WHAT'S NEXT?

FETTE COMPACTING

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FETTE COMPACTING MAGAZINE 2022/2

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CONTINUOUS MANUFACTURING
In flow

PROCESS ANALYSIS
Measuring like never before

CONTAINMENT
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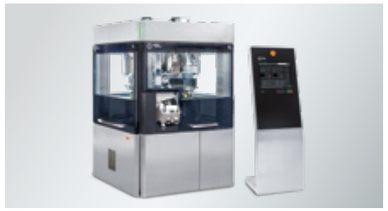

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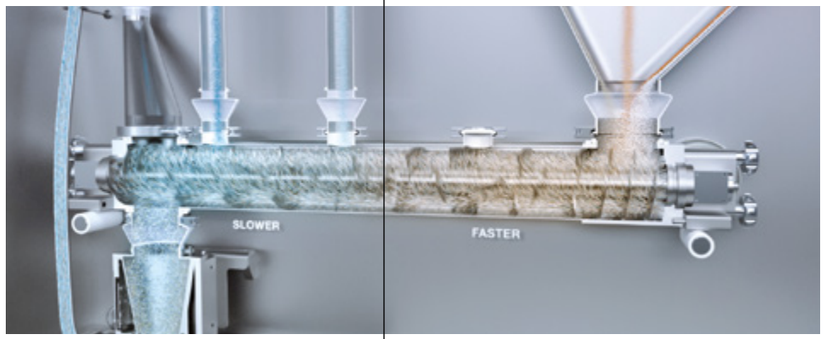

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DEAR READERS,

At the end of a special year, we invite you to several technology journeys:

In the new article on Continuous Manufacturing, we show the path the powder takes through the FE CPS dosing-mixing unit. Along the process stages, it becomes clear how many innovative developments raise Continuous Direct Compression to a new level overall. In the expert interview, you can also read about the special role played by Process Analysis Technology.

The journey continues into the digital future of the production of solid formulations: find out how the OSDi digital unit is immersing itself in the world of dynamic data. The networked future is already a reality in the smart factory of Boehringer Ingelheim. And in the middle of it all are two tablet presses from Fette Compacting.

Our other practical reports are also very close to the customer: from the commissioning of the new F30i double rotary tablet press at the pharmaceutical producer Servier to a unique service order at the pharmaceutical manufacturer Dr. Schwabe.

We wish you exciting insights!

Your team at Fette Compacting

TECHNOLOGY stands for all offers in production technology – from tablet presses through process equipment to tableting tools.

SERVICE comprises all services relating to machines, plants and process equipment, e.g., provision of spare parts, plant modernization, and the technical field service.

COMPETENCE is the umbrella term for all process-based services. These include training offers, product tests, performance consulting, and engineering.

Imprint

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NUMBER ONE

The F30i is the powerful double rotary tablet press in the new Fette Compacting i Series.

The French pharmaceutical company Servier commissions one of the first F30i from Fette Compacting. The high-performance double rotary tablet press impresses with its ease of operation, improved cleanability, and cross-generational system compatibility.

Servier is the second largest pharmaceutical company in France. In subsidiaries in 150 countries, the company employs 21,800 people worldwide. In 2021, the Servier Group, which is governed by a foundation, generated revenues of about 4.7 billion euros. The group invests more than 20 percent of its pharmaceutical revenues in research and development, working closely with academic partners, pharmaceutical companies, and biotech firms. This commitment is in line with the company's mission, which is dedicated to therapeutic progress and the needs of patients.

As a leading company in cardiology, Servier aims to become a renowned and innovative player in oncology as well. The group's continued growth is based on sustained research in cardiovascular and metabolic diseases, oncology, neuroscience, and immuno-inflammatory diseases. To promote access to healthcare for all, the Servier Group also offers a range of quality generic drugs covering most pathologies.

For tablet production, Servier relies on the innovative technology of Fette Compacting. Starting at the end of 2022, the company will use the F30i tablet press at its production facility in Gidy, France. The machine will produce Daflon, which is used to treat vascular diseases. That makes Servier one of the first companies in the world to use an F30i from Fette Compacting.

Old meets new

The F30i is a high-performance double rotary tablet press developed by Fette Compacting as part of its new i Series and presented to the public for the first time in 2021. It is designed for the production of large batches and enables an output of up to 1.6 million tablets per hour, which makes it particularly suitable for the production of best-selling drugs such as Daflon.

Like its sister machines F10i and F20i, the F30i is optimized for operator protection as standard. Even the standard variant is consistently dust-tight. Additional safety is provided by the fully-automated tableting process.

One feature that those responsible at Servier are particularly enthusiastic about is the cross-generational system compatibility displayed by the F30i. All process-related assemblies are the same or similar to those of the earlier machine models from the classic i Series. This is of particular advantage when companies use other tablet presses from Fette Compacting.

"There are currently nine Fette Compacting machines in service in our Gidy plant," reports Cédric Papon, Project Manager at Servier. "In the future, the F30i will work side by side with the 3090i machine and two FE55 tablet presses. Small modifications are already enough to transfer the die and segment rotors from the older machine to the F30i. The similarity of the components has made qualification and validation much easier for us and also saves time and money in daily use."

Easy to operate, easy to clean

Another big plus for Cédric Papon is the fact that the F30i can be cleaned much more efficiently and safely. Compared to the predecessor model, the cladding parts to be cleaned have been reduced by 71 percent. "For us, this represents a double advantage," says Cédric Papon. "First, the overall cleaning time shrinks significantly, effectively saving us money. Second, the reduced cleaning time reduces the need for our operators to go to great lengths to protect themselves from contact with the active ingredient during cleaning operations."

The F30i also excels when it comes to user-friendliness. It offers several smart software solutions that help even less experienced operators avoid typical operating errors. A modern Human Machine Interface (HMI) enables intuitive control, monitoring and documentation of the machine and process equipment.

"The HMI of the F30i is very similar to the version used on Fette Compacting's FE55. Since we also use the FE55 in Gidy, it is very easy for our employees to familiarize themselves with using the F30i," says Cédric Papon.

