

WHAT'S NEXT?

FETTE COMPACTING MAGAZINE 2020



FETTE
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A member of
Excellence United

NUTRITION

An acquired taste

F10i

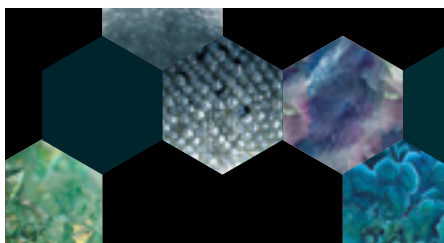
Field test at Artesan

OSDi

Seven digital tools for better production

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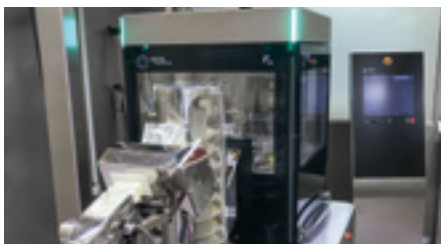
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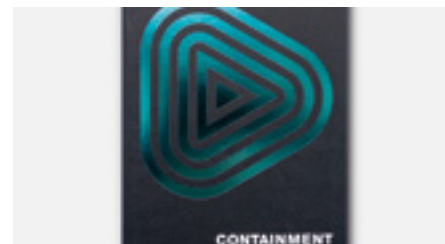
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DEAR READERS,

The worldwide Covid-19 pandemic has shown us just how important our health is. More than ever before, it has become clear how essential an efficient supply of pharmaceuticals is for the common good.

At Fette Compacting, our task is to support pharmaceutical companies in this key work. We do so by enabling safe, high-quality, and cost-efficient production of pharmaceuticals using our technology and expertise. In cooperation with our customers, we implement complex new projects and optimize existing production processes. At the same time, we also continue to work on innovations for the production of future solid formulations.

The fact that health is a key issue at all levels today is also indicated by the rapid market growth of nutrition supplements and biological solid formulation products. In this issue of What's Next?, we illustrate the technologies we use for the particular processing requirements in the nutrition market segment.

You can also discover how the tablet presses in the P Series are enjoying success in China, the extraordinary gains in efficiency achieved by the new F10i in its field test, and how pharmaceutical production can be improved using digital tools.

We hope you enjoy reading this magazine.

Stay healthy!

Your team at Fette Compacting



TECHNOLOGY stands for everything we offer in production technology – from tablet presses and capsule filling machines through process equipment to tableting tools and format parts.

SERVICE covers all the services related to machines, process equipment and installations such as spare parts supply, plant modernization and technical field service department.

COMPETENCE is the overarching idea behind all our process-related services. This includes training, product trials, application and Performance Consulting as well as engineering.

Imprint

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AN ACQUIRED TASTE

Health and well-being are more popular now than ever before and since the beginning of the coronavirus pandemic in particular. It is no wonder, therefore, that the markets for nutrition supplements and biological solid formulation products are undergoing rapid growth. At the same time, there are also increases in the technological and regulatory demands on manufacturing. Fette Compacting offers the appropriate solutions.

All over the world, consumers' appetites have been whetted. Studies are forecasting global growth of more than 8% by 2027 for the nutrition sector. Accordingly, biological products harbor a special potential. In accordance with a prognosis by Meticulous Research, the market for plant-based foodstuffs will achieve a value of 74.2 billion USD by 2027. This corresponds with an annual growth rate of up to 12 percent. But this trend is also associated with the increasing demand for ecologically-safe, regional and sustainable production.

One particular driver in the sector of nutrition supplements is the corona pandemic. Many people want to augment their nutrition and give their immune systems an extra boost. The boundaries often disappear between pharmaceuticals whose contents are pharmacologically effective while nutrition supplements and other foodstuffs cannot be advertised with claims of healing properties. In practice, this is not always clearly obvious, not to mention the varying specifications in individual countries.

Many products – a single claim

All in all, the nutrition sector comprises a huge variety of products ranging from mass-produced confectionery through small batches with unusual natural substances such as the Chinese caterpillar mushroom. These foodstuffs are often processed as tablets or capsules. Solid formulations offer the advantage of facilitating standardization and dosing of the concentration of ingredients. Especially for large production volumes, manufacturers benefit from comparatively simple production which is also easily reproducible.

At the same time, producers are obliged to meet the high requirements on food safety, which are expressed in the form of Good Manufacturing Practices (GMP). This requires a production technology working entirely reliably even as batches increase in size and product changes become more frequent.

High-tech and nutrition expertise

With its entire range of machines and services, Fette Compacting has stood for maximum efficiency and quality in nutrition production for decades. The technological range today comprises the tried-and-tested machines of the i Series and P Series through to the high-performance tablet presses in the FE Series and the capsule filling machines in the FEC Series. Furthermore, initial users are working successfully with OSDi digital tools (see pp. 22–27) and testing Continuous Manufacturing (see pp. 30–33 for basic principles).

But know-how also includes experience in stable processing of natural substances whose material properties can be subject to strong fluctuations. The machine experts at Fette Compacting are also masters in hygiene concepts which reduce the risk of cross-contamination, for example. This is supplemented by individual consulting services concerning tablet design and capsule size through to special shapes, complex curves, and engravings.

Over the following pages, we present some focal areas of nutrition and use practical examples to show how versatile this production area is. If you wish to find out more about Smart Food Performance at Fette Compacting, please contact: tablet@fette-compacting.com



Smart Food Performance
by Fette Compacting

NEXT LEVEL NUTRITION

Nutrition supplements

A trend towards more health awareness and preventive medicine can be observed worldwide. Many people use nutrition supplements to ingest additional vitamins and minerals. These also include dietary foodstuffs for certain groups such as sporty people, vegans, pregnant women, or senior citizens. Fette Compacting offers a wide technical range of mini to major batches for the production of nutrition supplements.

Biological products

Purely natural substances of ecological origin are currently very popular among consumers. The more natural essences contained in the final product, the better. Stability plays a key role in processing. In terms of process reliability and product quality, it is imperative that the production technology works absolutely reliably. Fette Compacting displays expertise in both tableting and capsuling such sensitive substances.

Confectionery

This production area could hardly be any more colorful or varied: confectionery includes all kinds of candy, gum, and lozenges, production of which is often high-volume and very complex on account of special product characteristics such as adhesive tendencies. A special area is represented by functional confectionery such as dextrose, for example, which is similar to nutrition supplements and in some cases makes special demands on solubility in order to display its optimal effect inside the body.

P SERIES SHINES IN CHINA

A market volume of 117 billion euros which has tripled since 2008 and projected growth to 145 billion euros by 2023: the Chinese pharmaceutical market is growing rapidly. This is driven by health reforms aimed at improving access to medication. And right in the heart of this development is the P Series from Fette Compacting. The reason for this is shown by the use of machines at BY-HEALTH, a leading pharmaceutical manufacturer in the southern Chinese city of Zhuhai.

Founded in 1995, BY-HEALTH has undergone rapid growth during the course of these reforms with output increases of up to 40 percent. Commissioned in 2012, the production facility in Zhuhai has a production capacity of up to 5 billion tablets per year. One of the drivers of growth is the KEYLID calcium tablet with current annual sales of one billion Yuan (around 130 million euros) and annual growth rates of up to 200 percent.

Within the framework of ongoing production expansion with 24/7 operation and at high pressure BY-HEALTH faced numerous challenges with its existing machines. They took up a lot of space against production output of maximum 300,000 tablets per hour and product loss was disproportionately high. This was compounded by fluctuations in tablet quality and a correspondingly high number of bad tablets.

No sooner sought than found
In search of an optimal machine park, BY-HEALTH turned to Fette Compacting in Nanjing. Following intensive consulting and tests, BY-HEALTH acquired its first tablet press from Fette Compacting in 2009 – the P2020. Eleven more would follow. „A decisive factor for BY-HEALTH was the swift reaction by support and the availability of certain spare parts to maintain their high production efficiency," explains Jack Deng, Sales Director at Fette Compacting China. „We were able to show that we can easily guarantee both."

