we are far ahead of our competitors, as we are the only supplier that can implement a truly continuous process. The competitors can only produce in sub-batches and often have problems with blocked (clogged) filters,“ continues Remmert.

Perfect project work of the L.B. Bohle team

The development and production of this completely new plant was also a challenge for L.B. Bohle: not only in defining the requirements , but also how the time frame from conception to completion was very demanding for the L.B. Bohle team.

> **„Once again, we have proven that we can solve complex challenges with know-how and outstanding team performance,“ Thorsten Wesselmann emphasizes the combination of knowledge and cooperation.**

“Our customer has always emphasized that our project team and their competence was an important factor in the procurement,“ Wesselmann continues.

L.B. Bohle’s continuous production line will soon be installed at its new production site in Eastern Germany. Production of analgesics is scheduled to start on QbCon® WG in the 1st quarter of 2021.

Milestone in pharmaceutical production: QbCon® WG revolutionizes continuous wet granulation and drying.

THE COATING EXPERTS

Optimum solutions for your application

When it comes to quick, trouble-free and efficient coating of tablets, tablet coaters from L.B. Bohle Maschinen und Verfahren GmbH have been setting the benchmark in all areas for many years.

Pharmaceutical film coating is an essential processing step in the production of solids. Tablets are often coated in order to modify how the active ingredient is released, to protect the substance against light or moisture, or to cover a bitter flavor in the tablet formula. Furthermore, tablets are color- or film-coated to facilitate swallowing.

Recently, the processing of active ingredients in the tablet coating - the so-called active ingredient coating - is becoming more and more relevant. It enables the production of combination drugs as well as the combination of two non-compatible active ingredients in one dosage form. In addition, it allows for the combination of different modified-release profiles of the same active ingredient in sustained release tablets. The tablet coating contains the quickly released initial dose while the tablet core contains the slowly released active ingredient. The formulation approaches might consist of up to 4 different coating methods. This leads to long processing times. For the successful development and production of such formulations, tablet coating uniformity is a mandatory requirement.

The optimum interaction of blending, spraying and drying is a crucial factor. All three processes must run simultaneously with the correct settings in order to achieve optimal coating uniformity. Tablet coaters from L.B. Bohle are most advanced in this area. They guarantee the shortest processing times, ensure optimum product results and offer the best combination of the three processing steps on the market.

Blending:
It is essential that the tablet cores move evenly below the spraying cones without causing mechanical load or damage to the tablet cores. The perfect solution is an extended coating pan (length to diameter (L/D) > 1) with the patented welded-in helical baffles from L.B. Bohle. The helical baffles facilitate a constant and careful blending of the flat tablet bed. This reduces the mass pressure inside the tablet bed. The rotating movement of the coating pan generates a radial blending which results in a dead-zone-free tablet bed. Due to the continuous conveying process by means of the twin spirals, the tablets are not subjected to severe accelerations which may otherwise result in tablet breaking or twinning.

Spraying:
Thanks to the pan's geometry, the largest possible spraying area is achieved within the moving tablet bed. This allows the use of a high number of spraying nozzles. Therefore, tablet coaters from L.B. Bohle, which offer higher spraying rates, reduce the processing time by around 30 percent compared to conventional coaters available on the market with L/D ratios < 1. Besides the quality of the suspension, the nozzle type, the number of nozzles and their distance to the tablets have an influence on the result as well. L.B. Bohle offers different solutions for the adjustment of the distance between nozzle and tablet bed, the spraying angle and the pressure parameters for vaporization.

The perfect result – This is the standard we set for our products. We stand for highest precision, efficiency and durability. Our coaters provide competitive advantages in your production every day and contribute to the development of your company.

Drying:
Thanks to an air flow system which differs distinctively from systems offered by competitors, tablet coaters from L.B. Bohle guarantee optimum energy and substance transfer. The process air is fed directly into the tablet bed. Thus, the air flows straight and in a controlled way into the tablet bed and ensures quick drying of the sprayed-on suspension. During the entire process time, the spraying nozzles are not subjected to the supply air flow so that they remain cool during the spraying process. This reduces spray-drying effects to a minimum and achieves coating efficiencies of more than 95 percent. This advantage is particularly relevant for the active ingredient coating as there are fewer spray losses and thus a more uniform tablet coating is achieved.

