

WHAT'S NEXT?



ME/1
**FETTE
COMPACTING**

FETTE COMPACTING MAGAZINE 2024/2



A CLEAN SOLUTION

WiP and containment for Dr. Reddy's

TOGETHER – FROM LAB TO PRODUCTION

Becoming a process partner

A STRONG TRIO

FE55 in operation at Ferrer

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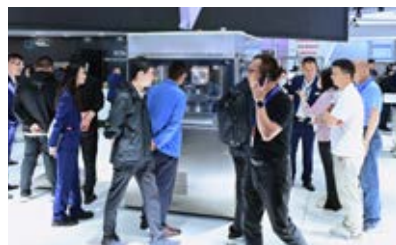
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Dear Readers,

New active ingredients, new processes, new regulations: 2024 has shown that the world of pharmaceutical and nutraceutical production is in a state of flux. In line with this, we present the second edition of What's Next? this year, in which we take a look at key developments and show how we are actively shaping this change in collaboration with our customers and partners.

Our cover story illustrates the importance of developing innovative solutions for safe and efficient production processes: the pharmaceutical manufacturer Dr. Reddy's Laboratories in India has already opted for their third wash-in-place tableting system from Fette Compacting. Read why the manufacturer relies on this technology to process its highly active ingredients and what is important for collaboration.

Cooperation also plays a decisive role in formulation and process development. We are constantly evolving from a machine manufacturer to an integrated process partner. In this magazine, we show you how the "Together – from lab to production" concept creates specific added value for our customers.

There is also a lot to report in the area of tablet presses: the FE Series has once again impressed Grupo Ferrer Internacional in Spain and our new i Series is setting high standards in efficiency and flexibility at Laboratorios Carnot in Mexico. All of these machines are all-rounders that are used successfully in both established and growing markets.

I hope you enjoy reading this publication!

Sincerely, Joachim Dittrich

CEO, Fette Compacting



A CLEAN SOLUTION



Dr. Reddy's Laboratories relies on the highest safety standards in the processing of highly active ingredients through high containment and wash-in-place (WiP) technology. This Indian pharmaceutical company has collaborated with Fette Compacting to develop a suitable overall solution.

Dr. Reddy's was established in southern India 40 years ago. Since then, the company has established itself worldwide with a broad portfolio comprising over 350 products in numerous therapeutic areas. These include, for example, drugs for gastrointestinal disorders, various types of cancer, cardiovascular diseases, infectious diseases, and pediatric diseases. Dr. Reddy's mission, "Good Health Can't Wait," reflects its commitment to providing affordable generic medicines and innovative services to improve the lives of patients.

"As a manufacturer of highly active medicines, we are committed to using leading technologies to optimize our production processes while ensuring the highest safety standards," explains Vivekanand Kamat, Site Head, FTO-SEZ Process Unit 2 at Dr. Reddy's. "Especially for the production of tablets with active to highly active ingredients, we attach great importance to comprehensive containment. We need absolutely dust-tight equipment with closed material handling and transfer. For us, this also includes a wash-in-place function to thoroughly clean the press chamber before product changes, to protect our operators and avoid potential cross-contamination."

Dr. Reddy's is not alone in these requirements, as the pharmaceutical industry has been experiencing a clear trend toward highly active ingredients for years. Containment systems are therefore increasingly prevalent, as they reliably protect personnel from exposure and dispense with the need for using fully protective suits. Tailor-made containment packages offer safety, feasibility and user-friendliness in a single system.

WiP and containment: the ideal combination

In its search for a suitable containment system, Dr. Reddy's approached Fette Compacting and found the right solution in three tried-and-tested 2090i WiP tablet presses. They are characterized by an integrated wash-in-place system that ensures efficient and safe processing of highly active substances. The machines have a washable compression chamber with automatic preliminary cleaning. In addition, smooth stainless steel surfaces and tool-free access to the components that come into contact with the product facilitate manual cleaning and changeover work. This also enables significantly faster format changeovers.



A washable containment system facilitates cleaning processes, protects the operators, and prevents cross-contamination.

” WE HAVE THE IMPRESSION THAT WE ARE IN GOOD HANDS. “

Biswajit Panda, Manager-Production, FTO-SEZ Process Unit 2 at Dr. Reddy's

The containment equipment provides complete control over dust emissions throughout the entire tableting process. An air management system continuously regulates the air flow. Glove ports allow maintenance or adjustment work to be carried out without breaching containment. In addition, hermetically sealed window flaps and rapid transfer ports (RTP) ensure the safe replacement of components.

“We expect output to remain constant within a tolerance of ten to a maximum of 15 percent during our production changeover,” notes Vivekanand Kamat. “Above all, we attach great importance to simple changeover systems that reduce the complexity of operation and minimize the risk of operating errors. The 2090i WiP has met and even exceeded these expectations right from the start.”

From FAT to needs-based training

In summer 2024, the Factory Acceptance Test (FAT) of the 2090i WiP in Schwarzenbek marked an important step in the company's partnership with Fette Compacting. “The FAT was well organized and the team had prepared carefully so that all tests were successfully completed on time,” claims Kamat with satisfaction. These positive experiences also underline the high adaptability of the containment and WiP technology to Dr. Reddy's specific requirements. They confirm the commitment of both teams to meet the highest quality and safety standards.

Dr. Reddy's also uses Fette Compacting's extensive training and service offerings to support a smooth production start-up. “For example, we need audiovisual training aids that convey the process and the critical aspects of handling containment in standardized modules,” says Kamat. “The Fette Compacting team is very responsive to this need.” And Biswajit Panda, Manager-Production, FTO-SEZ Process Unit 2 at Dr. Reddy's, adds: “We have the impression that we are in good hands here – with a partner who not only understands our technical requirements, but also proactively provides solutions for process optimization.”



The FAT in Schwarzenbek thoroughly tested the performance of the 2090i WiP.



