FOCUS ON THE FUTURE

Partner of the pharmaceutical industry
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Experts from all around the globe discuss the latest developments in continuous production at the inauguration of the Bohle Technology Center
On the global pharmaceuticals market with a sales volume of € 700 billion per year, our company is rather below the „reception radar“ with a share of € 40 million per year. Nevertheless, our special machines for pharmaceutical solids production have made their mark over the 30 years of our company history – notably when it comes to global corporations.

The question is: how did a company from the „Westphalian countryside“ succeed in becoming the technological leader in an industry that invests about 13 per cent of its sales volume in research & development? I firmly believe that intelligence, courage, trust and reliability are indispensable foundations of our success. This is added by a healthy balance between global presence and deep regional roots. Moreover, an uncompromising claim to quality has been the driving force of our work since the beginning: „The best solution for the customer, no matter what“. With great consistency, we have pursued our course from the development of machines for individual process steps for which we have identified potential for more efficient or powerful versions. Over the years, we again and again have closed gaps in our own product range through innovations. The open, partnership-based exchange with other leading special machine builders and the scientific researchers from universities creates ongoing impetus for our innovation process.

Our pilot plant for continuous production in the Technology Center drew worldwide attention which constitutes further motivation for us to take the pioneering role in this field. And all this does not happen secretly or in isolation. The opposite is the case: we invite everybody, to use this platform and jointly accelerate the breakthrough in continuous production.

With this magazine, we would like to take you on a journey through our company’s history and future as a technological leader – and introduce you to our employees, partners and customers without whom this success story would still be unwritten. A heartfelt thanks to all of them.

I hope you enjoy this glimpse behind the curtain

Lorenz Bohle
Impressive architecture and pioneering technology – at the Technology Center in Ennigerloh, L.B. Bohle combines all parts of continuous production in one modular plant for the first time. This offers our customers, cooperation partners and scientists a first-class platform for the development and presentation of continuous production processes.
The company founder Lorenz Bohle remains true to his founding motto: „Always ahead of the competitors“
All our efforts are aimed at providing our customers with the best solution available on the market. This simple, yet highly demanding success formula has been the motto of the company founder Lorenz Bohle ever since he started his own business in 1981. And this claim can be seen as the magic formula for more than 30 years of growth of the special machine builder for the pharmaceutical industry. Owner Lorenz Bohle takes pride in his company’s success story and is happy to outline the goals for the next decades: “We must be faster and better than the others to maintain the leading position among our competitors in our specialized niche market.”

As a man of action and entrepreneur, you have earned a distinguished reputation in the pharmaceutical industry. The company L.B. Bohle enjoys an excellent standing as premium manufacturer and technology driver. What caused you to start up your machine building company in 1981?

As plant manager of a pharmaceutical company, I had optimized the production processes to reflect the latest findings and there was no challenge left for me to tackle, if you will. In this process, I came across numerous weak points in traditional production which could have been eliminated through the introduction of new processes to achieve enhanced efficiency, higher quality and easier handling. The company was not willing to implement these ideas, so I founded my own company.

When did you achieve the breakthrough?

We started in 1981 with the KA tablet checker. Our handling solutions included lifting columns and containers. Container blenders, single-pot granulators, coating technology and fluid bed systems were decisive milestones. In the early years, we regularly recorded growth rates of 50 percent. More than 40 patents laid the foundation for the position we are enjoying today. The key factors always were our high quality standards and our focus on the best solution for our customers. Lorenz Bohle has been CEO of the company for more than 30 years. With a powerful combination of courage, inventiveness and high quality standards, he has made the special machine builder from Ennigerloh a top brand in the pharmaceutical industry.
customers. This also holds true for our service, of course.

What does L.B. Bohle stand for today?
Our technology solutions rank top in pharmaceutical solids production. We no longer only offer individual machines of top-quality but see ourselves as solution partners for the entire process. Our product portfolio includes an extensive range of systems for blending, sieving, weighing, granulating, coating and handling. To develop the best customer solution, we integrate special machines – such as tablet presses – and measurement technology of selected premium partners.

