KORSCH: MAGAZINE

The KORSCH AG Customer Magazine









Growing as a team

Dear Readers.

The external signals could not have been any clearer during the past year: the only successful way of mastering the challenges of tomorrow is to do so collectively. Lone wolves with blinkers on will gradually be superseded by those partnerships, which pool and augment skills in ways that make business sense. Ongoing digitalization is acting as an extra catalyst, making interconnectedness easier and providing further plant and machinery automation opportunities.

KORSCH is keen on actively shaping the future together with its partners from the business and science communities. Another key partnership, with French compaction simulator specialist MEDEL-PHARM, will come on stream this year, joining us and our longstanding process equipment teammate, L.B. Bohle. We are thus laying the foundation for further growth in the research and development segment. With the aid of this accumulated know-how, we will be in a position to develop new, efficient technologies that we will supply exclusively to global markets, thus making R&D teams more effective and productive.

In addition to sharing information with component manufacturers and system partners, we at KORSCH regard dialog with our customers in their role as longstanding partners as extremely important. To complement conventional communication via our sales and service organization, our INNOVATION CENTERS, which are now established worldwide, provide the ideal platform for communication and jointly enhancing products and processes. We look forward to journeying into the future together with you, es-

pecially in these complex times.

I wish you an inspiring read.

Yours sincerely, Stephan Mies CEO of KORSCH AG



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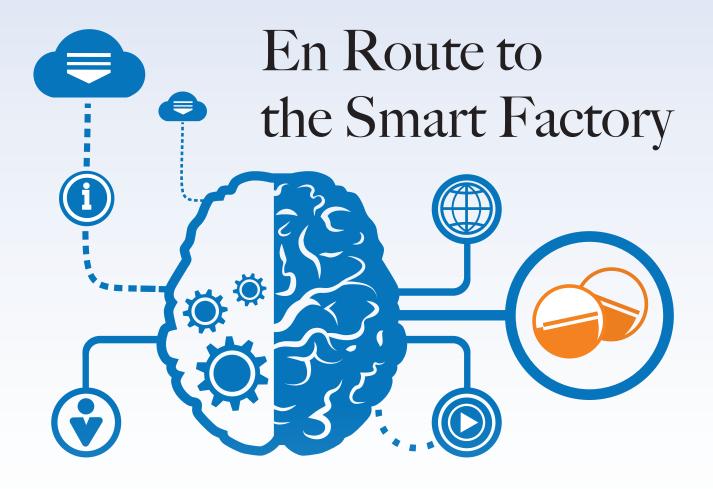
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Longstanding partnerships ensure seamless system integration.

While tablets had to be manually compressed one by one when the tableting industry was still in its infancy, modern-day tableting technology is now evolving into an increasingly digitalized process. In the search for even better KPIs, production components are becoming increasingly smarter as a result of faster throughput and significantly reduced downtime. The latest example of this from the KORSCH product portfolio is the X 3, a single-sided rotary press for small and midsized batches. In no way inferior to larger models, the X 3 has been fitted with the same smart sensor technology and represents a new generation of tableting machinery that informs operators in much more detail and at greater speed about current process events.

These smart components have been incorporated in various items of equipment to provide a comprehensive picture of the production situation: "For example, RFID chips that enable automatic parts detection have been installed. They know if parts have been installed correctly and are in proper working order after retooling. The installation can then notify the operator via its smart sensors and on the basis of its preset target status: the fill cam does not match your preset product. This enables errors to be avoided beforehand. Reading out supply circuits,

for example, enables operating modes to be controlled and enhanced, in terms of energy efficiency as well," Arno Rathmann, Head of Automation at KORSCH, explains.

The interfaces are what matter

When a tableting machine is fully integrated into a production line, the smooth transmission of individual components' data to the MES (Manufacturing Execution System) is vital. This higher-level system centrally manages all process events, e.g. sieving, blending, dedusting, or coating at the start or end of the process, within the installation as a whole. "We prefer to plan and de-



"As one of Europe's largest automation specialists, Siemens has for many years been a regular partner, with whom we collaborate very closely."