This partnership-based cooperation has led to a high level of satisfaction on both sides – from left: Biswajit Panda (Manager-Production, FTO-SEZ Process Unit 2, Dr. Reddy's), Durgesh Rajadhyaksha (Sales Head - Region and Key Accounts, Fette Compacting), Marcus Juckel (FAT Manager, Fette Compacting), Vivekanand Kamat (Site-Head, FTO-SEZ Process Unit 2, Dr. Reddy's), Martin Bruggemann (Project Manager, Fette Compacting).

” AS A MANUFACTURER OF HIGHLY ACTIVE MEDICINES, WE ARE COMMITTED TO USING LEADING TECHNOLOGIES TO OPTIMIZE OUR PRODUCTION PROCESSES WHILE ENSURING THE HIGHEST SAFETY STANDARDS. “

Vivekanand Kamat, Site Head, FTO-SEZ Process Unit 2 at Dr. Reddy's

Dr. Reddy's Laboratories fact check

Established

1984 in Hyderabad, India

Main areas of business

Generics, proprietary products, production of active ingredients, biotechnology

Main business areas

In more than 66 countries worldwide

Product portfolio

A broad portfolio across numerous therapeutic areas, including treatments for cancer, cardiovascular diseases and infectious diseases

Research and development

Dr. Reddy's invests heavily in research and development of new medications, including biosimilar products and innovative therapies.

Social commitment

With the Dr. Reddy's Foundation program, the company is involved in social projects that focus on education and improving the living conditions of disadvantaged communities in India.

EVOLUTION OF CONTAINMENT



The pharmaceutical industry has been processing highly active ingredients into tablets for around 80 years. Containment for operator, product and environmental protection has increasingly become a central issue for safe production. What follows represents a journey through time from the origins to the present of containment in tableting.

Containment has become essential to providing a high level of exposure protection while maintaining a high degree of efficiency. In particular, the increase in highly potent active pharmaceutical Ingredients (HPAPIs) in oncology and precision medicine requires state-of-the-art safety barriers. The solutions that Fette Compacting has helped to develop and optimize over the years range from basic dust-tight equipment to high containment.

The timeline illustrates some of the milestones that have contributed significantly to the evolution of pharmaceutical tableting standards and will continue to do so in the future.

1940s/ 1950s



US researchers develop the first industrial containment cell. At the same time, Fette Compacting manufactures the first tablet press for processing active pharmaceutical ingredients in 1948. The areas of containment and tableting are still a long way from a common technology, but from then on they gradually grow together.



1960s/ 1970s

In the 1960s, cytostatics and the contraceptive pill marked the start of large-scale industrial processing of highly active substances. In 1970 Fette Compacting also launched the first high-speed tablet press, the P2000. It did not yet have containment, but was already setting new standards in terms of safety and productivity. For example, the tablet presses were now designed as closed systems, with convenient access via window flaps.

1982

With the PT2080, Fette Compacting introduced the world's first computer-controlled tablet press. This step towards digitalization also formed the basis for subsequent data-supported process monitoring in containment systems.





2004

As the first manufacturer of tableting technology, Fette Compacting builds complete high-containment systems up to Occupational Exposure Band (OEB) Level 5. This corresponds to a maximum concentration exposure of one microgram per cubic meter in the production area during an eight-hour working shift. One important criterion is represented by isolator technology with fully-integrated process equipment. Additional safety provided by a system for air management from 2006 on.

WiP x50

2010

The wash-in-place concept was increasingly popular. In 2010, Fette Compacting was already delivering its fiftieth tablet press with WiP equipment.

1999

At the end of the millennium, Fette Compacting launched the 1090i WiP, the first washable single rotary press. This was followed in 2003 by the 3090i WiP, the first washable double rotarypress. Wash-in-place (WiP) technology opened up new possibilities for processing highly active materials thanks to safe cleaning of the process chamber. In addition, product changeovers could be carried out more quickly with a washable system.



2015

Dust-tight basic equipment and an optional containment package made the FE Series the new standard in tablet production. Fette Compacting equipped its high-performance presses with containment options for a wide range of requirements.

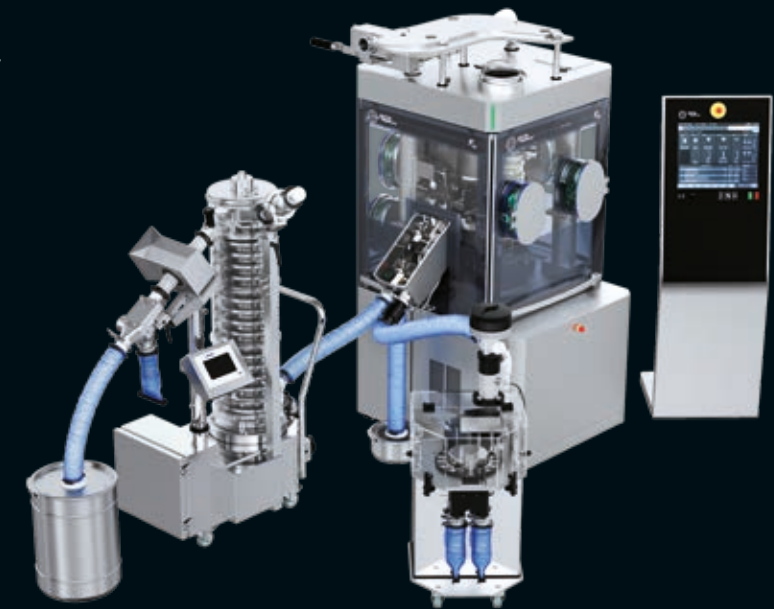


2017

One particular milestone was represented by the introduction of the Containment Guard. This process allows the retention performance of containment tableting systems to be precisely measured and documented. Even before the final risk assessment is carried out by the operator, the measurement ensures that the systems meets the required safety standards.