As a special machine builder, your company is exclusively and successfully focusing on the pharmaceutical industry. What chances and risks are associated with this position today and in the future?
Major corporations have been pushing ahead concentration processes for some years now. For many medium-sized, family-run businesses, the balancing act between globalization and the preservation of their independence presents a tough challenge. More and more renowned brands are taken over by corporations. The global players score in tenders because they offer comprehensive solutions for entire plants.
We have to leverage our strengths as a more flexible and highly specialized process expert. We take decisions more rapidly than corporate bodies and think beyond short-term market developments. It is important for us to maintain and expand our leading edge in technology and quality. Moreover, we offer open solution packages which can integrate the best provider for the respective process. For us as a family business, this is the only way of ensuring future growth. The Technology Center is a further milestone.

How long will L.B. Bohle be able to stand its ground as a family business?
We have rejuvenated the extended management and are optimally prepared for the future. Furthermore, the owner family has taken the necessary measures to ensure that the company will remain independent for at least 30 years after I am gone.
Continuous growth

There is one catch word that dominates all expert discussions in the pharmaceutical industry: continuous. Sometimes it refers to production, sometimes to the procedure or even to entire processes. L.B. Bohle Maschinen + Verfahren GmbH even goes one step further. „We have made continuous investments over the years as well,“ said Lorenz Bohle. This is also documented by the vivid history of the company.

The entrepreneur and his team set several milestones almost exactly at the same time: At the end of 2013, lean production for process machines starts up after only one year of construction in Plant 3 in Ennigerloh. In spring 2014, the Bohle Uni Cone BUC® process celebrates its world premiere at the Interpack in Düsseldorf. And the new Technology Center at the Ennigerloh headquarters houses the world’s first modular pilot plant for continuous production. Engineers, scientists, pharmacists and IT developers for the first time closed the loop circuit along the entire process including continuous production, sensor technology, analytics and controlling. Since 2011, the company has made investments in infrastructure and technology of more than ten million Euros.

Since the foundation of the company in 1981, Lorenz Bohle sets the pace for product development and growth: The first KA tablet checker is still under development in the 30-sqm-workshop with adjacent engineering office in the district of Westkirchen. Robert Stauvermann, today’s General Operations Manager, has been with the company since the beginning. In 1983, the company starts with the production of lifting columns and containers. In 1986, the still young company moves to Ennigerloh where it still has its current headquarters. A plant for the dust-free production of penicillin lays...
A system for the dust-free production of penicillin provides decisive impetus for growth which is why the company headquarters are relocated to today’s location in Ennigerloh.

Only one year later, the first container blender follows. Since then, more than 2,500 PM container blenders ranging in sizes between 2 and 12,000 liters have been built and supplied to clients. Bohle is considered the world market leader in this segment. In 1990, Lorenz Bohle pushes ahead globalization with the foundation of L.B. Bohle Inc. (USA). The first single-pot-granulator marks the entry into granulation technology in 1991. In 1998, the product range is expanded further: the first 70 kg coater is developed and delivered. Since then, coating of pharmaceutical solids has become another field of expertise of Bohle. In 2000, production is launched in Plant 2 at the Sassenberg site.

The first 200 kg coater with CIP equipment and a long cylindrical drum is launched in 2000 and the systems become considerably more compact with the tangential fluid bed process from 2003. Rapid, smooth coating with the BTC Bohle Tablet Coater substantially increases efficiency of tablet coating from 2007. Bohle’s patented air flow design within the coating pan reduces the likelihood of spray drying to a minimum. Continuous production takes a leap forward in 2009 with the BCG Bohle Conti Granulator. Only one year later, the engineers develop the continuous coater KOCO®. At the Interpack 2011, the new generation of KOCO coaters®, the Bohle BCG Conti Granulator and a new compact system are presented to the experts. The extension of the Sassenberg production site is inaugurated in autumn 2011, only half a year after the foundation stone was laid. Since then, the entire handling production takes place at this site. At the same time, L.B. Bohle acquires 20,000 sqm of developed land in Ennigerloh in order to double production capacity at the headquarters. At the ACHEMA2012, L.B. Bohle Maschinen + Verfahren GmbH presents the BRC 100 dry granulator to the public. The compactor closes a gap in the range of offers. Customers can thus obtain the machines for the entire production process – without tablet press – all from a single source. In mid-2013, the company has its Bohle Uni Cone BUC® process protected by a utility model.

LEAN PRODUCTION SHORTENS DELIVERY TIMES

In the same year, the company celebrated the inauguration of Plant 3. The 20,000 sqm premises now encompass a production site of 3,700 sqm. “The relocation to the new Plant
3 marks the beginning of lean production, "says Lorenz Bohle. The production of the process machines is largely standardized and thus significantly more efficient. "We can deliver machines already in four to five months instead of seven months as previously," explains Bohle. In times of increasingly short-dated investment decisions, this constitutes an essential competitive edge.