The cooperation continues

Ultimately, it is not the machines alone that make Fette Compacting a valuable partner for Servier. Cédric Papon explains: "Since 2019, our cooperation has noticeably strengthened. This is mainly due to the excellent service and the principle of proactive fleet management, which ensures that all our machines are ready for use and maximally efficient at all times."

Based on this good experience, the company intends to further expand its cooperation with Fette Compacting in the coming years, says Cédric Papon. This applies both to service and to the acquisition of new machines. Servier is already planning to purchase another tablet press at the end of 2022. Again for the plant in Gidy. Again an F30i.

SERVIER
moved by you

In its production facility in Gidy, France, Servier also uses the FE55 tablet press from Fette Compacting.

IN FLOW

The FE CPS guides powder into a continuous flow in a compact, precise and simple way. This opens a whole new chapter of Continuous Manufacturing in tablet production.

Continuous Manufacturing could soon become commonplace in the production of drug products and dietary supplements. In recent years, machine manufacturers have been working to bring new technologies to market. At Fette Compacting, too, Continuous Manufacturing is an important area for development, with focus on Direct Compression. This is mainly due to the growing applicability of Direct Compression thanks to advances in particle engineering, which can be combined with lean plant design and efficient process analysis.

Advantages of Continuous Direct Compression
Compared to the batch-to-batch process, Continuous Manufacturing scores with numerous advantages: integrated processes increase efficiency and process reliability, reduced capital investments and operational costs, shorter lead times and flexible batch size, better process control resulting in better product quality, and last but not least shorter time to market for new developed drugs. Finally, Continuous Manufacturing is a quality-driven technology that meets regulatory requirements in the best possible way and is therefore also recommended by the Food and Drug Administration (FDA).

Profile: FE CPS

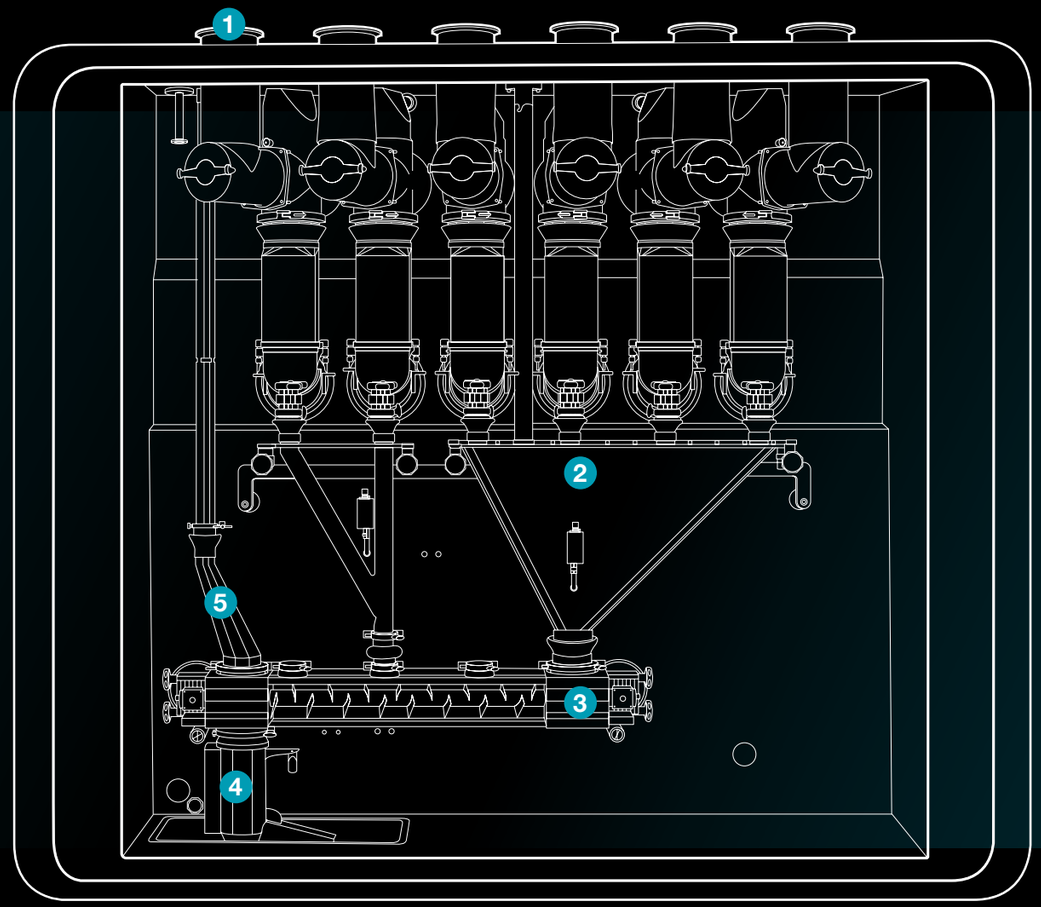
Compact:	one-floor set-up in an existing facility
Modular:	maximal flexibility in installation and application
Generic:	universal process design for wide range of formulations and throughputs
Safe:	dust-tight machine design with separate process and technical areas
Fast:	reduced complexity for extremely fast cleaning and changeover
Easy:	TRI.EASY for simplified set-up, operation and maintenance with one terminal for all processes
Controlled:	inline process monitoring using fully embedded spectroscopic instruments (ePAT)

CONTINUOUS
MANUFACTURING

The developers at Fette Compacting have achieved a breakthrough in 2022 in the form of the modular FE CPS dosing-mixing unit. This unit proves to be particularly compact and, in combination with a rotary tablet press and one central operating terminal, forms a complete Continuous Direct Compression line. The entire line can easily be integrated into existing tablet production facilities in a single level set-up. It relies on a dust-tight design as a standard, ease of operation and maintenance as well as fast cleaning and product changeover. The generic machine and process design is based on the same philosophy as for the tablet presses: only a few format parts need to be exchanged to switch over between products. As a result, the FE CPS can efficiently be used in a multi-product production environment.