2019

2019 saw Fette Compacting launch the new i Series in the form of the F10i single rotary press. One key feature of this next generation was comprehensive operator protection, starting with the dust-tight equipment fitted as standard on all models. The tablet presses could also be optionally equipped with a containment package.



2025/2026

Users worldwide rely on containment tableting solutions from Fette Compacting. In addition, there are plans to expand the laboratory capacities in Schwarzenbek for customers. In the future, the new building will also be able to process highly active products in order to test new drugs with all technological possibilities and transfer them to production.

TOGETHER – FROM LAB TO PRODUCTION



Dr. Marten Klukkert,
Vice President
Customer Development
Center at
Fette Compacting

A breath of fresh air blows through the laboratory and the halls in Schwarzenbek in northern Germany: At Fette Compacting headquarters, pharmacists and machine experts are continuing to advance our development towards becoming an integrated process partner. This change opens up far-reaching advantages for manufacturers.

Time is a critical factor in the pharmaceutical and nutraceutical market. Efficiency and flexibility therefore play a central role from the development phase onward. Pharmaceutical companies in particular are under enormous pressure to bring new drugs to market faster without compromising on quality and safety. This is precisely where Fette Compacting's new strategy comes in.

"We acknowledge that it is no longer enough to supply highly efficient machines and process equipment. Our aim is to use our decades of expertise and intensive, partnership-based exchanges with our customers to accompany the entire process from the initial idea to the marketable product – 'Together – from lab to production,'" explains Joachim Dittrich, CEO of Fette Compacting. In addition to efficiency gains, this approach also promises tangible added value for customers: Pharmaceutical manufacturers can optimize their processes, react more quickly to market changes, and accelerate the launch of new products.

Understanding processes at an early stage

"We already offer our customers a wide range of services well in advance of production," adds Dr. Marten Klukkert, Vice President Customer Development Center at Fette Compacting. "This means that we support pharmaceutical and nutraceutical companies from formulation development through to validation of their processes. The main aim is to integrate knowledge and technology to take the entire production process to a new level and ensure real added value for manufacturers."

Comprehensive process consulting begins with a database that bundles concentrated tableting knowledge from many tests and applications: the QED (Qualified Expert Database) knowledge database provides empirical values from more than seven decades of tableting experience. This source makes it possible for us to find specific solutions for every product and every process. "With QED, we can offer our customers a comprehensive pool of specialist knowledge. This allows us to quickly determine the best processes and machine configurations," enthuses Klukkert.

” OUR AIM IS TO USE OUR DECADES OF EXPERTISE AND INTENSIVE, PARTNERSHIP-BASED EXCHANGES WITH OUR CUSTOMERS TO ACCOMPANY THE ENTIRE PROCESS FROM THE INITIAL IDEA TO THE MARKETABLE PRODUCT. “

Joachim Dittrich, CEO of Fette Compacting

” MANUFACTURERS ARE OFTEN FACED WITH THE CHALLENGE THAT THE PHARMACISTS WORK ON FORMULATIONS OF THEIR ACTIVE INGREDIENTS AND EXCIPIENTS WHILE THE ENGINEERS WORK SEPARATELY ON PRODUCTION TECHNOLOGIES. WE CAN UNITE THESE TWO WORLDS BY WORKING CLOSELY TOGETHER AS AN INTERDISCIPLINARY TEAM. “

Dr. Ina Petry, Group Lead Application Consulting at Fette Compacting

Precise analysis of powders and tablets

While QED forms the digital basis for process partnerships, practical implementation begins in the laboratory area of Fette Compacting. This is where material and powder analysis is the first and already essential step in the development of medications and nutraceuticals. One of the core concerns of pharmaceutical production is the precise characterization and analysis of sensitive, highly regulated materials. To this end, Fette Compacting develops innovative solutions in its Customer Development Center that support users in the early development phase and create the best conditions for an efficient production process.

"The laboratory-based services start with advice on a new formulation and range from intensive powder characterization to test trials. In order to transfer the successes from the laboratory to the customer, we offer on-site training and application consulting," reports Dr. Ina Petry, Group Lead Application Consulting at Fette Compacting. "More than ever before, consulting and training now go hand in hand with all aspects relating to the process. Manufacturers are often faced with the challenge that the pharmacists work on formulations of their active ingredients and excipients while the engineers work separately on production technologies. We can unite these two worlds by working closely together as an interdisciplinary team."

With Lab Solutions, Fette Compacting offers a range of services that focus on the characterization of powders and tablets. "We help our customers to determine and analyze the critical material properties of their active ingredients, because the behavior of a powder is often the decisive factor for the efficiency and quality of subsequent tableting," emphasizes Petry.

Fette Compacting's Customer Development Center supports the principle of Quality by Design. This approach aims to optimize product quality through a deep understanding of production processes. "It means that we can identify the critical process parameters and quality attributes at an early stage and develop appropriate control strategies for, and with, our customers. In this way, they create robust processes for consistently high product quality," Petry continues.



Dr. Ina Petry, Group
Lead Application
Consulting at
Fette Compacting



An essential part of this entails the analysis of the powder's compaction and compacting properties. With the modular powder compaction analysis units of the F Lab Series, Fette Compacting can precisely examine the physical properties of powders. The analysis includes factors such as particle size distribution, density and flowability – all important parameters for a stable tableting process.

