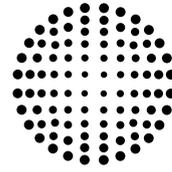


together from lab to production



FETTE
COMPACTING

**Holistic process partnership
for faster time-to-market**



together 
from lab
to production



Working together successfully from the first idea to the finished product



The pharmaceutical industry is facing growing challenges: New products need to be brought to market faster, while quality and safety requirements are increasing and formulations are becoming more complex. As an experienced process partner, Fette Compacting supports pharmaceutical and nutrition manufacturers with decades of expertise along the entire product life cycle - from the initial formulation idea to market launch and production.

Our holistic approach combines pharmaceutical development with production technology. The close integration of both areas results in innovative solutions for efficient development processes and rapid time-to-market. The focus is on understanding critical material properties and process parameters at an early stage, which allows for accelerated confirmation of progress throughout the entire OSD lifecycle.

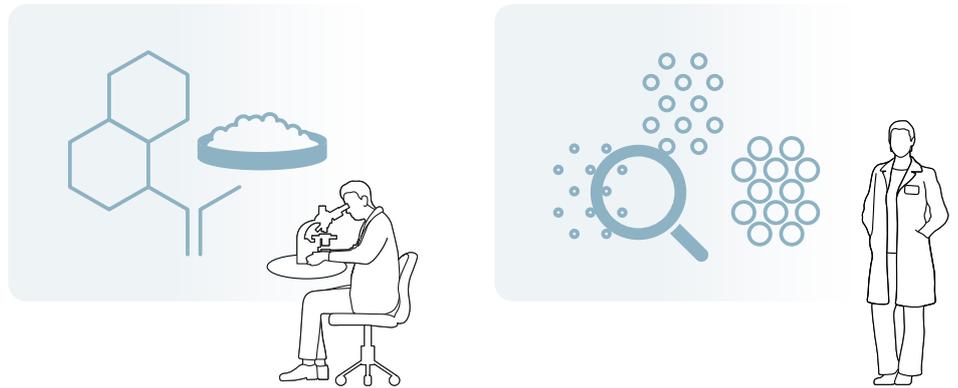
Fette Compacting's services start with formulation and process development. State-of-the-art analytics as well as extensive expertise lead to optimized formulations, processes and control strategies. When it comes to technology transfer, customers benefit from a seamless transition to production with support during the approval process. In addition, our experts support process validation and continuous optimization.

This partnership creates measurable benefits: shorter development times and accelerated market launches with minimized use of resources. The integration of knowledge and technology raises the production process to a new level of quality – for tailor-made solutions with real added value.



From knowledge to practical value: The integrated development and production process

Research and Development



Extended range of services
along the process chain:



Formulation development

Process development

Material characterization

Control strategy

Analytical laboratory services

QED knowledge database

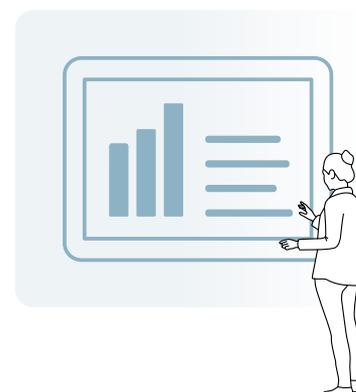
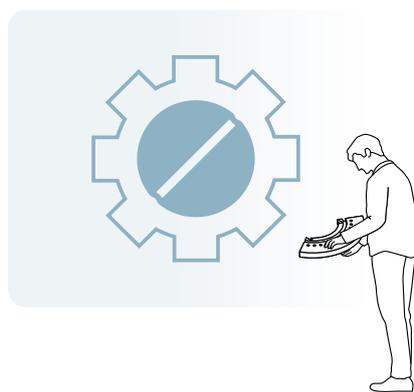
More than 75 years of concentrated expert knowledge from tableting form the digital basis for process decisions. The QED (Qualified Expert Database) enables fast, well-founded solutions for every product requirement.