The optimal coating system for every requirement

The BFC Film Coater is the high-end version of all L.B. Bohle coaters and offers high efficiency, optimal performance and lowest spraying losses. The BFC coater reduces the process time by around 30 percent while achieving excellent coating uniformity. The integrated high-pressure washing system guarantees a cleaning-in-place (CIP) with superior results. BFC coaters can process batch sizes of 50 to 980 liters. Thanks to the similar geometry, scale-up is no problem as with all L.B. Bohle coaters.

BFC

The BFC coater is the high-end version of all L.B. Bohle coaters and has been specially developed for fast and trouble-free coating. The BFC guarantees a unique uniformity and efficiency of tablet coating.

The BTC Tablet Coater is synonymous with economical tablet coating. Its main advantages are its simple, space-saving structure and the integrated control cabinet. With the BTC, L.B. Bohle offers an economical system for more efficient and longer processes in the pharmaceutical manufacturing industry.

The BFC Tripan is a particularly versatile system that can be operated with three pans. This allows processing batches of 7 to 75 liters. The pans are quickly and easily changed by means of a lifting device.

L.B. Bohle also offers optimum solutions for research and development. The BFC 5 Laboratory Coater is designed as a stand-alone unit. The entire ventilation technology as well as the electrical and control technology is integrated in the system. Commissioning is quick and easy as only an electrical power supply and a compressed air supply are required. The BFC 5 can be operated with two different pans, which allows the processing of batch sizes of 2 to 13 liters.

With the continuous coater KOCO®, L.B. Bohle meets the increased demand for continuous manufacturing processes. The KOCO® continuous coater is based on the proven patented design of all L.B. Bohle tablet coaters. However, in contrast to all other L.B. Bohle coaters, the tablet cores are fed through a product inlet opening on the top of the machine. The process analysis is carried out via an integrated Raman probe. The KOCO® can be incorporated in the production process either alone or as a fully integrated unit of the continuous production system QbCon®.

Containment? No problem!

In recent years, quantity and scope of containment applications have been significantly increasing in the pharmaceutical manufacturing industry. As a matter of course, L.B. Bohle offers the BFC for containment applications as well. The coaters will be designed according to customer specifications and the latest containment requirements. So far, L.B. Bohle is offering containment coaters for OEB levels 1 to 5. The containment coaters come with an automatic nozzle adjustment, infrared product temperature measurement, a connection for cleaning and drying as well as containment flaps, which are integrated in the process control or side doors with inflatable seals.

BTC

The L.B. Bohle Tablet Coater BTC stands for economical tablet coating. The BTC guarantees shorter process times than competitive systems.

BFC 5

The BFC 5 is a flexible laboratory coater and can be used for R&D and for small production batches. Due to two different drum sizes the BFC allows batch sizes from 2 to 13 liters.

Slotted coating pans for miniature tablets

For several years now, miniature tablets have been a common dosage form. They are particularly suited to be used as multi-particle dosage forms as they can be dosed individually and flexibly. Miniature tablets can either be filled into capsules or sachets or applied with miniature tablet dispensers. However, the small cores must be sufficiently stable, which is why they are often coated. The cores are coated particularly gently in a specially slotted coating pan with a corresponding perforation. Not only normal size cores can be coated, but also small cores with a diameter of 1.5 millimeters. Therefore, the system offers maximum flexibility and can be used to process different pellet sizes.

BFC 5 FOR CONTAINMENT APPLICATIONS

L.B. Bohle develops containment coater for R&D

A multinational corporation from Great Britain has entrusted L.B. Bohle with a very special task: construction of a containment coater for research and development. "We have only built coaters for containment applications for the production scale," says Executive Director Thorsten Wesselmann. "This is why we now had to develop a new solution for R&D," he says.

Standard BFC 5 as a basis

The Laboratory Coater BFC 5, which is currently used successfully in product development and for small batches, served as the basis machine for the project. In a second step, we configured the BFC as a high containment coater. A particular challenge was the installation of the entire technology in the smaller system.

Protection and comfortable handling

"We adopted some elements from projects and systems, among other things, the door from the BFC 50 as well as the sampling with inflatable seals from other successful projects," states Thorsten Wesselmann. Therefore, sampling can be performed easily at the front door of the coater.

> *"The industry's requirements concerning containment are increasing at a rapid pace due to highly potent active ingredients. Apart from comprehensive safety aspects for the environment and operators, we at L.B. Bohle attach special importance to comfortable handling."*
>
> **THORSTEN WESSELMANN**
> EXECUTIVE DIRECTOR

The BFC 5 Containment Coater is designed for OEB level 4 and is used by the customer for product development as well as for the manufacture of products for clinical trials.