Emulating processes instead of simulating them

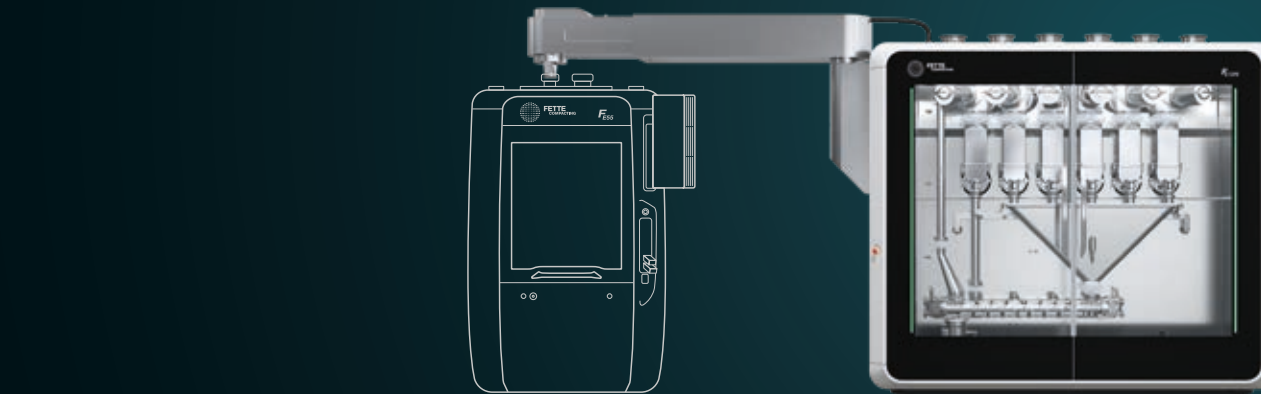
The next important step along the product life cycle involves process development. When passionate collaboration meets optimal technical equipment, entirely new possibilities open up. One of the most important technologies which will soon be in Schwarzenbek – and then in all Competence Centers – are several emulators that mimic real production conditions. In contrast to simulators, these analysis systems have the potential to test processes without conversion steps and loss of time under particularly close-to-production conditions. In the long term, they offer companies the advantage of validating their recipes and process parameters at an early stage and eliminating potential faults in the development phase before they occur in production. By using small quantities of material, valuable resources can be saved and precise predictions made about the subsequent production process.

Faster to production

Let's move on to technology transfer: the transition from research and development to commercial production is often associated with considerable challenges. This is where Fette Compacting provides support in the form of a seamless transfer service. "We offer various solutions that enable our customers to transfer their projects to production more quickly and react flexibly to changes," explains Klukkert. Support during scale-up is particularly valuable for users, as this not only saves time but also reduces the risks that can occur during commercial production.

In addition to increasing efficiency and optimizing processes, sustainability is also playing an increasingly important role, as explained by Dr. Martin Schöler, Vice President Technology at Fette Compacting: "The concept of sustainability is deeply embedded in our DNA, in every development and design. We are highly committed to minimizing material consumption and making processes more resource-efficient. One key to this is the FE CPS continuous processing system, which enables us to work with minimal quantities of material during the development phase. This allows us to gain valuable insights with just a few kilograms of material, which considerably speeds up the development process and significantly reduces material loss."

Dr. Martin Schöler,
Vice President
Technology at
Fette Compacting



FE CPS milestone

The FE CPS has also provided the decisive impetus to grow more strongly in the direction of process. As the system adapts to a wide range of production scenarios, it offers optimum conditions for development and production. With continuous direct pressing, the powder is fed from the dosing-mixing unit via the powder transport system into the tablet press without additional granulating. Compared to granulation-based production, several steps are eliminated, which reduces the space and energy requirements as well as the process costs.

The birthplace of this world first is Fette Compacting's innovation center in Mechelen, Belgium. This is where the idea of revolutionizing tablet production through continuous manufacturing was born. By testing various material and process-related scenarios, the system was enabled to process a wide range of ingredients in a throughput range of five to over 200 kilograms per hour. It can dose and mix up to six different powdered raw materials and transfer them to the downstream processes.

In the meantime, numerous product trials and several sales have confirmed the enormous interest in the FE CPS on the part of pharmaceutical and nutraceutical producers. In addition, there is a key component that was developed in close cooperation between Schwarzenbek and Mechelen: embedded Process Analytical Technology (ePAT). "With ePAT, we can continuously monitor the most important quality in real time and react immediately in the event of deviations," says Dr. Anna Novikova, Head of Process Consultancy at Fette Compacting. Using near-infrared spectroscopy (NIRS), ePAT monitors product quality directly during the production process. This technology makes it possible to check the chemical composition and physical properties of powders and tablets without incurring any interruptions or delays. "With ePAT, process control finally becomes simple, robust and efficient. The integrated sensor technology helps manufacturers ensure consistently high product quality and detect potential production errors at an early stage," says Novikova.



Dr. Anna Novikova,
Head of Process
Consultancy at
Fette Compacting

Proven technologies and services

In addition, it goes without saying that batch-to-batch process technologies are still available to users. The decisive factor is which solution is best suited to a specific product and production environment. For classic tableting, for example, users can rely on the tablet presses from the new i Series. It offers modernized models that allow flexible adjustments, advanced energy management, high network capability, innovative safety solutions for operator protection, and many other design advantages.

The proven production support services and performance consulting also come into play, as Lars Plüschau, Vice President Global Sales at Fette Compacting, explains: “Customer support is crucial to the success of our customers. The comprehensive consulting, training and modernization services offered by Fette Compacting are aimed at optimizing production efficiency and product development time (time to market). Tableting tools also play an important role in this. By supplying machines and tools from a single source, interface problems can be avoided, which considerably simplifies the production process and saves customers both time and money. This underlines our orientation as a reliable process partner that not only offers machines, but also customized solutions for the entire life cycle of a product.”

The journey continues

“Together – from lab to production” is the direction for Fette Compacting’s development journey. Meanwhile, the Schwarzenbek site is already working on its next innovation: expanding cleanroom capacities with the new ISO 8 standard opens up additional opportunities to test highly active substances under strictly controlled conditions. The planned cleanrooms will expand the portfolio, as more products can be tested under real conditions using all of the technologies available at Fette Compacting. This will make it possible to further expand collaboration with customers from the early stages of development, ultimately shortening the time to market.