KNOWLEDGE TRANSFER IN ENNIGERLOH
Lorenz Bohle banks on knowledge transfer with the investment in the Technology Center. "Our customers are increasingly relying on continuous production processes", explains Bohle. The new test and development center, which was inaugurated in early 2015, offers an excellent platform for research and practical development of this new process. "Now, the aim is to leverage the investments in production sites and the Technology Center to generate further growth stimuli," said the CEO. Those who know the entrepreneur know that he is already devising new ideas for innovative machines, processes and cooperation projects. The aim is always clear: "continuous growth".

THREE QUESTIONS TO

Robert Stauvermann,
General Operations Manager

Did you hesitate when Lorenz Bohle told you about his plans to start up a new machine building company?
It was a bold decision. I had a secure job as a metal worker back then. But it was tempting to start up a new business from scratch together with Lorenz Bohle and bring in my own ideas. We knew each other’s strengths from the time we worked for the same pharmaceutical toll manufacturer – him as a developer and man of action, me as a practical guy and tinkerer. The way from a 30 sqm workshop to a global special machine builder for the pharmaceutical industry has been worthwhile.

Is there a "gene for success" at L.B. Bohle?
Our common goal has lost nothing of its importance: to provide the best solution for the customer and highest quality, no matter what. For instance, we had a lot of machines produced at a manufacturer of farming equipment during the first year. But in order to safeguard quality, we decided to set up our own production. When more and more large orders came in, we knew we had made it. Innovativeness, courage and flexibility have certainly always been our competitive advantages.

How did the company develop further? And what does the future hold in store?
In the pharmaceutical industry, we saw the potential associated with an entry into process technology early on. With our Technology Center, we will stay a top player in continuous production for the next years. Qualified junior employees increasingly value the high degree of individual responsibility and the social environment that we offer as a medium-sized family business. Therefore, I am firmly convinced that Bohle’s success story will continue.
Highest precision and simple handling of the Bohle systems are held in high esteem by the industry manufacturers.
The technological solutions provided by Bohle rank top in pharmaceutical production. Based on long-standing expertise at all stages of the value chain, the specialists from Ennigerloh develop and produce efficient process and handling technology for pharmaceutical solids production. The product portfolio comprises all process steps: in addition to weighing, granulation and blending systems, the range includes chopping and sieving systems, film coaters as well as special containers and lifting systems which are tailored to the requirements of sensitive handling in the pharmaceutical industry. All machines are distinguished by simple handling, flexible production and small footprints.

ALL FROM A SINGLE SOURCE
But L.B. Bohle not only offers individual machines of top-quality, it also sees itself as a solution partner for the entire process. In this vein, the experts combine long-standing expertise with state-of-the-art control technology and also integrate the components of selected premium partners in the production process, if required. In addition, an extensive range of services complements the offer of the special machine builder. Apart from maintenance works, the technology leader also offers certification of the systems according to GMP guidelines as well as staff training.

THREE QUESTIONS TO

Thorsten Wesselmann,
Technical Manager

Which demands do your customer place on production?
First and foremost, they focus on efficiency and optimum production costs: rapid adaptation or conversion of the machines to a new product, little need for maintenance, cleaning and repairs as well as flexibility for the production of varying volumes are only some of the criteria. Moreover, new active agents and combinations thereof result in increased complexity and higher requirements for precision in tablet production. In the face of new and changed pathogens – such as EHEC or Ebola – the pharmaceutical industry is under pressure to shorten development times for new active agents. This can be supported through our production processes.

What is the major challenge for pharmaceutical machine builders?
Apart from machine building know-how, the overall process expertise is increasingly gaining in importance. As the complexity of the processes increases, so do the requirements for documentation. Moreover, we closely observe the trends to combine state-of-the-art sensor technology, analytics and IT technology. With our plant in the Technology Center in Ennigerloh, we are consistently pushing forward the issue of continuous production. Our aim is to maintain our technological lead over competitors.