During development of the P Series, the focus was on the optimal combination of cost orientation, precision, quality, and safety. Accordingly, the three P1010, P2020, and P3030 models are distinguished by their high outputs, compact size, and an outstanding price/performance ratio. They facilitate easy and flexible production as well as swift format changes. As a result, they meet exactly the challenges faced by BY-HEALTH.

For those responsible at BY-HEALTH, there is no doubt that the expectations on Fette Compacting and the new machines have been more than fulfilled. The P Series models guarantee a stable production process, a lower number of bad tablets, and high output. Maintenance and cleaning are significantly less complicated. Also the fast on-site support within 48 hours makes Fette Compacting China the perfect partner for the company's production goals.



P3030 tablet presses from Fette Compacting at BY-HEALTH in Zhuhai

Feasible, flexible and safe
The P2020 initially deployed is a versatile allrounder for medium-sized batches. In the case of BY-HEALTH, it permits an output of around 360,000 tablets per hour. And the space problems were also resolved: the P2020 is significantly smaller and only weighs about half as much as the existing machines of competitors. By using the P2020, output also increased to more than 99 percent and the number of bad tablets has fallen to practically zero. Meanwhile, BY-HEALTH is also using P3030 tablet presses which, with up to one million tablets per hour, combine feasibility with a high degree of flexibility and safety, particularly for large batches.

The success of the new tablet presses has led BY-HEALTH to honor Fette Compacting as a “Strategic Cooperative Partner.” In the course of site expansion to become a “smart factory,” the P3030 tablet press was also marked as a key production machine. The P Series also shines in Zhuhai on account of its industrial design: the site has officially been a tourist attraction since 2018 in its capacity as a “transparent factory.” A panorama window enables visitors to experience the production and swift speed of the P Series up close or observe the scenes as virtual visitors via a webcam.



KEYLID calcium tablets from BY-HEALTH



THE WORLD IN A CUBE

Drink more water! This is the mission pursued by the new waterdrop® company based in Austria. Its cube-shaped effervescent tablets contain fruit and plant extracts from all over the world. And Fette Compacting has been involved in this success story right from the start.

We don't drink enough. And this fact has hardly changed at all in recent years, as reported by waterdrop® in a study published in May 2020 where more than 1,000 persons were surveyed on their drinking habits by the Kantar research institute. Three-quarters of them were convinced that they drank enough water and other unsweetened beverages. But only half of them actually managed the recommended volume of 1.5 to 2.5 liters per day.

"Tap water is the perfect drink," explains waterdrop® founder Martin Murray. "It is healthy, thirst-quenching, free of calories, and strictly controlled in countries such as Germany. But many consumers find it tasteless which is why they ignore this obvious option."

From açai to lemongrass
Thus the idea originated several years ago to give drinking water a helping hand. In order to enrich it with flavor and vitamins, waterdrop® relies on natural fruit and plant extracts. "We compress the best essences from all over the world into small cubes," says Murray, "for example, açai and prickly pear from South America, moringa and mango from India, ginseng and lemongrass from Eastern Asia, or baobab from Africa."

The actual highlight is its dosage form. "Initially, we asked ourselves why isn't there a product which doesn't need a plastic bottle or can?" reminisces Murray. "Something so small it could easily be dropped through the neck of a bottle. Then the idea of the micro flavor tablet was born."



Tall order: the effervescent tablet must have dissolved in full and released its natural flavors in the water within one minute.

A science in itself

But a major obstacle had to be overcome before the finished product was available: the natural extracts had to be modeled into a stable shape, yet one which is so “unstable” that it would swiftly dissolve in water. Murray turned to the experts at Fette Compacting who had already realized many such hygroscopic formulations.

“Effervescent tablets are a science in themselves,” explains Frank Scheefe, the responsible Area Sales Manager at Fette Compacting. “What is decisive is the right mixing ratio of acid and alkali. Both components react in water causing the release of carbon dioxide and the tablet dissolves. If the proportions are not coordinated exactly, either the tablet dissolves too slowly or it becomes too soft and sticks during production. We also need to consider the fluctuating quality of natural raw materials.”



Lots of flavor: the waterdrop® mixture “Love” contains extracts of pomegranate, goji berries, and schisandra.

Aroma in only one minute

The German Competence Center operated by Fette Compacting carried out numerous compression trials to find the optimal mixture. The demands were high: the tablet must have dissolved in full and released its flavors within one minute. And then came the special design, as explained by Scheefe: “In line with their ingredients, the effervescent tablets also needed to look high-quality, inspired by the style of modern smartphones. This is how the cube shape with rounded edges evolved. And for which we developed a special mold.”

Fette Compacting used a 1200i tablet press for the compression trials. A press chamber coating also ensured reliable compression of the effervescent components, whereby a special powder was fed into the press room under pressurized air in order to coat the punch and die surfaces coming into contact with the compressed product.

“Always had faith in us”

“The decisive factor for me is that Fette Compacting always had faith in us despite the difficult design,” emphasizes Murray. “This is the type of collaboration we depend on.”

waterdrop®



Martin Murray,
waterdrop® founder

Waterdrop Microdrink GmbH
waterdrop® was founded in Vienna three years ago. The start-up attracted great attention in 2018 following its presentation on the German TV program “Die Höhle der Löwen” (which allows inventors to present their products and obtain funding from investors) on the VOX channel. Since then, the company has grown internationally and offers retail outlets and 15 self-run stores in addition to its online trade. Offices and hotels making micro-drinks available to their employees and guests represent an increasingly important target group. For further information please visit: <https://www.waterdrop.com/>



INNOVATION IN THE TIME OF CORONA

In the form of the F10i, Fette Compacting has launched the first tablet press of a new generation of machines. This single rotary press is versatile, connectable, dustproof, and system-compatible. In this interview, Thomas Friedrich, Director Product Management, and Jörg Gierds, Senior Product Manager, explain why these features are so valuable, particularly during Corona.

Mr. Friedrich, the pharmaceutical industry is changing. The coronavirus crisis has accelerated many of these developments. What does this mean for machine designers such as Fette Compacting?

Friedrich: Corona confronts our customers and us with new challenges. More than ever before, manufacturers must ensure the population's supply of medicines and continue to optimize the efficiency of their production. In this context, the performance of the entire machine park is relevant. With the F10i, we have developed a smart machine together with our customers that can be quickly digitally integrated, supports frequent product changes, and has been optimized for clean operation.

Mr. Gierds, what features does a tablet press need to have today?

Gierds: A major role is played by connectivity, i.e. exchanging data with other machines within the meaning of Pharma 4.0. That is why the F10i offers the technical prerequisites for state-of-the-art production environments, including process equipment integrated via plug-and-play. The open interfaces meet the usual standards of industrial automation with the result that the machine can be easily integrated into a manufacturing execution system and connected to the Internet of Things.



Thomas Friedrich (left), Director Product Management, and Jörg Gierds, Senior Product Manager

Just how important is the user friendliness of a tablet press?

Gierds: The easier it is to operate a machine, the more efficient production will be. For this reason, the new i Series ensures that even less experienced operators have a clear overview of all parameters and can avoid operating errors. This is aided by a Human Machine Interface (HMI), whose terminal permits intuitive control, monitoring, and documentation of the machine and process equipment. At software level, a Workflow Operation Wizard guides users through standard procedures.

Friedrich: Additional support is offered by the SmartInterface. Thanks to this server-based application, operators can monitor their production processes in real time using mobile end devices, enabling the production manager to retain full overview of manufacturing independent of location and deploy his personnel in a more proactive manner. This is a clear advantage, particularly in times of restricted contact necessitated by Corona.

Apart from the digital opportunities, how much efficiency potential is offered by the mechanical design of the machine?

Gierds: A lot. We have made sure that the new i Series is compatible with the tablet presses of the old i Series. Both have the same parts with product contact. Turret dies and segments as well as turrets can be easily exchanged. This horizontal integrability reduces the effort associated with validation, qualification, and spare parts storage which, in turn, translates into cost savings.