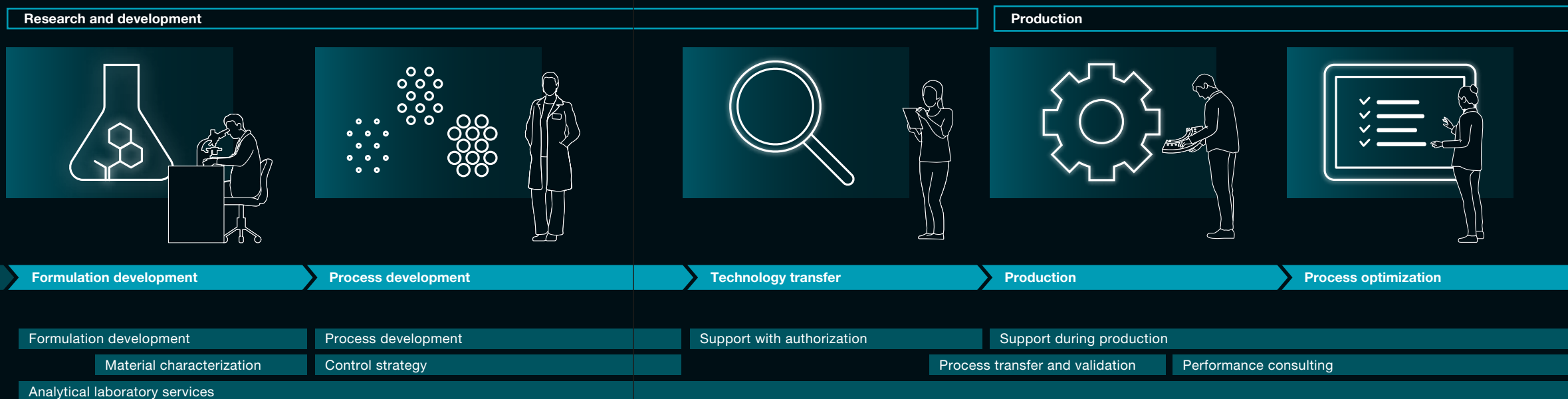
Lars Plüschau,
Vice President
Global Sales at
Fette Compacting



TOGETHER

From Lab to Production

As a comprehensive process partner, Fette Compacting offers comprehensive services and supporting technologies right from the early formulation development stage. Customers can benefit from this in many ways, in particular from a shorter time to market.



Extended range of services along the process chain:



GROWTH SPURT IN MEXICO



FAT (Factory Acceptance Test) of the F10i with Alfredo Arenas (Head of Engineering, left) and Rodrigo Hernandez (R&D, center) from Laboratorios Carnot.

With its headquarters and production facility in Mexico, the pharmaceutical manufacturer Laboratorios Carnot has been distributing its products since 1940. In the course of its growth strategy, the company will soon be opening a new plant in the state of Hidalgo, where the F10i tablet press of the new i Series and the tried-and-tested 102i from Fette Compacting will play a key role.

Laboratorios Carnot has primarily gained a reputation for its drugs in the areas of gastroenterology and gynecology. Best-sellers include products in the Libertrim family, which is part of the gastro line.

With double-digit sales increases in the past five years, signs are pointing toward growth, enabling the company to start expansion of its production capacities at the Hidalgo site. Laboratorios Carnot is planning to relocate production here from 2027 and to develop new medicines using innovative processes. Carnot supplies its products to South America and Central America as well as the Caribbean. With WHO- and FDA-compliant production conditions, the planned expansion is aimed at all countries that require corresponding certifications.

Efficient transfer and innovation

In connection with the growth plans, it was necessary to select suitable tablet presses. To this end, the company carried out product tests at Fette Compacting in Schwarzenbek. On the one hand, the F10i tablet press was used, a flexible single rotary press from the new i Series, which was designed for highly-efficient tablet production. On the other hand, the company tested the use of the R&D tablet press 102i. It can be used to test formulations in a material-saving manner as well as record production-relevant data.

” IN TERMS OF KNOWLEDGE TRANSFER, THE 102i HAS HELPED US ACHIEVE A BREAKTHROUGH. THIS TABLET PRESS AND THE NEW F10i ARE THE IDEAL COMBINATION FOR OUR PRODUCTION REQUIREMENTS. “

Rodrigo Hernandez, formulation expert at Laboratorios Carnot

“The 102i is of central importance to us in product development,” explains Rodrigo Hernandez from the R&D department at Laboratorios Carnot. “We are using it to smoothly transfer the production of our products previously manufactured in Mexico City to the new site. The 102i has helped us achieve a breakthrough in this knowledge transfer. In addition, it will also support us in other areas of development by providing placebos for downstream tests relating to packaging and coating. This tablet press and the new F10i are the ideal combination for our production requirements.”

Everything flowing smoothly

There is another reason for choosing tablet presses from Fette Compacting, which concerns the specific properties of some of Laboratorios Carnot' products. These involve rheological conditions, i.e. the flow behavior: “Until now, many of our leading pharmaceuticals can only be produced at a reduced speed – we want to change that,” adds Alfredo Arenas, Head of Engineering at Laboratorios Carnot. “The tableting technologies within the new i Series and R&D model have led to the best results in application tests, for example in material feed and downstream processes. In the future, we will use the tablet presses to produce our best-sellers in even larger quantities. At the same time, the rapid transferability from R&D allows us to drive forward our international growth targets with new products.”

Following the Factory Acceptance Tests (FAT) of both machines in Schwarzenbek, Fette Compacting is supporting Laboratorios Carnot with final process adaptation. It is already clear that the company is very interested in further innovations, as Alfredo Arenas confirms: “We are currently investigating whether a continuous manufacturing process with the FE CPS from Fette Compacting could also be considered as an alternative for some of our products.”



Efficiency to the i: F10i, F20i and F30i

The new i Series is characterized by high performance and system compatibility with the existing i Series. This minimizes the time and effort required to validate and qualify the machines from several months to just a few days. In addition, the new machine family is dust-tight as standard and features the latest technology.