Suitable for use in product development: The BFC 5 Containment Coater offers maximum protection for the environment and operator.

LABORATORY BLENDER LM 40 FOR INDIA

Customers rent blender for testing purposes

Even during the Corona pandemic, L.B. Bohle is enhancing its involvement in India and equips the Ahmedabad site with an LM 40 Laboratory Blender.

"Since September, our existing and prospective Indian customers have been able to rent an LM 40 from us and test it comprehensively in their production," says Executive Director Tim Remmert with respect to the enhanced commitment. Even before its delivery to India, the first prospective customers have signed up to rent the machine for test series. "Meanwhile, more prospective customers have contacted us and want to examine the LM 40 for themselves," he reports.

Laboratory blender for R&D

L.B. Bohle's LM 40 is optimized specifically for research and development. The blending system ensures a reliable scale-up to the desired production size. The blending results of the LM 40 can be easily transferred to a production-scale blender. The laboratory blender is state-of-the-art and meets all current GMP requirements with regard to design, operation and control.

> **"The Indian market is still highly interesting to us, and we will further reinforce our commitment in order to increase our market presence," explains Remmert with regard to the significance of the Indian site.**

Enhancing our service

In addition to our sales office in India, by also establishing a service point-of-contact in 2019, L.B. Bohle had already enhanced the Indian site. Now, in addition, the service team has acquired a calibration kit in order to calibrate the BRC Dry Granulator quickly and easily when needed, as there is still a high demand for the BRC Dry Granulator in India. L.B. Bohle has installed many systems to serve as references.

The LM 40 laboratory blender is now available to Indian customers for testing purposes. Designed specifically for research and process optimization, the LM 40 guarantees a reliable scale-up.

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MACHINE ACCEPTANCE TEST VIA VIDEO CONFERENCE

Factory Acceptance Test with customers from Brazil

The COVID-19 pandemic not only causes economic restrictions throughout the world, but it also fundamentally changes workflows and customer dialogue. Before the pandemic, it was common to carry out an Factory Acceptance Test (FAT) directly at L.B. Bohle. Global travel restrictions and measures to minimize the spread of the infection have forced L.B. Bohle Maschinen und Verfahren GmbH to find new ways to carry out machine acceptance tests with the customers.

> **"Together with our customers, we have come to the conclusion that acceptance tests can take place via live stream," explains Thorsten Wesselmann, Executive Director.**

Due to the corona pandemic, new ways to conduct an FAT had to be found. In cooperation with the customer, L.B. Bohle successfully uses a livestream and augmented reality.

The BTC 600 guarantees excellent production results. Batch sizes from 400 – 980 liters can be achieved.

"The transmission is quite simple and in combination with Augmented Reality, the customer can obtain a comprehensive picture of the system," he continues. The acceptance test via live stream has advantages for both sides: L.B. Bohle can still deliver the machines on time, thus allowing customers to begin manufacturing as scheduled.

Excellent cooperation with Maquidrex

With its Brazilian partner Maquidrex, L.B. Bohle has successfully implemented an SAT for a customer in real time. The SAT of the Tablet Coater BTC 600 EX for one of the largest pharmaceutical companies in Brazil included the "Installation Qualification" (IQ) and the "Operational Qualification" (OQ). After the SAT, a seamless transition of the coater to production could occur.

"We would like to take the opportunity to thank our partner Maquidrex for the outstanding work throughout the entire project. We appreciated the smooth communication and project implementation with the customer so that the coater can now be used for production as scheduled," summarizes Wesselmann.

L.B. BOHLE SCHWEIZ AG – ALWAYS CLOSE TO THE CUSTOMER

Quick service despite the COVID-19 pandemic

With the foundation of the Swiss service branch in 2017, L.B. Bohle has intensified its customer contact and has been offering its customers short response times for maintenance tasks and other services since then.

Especially during the first peak of the COVID-19 pandemic in late spring and early summer, our numerous Swiss customers have benefited from our service branch in Reiden. While other competitors were not able to maintain their service due to travel restrictions, L.B. Bohle's fast and easy service was available to customers the entire time.

Scheduled maintenance and calibration

Due to the many renowned pharmaceutical corporations located here, the pharma hub Switzerland occupies a prominent position not only globally, but also within the sales and service structure of the larger L.B. Bohle Maschinen und Verfahren GmbH. Because of this presence, the number of L.B. Bohle systems installed in the region is increasing steadily.