Are you currently observing any other trends on the market?

Friedrich: Operator protection is increasingly gaining in importance. Nowadays, it is no longer about merely protecting operators from toxic substances. Fully dust-free workplaces are the new standard. That is why the standard tablet presses in the new i Series are already consistently dust-free – from the press room to the connections between the machine and process equipment. The tablet press can also be upgraded to include the appropriate containment package for active or highly-active substances.



New i Series: the F10i offered by Fette Compacting represents a green light for a new generation of ultra-modern tablet presses.

ENTIRELY CONVINCED

After testing the new F10i tablet press offered by Fette Compacting for several months, pharmaceutical manufacturer Artesan is now reporting some remarkable results: all output volumes have been drastically increased, while it has been possible to noticeably reduce cleaning times and energy consumption.

It simply could not have gone better. The pharmaceutical manufacturer Artesan has been testing the new F10i from Fette Compacting since July 2019 – and can report some incredible results after only a few months. The F10i is the first tablet press of a new generation of machines with which Fette Compacting has further developed its established i Series. As a versatile and efficient single rotary press, it specializes in small batches and can be swiftly adapted to a wide variety of requirements.

» ADDITIONAL 66 HOURS OF PRODUCTION«

Jörg Gierds, Senior Product Manager at Fette Compacting



Days instead of weeks

Even commissioning of the F10i at the production site in Lüchow sparked a wave of enthusiasm. It usually takes pharmaceutical manufacturers several weeks to set up a new machine for production. This period was reduced to a mere two days for the F10i, thanks to the cross-generation system compatibility offered by the new i Series.

Apart from the F10i, Artesan also uses other tablet presses from Fette Compacting, including the P1200, P2200, 1200i, and FE55 models. Despite its innovative design, almost all of the process-relevant assemblies featured in the F10i are identical to those of previous models. “Because the old and new components are very similar, the efforts associated with validation and qualification were significantly lower for us,” confirms Torsten Schewe, Team Leader at Artesan.

The field test showed that the F10i is a suitable substitute at Artesan for the P2200 offered by Fette Compacting, adds Schewe. “Even large magnesium tablets requiring a pressing force of 70 to 80 kN could be pressed without any problems. And machine usage was noticeably quiet.”

More output, less energy consumption

The production capacity displayed by the F10i at Artesan was particularly impressive: on average, it increased the output of all products tested by 63 percent. In individual cases, it was even possible to quadruple the previous production volume. These incredible figures are based on the efficiency of the machine as well as the consulting competence offered by Fette Compacting.

“We adapted the process parameters during installation and optimized the filling device set-up. This noticeably improved the output displayed by the F10i,” explains Jörg Gierds, Senior Product Manager at Fette Compacting.

Despite the high level of output, the F10i works extremely economically. So economically, in fact, that during the entire period of use, Artesan was able to save 15 percent energy over a comparably high-performance machine. This is due to an extremely powerful torque drive that can be operated in the optimum range even at high production volumes.

The F10i also proved to be extremely efficient in terms of time as a valuable resource. As a contract manufacturer, Artesan converts each of its tablet presses to a new product roughly twice a week. In order to minimize cleaning of the F10i, the engineers at Fette Compacting have reduced the surfaces of the cladding components to be cleaned by 70 percent. For Artesan, this means 45 minutes saved for each product change. Over an entire year of production, this adds up to 3,910 minutes which corresponds to an additional 66 hours of production.

No problem presented by complex geometries

The fact that the F10i makes lots of things much easier, particularly in the case of complex geometries, was revealed by the production of a convex tablet. On account of its unusual shape, it was often necessary in the past to align the tablet scraper of a machine to the format of the respective tablet. This adjustment was not necessary with the F10i. “This proves that the F10i can be easily adjusted to a wide variety of products and can even cope with complex shapes,” claims Gierds.

Considering these numerous advantages, Team Leader Torsten Schewe draws a clear conclusion: “The field tests were convincing right across the board. With the F10i, Fette Compacting has built a tablet press which represents a real gain at many levels. On conclusion of the test phase, we will be integrating the F10i in our regular machine park as swiftly as possible. And we will also be definitely considering the new machine type when planning our investments for the years to come in order to position ourselves efficiently for the future.”



In the field test at Artesan, the F10i was convincing with its high production performance and energy-saving operation.



SUGAR IN THE ELBE PHILHARMONIC HALL

Efficient industrial safety means that pharmaceutical manufacturers are dependent on the appropriate method of containment. In its new containment manual, Fette Compacting demonstrates the demands the technology is required to comply with and why machine manufacturers will play a decisive role in the task of safe and cost-efficient containment in the future.

In recent years, Dr. Eng. Martin Schöler, Head of Engineering & Design at Fette Compacting, has collaborated with colleagues to develop the Containment Guard. This seven-cycle measurement method makes it possible to reliably determine the performance of containment tableting systems in advance.

Schöler summarizes the results of his work in the containment manual and offers a comprehensible introduction to the topic. He approaches complex issues from the machine manufacturer's perspective while theoretical knowledge is combined with practical findings on the dispersion of substances. The following excerpt from the manual involves the classification of measured values and shows the physical challenges faced by containment.

»PHARMACEUTICAL COMPANIES ARE OBLIGED TO DEFINE LIMIT VALUES FOR ACTIVE PHARMACEUTICAL INGREDIENTS USED DURING PRODUCTION AND TO PROVIDE EVIDENCE OF HOW THESE LIMIT VALUES HAVE BEEN DETERMINED.«

Dr. Eng. Martin Schöler, Head of Engineering & Design at Fette Compacting

Active pharmaceutical ingredients (API) are often divided into so-called bands. The Occupational Exposure Bands (OEB) are intended to enable the hazards of active ingredients to be roughly assigned. This procedure is initiated by researching pharmaceutical companies that already have to assign the hazard level for new active ingredients without however having completed the studies on the effect of the substance (animal or human studies).

Furthermore, this classification allows pharmaceutical companies to define specific minimum protective measures for classes of active ingredients. There are many different class definitions that as a rule are company-specific. All class systems refer to the grouping of the active pharmaceutical ingredient (API), irrespective of the total quantity handled or the dilution of the active ingredient. The OEB classification however also has its disadvantage in that the grouping of a pure active ingredient into a class is often mistaken by system manufacturers with the description of system features, that actually refer to the mixtures of active ingredients and excipients.

For a copy of the Containment Guide please contact: containmentguide@fette-compacting.com