More information:



A STRONG TRIO

Grupo Ferrer Internacional is dedicated to the development of transformative medicines for serious diseases. “Transformative” means that the drugs not only alleviate symptoms, but also fundamentally change the course of the disease. The aim is to sustainably improve patients’ quality of life. In order to fulfill this mission under the highest quality standards, the pharmaceutical company has opted for a third FE55 tablet press.

Ferrer, which has its headquarters in Barcelona, is known worldwide for its solutions for the treatment of life-threatening diseases. With a focus on vascular diseases, lung diseases and rare neurological disorders, the pharmaceutical manufacturer is setting new standards in healthcare in more than 100 countries. “Our 1,800-strong team is driven by a common goal: to significantly improve the lives of sick people,” emphasizes Lambert Guri, Senior Engineering & Facilities Manager at Ferrer.

The product range includes numerous medications in tablet form. The company places high demands on their production: maximum production capacity of the tablet presses and smooth processes thanks to

compatible machines. Ferrer also needs the right technology for two-layer tablets in order to be able to combine different active ingredients. “For us, it is crucial that production is not only efficient, but also flexible and absolutely reliable in terms of quality,” Guri continues.

30 years on a joint mission

The long-standing collaboration with Fette Compacting, which began over 30 years ago, was a decisive factor in the selection of the new FE55 tablet press. Ferrer already owns two high-performance rotary presses of this type. The company has now opted for a third machine to increase production capacity and ensure continuity with maximum system harmony.

” **FOR US, IT IS CRUCIAL THAT PRODUCTION IS NOT ONLY EFFICIENT, BUT ALSO FLEXIBLE AND ABSOLUTELY RELIABLE IN TERMS OF QUALITY.** “

Lambert Guri, Senior Engineering & Facilities Manager at Ferrer

Why the FE55? The FE Series medium tablet press is one of the most powerful and versatile machines of its kind. It makes it possible to produce more than 90 percent of all common tablets, including the two-layer tablets developed by Ferrer. Maximum efficiency is ensured by the ratio of the number of punches to the footprint – up to 87 punches per to 1.6 square meters – and a special pattern for two-layer tablets.

The equipment with three compressing stations instead of two results in longer compression holding times at lower compression, which leads to gentler processing of valuable pharmaceutical materials. This configuration also allows precise control of the compression force and improves the



Fine tuning of the system parameters: in the production of transformative medicines, every process detail is crucial.



Kick-off in Schwarzenbek: the FAT with the project team from Ferrer and Fette Compacting was a successful start for the third FE55.

compaction of difficult-to-compress formulations. The result is denser and more uniform tablets of the highest quality.

In addition, the FE55 is designed to be easy to operate and clean. The TRI.EASY design from Fette Compacting ensures that the machine is user-friendly in terms of operation, maintenance and changeover. It offers 360-degree access and tool-free intervention during product changeovers. An intuitively controllable Human Machine Interface (HMI) provides operators with the necessary overview to easily monitor and adjust all parameters.

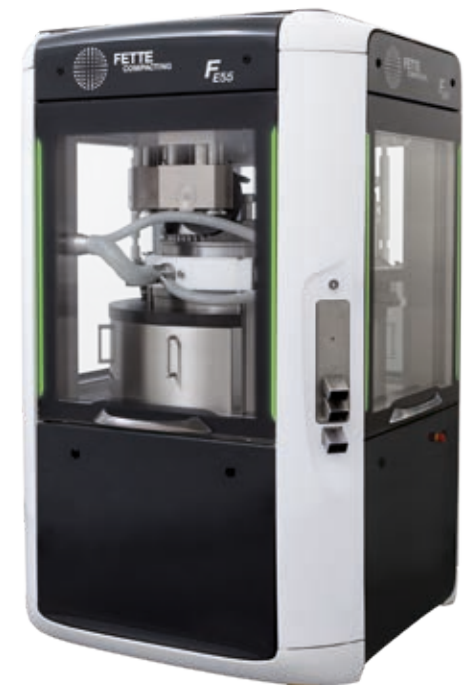
Future-proof positioning

With the integration of the third FE55, Ferrer expects a significant increase in its production output. The positive experience with the machines in use means that the company has a high level of confidence in the new tablet press. This confidence has been further strengthened by successful test runs and the Factory Acceptance Test (FAT) at the Customer Development Center in Schwarzenbek.

This successful cooperation is also characterized by intensive services. Fette Compacting’s technicians in Spain have extensive know-how and ensure smooth maintenance of the machines. Following installation of the new FE55 in Barcelona, further validation steps are pending in order to optimally integrate the machine into the production environment and guarantee the highest product quality. “With the third FE55 tablet press and the proven collaboration with Fette Compacting, we believe we are ideally equipped to continue fulfilling our health mission in the future,” summarizes Lambert Guri from Ferrer.

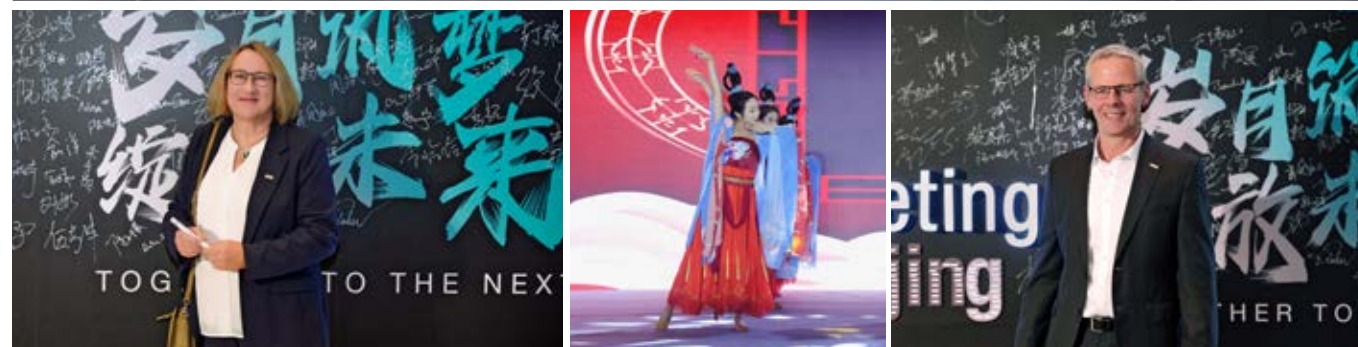
” **WITH THE THIRD FE55 TABLET PRESS AND THE PROVEN COLLABORATION WITH FETTE COMPACTING, WE BELIEVE WE ARE IDEALLY EQUIPPED TO CONTINUE TO FULFILL OUR HEALTHCARE MISSION IN THE FUTURE.** “