Will traditional individual machines become less important in the future?
The opposite is the case: notably in the segments of containers and handling products, weighing, blending, sieving and granulating systems will remain our core business in the future. It is not by incidence that our Handling Site in Sassenberg is already reaching its capacity limits despite the extension in 2011. The demand for individual solutions remains high. Moreover, these machines are the basis of integrated processes. And even containers and lifting solutions often function as a link in the systems. But we also have to bear in mind that the demand for comprehensive/integral system solutions is increasing – especially when it comes to the global players in the industry. We are optimally prepared for this development as well.
For the production of pharmaceuticals, exact weighing of the substances is a decisive process that determines the quality of the product.
The Bohle weighing systems for solid particles are distinguished by highest precision and make a crucial contribution to compliance with GMP standards (good manufacturing practice) in the pharmaceutical industry. Apart from recipe-controlled weighing and dosing of the excipients/active substances, which is also possible using several weighing systems, they are also involved in the feeding of the production batches. The comprehensive solutions offer highly variable and flexible modular design that can be adapted to meet the individual requirements of our customers.
L.B. Bohle offers a broad range of options and product expansions in order to provide every customer with the system set-up that is tailored to their special applications. At the same time, the systems are easy to operate, economical and efficient. Whether wet or dry granulation – no manufacturer offers more comprehensive solutions than L.B. Bohle. Thanks to different sizes and processes, we can offer the customers the right technology for all stages of the granulation process. The recent introduction of the patented Bohle Uni Cone BUC® technology, which ensures coating of even the smallest particles, and the newly developed compactors BRC 25 and BRC 100 complement our portfolio. Innovations by Bohle not only excel by high quality but also through easy operation and cleaning.
Small in size but great in performance

When agglomerates have to be ground to powder or different particle sizes must be separated, it all comes down to the right sieving system. For the processing of high-quality powder or granulates, Bohle has developed powerful grinding and sieving machines in compliance with GMP criteria to precisely determine the particle size of the end product. With the BTS and BTM series, we offer globally acknowledged systems which can be flexibly deployed thanks to their mobile or stationary design and are suited for integration in existing plants. Simple cleaning of the components is an essential feature of these products.
It’s all in the blend

Blending processes in the pharmaceutical industry are extremely challenging as a reliable distribution of active substances can only be ensured with a homogeneous blend.

In this area of blending technology, L.B. Bohle is the world market leader with more than 2,500 machines sold. From small laboratory blenders through to big production machines, container volumes of one to 12,000 liters are implemented. Our PM systems are not only distinguished by their patented technology with counter-current process but also by maximum flexibility in their application. They not only assume a blending function but also act as feeders of the process machines. Apart from the successful PM series, the range also includes blenders for third-party containers.
Perfection in the process

Spraying, drying, blending – in order to achieve perfect results in the coating process, all production steps must be perfectly aligned.

Whether laboratory or process machine – coaters made by Bohle are at the cutting edge of technology and guarantee high profitability. Apart from homogeneous coating, careful handling of the tablets is one of the distinguishing features of the machine series. A flat tablet bed in large drum geometry and continuous adjustment of the inclination angles ensure optimal movement of the cores. The systematic compulsory guide in the drum enables continuous product movement. This prevents tablet twinning and considerably reduces losses in solids and coatings. The special air system creates advantages in process technology as the risk of spray drying of the suspension is eliminated. The coaters excel by easy operation and cleaning.
Handling made easy

A range of different containers and lifting systems are used for the supply of raw materials, the transport of the products or secure sealing or storage.

For careful handling of pharmaceutical products, L.B. Bohle has developed a broad range of optimized handling solutions. Be it the transport of containers, pallets or other units – we have the perfect solution for every task. The portfolio ranges from stationary lifting columns to mobile hubs for pharmaceutical transport that even offer the possibility of linking process machines as concatenated systems. Thanks to their optimized design, all Bohle systems feature a small footprint and offer good cleaning properties thanks to their smooth surfaces. Moreover, they are easy to operate and comply with the latest safety regulations.
In the early 1990s, L.B. Bohle established its own distribution and service site in the US. About 30% of the turnover are generated in the largest pharmaceutical market.

**Turnover of 39 Mio Million Euros in 2014**

Growth market South America: the sales team has been strengthened further in 2014. In Brazil, Argentina and the neighboring countries, economic growth entails an increase of pharmaceutical sales. Notably in the recent past, large process machines, such as this fluid bed system, were sold.
In India, the pharmaceutical industry grew at a faster pace than in all other countries in the past years. Large manufacturers of generic pharmaceuticals supply the world market from there. Bohle is targeting this market.