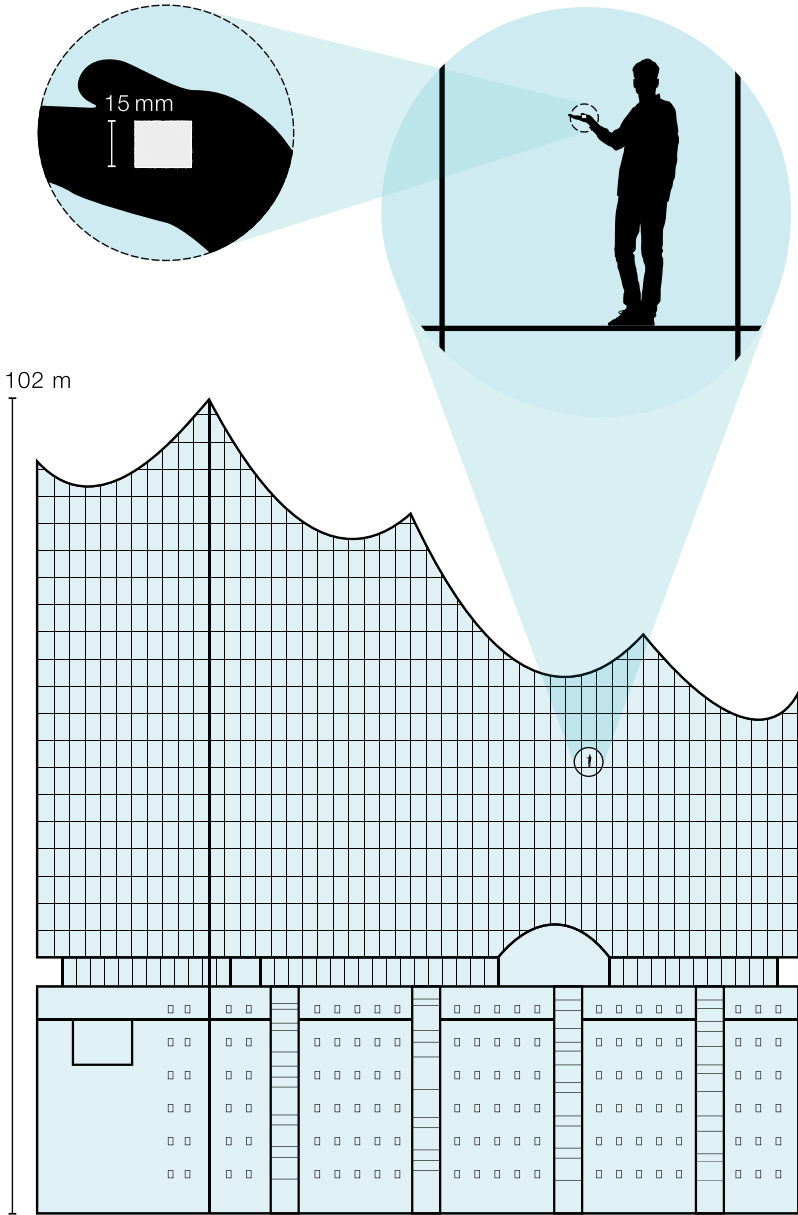


CONTAINMENT GUARD

Apart from assigning the limit values to the substance systems, it is also hard to imagine the magnitude of the concentrations. This is mainly because there are virtually no comparative figures in real life, where a substance is available in quantities within the μg range. In order to clarify the concentrations in the containment area, analogies are therefore often used.

The illustration of ratios is hereby based on the use of familiar reference elements such as for example the Elbphilharmonie in Hamburg and an ordinary sugar cube. One of these sugar cubes weighs 3 g. If the sugar cube is distributed evenly in the Hamburger Elbphilharmonie (length and height above 100 m), this then gives an indoor air concentration of approx. $5.5 \mu\text{g}/\text{m}^3$. Even though the comparison may seem extreme, these are concentrations that must be adhered to on a daily basis in the pharmaceutical industry.

Pharmaceutical companies are obliged to define limit values for active pharmaceutical ingredients used during production and to provide evidence of how these limit values have been determined. In addition to this, there are also publicly accessible lists for wellknown substances, that document the limit values and that are available in order to comply with occupational safety and health. For new active pharmaceutical ingredient and those not yet fully explored, the data available is however often incomplete, which is why the initial classification of an active pharmaceutical ingredient may be much higher (safer) and then drops over time as more detailed results of the effect become available.



A single sugar cube, evenly dispersed in the Elbe Philharmonic Hall, Hamburg: such low ambient air concentrations need to be maintained daily in pharmaceutical production.

“USERS OFTEN FIND IT DIFFICULT TO FORMULATE THEIR REQUIREMENTS”

For more than 30 years, Dr. Andreas Flückiger was responsible for assessing health and workplace hazards at Hoffmann-La Roche AG. Since 2019, he has been sharing his expertise and experience as a consultant for occupational toxicology and containment. In this interview, he reveals what users should pay particular attention to when planning and implementing a containment project.

Dr. Flückiger, what significance does the topic of containment have for pharmaceutical production?

Flückiger: In formal terms, containment is the primary measure specified by law for protecting production personnel from overexposure. It is also an effective measure for controlling cross-contamination in production. But above all else, I regard it as a development toward an improved understanding of quality.

What are the essential drivers of development?

Flückiger: The new GMP guidelines enacted by the European Medicines Agency (EMA) in 2014 require cleaning standards to be based on scientifically-derived limit values or so-called permitted daily exposures (PDE). This served as a reminder to many that identically-derived occupational exposure limits should also be used for implementing those protective measures at the workplace that are required by law. Furthermore, new highly-active pharmaceuticals have increased the awareness of good personnel protection.

In your opinion, how advanced is the state of the containment technology?

Flückiger: I would regard it as being very advanced. There are only few situations where no adequate containment solutions have been developed so far. Compared to GMP, for example, the rules of containment are often not implemented as the preferred means of occupational safety, nor are they subject to adequate inspection by the authorities.

Where do you see specific needs for action?

Flückiger: Action is required in terms of implementation and in enforcement of the principle specified by law that personnel must be protected by means of technical solutions, i.e. adequate containment, and not primarily through personal protective equipment. Some containment solutions still need to become even more ergonomic to avoid slowing down work processes too much. One decisive criterion is how well users are capable of operating the technology.



Dr. Eng. Martin Schöler (left) and Dr. Andreas Flückiger

Where are the essential challenges for users?

Flückiger: Technical solutions are available for most processes. What is decisive is personnel training. Employees do what they have learned. The introduction of containment solutions requires additional worker instruction. This is not a difficult obstacle. I see problems in practice insofar as users often have difficulty formulating their containment requirements. And there is a major potential for improvement when transferring material from one production step to the next. Goods in drums or continuous liner bags may be good solutions for the supplier but the recipient then has the task of getting the material to the next production level without breach of containment. It should also not be necessary to open any container to draw a sample.

What possibilities do users have to determine the appropriate containment level for their requirements?

Flückiger: The user must specify the products he wishes to deploy his plant for, not only taking consideration of the current portfolio but also with a view to the future. Key parameters for plants manufacturing the finished product forms are not only the limit value of the active ingredient but also its likely dilution in the formulation. Experienced equipment manufacturers have data on the containment offered by their machines and they have extensive experience from developing solutions with other customers.

What role does tableting play in the containment chain?

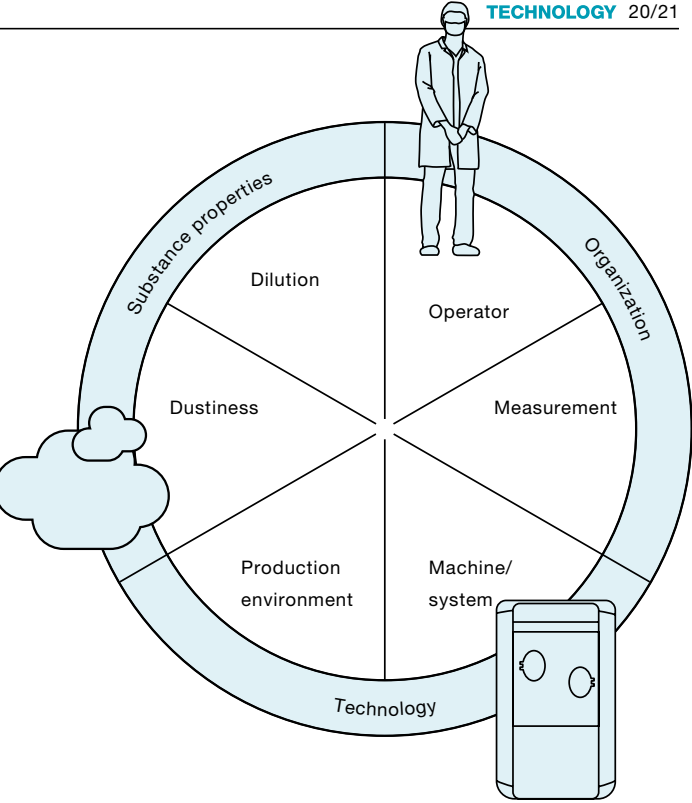
Flückiger: As a production step which is often marked by a high throughput rate and fast-moving parts which are capable of widely dispersing particles, containment is of decisive importance for tableting. Closed compression includes attachments to the press such as dedusters, metal checkers, IPC sampling, and collecting tanks for the cores which need to be as closed as the press itself. This is where machine manufacturers are called upon. It is equally important to establish a closed containment chain. Particularly, the material to be compressed should be delivered in containers that can be docked to the press in a contained way. Finally, it must be possible to connect the containers with the tablet cores to the coater or packaging machine without a containment breach.