Lambert Guri, Senior Engineering & Facilities Manager at Ferrer



FOR CHINA AND BEYOND

In September 2024, the anniversary was duly celebrated in Nanjing.



” **YOUR ENORMOUS TRUST AND MANY YEARS OF LOYALTY TO THE TECHNOLOGY AND SERVICES OF FETTE COMPACTING ARE THE REASON WHY WE ARE WHERE WE ARE TODAY IN CHINA.** “

Joachim Dittrich, CEO of Fette Compacting

For 20 years, Fette Compacting China has been supporting customers in China and internationally. The new F10p tablet press was launched to mark the anniversary. Further innovations will follow to support the still growing number of customers even more comprehensively.

Success is best when it can be shared. That is why Fette Compacting China invited customers to celebrate its 20th anniversary in September. Guests and hosts exchanged views about developments in the market, toured the plant and rounded off the day with a festive dinner. In his speech, Joachim Dittrich, CEO of Fette Compacting, thanked everyone who had contributed to the company's success. Addressing the customers, he said: "Your enormous trust and many years of loyalty to the technology and services of Fette Compacting are the reason why we are where we are today in China."

The success story of Fette Compacting China began more than 20 years ago with a realization: China was becoming a hotspot for business growth and low-cost but high-quality industrial production. This was accompanied by the need for cost-efficient, high-performance machines. This realization was decisive for the founding of Fette Compacting China. Looking back, the establishment of a complete company with production, after-sales services and a laboratory has contributed significantly to the reputation and business development of Fette Compacting in China.

New p Series: proven and highly modern

Dynamic – this is perhaps the best word to describe Fette Compacting China, as demonstrated by its numerous innovations (see timeline on the following page). The next generation of the p Series is being launched this year to mark the company's 20th anniversary. Each of the three models combines high productivity, robustness and compactness. In addition, the new p Series impresses with modern energy-saving technology, even more intuitive operation, and simple solutions when it comes to integrating process equipment. The smallest new model, the F10p, is suitable for small to medium-sized batches. The F20p serves as a flexible all-rounder and the large F30p can produce up to 1.14 million tablets per hour.

"The p Series has really helped to open up new markets for Fette Compacting," explains Dr. Andreas Risch, Managing Director at the Chinese site since 2016. "Its reliability, quality, cost efficiency and sustainable performance have won over many companies." Recently, further development was necessary, because although the p Series is still working well and has been continuously updated, several components are approaching the end of their industrial life cycle. Risch explains: "With the new p Series, we are able to offer our customers and all interested parties tablet presses that are both tried and tested and in compliance with the state of the art. In my view, it is an important signal and commitment to our customers as well as the industry as a whole that Fette Compacting continues to offer the widest range of solutions for tablet manufacturers."



Shaping the market: Highlights from 20 years

- 2004** The P2020 is launched to coincide with the founding of Fette Compacting China.
- 2009** Fette Compacting China starts direct sales.
- 2011-2014** New models of the p Series are launched onto the market.
- 2015** Trainers share their technical and process knowledge at the new LMT Group Academy in China.
- 2018** Fette Compacting China moves into the new plant with a state-of-the-art Competence Center.
- 2022/2023** A Chinese-German team works on a platform for the new p Series.
- 2024** Launch of the new p Series with the three models F10p, F20p and F30p for the respective customer requirements.

Providing customers with the best possible support

Fette Compacting China is also part of the Group's global strategy: from a pure machine manufacturer to an integrated process partner. This includes getting involved in the entire process at a much earlier stage and supporting customers as early as formulation development and validation. The team in China also wants to provide intensive support in building up expertise in local companies for processes such as continuous direct compression with the FE CPS. All of these services are currently being further expanded.

In addition, the "China-for-China" portfolio is also being expanded. New products, some of which are being developed with regional partners, will complement the range and offer customers added value in the areas of tablet production and upstream and downstream processes.

But it's not just about business. Fette Compacting China is also working to improve sustainability. The focus is on the environment and climate change, health and safety, and the global supply chain. "As a company, we are aware of our responsibility and have set ourselves ambitious goals in this area, too. This is how we improve our sustainability and that of our customers," emphasizes Risch.



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” WITH THE NEW P SERIES, WE ARE ABLE TO OFFER OUR CUSTOMERS AND ALL INTERESTED PARTIES TABLET PRESSES THAT ARE BOTH TRIED AND TESTED AND IN COMPLIANCE WITH THE STATE OF THE ART. “

Dr. Andreas Risch, Managing Director of Fette Compacting China

FROM THE WORLD OF FETTE COMPACTING

Leading trade fairs in India and China

Full steam ahead in Asia

In India and China, Fette Compacting presented a range of innovative technologies for the pharmaceutical and nutraceutical industries. The spotlight was on the FE CPS continuous system and the new p Series, enabling users to significantly increase their productivity.

The PMEC in Greater Noida, on the outskirts of the Indian capital Delhi, kicked off the event at the end of 2023. Under the motto "Together to the Next", Fette Compacting presented the FE55 tablet press, the F10i single rotary press with containment option, and the F Lab 10 powder compaction analysis unit. One of the highlights was the first live video demonstration of the FE CPS for continuous production.