Arno Rathmann



Arno Rathmann navigates the intuitive, Smart-Touch HMI.

velop fully integrated continuous production lines jointly with an established partner like L.B. Bohle, whose components we are familiar with. Our interfaces dovetail perfectly. It, of course, makes commissioning so much easier, not only if all the plug connections match, but also if the machines communicate reliably with one another, in order to ensure material and data flows. Central formulation management or batch reporting is only feasible on this basis," says Arno Rathmann. A fully intergrated production line featuring the X 3 as its centerpiece can even be viewed at the premises of KORSCH's long-established partner, L.B. Bohle.

Cloud solution delivers centralized data management

"As one of Europe's largest automation specialists, Siemens has for many years been a regular partner, with whom we collaborate very closely in terms of equipment components, like our user-friendly Smart Touch HMI, control cabinets or installation plates. The direct contact that we have locally in Berlin is beneficial to proactive, partnership-based communication between our two companies. For example, this partnership generated a specifically enhanced torque motor for our machinery," Arno Rathmann relates.

Siemens is also the partner of choice for the cloud solution that delivers centralized data collection at KORSCH. "Siemens MindSphere enables us to dock on to a well-engineered and supremely compatible cloud product, to which our customers are also happy to entrust their data. Siemens has already invested plenty of resources and completed a great deal of development work in this field. This certified expertise is a key reason why we partner with Siemens, because data security and reliability have top priority," Arno Rathmann explains. This higher-level system enables customers to check the current status and the history of their entire production line from anywhere within their business and conduct analyses. Alternatively, KORSCH also offers Pharmalnsights® - a local edge solution for data management.

A new, smart machine generation

The Smart Factory principle has set tableting on a course into the digital future. Alongside increasingly more accurate sensors, which can detect even the minutest system anomalies in fractions of seconds, maintenance intervals can now be predictively planned to ensure machinery availability, by seamlessly monitoring and tracking machine status. When digitally accumulated process knowledge is analyzed, artificial intelligence will increasingly assist this wealth of experience to generate further increases in efficiency. The aim is to eliminate operator errors almost entirely. " The machine of the future should know which is exactly the best solution for it in any given situation. Having partners we can absolutely rely on and with whom we can communicate openly as well as equally digitally receptive customers, is enabling us to head gradually in the direction of Pharma 4.0," Rathmann promises.



Two Specialists Charting an Innovation Course

KORSCH and MEDELPHARM are jointly aiming to revolutionize the R&D segment.

It was made official on January 11, 2021 – KORSCH AG is entering into an exclusive sales partnership with the French manufacturer of R&D tableting equipment, MEDEL-PHARM S.A.S. In the following interview CEOs Stephan Mies (KORSCH) as well as Ingrid Coyle and Bruno Villa (both MEDELPHARM) talk about the background to this collaborative venture, what is required of the joint R&D line and visions for the future.

KORSCH:MAGAZINE: Could you please start by telling us how the partnership came about in the first place.

Stephan Mies: Bruno Villa and I have been acquainted now for around fifteen years. Irrespective of any business affiliations during this period, we have kept in regular contact, met up at trade fairs, and shared a connection through our longstanding partner L.B. Bohle. MEDELPHARM engineers exciting, highly innovative products. And when we look back at KORSCH's 100-year history, those initial successes with our EK 0 product and our enduring links with the pharmaceutical faculties of many universities, often as an exclusive supplier, then this partnership means that KORSCH is going "back to its roots" to some extent.

KORSCH:MAGAZINE: Both companies are family-run. Did that play a role in your decision to enter into this partnership?

Stephan Mies: Of course. We also have similar mid-sized business structures in common – commitment to and identification with the business are simply bigger than what you find in a large corporation. We are equals – that is important. During the course of many constructive conversations over the last few years, we have increasingly compared notes on our objectives and strategies and have realized how well our products complement one another in the global tableting market.