How high will the future share of pharmaceuticals produced under containment conditions be?

Flückiger: Some level of containment is always required. The question is: “How much containment do I need?” I am convinced that considerable containment improvements are still required in the plants. This is driven by an awareness of the fact that a dependence on personal protective equipment needs to be reduced and by new pharmaceuticals which are more receptor-targeted and therefore often more highly active.

How long does it take to implement contained production?

Flückiger: The design and construction of a new high-containment plant does not take longer than the construction of an open plant. On the other hand, retrofitting of an existing facility is more complex and sometimes it is even impossible with the result that some parts of a plant need to be replaced in full.



Using basic schematic presentations, the containment manual compiled by Dr. Eng. Martin Schöler explains complex measurement methods in the area of containment technology.

Where are the economic advantages of containment?

Flückiger: To be honest, containment has its price and can slow down work processes. But these disadvantages are often offset by reduced costs for personal protective equipment and its consequences such as changing times and mandatory showering. There will be less cleaning effort for production areas which remain cleaner, less product loss, and improved management of cross-contamination via the airborne and mechanical routes. This permits a relaxation of secondary containment, leading to savings in ventilation and in the airlock systems.

What do you advise users confronted with the topic of containment for the first time?

Flückiger: At the risk of making it all sound too easy: Buy the containment manual offered by the ISPE which is available in both German and English. Participate in a seminar on the topic and specify unambiguous User Requirement Specifications for the requisite containment for each work step planned. What's more, don't buy any equipment if you don't know in advance how much containment it will offer you.

About Dr. Andreas Flückiger

Dr. Andreas Flückiger is a consultant for occupational toxicology and containment. He was Chief Occupational Health Officer at Hoffmann-La Roche AG until 2018 and therefore responsible for occupational safety throughout the corporation. As an occupational physician, he was responsible for assessing health and risks in the workplace for more than 32 years. Dr. Flückiger is a member of several professional associations and offers consulting and training on the topics of occupational toxicology, exposure limit values, and containment.

OSDI – FAST TRACK TO SMART SOLUTIONS

With a new division, Fette Compacting is concentrating on the question of how digital tools can improve pharmaceutical production. In exceptional times such as the coronavirus crisis, it becomes apparent just how swiftly and comprehensively pharmaceutical manufacturers need to react to changing production conditions. This requirement on agility can be organized more efficiently using digital tools.

Nomen est omen when it comes to the name of the new business unit: OSDi combines the terms “Oral Solid Dosage” and “Digitalization.” The OSDi unit at Fette Compacting focuses on comprehensively optimizing pharmaceutical production. With new, digital solutions, it is a reaction to the requirements and requests expressed by pharmaceutical manufacturers and paves the way for efficient and safe production.

To this aim, the OSDi team applies an agile approach based on the principles of Design Thinking and Lean Start-up. These methods are linked by the fact that they are consistently oriented toward the requirements of users. This is also apparent in the fact that users are actively included in the development process, as explained by Britta von Selchow: “Instead of tinkering around for ages in order to deliver a finished product, we take an iterative approach and are in constant contact with our users.”

Von Selchow has developed the OSDi unit in her capacity as Head of Digital Product Innovation. She describes the methods of this new business unit as being “unusual for some of our colleagues. Fette Compacting stands for perfect solutions. Therefore, it was a strange feeling initially to only send a rough idea to the customer.” It helped that Fette Compacting has always had a close working relationship with its customers. In the case of the new software products, only the frequency of coordination has increased as well as the degree of maturity displayed by the initial design. “One rule for agile collaboration is: ‘If you aren’t ashamed of your first prototype, you were too late going to the customer,’” is how von Selchow summarizes it. In her experience, it’s always worth a rethink: “Our customers trust and support us, also because they find it exciting to see the ideas we apply in solving their problems.”



»IF YOU AREN’T ASHAMED OF YOUR FIRST PROTOTYPE, YOU WERE TOO LATE GOING TO THE CUSTOMER.«

Britta von Selchow, Head of Digital Product Innovation at Fette Compacting

Products designed faster using agile methods

Thorben Schley is one of the trailblazers brought on board by Britta von Selchow. He has been part of the unit since August 2019 in his capacity as Senior Innovation Architect. He has a digital processing background, has advised medium-sized companies, developed so-called corporate start-ups, and utilized agile working methods in the process.

In practice, agility means that the OSDi team initially draws up product sketches on the basis of users’ “pains and gains.” These are then sent back to the customer for a second opinion. Using the feedback obtained, the unit collaborates closely with customers to create a click dummy, a prototype, and finally, the finished tool.

The advantages of this method are obvious: the customers’ perspective is decisive right from the start. Ideas with less potential can be detected swiftly and rejected if necessary, which shortens the development process and conserves resources. “Our customers attribute a surprisingly high priority to some ideas such as AR-supported remote maintenance. Then we really rev things up and get them to market faster,” explains Schley. However, it can also happen that the development team is obliged to drop an approach which had initially inspired great enthusiasm. “Consistent customer orientation also means taking feedback seriously, particularly when it’s difficult. This is necessary in order to focus our strengths on ideas which have a lasting potential.”



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knowledge
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CONTROL
from data
to performance

Data-driven performance. These tools enable users to monitor their plants' production data – independent of location and in real time. The faster they can react to deviations, the better it is for overall performance.

GUIDE
your production
without interruption

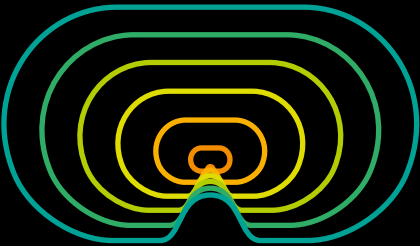
The end of downtimes. Using the SmartGuide, operators can remedy frequent errors at the instruction of technical experts. On request, a LiveGuide tool offers personal live chats and video conferences with experts.

**SEVEN DIGITAL TOOLS
FOR BETTER PRODUCTION**



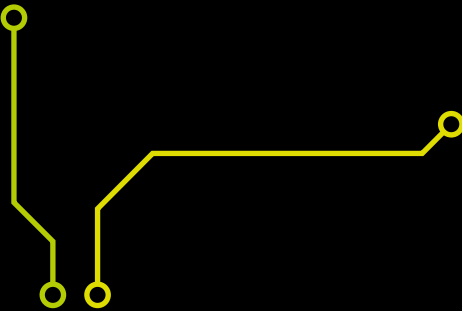
SmartCollege
"The most difficult phase is training new personnel."

Via the SmartCollege, experienced trainers at Fette Compacting make learning content available by app. Using interactive graphics, animations, and detailed instructions, new employees can familiarize themselves with the entire process of tablet production. In several modules, the learning platform illustrates how individual parts of the machine are assembled and protected from wear, for example. After each module, the trainees are obliged to complete a small test on the training content. Learning progress is depicted in an overall summary.

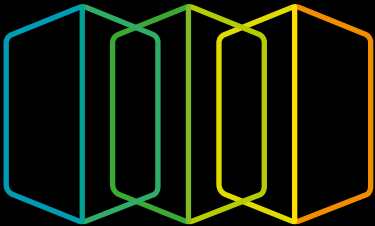


VRCampus
"The machine is only ever as good as the person operating it."

VRCampus is virtual training which intensifies employee training. The first virtual training unit offered by Fette Compacting involves preparation of an isolator for cleaning. Without blocking the real machine, employees can practice the process as often as they want using virtual glove ports, VR glasses, and a gaming notebook. Initially, the standardized process is supported by a friendly avatar called Helmut and a virtual checklist. Once participants feel sufficiently confident, they can move to a test mode where they can clean the isolator without instructions. Those who pass the test receive a certificate. Gaming elements such as a high score also make VR training more fun and increase the motivation of the participants.



LEARN



FleetManager

"I need to have an overview of the machine park at all times."