Formulation development

The experts in Fette Compacting's Competence Centers support customers from the early stages of drug development. From basic formulation consulting to precise material characterization, lab solutions combine pharmaceutical expertise with analytical precision.

Process development

Innovative emulators are at the heart of holistic process development that translates an understanding of materials into robust production strategies. The early integration of state-of-the-art process analytics (ePAT) results in validatable processes with maximum efficiency and minimal product usage.

Production

Regulatory Support
Production support
Process transfer and validation
Performance consulting
Technology transfer

The critical transition from development to commercial production is ensured by a seamless transfer service. Fette Compacting's ability to provide multiple solutions facilitates both the smooth transfer of projects, and adaptive flexibility to changes.

Production

Fette Compacting offers two options for industrial production: Continuous Manufacturing with the FE CPS sets new standards in Continuous Direct Compression, and processes up to six materials with throughput rates from 5 to over 200 kg/h. State-of-the-art tablet presses with innovative containment solutions are available for classic batch production. In both cases, users benefit from embedded process analytical technology (ePAT) for real-time monitoring of quality parameters.

Process optimization

We provide on-site optimization of ongoing production processes by experienced performance consultants. They use systematic analyses to identify improvement opportunities and develop tailored optimization strategies. The spectrum ranges from increasing efficiency and improving quality to reducing costs. Regular performance reviews and targeted service assignments ensure optimum production conditions in the long term.

Lab Services

Expertise for ideal formulations

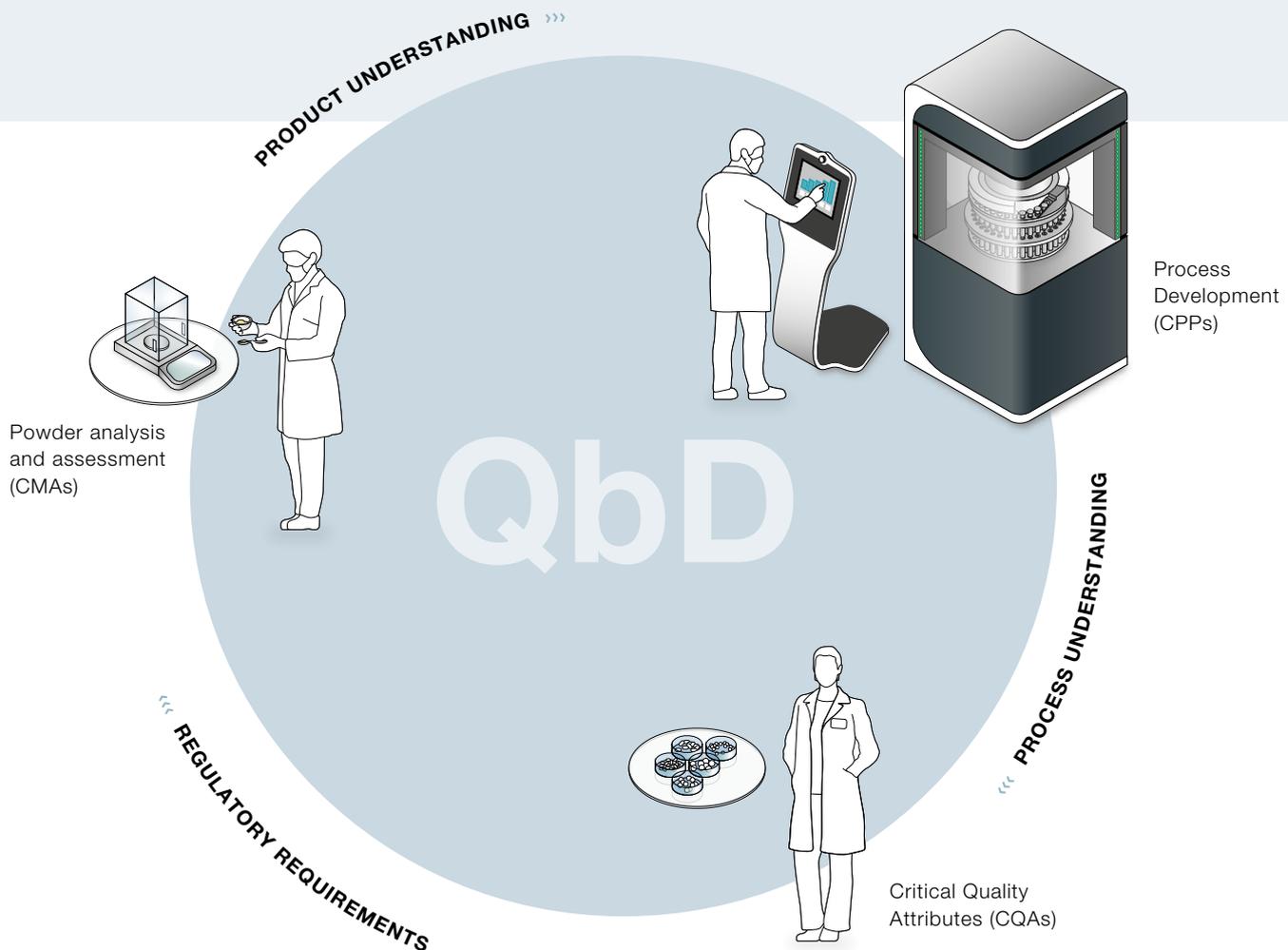
Based on the Quality-by-Design approach, the experts at Fette Compacting provide support in the systematic identification of critical material characteristics (CMAs) and develop robust control strategies for subsequent production.