From Westphalia for the world: two plants at the headquarters in Ennigerloh and the plant for handling machines in Sassenberg (photo) constitute the core of the special machine builder with 30 years of tradition. The Service Center and the Technology Center are also located in Ennigerloh.

15,000 SQM OF PRODUCTION AREA

40,000 SQM OF OPERATING AREA

40 SALES PARTNERS WORLDWIDE
The faces behind the medium-sized enterprise

250 highly-qualified employees make the difference: the success is based on more than 30 years of expertise in the development and construction of process machines. „We work hand in hand with customers, partners and scientists. “
About 80 per cent of the turnover is generated outside of Germany today. How does a medium-sized machine builder generate such a success in the world markets?

Tim Remmert: Our customers increasingly appreciate us as a supplier of comprehensive solutions rather than a pure machine builder. We are able to correspond to complex customer requirements in a very flexible way and always offer individual service. This ability also puts us in a strong position among our competitors. For instance, we have won several major orders in Central America and Asia in the first half of the year. As our company’s history has shown, such orders can serve as a reference for access to important growing markets.

What other success factors are there apart from technological expertise?
In general, the quality of our machines and the innovations...
of our development department are the basis for high demand. The highly-specialized production of pharmaceutical solid particles also requires a high degree of customer trust which must be earned and fostered. Lorenz Bohle has proven early on that he understands the needs and chances of globalization for our industry. Apart from his personal presence at trade fairs, he has established a global sales team that acts as a direct contact for the customers. Already in the early 1990s, he established an own distribution and service subsidiary in the US – today the most important pharmaceutical market with a sales volume of more than 300 billion dollars.

Bohle generates almost one third of its turnover in the US. How is distribution organized in other growth regions?

With 40 offices or sales partners, we have a strong presence in all relevant target regions. It is important to make distinctions between the individual markets of course: in South America and Asia, we have recently further reinforced our presence. India certainly plays a key role with a rapidly growing pharmaceutical industry. We have won a large order for a process machine there. In the Chinese market, we score as a reliable partner of the top pharmaceutical manufacturers that rely on our support for the construction of new production plants. In the mid-term, we still see promising opportunities as the government attaches great importance to domestic production. The pharmaceutical manufacturers know and value our machines “made in Germany”.

In how far has the offer and sales process changed over the past years?

Customer requirements have become increasingly extensive and complex. For instance, they require detailed information on the future maintenance and service works. How can you defy the mechanical engineering groups with a strong global presence in such tenders?

On the one hand, we have to standardize offer preparation to the greatest extent possible. A modular structure facilitates flexible service at short notice to meet the individual needs of the customers. On the other hand, our service teams can respond quickly and are represented in all important regions.

As a long-term Sales Manager, you have been appointed to the management in 2015. What are your objectives?

Our industry is characterized by a constant need for innovation and enhancement. And – as the pilot plant for continuous production in the Technology Center demonstrates – L.B. Bohle sets the pace. We intend to communicate this technological lead more strongly in our sales activities as well. Therefore, we invest in the training of our sales staff. The added value – for instance of the plant with continuous production and new measurement technology – must be communicated more intensively to the customer. A second aspect for future growth is rapid delivery which can be obtained through the advancements in lean production.

> Innovative solutions for every customer «

Tim Remmert, Sales Manager
»We are Bohle«

MELANIE SCHEMANN
Design Engineer

„At L.B. Bohle, everyone is given a chance. Having completed training as a metal worker, I wanted to achieve more and asserted myself as a woman in the male domain of mechanical engineering. Today, I truly enjoy my work as a Design Engineer. Team work is our top priority.”

ANDREAS ALTMEYER
Service Center Manager

At L.B. Bohle, we work as equal partners in a team of process engineers, machine builders and software developers. We develop the best solutions together with our customers.

NANA ATUOBI
Sales Employee, USA

“In a competitive global environment, Bohle is firmly established as a provider of coating and granulating systems and process machines for pharmaceutical solids production. It’s so great to be part of this success story.”
PAUL LEE  
Service, USA

“High-tech 'made in Germany' enjoys an excellent reputation worldwide. Our machines are deployed by all pharmaceutical giants in the US. Our customers appreciate the precision of the process machines, the uncomplicated handling and the minimum need for maintenance.”

DANIEL DÜCK  
Trainee, 3rd training year

“We at Bohle are a real team. Experienced employees pass on their knowledge to us in the training. Moreover, it is really exciting to see that our machines from Ennigerloh in Münsterland enable the production of pharmaceuticals all over the globe.”