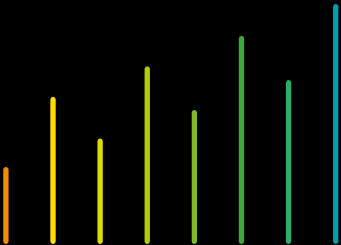
The FleetManager from Fette Compacting offers a quick overview of the machines at all locations. A quick glance at a mobile end device indicates which machines are running and which ones are down. Users can arrange their machine park in the app and focus on individual production halls or manufacturing lines in particular. The Production Asset Manager also enables comprehensive documentation of the current machine status which can be retrieved at any time.



SmartInterface

"I would like to access the machine data in real time – including outside the cloud."

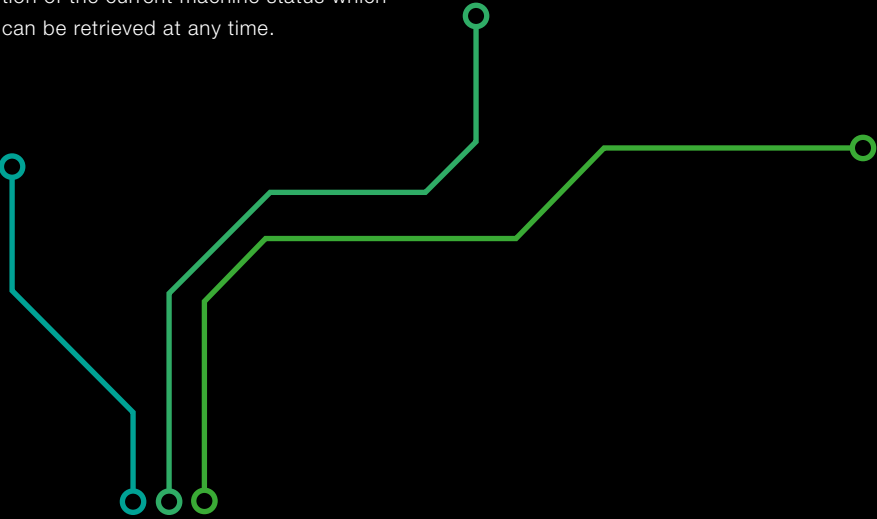
The SmartInterface offered by Fette Compacting makes it possible to access real-time production data at any time and in any location. The KPI dashboard offers a basic overview of the current production and machine status. The monitoring functions can be used for recording and exporting all process values.



ConditionMonitor

"I would like to know at an early stage when something goes wrong in production."

The ConditionMonitor offered by Fette Compacting collates production and machine data, harmonizes them, and visualizes them on any device via the secure OSDi cloud. Maintenance teams use the app to see the real-time status of their machines and plants. A comparison with historical measurements indicates deviations at an early stage and prevents downtimes. Fette Compacting tablet presses and process equipment and third-party machines can be connected using the ConditionMonitor.



CONTROL



SmartGuide

"Minor error messages are sometimes disregarded."

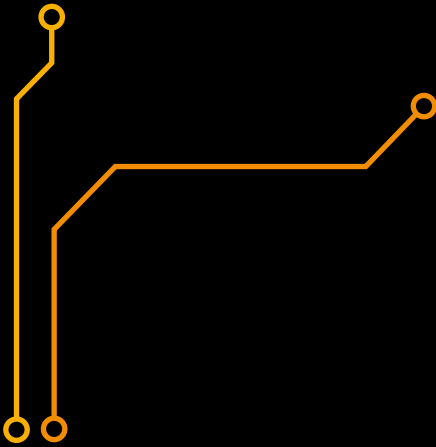
With the SmartGuide, operators can remedy frequent errors step by step at the instruction of technical experts at Fette Compacting. The app runs on a mobile device or computer. Images, animations, or videos provide information on the respective error and illustrate the steps for a solution. Furthermore, users can create their own instructions for their machines, regardless of the brand.



LiveGuide

"When machines are down, we have to get them running again swiftly."

This application permits a live chat and video conference via which Fette Compacting collaborates with operators to remedy errors. Users can also communicate directly with each other and even include other experts if necessary. Accordingly, the tool can be deployed for any equipment in production. Operators use the app on a mobile device and can implement the instructions directly on the machine. Augmented reality increases the precision of troubleshooting via visual tools such as a "finger pointer." The LiveGuide saves all solution instructions in a customer archive, enabling users to access them at will.



GUIDE

Three questions for Thorben Schley

Mr. Schley, what is your task in the OSDi unit at Fette Compacting?

I work as a method coach and product manager at Fette Compacting. Before that, I worked as a digital consultant, so agile working methods went with the job. I was able to take some of these methods with me to Fette Compacting and establish them for product development.

How does Fette Compacting benefit from agile methods?

The innovation cycles in mechanical engineering are usually somewhat longer but this is currently in the process of change. Apart from the machine, services are also increasingly gaining in importance. As a general rule, agile methods help us to be faster and to deploy resources in a more targeted manner. Where services are concerned, it is about designing entire processes without losing sight of the customer's requirements. In both areas, the key is to improve collaboration within the company and with the customer.

What significance do digital solutions have for pharmaceutical production?

After almost one and a half years in the sector, I still have an outsider's view of pharmaceutical production. The core processes in tableting and capsule filling are and remain mechanical but the associated processes become more efficient, faster, and even safer thanks to digital solutions. In my opinion, the main factors here are the qualifications of those operating the machines and the intelligent use of data in order to optimize production.



Thorben Schley, Senior Innovation Architect at Fette Compacting

VIRTUALLY BECOMING A REAL CONTAINMENT EXPERT

Boehringer Ingelheim is laying another foundation for innovative pharmaceuticals in the form of a new tablet factory. Thanks to VR training, personnel can be trained to handle containment even before the factory opens.

As of 2021, around 75 employees in the “Solids Launch Factory” in Ingelheim will be developing new production methods and manufacturing pharmaceuticals for international market launches. 2090i WiP (Wash-in-Place) machines supplied by Fette Compacting will be deployed for the first time to process highly-active ingredients. Thanks to the virtual VRCampus training program, employees are already practicing the unfamiliar steps in the isolator.

VRCampus was developed in collaboration with the Bizzlogic agency and the project was overseen by Tim Klingenhof, Head of Training at Fette Compacting. “We were just planning our training program when Boehringer Ingelheim requested our support. The timing was perfect. This enabled us to cooperate with a user to develop an initial training module,” is how Klingenhof explains how the project got started.

Apart from training ahead of commissioning, VRCampus offers Boehringer Ingelheim additional advantages, too: “Virtual training means that the machines are not tied up at a later stage and no costs are incurred for their operation,” according to Klingenhof. “Training can be conducted independent of location which makes the use of VRCampus very flexible. A room measuring 3 by 3 meters, VR goggles, a gaming notebook, and our software – that’s it. And employees lose their inhibitions about doing something wrong or even damaging something.”