The path of the powder
A quality-by-design approach was adopted throughout the entire development phase, resulting in the generic process design of the FE CPS. This was complemented by scientific testing of the various individual unit operations using a wide range of different powders and formulations to fully understand the process dynamics. As a result, the FE CPS can process a wide range of ingredients at a wide range of throughputs from 5 to 200 kilograms per hour. Thanks to its generic design the FE CPS is extremely flexible and therefore widely applicable in any powder processing application where various single ingredients need to be accurately dosed, blended and transferred to a downstream process. This can be tablet compression but also capsule filling and dry or wet granulation.

Behind this flexibility is an ingenious machine design of successive unit operations that the powder passes through on its way from the multiple material inlet ports down to the blend outlet port, which is connected to the inlet of the downstream tablet press. The individual unit operations are presented in more detail below.



1. Material feeding
The FE CPS has up to six material infeed ports. A material infeed can be a single ingredient or a pre-mix of multiple ingredients. A pre-mix is used when the total number of ingredients exceeds six or when the concentration of an ingredient in the formulation is particularly low. Each material infeed port is equipped with an ARS (Automatic Refill Systems), which must feed the material reliably and consistently to the next unit operation in an intermittent way. As single ingredients can have extreme powder characteristics in terms of density, flow ability, cohesion, adhesion, etc., accurate and reliable refilling can easily be disturbed by powder sticking, blocking, ratholing and other powder phenomena. As this first unit operation is critical for the correct operation of the entire line, Fette Compacting has developed its own refilling system with special screws. They can convey very challenging raw material into the dosing process in a reliable and consistent manner.

2. Dosing
Dosing is at the heart of the FE CPS. Up to six gravimetric (Loss-in-Weight, LIW) powder dosing feeders are used here. For each feeder, the concentration of the respective material in the formulation is stored in the product recipe. Combined with the required line throughput, the control system automatically calculates the required feed rate. The LIW feeders use twin screws to dose the material at the required feed rate and with minimal feed variability into the next unit operation. Different types of twin screws are available for optimal LIW dosing performance for any powder at any feed rate.

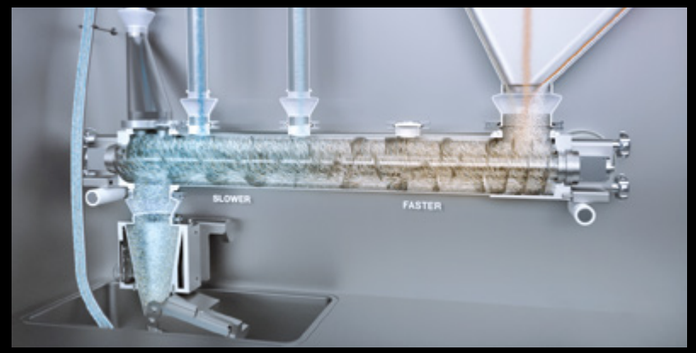
3. Blending
The FE CPS is equipped with a Fette Compacting proprietary purpose-designed horizontal tubular continuous powder blender. Its ingenious design differentiates from any existing horizontal tubular blender by its two successive but independent mixing zones, without a dead zone in between. This allows mixing processes with high and low shear intensity to be combined in a single mixer and the best mixing results to be achieved according to formulation requirements. The blender is equipped with four inlet ports: two in the first blender zone and two in the second zone. The various ingredients are fed from the LIW feeders to the inlet ports of the blender using a combination of drop tubes and transfer funnels. Each specific funnel configuration determines which feeder outlet is connected to which blender inlet. Various funnel configurations are available, offering great flexibility to achieve optimal process set-up for a wide range of formulations.

4. In-line quality control
At the outlet of the blender, there is the option of using embedded Process Analytical Technology (ePAT). A near-infrared spectroscopic sensor checks the homogeneity of the mixed powder and concentration of the API, among other things. As a result, process parameters can be quickly adjusted in the event of quality deviations. Especially in product development, it is relevant to continuously record and optimize the mixing process (more about ePAT from page 11).

5. Conveying
As the last step before tableting, the powder blend must be conveyed to the inlet of the tablet press in a uniform manner without any risk for segregation. This could be done by gravity if the FE CPS is installed above the tablet press but is to be avoided because this would require extremely tall production rooms, while additionally long powder drop heights might induce segregation. For this purpose, a special powder transport system was developed, which conveys the product in dense phase without risk of segregation over a distance of ten meters and more. Via a conveying hose, it reaches the conveyor arm of the FE CPS, which can be flexibly aligned with the inlet of the tablet press. This ensures that the thoroughly blended powder reaches the tablet press without any disturbances and is pressed there in the usual quality. The blend conveyor system also allows for a two-room set up of the direct compression line. The FE CPS can be installed in one room, while the tablet press is installed in the adjacent room. This can be of particular interest in case the system needs to be installed in an existing tablet production facility.

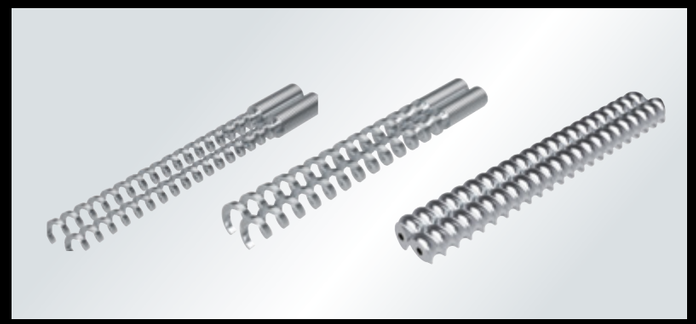
Join the flow
Following the construction of two prototypes, the FE CPS was presented to the trade public for the first time during the Continuous Manufacturing Circle in the summer of 2022 (more from page 14). The reactions during the launch event and the many individual machine demonstrations afterwards prove the strong interest of pharmaceutical and nutraceutical manufacturers in this new compact, generic and easy-to-use technology. Multiple product trials with customers have been conducted in the meantime – all with good to excellent results in terms of ease of line set-up, product quality and throughput capacity. It was proven that formulations developed for batch manufacturing could be run on the Continuous Direct Compression line without any change of ingredients. This was even the case for several formulations, which are originally wet and dry granulation based! It proves the huge potential of Continuous Manufacturing, and more particularly of Continuous Direct Compression. Numerous discussions are already taking place with various customers for specific applications.