> ***"We have carried out our installations, maintenance tasks and calibrations as scheduled, especially at large corporations. Our customers appreciate the short distances, direct contact and fast response times."***
>
> **THORSTEN WESSELMANN**
> EXECUTIVE DIRECTOR

Reiden site proves to be ideal geographic location

The German company management has chosen Reiden for the new service branch because of its ideal geographic location between the Swiss pharmaceutical centers. In the regions of Basel, Espace Lémanique and Zurich-Zug-Lucerne, three quarters of the gross value added by the Swiss pharmaceutical industry have been generated recently.

For L.B. Bohle, the Swiss branch office has another positive effect: Customers in nearby countries such as Southern Germany, Austria, France and Northern Italy can be reached faster from this location.

Our customers cannot only rely on machines and systems from L.B. Bohle. Our competent service and after-sales team is also available at flexible times to best accommodate the customer.

CONTAINMENT-WORKSHOP

Expert gives a comprehensive overview

In the pharmaceutical industry, one term is becoming increasingly important: containment. It describes the process of containing a substance within a defined space, a method that is suitable for protecting operators and the environment in case of high toxicity and product reactivity.

More than 60 percent of pharmaceutical products are manufactured as tablets, capsules, dragées or similar oral dosage forms. Especially in new products the active pharmaceutical ingredients (APIs) are becoming increasingly more potent. In some markets, the segment for high potency active pharmaceutical ingredients (HPAIs) is growing in the double-digit percentage range, especially driven by oncological drugs.

Workshop with Rottendorf Pharma

In cooperation with the contract manufacturer Rottendorf Pharma, L.B. Bohle was able to convince the expert Dr. Andreas Flückiger to give a one-day workshop. At the Ennigerloh Service Center, Dr. Flückiger lectured on the topics "Risk assessment and risk management in pharmaceutical manufacturing" and "Exposure and exposure management with the focus on occupational health and safety and a sideways glance at GMP". Dr. Flückiger presented the current state of technology as well as comprehensive new insights and applications of containment to approximately 45 participants.

Containment expert Dr. Andreas Fückiger spoke at L.B. Bohle.

"Our customers increasingly request containment solutions for their manufacturing process," says Tim Remmert (Executive Director). "Our projects are becoming more and more complex due to containment requirements. Therefore, it is important that our team is always up to date," he continues.

Internationally successful contract manufacturer in the vicinity

For decades, L.B. Bohle has been maintaining a successful cooperation with Rottendorf Pharma, which is located in Ennigerloh as well. "We regularly equip Rottendorf Pharma with systems for tablet manufacturing and thus have the opportunity to pay reference visits. In addition, we support each other in several areas, especially when it comes to professional training," says Remmert, describing the close cooperation with the contract manufacturer.

More than 45 participants learned about the latest trends in containment.

FOUR APPRENTICES START THEIR CAREERS

Training in the technical / industrial sector

In the beginning of August, four apprentices started their professional careers at L.B. Bohle Maschinen und Verfahren GmbH.

Niklas Massmann and Robin Pieck have set their sights on diplomas as industrial mechanics in mechanical engineering. Till Steinkamp is training to become an electronics technician in the field of industrial engineering. In addition, L.B. Bohle trains Maxim Belikow to become a machinist for lathe systems.

Training despite the COVID-19 pandemic

"Especially at the present time, we take the training of professionals for granted. In the entire Münsterland region, the number of training contracts is declining. However, we stay on track and continue to train as planned," says Thorsten Wesselmann, Executive Director, emphasizing the significance of the continuous training of the younger generation. "As a company deeply rooted in Ennigerloh, we enjoy fulfilling our task as a professional trainer. Today's career starters are tomorrow's professionals," states Wesselmann.

Every year, the technology company in Ennigerloh trains young people in the technical / industrial sector and offers the apprentices a perspective in a growing family-owned business after successfully completing their training.

Secure future in the company after training

"During their training, the future professionals already get deep insights into our machines, procedures and workflows. It is therefore just natural, that we want to retain this know-how and potential within our company after the training," says Klaus Emmerlich, Coordinator of the technical / industrial training with regard to the futures of the apprentices. After successful completion of the training, L.B. Bohle offers real-world job opportunities, comprehensive further training and development opportunities, e.g. a practice-oriented course of study.

Starting point into professional life: Training coordinator Klaus Emmerlich with the new apprentices Robin Pieck, Niklas Maßmann, Till Steinkamp and Maxim Belikow (from left to right)

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