Bruno Villa: MEDELPHARM and KORSCH have the same, unifying standards of product quality and performance. What matters to both our companies is not just the longevity of the equipment manufactured in France (MEDELPHARM simulators) or Germany (KORSCH machines), but also good performance figures, rapid product changeover capability, including appropriate GMP-compliant cleaning as well as ease of

operation. After all, not only highly qualified research assistants, but also other well-trained staff should be able to operate the equipment safely and effectively. What is the use of having the fastest car if I can't drive it?

KORSCH: MAGAZINE: What does your partnership look like in practice?

Stephan Mies: We are starting out with a sales partnership, in other words. KORSCH will from now on handle global sales of MEDEL-PHARM's products on an exclusive basis. Given our global sales and service network, that therefore makes us the go-to contractor for all potential customers. Conversely, we now have access to MEDEL-PHARM's established sales channels in France and Belgium. By combining our XP 1 and XL 100 models with MEDELPHARM's two R&D products - STYL'One Evo and Nano, this will enable us to offer the world's most advanced tableting line for research development applications. KORSCH's product offering provides a seamless transition from the simulation, initial compression tests and scaling-up involving smaller batches offered by MEDELPHARM.





Research and Development in Focus

From now on, both MEDELPHARM products are available for demonstrations, tests and for training purposes in the KORSCH Innovation Centers in Berlin, Boston/USA and at some point in the future also in Mumbai/India.

Bruno Villa: We regard it as a major breakthrough that our sales team in France is now able to offer a full range of tableting equipment from R&D to manufacturing. The STYL'One range and the XL 100 are a perfect combination. MEDEL-PHARM serves a niche in the tableting segment, which in turn provides a range of benefits to a broad user base.

KORSCH:MAGAZINE: What would those be?

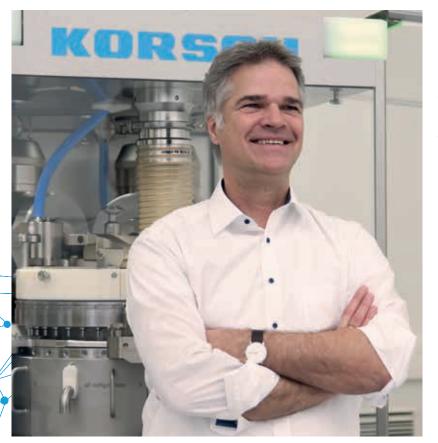
Ingrid Coyle: Tableting simulation was regarded with skepticism in the pharmaceutical segment for a very long time. Hydraulically operated simulators were disparagingly termed expensive, oil-losing tools that were anything but user-friendly and the sole preserve of a scientific elite. We at MEDELPHARM - with both mechanical and software development roots - saw this problem as an opportunity to create a user-friendly device that benefits from both the flexibility that computers provide and from the stability offered by mechanical tablet presses. There

is a massive amount of optimization potential lying dormant in the R&D segment, which we can leverage using precision smart simulation software. Our STYL'One Nano is an attractive entry-level product that adds sustainable value to any institution's or company's R&D department.

Stephan Mies: In essence, tableting has not really changed since its emergence as an industry. But these digital technologies now enable us to go into much greater detail. For example, formulations need to be developed on a small scale first of all. Simulating a tablet's properties when a combination of active ingredients and excipients is being newly formulated saves time and money. Furthermore, the interaction between our products enables the issue of active ingredient dispersion, for example, to be examined even more effectively. Last but not least, prior simulation makes the key process of validating formulations much faster and more reliable.

KORSCH:MAGAZINE: How complex is machine operation?

Ingrid Coyle: A key component of our corporate identity as a service provider is training people to operate our equipment in our "Science Lab".





Partners by conviction: Ingrid Coyle and Bruno Villa (both MEDELPHARM) and Stephan Mies (KORSCH)

Without wanting to go into every detail about the Science Lab's technical facilities, we would instead like to emphasize that our scientists and lab technicians are perfectly placed to conduct particle characterization analyses and to test formulations. After all, I not only have to be able to operate the equipment, but also need to know how to interpret the data collected and put it to productive use. In early stages of formulation development that can provide important information about what modifications still need to be made to the product, in order to manufacture it safely and efficiently.