If you would like to learn more about the FE CPS, simply contact us at **tablet@fette-compacting.com**. Our experts will give you more detailed insights and advise you on your individual Continuous Manufacturing project. Two Continuous Direct Compression lines are available for live demonstrations at the sites in Schwarzenbek (Germany) or Mechelen (Belgium). Please feel free to make an appointment and come and see for yourself!



Possibility of mixing with high and low shear


Three funnel configurations for conveying into the mixer


Three sets of twin screws for the metering unit

MEASURING LIKE NEVER BEFORE

In Continuous Direct Compression, Fette Compacting is also breaking new ground in terms of Process Analytical Technology (PAT). With the FE CPS, it has succeeded in fully integrating PAT sensor technologies. Dr. Anna Novikova, Manager Application Center and Pharmacist at Fette Compacting, has played a major role in this. In this interview, she explains what makes the new measurement system so unique.

Dr. Novikova, what is the significance of PAT for tableting?
Some pharmacists and process experts say: “Efficient production will only succeed with PAT.” This shows just how important the analysis of production processes has become. With the right technology, processes can be better understood and controlled, which becomes a decisive criterion, especially in continuous plants. In this context, PAT has the potential to increase product quality and process efficiency, shorten time-to-market, and save money. However, the fact remains that PAT has not yet become widely accepted.

Why is that?
Users often express concerns about the potentially high effort required for setup and the difficult handling for operators. In fact, third-party equipment and programs are still often used, which can only be handled safely and efficiently by specialists. The software is usually only slightly integrated into the production line or not integrated at all, resulting in the high effort required to implement the PAT system. Instead, many users stick to time-consuming laboratory tests or struggle with complicated predictions about residence time distribution models that have to be set up first and then validated at great expense.

How do you counter these concerns?
We have been working extensively with process analytical techniques for years and have developed a solution for Continuous Manufacturing that is both simple and efficient. For example, the Direct Compression line with the FE CPS has a new type of technology for inline process analysis that we have called ePAT – embedded Process Analytical Technology. Here, highly-sophisticated sensors are integrated into the process units and permanently monitor the decisive quality attributes. The measurements are taken directly in the product flow and allow the production process to be adjusted quickly if necessary.

How does this embedding work?
The measurement technology is fully embedded in the control system, which means that the sensor spectrometers are directly connected to the machine’s integrated controller. Via sensors for near-infrared spectroscopy, or NIRS for short, product quality can thus be monitored in real time. The entire measurement system has become very simple and reproducible with ePAT, with full mechanical and digital integration. We have equipped the line with watchful eyes that monitor all relevant process steps at all times. Thanks to their integration, we can now measure like we have never measured before.

„THE ENTIRE MEASUREMENT SYSTEM HAS BECOME VERY SIMPLE AND REPRODUCIBLE WITH EPAT, WITH FULL MECHANICAL AND DIGITAL INTEGRATION. WE HAVE EQUIPPED THE LINE WITH WATCHFUL EYES THAT MONITOR ALL RELEVANT PROCESS STEPS AT ALL TIMES.“

Dr. Anna Novikova, Manager Application Center, Pharmacist at Fette Compacting

What are the benefits for users?
They get a precise tool with ultra-short measurement times that is absolutely cGMP-compliant, right down to method management, i.e. complies with current Good Manufacturing Practice in pharmaceutical production.
Other advantages include the industrially robust design, the tool-free installation and removal, the ease of operation via the Human Machine Interface of the tablet press, and the equally simple cleaning of the sensors.

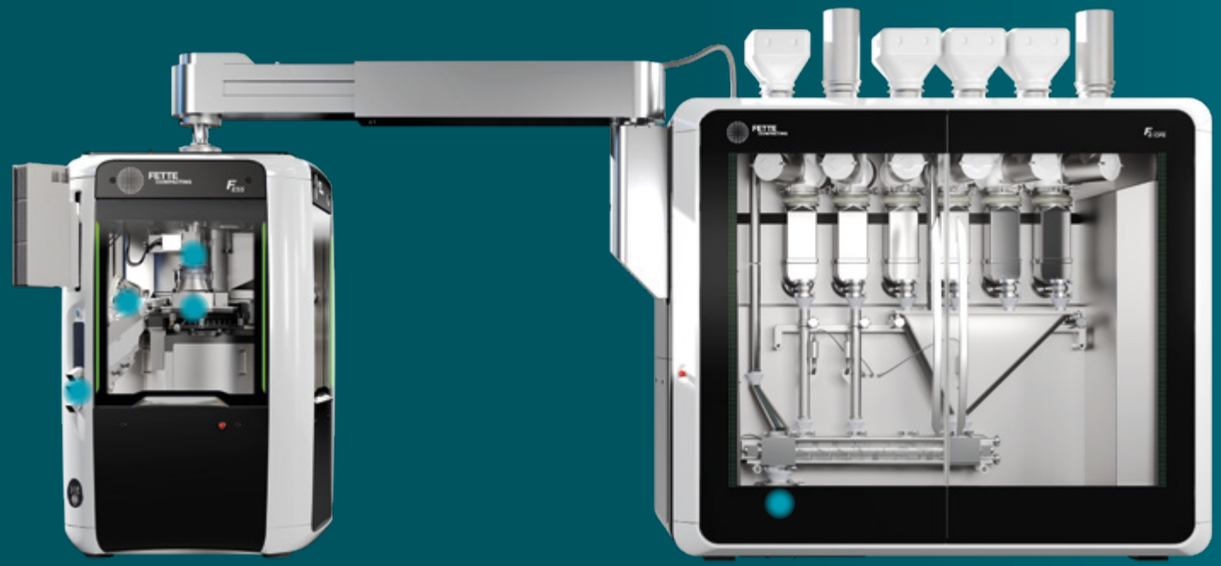
Where is the sensor technology installed in the system?
There are several possible measurement points, and a distinction must be made between two basic types of measurement: First, we measure the blend uniformity (BU). This is done with an active measuring head that can be mounted at various positions, from the outlet of the blender through the inlet of the tablet press and the Fill-O-Matic, to the process chamber of the tablet press. Secondly, we record the active ingredient concentration of the tablets. This measurement, which takes place at the tablet discharge on the die table, allows 100 percent inspection, including rejection of individual tablets that do not meet specifications.