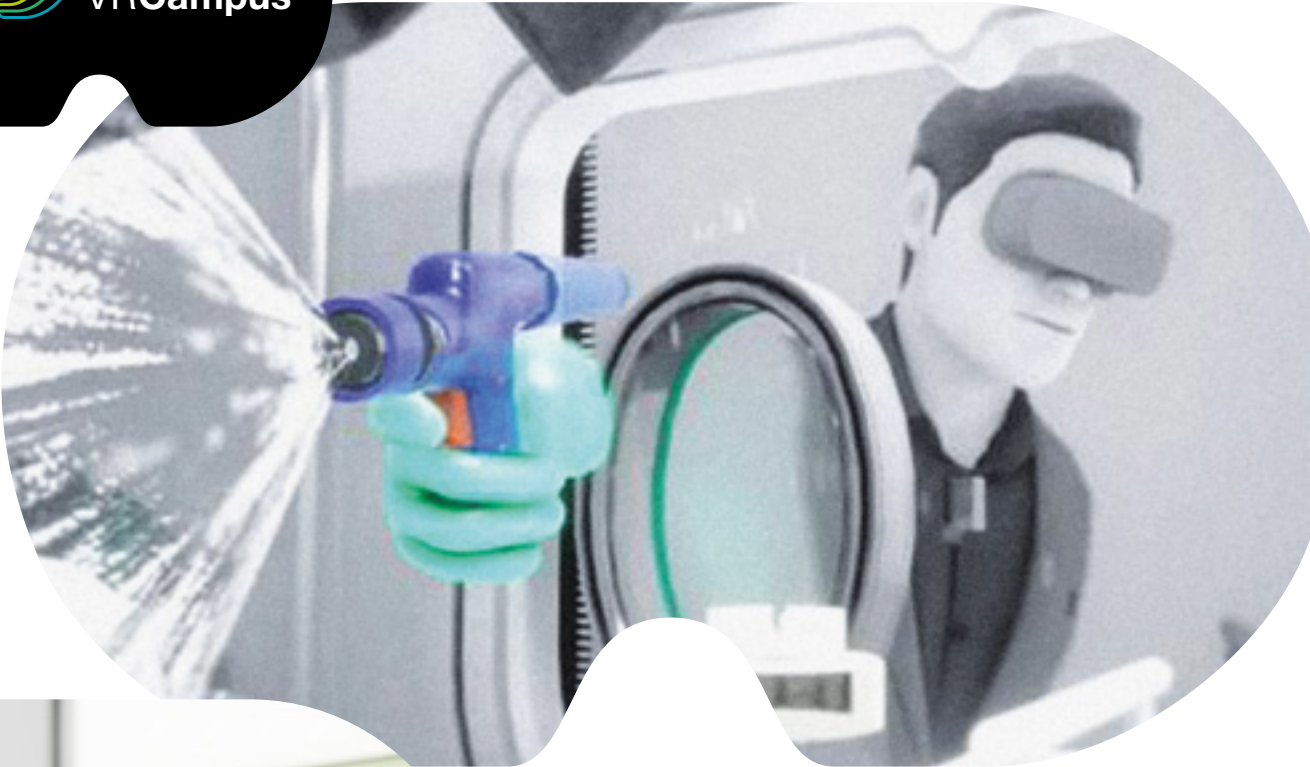


Individual steps can be practiced using a checklist.

Process reliability with a high score

Companies benefit from adherence to standardized processes. “Employees often train each other. Although understandable, this also harbors the risk of errors being passed on from one to the other. And these minor changes all add up. VRCampus ensures a consistent training standard,” claims Klingenhof. An additional incentive is offered by gamification elements: on completion of a test, operators receive a certificate and can compare themselves using a high-score list.

Martin Döhms, responsible for coach support at Boehringer Ingelheim, was immediately aware of the opportunities: “Our employees experience a working environment in production which is continuously being modernized. Even under the new containment conditions, they still need to be able to handle the process equipment in the isolator. Virtual training enables them to practice handling in the unfamiliar glove ports ahead of actual operation.”



Virtual product residue in the isolator is removed using the WiP cleaning nozzle.



Avatar Helmut provides users with support during virtual training.

From discovery mode to perfect cleaning

Depending on the learning level, users can familiarize themselves with the machine in “discovery mode” and see into the isolator interior from all angles. During the first training level – and according to instructions and tips provided by avatar “Helmut” – the aim is to remove product residue inside the isolator and work through all steps using a checklist. Helmut Bommrowitz, the long-time head of the customer center, served as a model for the avatar.

Fette Compacting is currently planning a training module for a cleaning changeover. Here, too, Helmut is sure to have the right tips to hand.



The right handling: the parts must be dismantled in the right order.

FLOW INSTEAD OF STOP-AND-GO

Continuous Manufacturing is increasingly gaining in importance in the pharmaceutical industry. More and more oral solid dosage forms are manufactured by continuous production. In the form of direct compression, Fette Compacting is relying on the most efficient variant of continuous tablet production.

It now looks like the pharmaceutical market is at a turning point. For more than a century, pharmaceutical companies have been manufacturing their tablets and capsules almost exclusively in batch procedures where individual production stages are processed strictly in succession. This stop-and-go method still remains the most popular way of producing solid formulations today. However, one look at market developments in recent years indicates that the traditional leading position held by the batch process could soon start to falter.

Even today, increasing numbers of oral solid dosage pharmaceuticals (OSD) are being produced using Continuous Manufacturing methods. Since 2015, the Food and Drug Administration (FDA) has approved six pharmaceutical products in tablet form for production with continuous processes, including drugs for the treatment of cancer and cystic fibrosis.

From the manufacturers' point of view, one of the decisive arguments for continuous production is the great potential for safe and cost-saving processes, whereby the high efficiency of the process plays a significant role. According to the FDA, the international pharmaceutical industry is currently losing up to 50 billion USD a year due to inefficient processes.

Compact and efficient: direct compression
Continuous Manufacturing is based on a new understanding of processes: the product in one process forms the direct base material for the next one. Unlike batch procedures, continuous lines are operated without interruption over a longer period of time. The continuous flow of materials does not require any storage space for intermediate products and makes it possible to scale batch sizes solely over the lines' runtime. This process also facilitates swift market launches of new products as the same line can be used for both development and production.

As a general rule, the more streamlined the design of the continuous line, the more efficient the production process. For this reason, Fette Compacting relies on the compact set-up of direct compression for its continuous tableting lines.

After the dosing process, the powder is fed directly from the mixer into the tablet press without any additional granulation. If required, the tablets can also be coated afterwards. This dispenses with several cost-intensive production steps resulting from the usual granulation processes, which are often necessary in batch production. This streamlining of the process is made possible by an uninterrupted material flow with consistently high product quality.

Quality control in real time
Because direct compression only takes a few steps, it requires minimum equipment which keeps the space requirements low compared to other continuous processes. Quality-reducing factors such as vibrations during transport of intermediate products which can lead to segregation can also be significantly reduced.

The direct compression lines supplied by Fette Compacting are based on the efficient tablet presses of the FE Series. Together with a horizontal mixing system and high-precision dosing units, these form a safe and efficient continuous system for a wide range of capacities.

The constant high quality of products is guaranteed by highly-developed PAT (Process Analytical Technology) sensors for which Fette Compacting primarily relies on near-infrared spectroscopy (NIR). NIR sensors in the tablet presses analyze in real-time each tablet in terms of its concentration of active ingredient . This makes it possible to optimize the production process using the data gleaned and to ensure the quality of the finished tablets.

Where the NIR sensors reach their performance limits, Raman spectroscopy is applied to determine even minute concentration of active ingredient using its powerful laser. In special cases, laser-induced fluorescence (LIF), UV, or terahertz spectroscopy can also be relied on.



NIR sensors in the tablet press analyze the concentration of active ingredient of the products.

Testing Continuous Manufacturing
Fette Compacting retains an entire test line for direct compression in the Competence Center in Schwarzenbek where customers can run product tests, trial individual components, or adapt the complete production line to their own requirements.



Direct compression line supplied by Fette Compacting: FE55 tablet press with dosing unit and mixing system

Direct compression	Dry granulation	Wet granulation
► Dosing ► Mixing ► Tableting ► Optional: Coating	► Dosing ► Mixing ► Roll compacting ► Grinding ► Tableting	► Dosing ► Mixing ► Wet granulation ► Drying ► Dosing ► Mixing ► Tableting

Pmax® RECIPE FOR SUCCESS

At its British site in Macclesfield, AstraZeneca produces three variants of one of it's leading breast cancer tablets. The company has increased its production volume on account of the increased demand worldwide. But the existing machine setup made it impossible to achieve the optimal output volume. Fette Compacting provided support in finding a solution and even succeeded in exceeding the set goals.

The production facility in Macclesfield near Manchester has already been using tablet presses from Fette Compacting for more than 20 years. Due to the complex interactions of the processes, new production conditions pose a challenge even for experienced operators. The aim was to increase the production quantities. The granulation and tableting cycle times were not coordinated anymore, as there was a bottleneck in tableting. In the case of breast cancer tablets, there was always a jam in the granulation process and the IBC granulation containers were not emptied quickly enough.