Stephan Mies: But it also allows me to draw some conclusions about my future choice of tableting equipment: which fill system, which compression forces, which turret

KORSCH XP 1



- R&D Single-Punch Press with small batch capability
- For feasibility studies, screening & product characterization
- Full instrumentation and data analysis

speed etc. The baseline data for the simulation originates from empirical data obtained from common makes of tableting machine, including KORSCH products.

KORSCH:MAGAZINE: What projects have you got planned for the future?

Bruno Villa: MEDELPHARM plans to keep on enhancing current tableting R&D technologies. One example: we will meet growing demand for "containment" solutions for our STYL'One Evo and Nano models, which will be available in 2021 in line with our strategy of "making highly innovative technologies accessible to a broad audience".

Stephan Mies: The market will definitely comprehend the rationale behind our partnership and the as-

sociated benefits for customers. We will emphasize this through joint appearances at seminars, pharma forums, and trade fairs. We will gradually extend our partnership to include other areas as well. With MEDELPHARM at our side, we will be gaining further insights into innovating and enhancing products and formulations - and our customers will benefit directly from these efforts. MEDELPHARM's data acquisition and analysis work complements our products superbly and the tablet behavior data collected is the key to scaling up at a later stage. Customized forms of medication all the way through tablet pressing will be a topic of interest in the near future. For example, Amazon recently announced that it wanted to enter the online pharmacy market. Given the consumer knowledge that such a corporation possesses, that could really energize the industry. So, it's worth our while to keep on questioning established manufacturing methods in that respect.

KORSCH:MAGAZINE:: Many thanks to you for the interview.

Please find further information at r-d-in-focus.com

MEDELPHARM STYL'ONE NANO



- Benchtop Compaction Simulator
- Single-layer formulation development
- Integrated analysis software

MEDELPHARM STYL'ONE EVO



- Versatile Compaction Simulator
- Multi-layer capability
- R&D at production speed

KORSCH XL 100



- Small-Scale Rotary Press
- Product development and clinical batch production
- Exchangeable turret for maximum flexibility



Partnerships provide more product and process enhancement opportunities at the INNOVATION CENTER.

The KORSCH Innovation Center is not your usual tableting equipment showroom. A wide range of different projects involving customers and partners make the IPC laboratories and testing facilities in both our Berlin headquarters and in South Easton/ Boston (USA) hives of activity. This is where customers' R&D teams and KORSCH's specialists, comprising pharmacists, process engineers and tableting experts, can join forces in an ideal research environment. The spectrum of supervised tests ranges from classic pharma feasibility studies via scale-up applications, through compression testing for FC&TC (Food, Confectionary and Technical/ Chemical) product development purposes. Tests involving multi-layer or core-coated tablets can even be conducted using the appropriate KORSCH tableting equipment.

To ensure realistic production conditions, our collaborative partner L.B. Bohle, provides machinery relevant to upstream and downstream process steps, like a vacuum conveyor for machine feeding, a gravity blender, a conical grinder for the uniform crushing, sieving and/or deagglomeration of powder components and, a dry granulator or a roller compactor, to complement the wide range of KORSCH machine types. In turn, KORSCH has installed its new X 3 for small and mid-sized batches in the continuous production line at Bohle headquarters in Ennigerloh.

"We back each other up and complement each other. KORSCH provides the tableting know-how, while Bohle has in-depth knowledge of upstream and downstream processes. This enables us as a team to find the best solutions for our customers," says Sebastian Eichler, Head of the INNOVATION CENTER. But sometimes, equipment or materials that are not yet marketable are tested on site, as was recently the case with a new magnesium stearate spraying solution, which prevents punches and die walls from sticking.

Fine-tuning product development

The success of a new product depends on various factors, while its







The joint R&D line of KORSCH and MEDELPHARM at the INNOVATION CENTER Berlin

compressibility is dependent to a large extent on composition and proportions of active ingredients and excipients. A high reject rate can be remedied by minimal changes to a formulation. Dr. Friederike Gütter, who has a doctorate in pharmacy, provides advice in such cases and searches for new options together with the customer in close consultation with established excipient partners: "For example, a customer sometimes may want their tablet to swell up in water. If there is no appropriate substance in our wide lab range, I refer this desired characteristic to our partner. They send us recommended samples that we can experiment on here."