How is it decided at which measuring points sensors are required?
That depends on the manufacturer's objective. For example, if we are talking about the research and development phase, the goal is to collect as much data as possible and learn everything about the processes. In this case, we equip several measuring points and possibly use an additional NIRS Checkmaster that can be easily connected to the Direct Compression line. If we are already mid-production and know the process flows, the question is more likely to be, which measuring points are still relevant for quality control. As a rule, one or two sensors are sufficient in ongoing production to continuously control critical steps.

Why do you use near-infrared spectroscopy for this?
It has proven to be particularly efficient among measurement methods. Its main advantage is that the spectral range from 750 to 2,200 nanometers covers most different active ingredients. The near-infrared rays penetrate deep into the tablet without damaging it. Ultra-fast quality checks on larger sample volumes are feasible with NIRS, which is why the method is so well suited for Continuous Direct Compression. In addition, the same NIRS measurement provides information on both the chemical and certain physical properties of a sample. The ingredient concentration of active formulations can thus be determined just as reliably as other factors, such as density and moisture content.

How was the control system integrated?
With the FE CPS, a single control system performs all machine, process and quality control functions, regardless of whether the unit is run in stand-alone mode or as part of a continuous plant. The system control architecture consists of a high-speed embedded controller and an industrial PC for the operator terminal, including central management of the recipe and the spectroscopic method as well as the reporting.
We have combined this simplified hardware architecture with Fette Compacting's tried-and-tested software. This ultimately reduces validation efforts and results in a robust, reliable control system.

What do you recommend to manufacturers interested in ePAT?
Let us sound out at an early stage whether and how integrated process analysis is suitable for your projects! At the beginning of the consulting process, the question usually arises of how exactly the quality of a product is defined. On this basis, we can develop lean processes and find ways to move away from expensive laboratory work to real-time process analysis. During product trials, we test sensors at several measuring points and thus work our way to the appropriate measuring system. We also assist users with the subsequent calibration of the sensors and ensure overall that they exploit the full efficiency potential of their continuous tableting.



Sensors for ePAT are available at several measurement positions.

At the Continuous Manufacturing Circle in the summer of 2022, Dr. Anna Novikova presented the new measurement possibilities with ePAT at the FE CPS for the first time.

Blend measurement sensor (top) and tablet measurement sensor (bottom).

A TWO-DAY GLIMPSE INTO THE FUTURE

In the summer of 2022, everything at Fette Compacting revolved around the future of tablet production. Continuous Manufacturing is paving the way for this.

At the Continuous Manufacturing Circle, more than 100 participants discussed the opportunities and challenges of Continuous Direct Compression at the Competence Center in Schwarzenbek. This two-day event offered a varied mix of keynote speeches, panel discussions, workshops, networking, and a world premiere.

Concentrated expertise

The event brought together in-depth process and product knowledge from various companies. Thus, panel discussions were held by several industry experts specializing in Continuous Manufacturing. Among other things, they considered how producers can answer the pressing questions of greater efficiency, less complexity, and faster responses to challenging market conditions.

"There is no doubt that Continuous Manufacturing will play a dominant role in the development and production of pharmaceuticals in the future," claimed Dr. Krumme of Novartis, who also delivered the keynote speech. "The only question is when this will be the case. And that very much depends on the commercial availability of modular solutions that pharmaceutical companies can implement in existing production environments. I believe there will be exponential growth in this area, initially with cautious steps and then with increasing momentum as confidence in the new technology grows."

World premiere of FE CPS

As a response to this, Fette Compacting presented its new Direct Compression line at the Continuous Manufacturing Circle, in which the metering and mixing of the powder has been arranged in a compact, closed unit for the first time in the form of the FE CPS. More information can be found as of page 6 in this magazine.

Clear the stage for the FE CPS: At the Competence Center in Schwarzenbek, the audience was able to take a first look at the world innovation.

Joachim Dittrich, CEO at Fette Compacting (right), kicked off two days of expertise and networking. The event was presented by presenter Kilian Reichert (left).

Intensive exchanges among industry experts (from left): Presenter Kilian Reichert; Dr. Anna Novikova, Manager Application Center and Pharmacist at Fette Compacting (co-presenter); Dr. Markus Krumme, Vice President Continuous Manufacturing at Novartis; Frank Eismann, Venture Manager at Bayer Consumer Health; Wayne Sinclair, Associate Director Process Analytical Technology at Teva Pharmaceuticals; Lawrence De Belder, Executive Consultant Continuous Manufacturing at Pharmatech Associates; Dr. Marten Klukkert, Manager Technology Center and Pharmacist at Fette Compacting

"There is no doubt that Continuous Manufacturing will play a dominant role in the development and production of pharmaceuticals in the future."

Dr. Markus Krumme, Vice President Continuous Manufacturing at Novartis

In this video, we have captured some special moments of the event for you:

THE SMART TABLET FACTORY

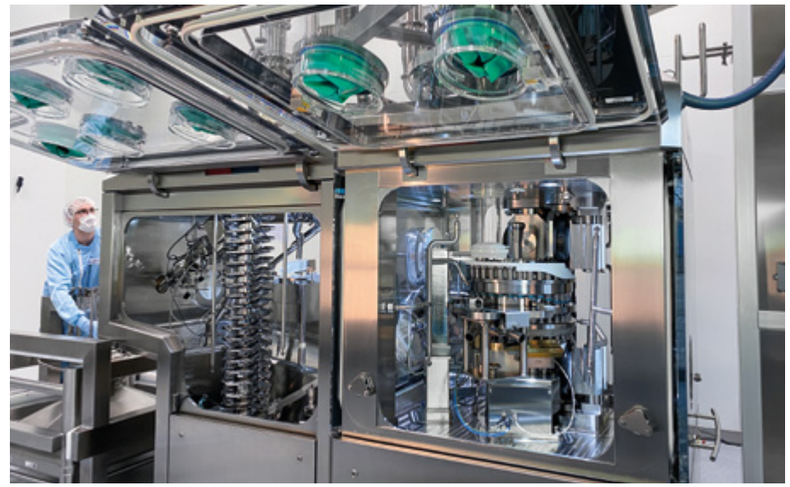
In Boehringer Ingelheim's solids launch factory, almost all production processes are self-controlled. This state-of-the-art plant technology also includes two tablet presses from Fette Compacting.