JUAN JOSE RULLAN  
Sales, Puerto Rico

“When we started presenting the company and the products 20 years ago, everybody said: Bohle... who? And today we have a broad base in Puerto Rico and Bohle has become a multinational company in more than 30 countries. Mr. Bohle is a renowned expert and entrepreneur.”

250 EMPLOYEES  
are working in production, sales and service worldwide.
Lorenz Bohle makes no compromises when it comes to the quality of an individual machine or comprehensive process systems. As soon as the customer’s requirements exceed the current product range, there are only two ways for the passionate mechanical engineer and process developer to achieve highest customer satisfaction and thus the success of the brand. He either develops new solutions himself – such as the dry granulator BRC or the Bohle Uni Cone process – that are better than all the other offers in the market. Or the Bohle team leverages its industry knowledge and involves experts for individual machines or for control and measurement technology in the development. In times when the pharmaceutical industry relies on solutions from one source, cooperation with reliable partners is gaining more and more importance.

ON EQUAL FOOTING
In this context, comparable size and a similar corporate culture are important success factors for cooperation. “We thus act on equal footing with our partners and leverage our expertise to mutual benefit,” explains Lorenz Bohle. Moreover, most family-run machine builders have flat hierarchies. This makes them considerably more flexible – just like Bohle. Within the relatively small circle of machine builders for the pharmaceutical industry, everybody knows everybody and whether they deliver top quality. This has led to reliable cooperations over the years.

The most recent example for intensive cooperation is the continuous production plant in the Technology Center in Ennigerloh. “We contributed our premium quality in the areas of granulating and coating,” says the initiator Lorenz Bohle. With the companies Gericke AG and Korsch AG, we have gained the support of two technological leaders in the area of blending and dosing and tablet press technology, respectively. Moreover, the machines had to be equipped with state-of-the-art sensor and measurement technology and all data had to be integrated on a common platform via standardized interfaces. The software integration, in turn, forms the basis of permanent monitoring, controlling and documentation of the continuous production process. The new Manager Scientific Operations, Dr. Hubertus Rehbaum, in turn involved experts in the project. “Cutting-edge spectroscopy technologies such as NIR and Raman enable precise measurement and analysis as part of the individual production steps”, he said. With Kaiser Optical Systems, Sentronic and...
Kraemer Elektronik, leading companies in this area were involved in the development and installation of the pilot plant.

Together with the IT partners and scientists from Graz University, the mechanical engineers from Aachen University developed models for the simulation of processes and measures and for the definition and automatic initiation of interventions. This “evolution process” will continue in the future.

COOPERATION IN SERVICE

“We really appreciate the cooperation as partners with the Bohle team and enjoyed contributing to the innovation project,” said Stephan Mies, CEO of Korsch AG. Together with all partners, pioneering work is being accomplished in pharmaceutical solids production in the Technology Center. For years now, the cooperation has been going beyond the joint development of process solutions. For instance, the two companies increasingly made use of their respective service and distribution structures for the extension of their global presence.

The customers from the pharmaceutical industry value the traditional claim to quality of medium-sized enterprises – be it large pharmaceutical groups or medium-sized producers. “We have been deploying Bohle machines since the 1990s – from handling through to process systems,” says Wolfram Matkewitz, Menarini. Since 2008, the company has succeeded to reduce process times by up to 20 per cent with a BFC 400 system,” explains Matkewitz. The broad product range is a further plus: “Bohle is the only manufacturer that offers all technologies in the area of granulation,” says Dr. Hans-Georg Feldmeier, Chief Production and Technology Officer of Dermapharm AG. The intelligent material flow concept enables very easy operation. Low-dust working environments, easy cleaning and easy operation are the key benefits of the technologies made by Bohle.

THREE QUESTIONS TO

Stephan Mies, CEO Korsch AG

Why do you cooperate with Lorenz Bohle and his company?

Our companies have known each other for more than 20 years. As a special machine builder for the pharmaceutical industry, we are operating in the same niche but with different products. Our machines perfectly complement each other in the overall process. Another advantage is that our companies have a very similar philosophy: both are family-run companies, have the same size with about 200 employees, deliberately produce in Germany and rely on a very high degree of specialization as well as premium quality to stand out from global competitors.

What are the advantages of family-run businesses compared to corporate groups?