Non-pharmaceutical product development generally offers more leeway as far as active ingredient formulation is concerned, because these products are not subject to the strict market approval rules set by the medicinal products regulators. Pharma applications nevertheless benefit from tests in the INNOVATION CEN-TER, when, for example, compression forces or turret speeds can be fine-tuned. But also, when other upstream or downstream process steps are scrutinized in terms of safety and cost-effectiveness - like material feeding, dedusting, or conveyance.

Partnership with TU Braunschweig

KORSCH also has a longstanding, active partnership with the prestigious TU Braunschweig, Specializing in solid dosage forms, the university's Pharmaceutical Institute was provided with an XL 100 on permanent loan. "The TU's excellent reputation, which is thoroughly warranted, as well as our geographical proximity are arguments in favor of our partnership. It not only generates a number of Bachelors and Masters dissertations every year, but also enables us to share scientific information. Studies and foundational research at the TU regularly provide us with additional new insights, for example about the characterization of powders. This enables us to improve how we classify our tests for the purposes of comparability. Occasionally we also send a powder to Braunschweig to be analyzed," Sebastian Eichler explains. The objective of this work is to set up a database that will enable us to make the process of mathematically computing compressibility increasingly more accurate.

Tableting simulations in action

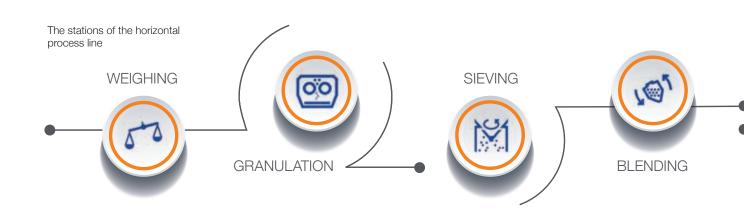
That is exactly what the tableting simulators manufactured by KORSCH's collaborative partner MEDELPHARM are geared towards (in the interview starting on page 4). Coinciding with the start of the new sales partnership, STYL'One Evo and Nano units were installed in both KORSCH Innovation Centers (Berlin and Boston) for demonstration and testing purposes. Research and development are therefore entering a new digital era. Both instruments enable a full range of tableting equipment to be simulated - that considerably minimizes the inputs required for any series of tests. Large quantities of powder are seldom available, especially when a new product is being tested. These simulations make these quantities unnecessary. "We were trained accordingly by our partner in how to operate these instruments, meaning we can also provide appropriate simulation advice to our customers. Capacity utilization at the INNOVATION CENTER is generally very good, which is why we are delighted about the capacity increases that both new instruments have provided us with. Last but not least, we regard simulating our own equipment as a very worthwhile exercise. At two to three pressing sequences within one to two hours, the time needed is comparatively short," Sebastian Eichler states. An XP 1 or EK 2 are available on site for further practical tests. Parameter settings derived from simulations enable further tests on KORSCH equipment to be configured quickly and with greater precision. This also saves time and possibly avoids failures. "In contrast, product flow can't be simulated, so that is where we as process experts reenter the picture. Nonetheless, both products complement each other perfectly in the R&D environment."

Efficiency Right Down the Line

KORSCH is developing continuous production process lines in partnership with L.B. Bohle.



The joint Conti line at L.B. Bohle in Ennigerloh - the X 3 as the new centerpiece



In terms of the overall process, from powder to packaging line, each individual component has to dovetail with the next. Reliable product quality attributes and continuous technology enhancements are essential to enable these partnerships to meet market requirements. As far as integrated process solutions are concerned, L.B. Bohle, the manufacturer of process and handling machinery, has been our partner of choice for many years as well as in a wide range of projects completed all over the world.