Networked production, smaller batches, increased flexibility: with the new Smart Factory, Boehringer Ingelheim aims to manufacture its new drug approvals to the highest efficiency standards. The pharmaceutical specialist has invested around 90 million euros in the Solids Launch (SOL) factory at its Ingelheim site. The plant technology is already highly digitally networked, and these networks are being extended further to enable all processes to control themselves. This will enable the factory to respond independently to changes based on production data, quality parameters, and environmental conditions. "We can now bring new drugs to market even faster, which also benefits patients," explains Martin Döhms, Process Specialist in the Engineering division at Boehringer Ingelheim.

Automation meets containment

Only medications in tablet form are produced in the SOL, with operator protection featuring containment playing a central role. "For all our automation, the know-how of our well-trained employees continues to be in demand," claims Martin Döhms. "Around 50 employees work in the new factory, monitoring processes, re-tooling equipment, and continuing to drive forward the industrialization of processes and equipment, among many other tasks. We need suitable containment protection for the operators at the machines. After all, we process active ingredients there up to OEB level 4, i.e., into the highly-active range."

To process these active ingredients safely and quickly, Boehringer Ingelheim opted for a 2090i WiP (Wash-in-Place) tablet press with isolator and air management from Fette Compacting. The system combines proven technology with maximum flexibility: it has a modular design with the result that many components can be easily replaced. In this way, the tablet press can be quickly converted to other formats. The process equipment is integrated into the isolator, which – like the tablet press – has glove ports and a dual-flap system (Rapid Transfer Port (RTP)) for feeding and discharging materials. This spares operators the strains associated with working while wearing full protective suits. Automatic cleaning of the WiP system provides additional relief and reduces downtime.



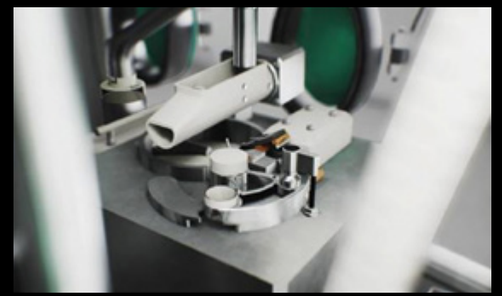
In the Smart Factory, Boehringer Ingelheim produces its new drug launches for the global market.

The 2090i WiP tablet press with isolator offers comprehensive operator protection up to the processing of highly-active substances.

The second tablet press used by Boehringer Ingelheim in the factory is an FE55. The high-performance rotary press is suitable for a wide range of products and, with a maximum output of more than 600,000 tablets per hour, delivers particularly high performance. Its innovative filling system enables simple and safe feeding of complex product mixtures.

Training with Virtual Reality
Boehringer Ingelheim employees were able to try out the handling of containment in advance with VRCampus, a virtual reality tool from Fette Compacting‘s OSDi digital unit. With the help of the software, the employees were able to practice the unaccustomed manual operations on the isolator even before the factory opened. Since Fette Compacting itself was still working on the training program, the OSDi team developed the first training module together with Boehringer Ingelheim. „We were particularly enthusiastic about the cooperation during the project and the extensive expertise,“ Martin Döhms emphasizes. „This enabled us to put the machines into operation smoothly.“

Together into the digital future
Boehringer Ingelheim is also interested in further digital solutions from Fette Compacting. The company and OSDi are currently planning a pilot project for the ConditionMonitor and PredictiveMaintenance tools, which will enable employees to keep a constant eye on the conditions of the plants and make reliable predictions (for more information, see from page 20). Starting at the end of 2022, the tools will be tested as a pilot in the SOL factory for an initial period of one year. „We have a strong interest in expanding the topic of predictive maintenance and see great potential here to make our plants even more economical,“ says Martin Döhms.



With the help of the VRCampus tool from OSDi operators could test the work on the isolator virtually in advance.

VRCampus

DIVING INTO THE WORLD OF DATA

Production data is everywhere. Collecting, understanding and using it requires a great deal of expertise. The OSDi (Abbreviation of Oral Solid Dosage intelligent) digital unit develops digital tools that help users get even more efficiency out of their machines and processes.

What is the production status of a machine? Does the quality of the end products remain constant? When data is expertly collected and used, it can assist in many areas. For example, monitoring production or the condition of wear parts.

„These are the core competencies of OSDi. We are developing various software solutions that use data to identify and leverage efficiency potential in the production of solid formulations, for example in the area of maintenance," explains Britta von Selchow, Head of OSDi Digital Solutions.

Flexibility and dynamics
With the help of data and OSDi's software solutions, users can design their maintenance strategies more efficiently – and react before failures or quality losses occur. In this way, they are moving away from a fixed-time maintenance strategy, i.e. maintenance that always takes place at a fixed time at regular intervals. Instead, they are developing a condition-based maintenance strategy that is based on the actual condition of the machine and even predicts and incorporates AI-supported wear and tear.

Condition monitoring: What is the condition of the machine?
How does maintenance based on data work? The OSDi tool ConditionMonitor collects data from production machines and compiles the most important parameters in an intuitive and comprehensive dashboard. This gives users a precise overview of the real-time status and warnings of their machines. Frequent errors are easy to analyse and extract to start root cause analysis in a focused way. In addition, the tool compares the current data with historical measured values. This way, it prepares for deviation analysis at an early stage and helps to avoid downtime. "The ConditionMonitor is currently available as a minimum viable product. We are testing it together with our customers and development is ongoing," reveals Britta von Selchow.