We are no generalists that build plants for the general requirements of the pharmaceutical industry overnight. Both L.B. Bohle and Korsch stand for great innovative strength and development-intensive projects. Our machines are developed in Germany and range in the upper price segment. We live up to common values in our family-run companies that create a high degree of loyalty among our employees. They identify with the company and the products and that is what makes us so successful. However, as independent medium-sized enterprises, we are “doomed” in the most positive sense of the word to establish cooperations in order to hold our ground among competing corporate groups.

Are there any further synergies apart from research and development of the continuous production process?

What is important is that we make use of common knowledge platforms and thus safeguard our technological leadership. The best example for this is Bohle’s new Technology Center. In addition, I see many more options: there are a lot of potentials in global presence – be it in sales or service – in trend research and certainly also in the area of procurement. We are both convinced that we will continue to make full use of our strengths as independent family-run businesses.
Almost every machine in the pharmaceutical industry is one of a kind. In pharmaceutical solids production, the customers often have very specific preparations in mind when a new plant is being developed. Therefore, the Bohle experts develop and build machines in close cooperation with the customers.

In Bohle’s research and development department, pharmaceutical experts, mechanical engineers and process and software experts work hand in hand. Since 2005, the entire production process can be tried out in the company’s own Service Center. On an area of more than 600 square meters, the production of batch sizes between 10 and 30 kg is possible. Weighing stations, single pot high-shear granulators, fluid-bed technology, container blending, sieving and milling stations, tablet presses, coating and dry granulators can be used in a modular way or for clinic sample production. “This is complemented by our seminar rooms, where customers and scientific partners find ideal conditions for joint research & development activities”, says Dr. Hubertus Rehbaum, Manager Scientific Operations at Bohle. Thanks to the direct interlinkage with the Technology Center, which was inaugurated in spring 2015, this open research platform continues to gain significance.

For L.B. Bohle, ongoing further development of the machines and processes is an inherent part of the business model. More than 40 patents strengthen the position as a technological leader in the industry. The innovative solutions range from ventilation systems through to specially shaped spirals which prevent spray drying during the coating process, for instance. It was only in 2013 that the company had its Bohle Uni Cone technology patented. With this process, even the smallest particles can be coated with the active substances very precisely. In the pilot plant for continuous production in the Technology Center, many more patented solutions are to be developed in the near future.
Dr. Hubertus Rehbaum, Manager Scientific Operations, L.B. Bohle

**What is the significance of the Technology Center in your opinion?**
We have created a platform that enables us to further promote continuous production in the overall process together with customers and scientists. After about ten years of theoretic research in the industry, we are now taking the next step with the pilot system and its practical implementation in the production process. We are already able to supply parts of the system – the tablet press and the high-speed coater – as an integrated solution.

**Which advantages are provided by continuous production or processes for the manufacturers in the pharmaceutical industry?**
For the first time, we have closed the loop circuit along the entire process including continuous production, sensor technology, analytics and controlling in the plant. This results in tremendous time savings in production. For instance, small batches for the production of clinical samples – for clinical studies prior to the approval of new preparations – can be produced more rapidly. Series production is set to start as soon as we have received FDA clearance. There is no need to develop, install and validate a new production line.

**You joined Bohle in 2014. What attracted you to the company?**
Bohle enjoys an excellent reputation as an innovator in the pharmaceutical industry and in mechanical engineering. I was also welcomed with open arms and was able to join specific projects right from the start. I was impressed by the commitment and clear focus of Lorenz Bohle and his team. Instead of holding endless discussions, all colleagues join forces and think up practical solutions.
Prof. Fernando Muzzio expressed his enthusiasm for the pilot plant in the Technology Center at the inauguration. Since 2007, the renowned MIT has been persistently performing research and development activities for continuous production but the plant in Ennigerloh in Münsterland really represents a milestone on the way to practical application in the pharmaceutical industry. The difference in dimension of the US-research institution on the one hand and the machine builder from North Rhine-Westphalia on the other hand vividly illustrates the significance of the leap in technology. Prof. Muzzio of Rutgers University outside New York has been doing research as one of the world’s leading experts in this field. Lorenz Bohle and his team have created a unique platform together with scientists from the universities of Düsseldorf, Graz and Aachen in the placid town of Ennigerloh. It serves as a basis to further develop processes for continuous production which can be transformed into practical projects together with customers, mechanical engineers, pharmaceutical experts, IT and control experts.