"The L.B. Bohle product portfolio is the ideal complement to KORSCH's tableting equipment. Our machinery and control systems dovetail perfectly, meaning we are jointly able to create and install complete, smoothly operating process chains," Frederick Murray, Director Global Sales at KORSCH, explains. "This partnership represents a joining of forces between two independent family businesses, which are founded on the same values and the same understanding of quality and innovation leadership. We have been establishing harmonized, decentralized sales and service structures gradually for several years now. Our objective is always to be focused on the customer," says Tim Remmert, Executive Director at L.B. Bohle.

Automated continuous production lines

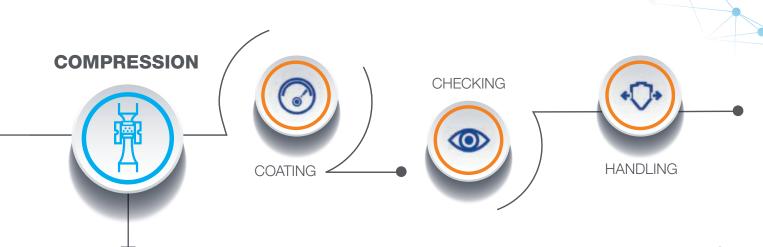
All the factors inherent in a proactive partnership enable planning and installation of continuous production lines. "In contrast to batch production, integrated solutions help to increase efficiency, quality, safety and flexibility within the process," Tim Remmert explains. The key element in this respect is the consistent use of innovative automation technology. This in turn requires an understanding of complex processes, which is what both long-established providers and specialists in their respective fields already have in common and what they are enhancing through continuous communication.

Tableting is already a continuous system and features an automated inspection system, like the proven PAT for controlling tablet weight. An additional NIR sensor in the material feed enables the homogeneity of the mixture to be compressed to be continuously controlled. This enables the tablet press to be fully integrated into a continuous production environment.

A central control system monitors and adjusts the entire process. Operator errors can increasingly be preempted. Both KORSCH and L.B. Bohle complete system components incorporate full, automated process monitoring of preset parameters using sensor technology. This enables anomalies and discrepancies to be localized with the utmost precision and corrected "in line" at an early stage. If these occurred in batch production, the entire output would be faulty. A central event log continuously records all processes and events.

Conti in the midrange segment

The X 3 midrange tablet press is the perfect complement to L.B. Bohle's QbCon® conti-line, particularly given its size and wide range of automation features. "In this case, output is defined by the equipment's runtime. Numbering up is undertaken instead of scaling up. That means that more efficient tableting equipment is often not selected, but the equipment line is simply duplicated instead, again featuring a flexible midrange machine as its centerpiece," Frederick Murray states. Nonetheless, 25 to 30 kilos of tablets per hour, which equates to a quarter of a ton within a regular 8-hour shift, can be produced this way.





Consistency in Action

Longstanding partnerships ensure seamless system integration.

Not only is a seamless pressing operation vital to the efficient, safe manufacturing of a tablet, so too are a whole series of processes within the so-called periphery. All immediate, pressing-related components are termed vertical periphery components. The horizontal periphery, on the other hand, includes all processes upstream and downstream of the tablet press. Fine-tuning all components is what matters, whenever a large quantity of processes have to mesh seamlessly.

"Peripherals provided by customers often harbor problems when it comes to integration. KORSCH regards itself as a provider of systems, and its longstanding partnerships enable it to conceptually design full tableting systems. This ensures efficient product flows and that no unit is too big or too small to fit the attached installation. There is no "plug & play" solution, not even if electrical connections are involved. We agree appropriate connector configurations with our periphery partners, especially as the trend is towards full integration. This means that everything can be controlled via the tablet press," Bernd Duchstein, product manager at KORSCH, explains. Periphery components have to function seamlessly, especially when continuous production is involved. So it is worth segmenting the process into its constituent parts and scrutinizing it.