Understanding data
What information is hidden in the data that is available? OSDi's PerformanceManager tool acts as an extension of ConditionMonitor, providing users with recommended actions and settings based on the data collected. "PerformanceManager compares real-time data with historical data. Our experts analyze this and enrich it with their own empirical values to obtain a reliable data basis for production optimization," says Britta von Selchow. The application actively points out potential for performance improvement to users and supports them in the form of recommendations for action – delivered in OSDi's recently launched online learning app alva. Currently, the PerformanceManager is in the prototyping phase and is being further developed.

Britta von Selchow,
Head of OSDi Digital Solutions at Fette Compacting

Condition-based maintenance: Predicting wear and tear with AI
The PredictiveMaintenance application goes one step further and uses self-learning technology to determine wear before it occurs. "The tool analyzes data from the past and the current batch. In this way, it helps establish more efficient and individual maintenance strategies," explains Britta von Selchow. The application calculates the optimal time to clean, maintain or replace components and reduces unplanned downtimes. The OSDi team has already conducted extensive tests to identify the wear levels of core components and created first algorithms. The knowledge gained is currently being validated and optimized with pilot customers.

"Data can increase the efficiency of solid formula production in so many areas. Our digital tools enable our customers to exploit this potential," is how Britta von Selchow summarizes the work undertaken by the digital unit.

Some of the numerous data, that is generated during production.

STRONG POSITION

Following extensive investments, Fette Compacting's tool production is ideally positioned for the future. Stephan Schilling, Head of Business Unit Tableting Tools, explains what this means.

Mr. Schilling, what demands do your customers place on the tools?
In principle, it's quite simple: our customers want tools that meet their quality requirements and are available in a short time, whereby it is important that the tools can be used immediately and produce a high tablet quality. In addition to quality, there has been a trend in recent years for tools to withstand higher loads due to pressing forces and higher speeds in the machine. This improves machine performance and output.

How are you adapting to this?
We consider the entire value stream, from order entry to delivery to the customer – and even beyond departmental lines. In this way, we create transparency and identify potential, which we then work on in a structured way.

Please give an example of such potential!
For example, our team is working on the further development of our materials and coatings. This enables us to further improve tool performance. We can also increase their service life by using our special standards, including segment technology and FS12® punches.

What modernizations have you recently carried out?
The production hall in Schwarzenbek has been completely renovated and equipped with state-of-the-art machinery. This enables us to respond quickly and flexibly to all customer requests. Our employees are equally flexible, always acting in the best interests of our customers. Every day, they strive to increase quality and reduce throughput times in production. Ultimately, this is obvious to our customers who are then willing to place their trust in us.

What is your position on the problem of product piracy?
We must succeed in always being better than such competition, and we must protect our core competencies. Our most valuable asset is the knowledge in the heads of our employees, and no one can copy that. Therefore, I'm not afraid of imitators or even of product piracy, but am confident that a high-precision and continuously developed original tool is always better than a copy.

Segment technology is now 20 years old. What does this anniversary mean to you?
Nothing less than a revolution in tablet production! Segments are still gaining in importance year after year. Shipments of segment rotors are rising continuously. After a hesitant start-up in the early years, it is now a globally established technology.

This year is also marked by EasyCare. What is behind it?
EasyCare is a comprehensive system for the safe handling and GMP-compliant cleaning of tableting tools. The product range comprises several elements that are available individually, but above all develop their full efficiency impact in combination. These include our TRI.EASY Tool Box System, a cleaning machine from our partner ARUNA, and a polishing machine from our partner nortec. The wash trays, for example, are precisely coordinated to the cleaning machine, ensuring simplified handling during cleaning and increased efficiency during washing.

Stephan Schilling, Head of Business Unit Tableting Tools at Fette Compacting

How mature is EasyCare?
The system is ready for the market. Customers can test all the modules at the Schwarzenbek site, where they have the opportunity to obtain an exact impression. Several Tool Boxes are already in use at customers' sites, as are the first machines we are operating with our partners. In the long term, EasyCare will be an important component in our portfolio, because the use of high-quality tools requires careful handling.

What tool innovations are you working on?
We continue to develop our tools on a daily basis. One focus is on increasing load-bearing capacity. The use of new materials and coatings allows significantly higher pressing forces and gives users the option of getting the most out of their machines.

What other plans do you have for the future?
We want to make the Business Unit Tableting Tools a full-range supplier for everything to do with tableting and offer our customers integrated solutions. If the tablet presses from Fette Compacting also have the right tools, users are guaranteed the greatest possible system harmony and thus maximum efficiency. This is something we are fully committed to.

TABLETING
TOOLS

DR. SCHWABE AND THE LEANMASTER

Unternehmensgruppe Dr. Willmar Schwabe
From Nature. For Health.

Over the years, individual repair orders have evolved to form a fixed inspection and maintenance schedule at Dr. Willmar Schwabe for what is now a unique system from Fette Compacting. The tablet distribution system Leanmaster offers great machine availability and thus ensures the company's high quality standards.

Fette Compacting has been supporting the Karlsruhe-based family company Dr. Schwabe since the early 1970s. What began with a P2 tablet press has grown over the years into a machine park. The production of herbal medicines such as Tebonin®, Crataegutt® and Refluthin® is based on seven tablet presses of type 2090/2090i, a P1200 for galenic development, and various tableting tools. As a result, Dr. Schwabe now produces over three billion tablets per year.

With the aim of increasing productivity, the company introduced Fette Compacting's Leanmaster to all production lines in the late 1990s. The automatic tablet distribution system with integrated in-process control enables round-the-clock production without the need for an employee to be on site. A special feature: Dr. Schwabe still uses the Leanmaster today because the system has proven itself over decades.

This presents Fette Compacting's service technicians with a unique challenge: during every inspection and maintenance procedure, they have to manually check all mechanical parts of a tablet press and replace them if necessary. They also check all electrical and mechanical settings and finally recalibrate the production speeds and compression forces. Although the machine detects electrical and sensor errors itself, the technicians still have to scan the machine-generated diagnostic log at the end for errors in production.