Due to the structure of the site, additional personnel, shifts or machines did not represent an alternative to increasing output. What was needed was operative and process-based optimization. "Initially, we considered multi-tip punches but this would have obliged us to dispense with individual exfiltration of bad tablets," claims Graham Patten, Technical Manager at AstraZeneca.



Pmax® turret with segments (top); compared to EU19 punches (left), FS12® punches (right) permit 66 instead of 36 stations.

Pmax® and FS12® – the ideal combination
“A particularly efficient and elegant solution for increasing output entails the use of a Pmax® turret in combination with FS12® punches and segment technology from Fette Compacting,” adds Global Account Manager Martin Davies, who was responsible for on-site consulting by Fette Compacting. Segments replace traditional dies and feature tablet profiles which are integrated directly in the segments. This enables the integration of significantly more tableting stations even if the tablet size remains unchanged. In combination with an FS12® punch, this was 66 instead of 36 stations at AstraZeneca.

FS® punches are also characterized by an application-optimized headform. As a result, the dwell time increases, running performance is smoother, and wear is reduced on all components involved. The Pmax® turret also has a major influence on plant performance. At AstraZeneca, it permitted a speed of 115 rotations per minute and therefore up to 470,000 tablets per hour. “One major advantage of this solution is its uncomplicated conversion as the product and machine features remain unchanged. What's more, individual tablet exfiltration permits reliable quality assurance,” explains Martin Davies.

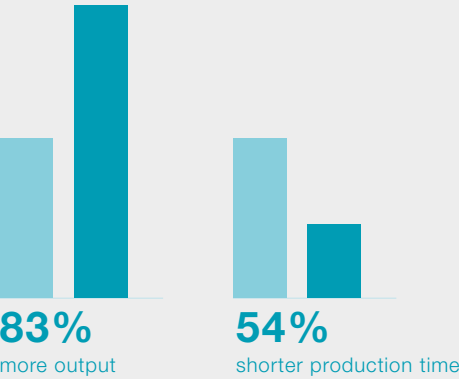


Pmax operating team with Macclesfield Site Manager

Amortization in three weeks
Using the same turret speed, application of the new tools at AstraZeneca led to an output increase of 83 percent. Batch production time was reduced from 14 to 6.5 hours on the smallest tablet variant. Furthermore, even fluctuations in weight, thickness, and hardness have been reduced. The Pmax® turret with all of its segments and punches can be removed in one piece and cleaned offline. This shortens changeover times and ensures that production can recommence faster.

Investment in the new tools paid off swiftly for AstraZeneca: “A capital expenditure of only 350,000 GBP was required to increase output. As a result, amortization was possible after three weeks of operation,” is how Graham Patten describes the success of the project.

Results after conversion to Pmax®



EVERY LEVER COUNTS

True to the motto of “Lifetime Efficiency,” Fette Compacting supports companies along the entire life cycle of machines. From product design, selection of the ideal machine configuration, and ramp-up through adaptation on demand to continuous optimization, whereby the performance consultants are responsible for analyzing numerous parameters and machine settings – right through to the machine park as a whole. A project at the German subsidiary of a major pharmaceutical manufacturer uses existing processes as an example to show how many small and large measures can be applied to improve important production parameters and keep production efficient over the long term.

Optimizing production is a continuous process. At Fette Compacting, it starts with an analysis of the production requirements and conditions in the Competence Center and continues along the entire life cycle of machines. “Even if no specific bottlenecks or quality problems arise, practically every ongoing production process harbors untapped potential,” claims performance consultant Jochen Gäth. This is indicated by several examples of his last optimization project at a company producing hundreds of different products at a site in eastern Germany, some of them displaying complex features. Type 3090i and 2090i machines from Fette Compacting are in operation. Jochen Gäth took a closer look at all of the processes and machines on site.

Optimal handling of tableting tools

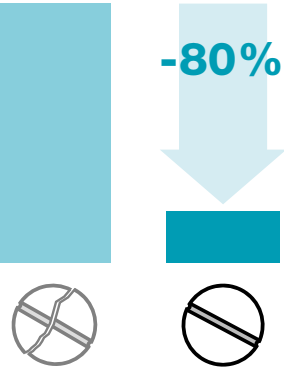
Gäth identified an initial lever in the area of Tool Management. Accordingly, for the purpose of better parts planning he recommended recording more information on the number of tablets produced and on the respective product per tableting tool as well as improved documentation of the standard processes. An optimized polishing time for standard applications also led to 50 percent savings in time. Furthermore, an extended polishing time was to be applied for products to be bonded, ensuring a significantly smoother surface. None of these measures incurred external investment.

Refresher training for fewer rejects

Next step: production ramp-up. Gäth detected a lack of pre-filling of the segment holes when the machine was ramped up. Pressing force control activated at the same time caused unnecessary wear to the punches as well as a high reject rate. It was possible to reduce the number of bad tablets from 24,000 to 5,000 per batch. Overall annual savings amounted to around 1.2 million tablets. Among others, Gäth recommended regular, in-house refresher training for operators in order to guarantee optimal handling.

The very best for every product

On account of the high number of products, the first step entailed Fette Compacting concentrating on a few particularly promising or complex tablets. The latter included a preparation for reducing cholesterol levels which tended to bond at the score in particular. Ultimately, an adapted configuration of the Fill-O-Matic with numerous process-optimized components and machine parameters led to improved filling. The customer was not at all aware of this untapped potential as the fundamental production targets were being reached. But now he can benefit from 40 percent more output in the future.



Optimal handling can drastically reduce the number of bad tablets.



Preparation is everything

The next optimization step involved potential automation to reduce personnel requirements for night shifts. However, an analysis indicated that the process could be designed efficiently in a much easier way. Gäth discovered that – in order to free up personnel capacities for other tasks – better preparation of the machines for the night shift would suffice. This ensured that the operators could concentrate solely on operating up to 5 machines instead of possibly being responsible for both operation and conversion of two machines at the same time.

And last but not least, Gäth subjected the maintenance processes to a risk-based analysis. As a result, it was possible to streamline annual maintenance by deleting maintenance measures already being applied on a regular basis from the annual maintenance – despite unchanged quality and performance. Consequently, the annual time required for each machine without calibration was reduced from 24 to 12 hours.

“We were able to identify numerous optimization levers in all areas of the production process and then implement the corresponding measures. Often in areas which the customer would never have thought of. This is exactly what distinguishes Lifetime Efficiency: making continuous use of the entire range of analysis in order to guarantee efficient production over the long term,” concludes Jochen Gäth

Checklist

Seven levers for efficient production

- 1. Lifecycle: Have the entire life cycle of all machines, processes, and settings regularly reviewed for untapped optimization potentials.
- 2. Tableting Tools: Ensure that wear data are collated systematically and comprehensively and that standard processes are documented in a comprehensible manner for all operators.
- 3. Machine start-up: Conduct regular refresher training with your operators to achieve optimal results at all times.
- 4. Product management: Ensure that the equipment, setting, and parameters are selected in such a way that they are optimally coordinated to the product as this is a decisive factor for complex products in particular.
- 5. Process equipment: For each process, check whether manual work steps can sensibly be replaced by mechanical ones.
- 6. Automation: Before considering automation, you should ensure optimal coordination between personnel and processes.
- 7. Maintenance: Document regular maintenance measures as these steps can be saved during annual maintenance.

Would you like to take a closer look at your production? Talk to our Performance Consultant Jochen Gäth:

Jochen Gäth
phone: +49415112331
email: JGaeth@fette-compacting.com





“Where health and technology are concerned, there should be no limits.”

We at Fette Compacting think in global dimensions – that goes without saying. But only by closely networking our worldwide creative potential and talents from many countries can we work efficiently for human health.

Read more about our corporate values at www.fette-compacting.com

Volker Reinsch, Director Corporate Marketing & Communication, Schwarzenbek, Germany
Jian Sun, Senior Regional Sales Manager, Fette Compacting (China)



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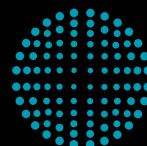
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