Professor Peter Kleinebudde of Heinrich Heine University Düsseldorf has maintained a close relationship with L.B. Bohle Maschinen + Verfahren GmbH for more than 15 years now. „Notably in the field of tablet coating, we have focused on continuous production at an early stage,“ recalls the scientist. The company always provided the group of researchers with state-of-the-art machines. „We are already using the third version of the drum coater,“ explains Prof. Kleinebudde.

But Bohle plants are not only the main focus of research projects at the university. „We regularly make use of the outstanding-
ing possibilities to conduct test series provided by the Bohle Service Center,” comments the expert on the uncomplicated cooperation. Prof. Kleinebudde regards the new Technology Center as a further step towards a fascinating exchange: “Even though the pilot plant is already working, there are still unanswered questions regarding continuous production which we will not find an answer to in the next two or three years.”

LOOP CIRCUIT ALONG THE PROCESS
“For the first time, we have closed the loop circuit along the entire process including continuous production, sensor technology, analytics and controlling in the new modular plant,” explains Dr. Hubertus Rehbaum, Manager Scientific Operations at Bohle. The key benefit for the pharmaceutical industry lies in tremendous time savings in production. For instance, small batches for the production of clinical samples – for clinical studies prior to the approval of new preparations – can be produced more rapidly. "And series production is set to start as soon as we have received FDA clearance. There is no need to develop, install and validate a new production line," says Dr. Rehbaum.

US professor Muzzio encourages all parties involved not to give up even in light of many unanswered questions and potentially critically points: if mechanical engineering and the pharmaceutical industry “want to achieve continuous production, we simply have to do it now.” With the insight gained in the Technology Center in Ennigerloh, L.B. Bohle Maschinen + Verfahren will certainly meet with the greatest possible interest in the US, the world’s largest market for pharmaceuticals.

Prof. Peter Kleinebudde,
Düsseldorf University

What is the status quo of continuous production in the pharmaceutical industry? Which developments do you expect in the future?
We have been engaging in research on continuous production for more than 10 years now and the launch of the Novartis MIT project by 2007 has been greeted with great interest within the industry. It is already being applied in practice in individual process steps – such as extrusion and compacting. Continuous production has not been established along entire process chains. But the market is broadening. We see progress.

Which advantages are associated with the Bohle Technology Center for the pharmaceutical industry and for you as a scientist and your research activities?
In the Technology Center, the industry and we as scientists can gain experiences with continuous production along the entire process. This is highly interesting because there still are a lot of unanswered questions. Which sizes can be profitably produced with this kind of plant? Until now, the pharmaceutical industry has produced rather large volumes in general. But recently, the focus has shifted to the flexibility of this multi-functional plant. The variability of the different granulation methods opens up a great range of options.

What do you appreciate about the cooperation with Lorenz Bohle and his team? How will it develop in the future?
We have been closely cooperating in the field of coating for more than 15 years. Lorenz Bohle is a reliable partner who leaves us a lot of freedom for our research. We were also involved in the design of the Technology Center as part of the scientific team. Two PhD students regularly visit the Center in Ennigerloh to carry out experiments. The Technology Center offers the possibility to conduct research on questions regarding continuous production and we are glad to be involved in this fascinating project.
Bohle Technology Center

**BCG30:**
By application of liquid and controlled shear forces to the powder blend, the Bohle Continuous Granulator is used to produce wet granules for further processing.

**BCD30:**
The Bohle Continuous Dryer features four independent drying processes, working in parallel to produce dry granules with a homogeneous moisture content. By the use of integrated NIR probes, the drying process is monitored constantly.

**Investment sum:**
approx. EUR 2 million for the building and equipment, another approx. EUR 3 million for process equipment and software

**Start of construction:**
spring 2013

**Official opening:**
26/27 March 2015

**Partners (industry):**
Korsch AG, Gericke AG, Siemens AG, Kaiser Optical Systems, Sentronic and Kraemer Elektronik

**Partners (research):**
Heinrich-Heine-University Düsseldorf, Research Center Pharmaceutical Engineering University of Graz, RWTH Aachen and Rutgers University New Jersey
KOCO®:
We developed the KOCO specifically for fast, semi-continuous coating processes. Due to the narrow residence time distribution of the cores, a uniform weight gain is achieved. This constant process quality allows to use the KOCO also for functional coatings. And through the use of a Raman probe in the coating drum, the process can be monitored in-process.