With the help of the OSDi LiveGuide app, the fault is quickly identified and rectified.

Digital support for a veteran system
It is precisely this detailed work that is behind the service philosophy pursued by Fette Compacting: making customers' highest quality requirements possible even under demanding conditions. Because: high machine availability is an absolute must for stable and reliable tablet production.

Sebastian Kopf, Group Manager Maintenance at Dr. Schwabe, supports the service technicians at Fette Compacting in this regard. "Three months ahead of a service date, we inspect the equipment and order spare parts. This way, we always have the requisite parts on site in time for the two appointments in spring and fall," Sebastian Kopf explains. "We maintain long-term contact with Fette Compacting's service technicians. Most of them have been coming to us for a very long time and know us and our machines. That's a major advantage."

This advantage saves the company both time and money: "We had a malfunction on a tablet press that occurred repeatedly, but only sporadically. With the expertise of Fette Compacting's service technicians, we were able to isolate the fault and ultimately rectify it," says Sebastian Kopf. "The LiveGuide app also helped us a lot in this process, as it made troubleshooting transparent. That way, everyone involved was always on the same page." LiveGuide enables faults to be quickly identified and reliably rectified via live chat with the technical team at Fette Compacting.

Fast, reliable, trustworthy
What Sebastian Kopf appreciates most about this collaboration is the direct contact and the speed of the service technicians. "We can't afford any longer downtimes in production. At the same time, the availability of spare parts on the world market is extremely limited. We benefit enormously from cooperation with Fette Compacting, which often delivers spare parts to us directly the next day. That is really impressive."

To make this possible, service technicians such as Rolf von Appen are on the road a lot. "The traveling and the various challenges still excite me today just as much as they did 22 years ago when I started in Service," Rolf von Appen tells us. "I particularly enjoy visiting long-standing customers like Dr. Schwabe because we are a good team and the people there know exactly which special repair tool I need and even how I drink my coffee."

On this basis of trust, both sides want to continue their successful cooperation in the future: "In the long term, we will gear our production to a new type of machine to optimize setup times and increase our production capacity," says Sebastian Kopf. When that time comes, he can rely entirely on the support of Rolf von Appen and his colleagues.

The cooperation is based on reliability and trust. In the picture (from left): Rolf von Appen, Service Technician at Fette Compacting, and Sebastian Kopf, Group Manager for Maintenance at Dr. Schwabe.

"We benefit enormously from cooperation with Fette Compacting, which often delivers spare parts to us directly the next day."

Sebastian Kopf, Group Manager Maintenance at Dr. Schwabe

FROM THE WORLD OF FETTE COMPACTING

Joint stand at the ACHEMA

In August 2022, the ACHEMA opened its doors again in Frankfurt am Main for the first time in four years. Fette Compacting was present at the world's leading trade fair for the process industry – in a joint exhibition area with the partnersof Excellence United. The open exhibition stand offered plenty of scope for exchange, so that this year the focus was primarily on networking.

In the Fette Compacting area, trade show visitors learned about the latest innovations in tablet production and followed the livestream, which provided insights into Continuous Direct Compression with the FE CPS and presented the new F20i tablet press. In addition, the focus was on the alva learning app from OSDi and the EasyCare system solution for tableting tools.

The next trade shows:

CIPM Autumn	Dec. 9 – 11, 2022 in Tianjin, China
Maghreb Pharma	Feb. 7 – 9, 2023 in Algiers, Algeria
Pharma Technica	Mar. 28 – 29, 2023 in Wiesbaden, Germany
Interphex	Apr. 25. – 27, 2023 in New York, USA
CIPM Spring	Date to be announced, in China
Interpack	May 4 – 10, 2023 in Düsseldorf, Germany

New features for the learning app alva

OSDi's learning software alva helps to qualify new operators for work on tablet presses in a simple and intuitive way. To make onboarding even easier, a new dashboard is now available. It allows users to filter training courses by operator, mechanic and electrician user groups, as well as by machines, thus enabling them to reach the learning units they are looking for even faster. An additional icon allows direct access to the previous training session. This enables users to pick up right where they left off.

Furthermore, alva can now be integrated into the user's existing learning management software. For this purpose, an interface has been set up via which alva sends all relevant data to the customer's software. This also provides the respective HR department with a precise overview of the induction of new employees.

alva

Expert knowledge at your fingertips

Small machine, major impact

In the development and production of tablets, powder compression is a complex and decisive process. Technical parameters such as pre-compression, main compression and ejection force must be precisely matched to the desired product properties – for example, the density and breaking strength of the tablets. Particularly in the case of new formulation developments in laboratories, problems concerning brittleness or adhesive properties occur time and again, sometimes resulting in high costs.

This can be remedied by a new series of powder compaction analyzing units (PCA units) that Fette Compacting now distributes together with its British cooperation partner Gamlen: the F Lab Series is extremely economical in terms of space and material. It enables rapid testing of ingredients and formulations, and its software allows fully-automatic analysis of the compression process, so that formulations can be optimized easily and in a resource-saving way during the development stage. Handling the unit and software is easy to learn – usually in less than two hours. The F Lab Series has been available in two versions since November 2022: with an operating load of up to 500 (F Lab 5) and 1,000 kilograms (F Lab 10).

The data obtained can be used to reduce material costs and shorten times for upscaling and time-to-market. In addition, the PCA unit is ideal for further deepen the product knowledge during ongoing production and to finding the best solution more quickly when troubleshooting.

As the smallest machine series from Fette Compacting and cooperation partner Gamlen, the F Lab Series is suitable for efficient product developments as well as for quality control in production.

At Fette Compacting, we are:
The world market leader for tablet presses in the pharmaceutical and nutrition supplements industry. Working toward improving human health – in medicine and nutrition. A family-owned company with a global alignment and always open for new talent. A career kick-off for graduates offering international opportunities and possibilities.

Fette Compacting Global Family – be imaginative, be efficient.
Join the Family! **www.fc-gf.com**

FETTE COMPACTING
be efficient

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