At PMEC 2024, Fette Compacting is now going one step further, as Ashok Gourish, Managing Director of Fette Compacting India, explains: "At this year's PMEC, the focus will be on our FE CPS dosing-mixing unit, which is celebrating its premiere in India. This on-site presentation underlines our relentless pursuit of innovation. But the FE CPS is more than just a product: It represents our commitment to the highest standards of efficiency and quality in pharmaceutical production. In addition, we show that our solutions offer a holistic view of the entire production process, supported by our comprehensive range of consulting and services."

Visitors to the Fette Compacting stand in China were also able to experience a great deal of passion for processes and technologies: In spring 2024, the sales team from Nanjing presented the F30p tablet press for the first time at CIPM Spring in Qingdao. The new p Series is characterized by state-of-the-art standards in terms of productivity, universality, robustness and efficiency. The team in Xiamen then exhibited all three models of the new p Series for the first time at CIPM Autumn in November 2024 (more on the new p Series and China from page 22). The continuous direct compression line with the FE CPS also celebrated its premiere in China at this trade fair.

This continuous line represents an integrated processing solution that goes beyond pure tableting and covers the entire process from mixing to direct compression in a single system," emphasizes Dr. Andreas Risch, Managing Director of Fette Compacting China. "This is a significant step toward efficiency and sustainability, which supports the growing demands on energy and raw material savings. This development will attract a lot of attention in China."



The continuous direct compression line with the FE CPS is the technical star at the PMEC (still via live video demonstration in 2023, on site for the first time in 2024). Photo: Chirag Shah, Aby Bapu, Vishal Shah, Saughta Ghose, Joachim Dittrich, Ganpat Pote, Durgesh Rajadhyaksha.



Dr. Andreas Risch, Managing Director of Fette Compacting China (pictured right), received sterling support at the premiere of the F30p tablet press at CIPM Spring 2024.

Specialists conferences in Austria and Mexico

Expertise in demand

The ECCPM conference in Graz and the ISPE Pharma 4.0 Conference in Guadalajara were recent meeting places for industry experts in pharmaceutical production. Experts from Fette Compacting provided ground-breaking insights into process technology.

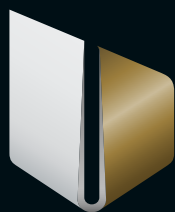
As part of the ECCPM (European Conference on Continuous Pharmaceutical Manufacturing), which took place from September 11-12, 2024 in Graz, Austria, Shana van de Steene, Application Specialist at Fette Compacting, spoke about key developments in the continuous direct compression of solid oral dosage forms. In her presentation, she emphasized how continuous manufacturing processes can be designed to be reliable, efficient and user-friendly.

Shortly afterwards, Dr. Martin Schöler, Vice President Technology at Fette Compacting, spoke at the ISPE Pharma 4.0 Conference, which took place in Guadalajara on September 25 and 26, 2024. His presentation used three case studies – embedded Process Analytical Technology (ePAT), Next-Gen Software Development, and Qualified Experience Database (QED) – to illustrate how digital innovations can significantly improve process efficiency and product quality.

iF Design Award and German Brand Award Five-fold success

Fette Compacting won three awards at the prestigious iF Design Awards 2024. The winning projects include the innovative FE CPS continuous processing system, the technologically pioneering tablet press F20i and the corporate website with a great user experience. The iF Design Award, which has been presented since 1954 and is regarded as a global seal of quality for excellent design, honors exceptional contributions in various areas of design and technology.

In addition, the jury of the German Brand Award honored Fette Compacting with two prizes this year: an award for excellent performance in the area of corporate social responsibility and another award for excellent brand management.



german
brand
award
24



” **THE MATERIALITY ANALYSIS HELPS US TO IDENTIFY THE MOST RELEVANT SUSTAINABILITY ISSUES FOR OUR COMPANY AND OUR STAKEHOLDERS.** “

Sabrina Reinsch, Corporate Sustainability Manager at Fette Compacting

Sustainability

Essential information at a glance

Frameworks such as the Corporate Social Responsibility Directive (CSRD) oblige companies to meet new standards in non-financial reporting. The LMT Group with its two operating divisions Fette Compacting and LMT Tools will also have to report in accordance with regulatory requirements from 2026 on. To this end, the project team led by Corporate Sustainability Manager Sabrina Reinsch is already setting the course for this and has carried out a comprehensive materiality analysis.

Ms. Reinsch, why was the materiality analysis so important for the LMT Group?

This analysis not only enables us to meet the requirements of the CSRD, it also brings many benefits for us as a company and for our customers: the materiality analysis is a central component of any sustainability strategy. It helps us to identify the most relevant sustainability issues for our company and our stakeholders. By prioritizing these topics, we can target our resources and focus on the areas that contribute the most to becoming more sustainable.

What hurdles did you overcome during the analysis?

This was the first time we carried out a materiality analysis, so it had to be well organized as many different departments work together. It was particularly important to us to document all results and processes in detail so that they are comprehensible for our customers and in the audit by our auditor. We also involved our management at an early stage in order to create a clear understanding of the strategic importance of the analysis. We systematically planned the entire procedure and sought advice from external experts.

What are the results of the materiality analysis?

The results are in line with the topics that we have already identified as relevant and integrated into our sustainability strategy. We were very pleased with this because it shows that we are on the right track. Specifically, we identified 11 of the 18 topics examined in the areas of environment, social affairs, and governance as material, including climate protection, circular economy, energy, working conditions, and anti-discrimination. We will focus even more strongly on these topics in the future. This will enable us to optimize our sustainability efforts and continue to improve.



Sustainability Report 2023

The new Sustainability Report for Fette Compacting is available. It provides insights into the strategic areas of activity of economy, ecology, man and the environment, and responsible corporate leadership.

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