Key process details

After granulation and blending, a vacuum conveyor or a lift column including an IBC are used to feed the press. The relevant production room height needs to be factored in when integrating a lift column. Once the material is in the tablet press, one of the operations to be completed by the vertical periphery components is spraying the punch faces and die walls with magnesium stearate, if the non-stick effect issue cannot be resolved via the tablet formulation. Here, micro-coating in the form of an external lubrication of the punches and die walls contributes to production reliability. Dust is continuously vacuum-extracted by industrial vacuum cleaners at up to eleven locations within the press. Suction power can be specifically controlled, depending on product type.

Other minute particles accumulate when the tablet deduster is in operation. When the tablet is discharged

from the press, it is conveyed upwards with the aid of an upward vibrating conveyor and is deburred at the same time. A stream of compressed air helps to vacuum off the accumulated dust particles. "Brushes were previously used, however the process of cleaning them to avoid cross-contamination was too laborious. To comply with GMP guidelines, it therefore makes sense to stick entirely with stainless steel and plastic solutions," Duchstein explains. Once dedusting has been completed, the integrated metal detector on combination units then kicks in and checks the tablets to ensure they do not contain any foreign matter. The inspected tablets are then directed into containers with the aid of a multi-position diverter. After that, the tablets are sent to the packaging line.

In-process inspection takes place in parallel to the production line with the aid of KORSCH PharmaCheck® 3.

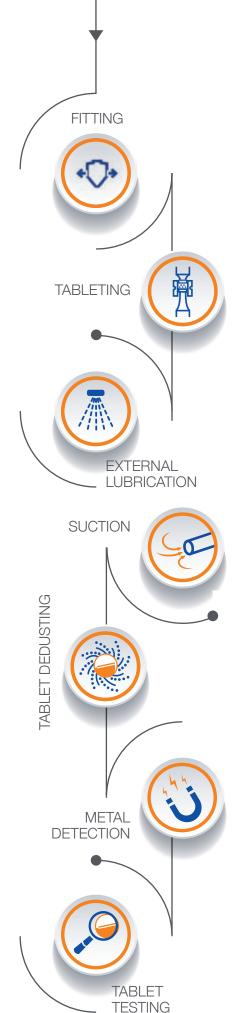
Bernd Duchstein

Born 1979 in Berlin

Qualified industrial engineer

- KORSCH product manager since November 2018
- Prior to that, 15 years experience in the machine tool industry
- Also visiting lecturer at HTW Berlin



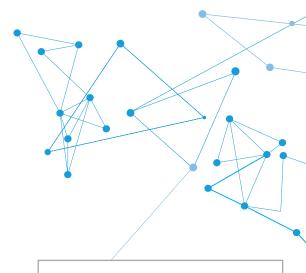


In this case, tablet weight, height, hardness and diameter are checked. The following premise always applies here: maximum output at minimum rejects.

Special case: containment

Precisely matched components play a particularly important role where OEB 4 or 5 applications are involved. Standard peripherals do not meet stringent safety requirements, meaning that containment equipment is usually offered as a fully integrated package. All connections must always remain sealed, to prevent tiny, highly potent or highly toxic particles from escaping. Feeding is ensured using vacuum technology or split butterfly valves. A centralized dust collection capability, on wash-in place (WIP) installations, is critical for contained dust extraction and batch reconciliation.

"KORSCH's customers are used to their tablet presses operating smoothly. That is why we thoroughly vet our (peripheral) suppliers. Our INNOVATION CENTER enables us to offer ideal facilities on site. But we have enjoyed excellent, longstanding working relationships, in some cases for 30 years, with a large number of suppliers. This accumulated project know-how also enables us jointly to come up with new solutions, if required. For example, our dedusting equipment with wet cleaning capability was developed together with a Berlin-based partner," Duchstein relates. While some customers are increasingly tending towards being supplied with individual process components direct from OEMs, experience shows that the more complex the equipment, the more important centralized, expert planning is. "Every customer is glad when they can turn to a single point of contact rather than having to go to ten different ones, when service, maintenance or spare parts issues need to be addressed. If their machinery is not operating, then things have to happen fast. That is when you appreciate a full, reactive customer support service that knows your machinery inside out," says Duchstein.



IMPRESSUM

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