Laboratory services:

- + Advice on new formulations and feasibility studies
- + Characterization of active ingredients and excipients
- + Analysis of powder mixtures and individual tablets
- + Comparative studies of different formulations
- + Development of optimal process parameters
- + Clinical Batch
- + Stability test

Expert support:

- + Interdisciplinary teams from pharmacy and process engineering
- + On-site training and application consulting
- + Support with method development
- + Transfer from laboratory to production processes
- + Documentation in accordance with regulatory requirements



F Lab 10

Precise material analysis for formulation development



The F Lab 10 enables material characterization in the early development phase. The modular analysis system provides a comprehensive picture of all critical powder and tablet properties - with minimum material usage and maximum informative value for the subsequent production process.

System variants:

- + For tablets up to 15 mm (compression force up to 10 kN)
- + Flexible integration of additional analytical instruments
- + Automatic data transfer of all components
- + User-friendly software for complete data analysis

Analyzing process:

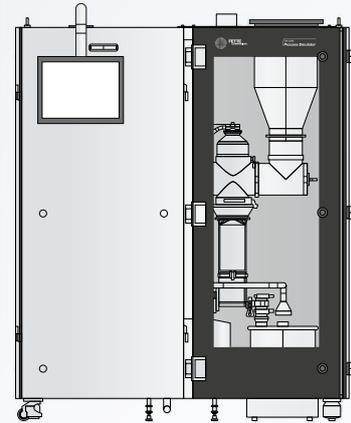
- + Simple powder compaction with minimum sample quantity
- + Precise measurement of all tablet properties
- + Comprehensive evaluation via computer program
- + Complete measurement series in less than one hour
- + Visualization via intuitive graphics

Emulators

Process development under real conditions

FE CPS **Process Emulator**

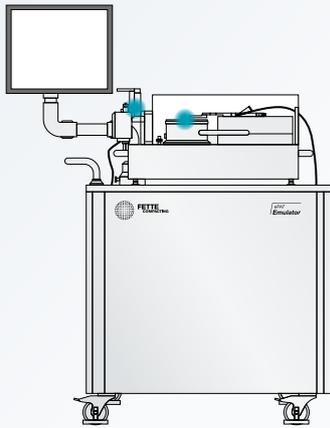
Fette Compacting's emulators enable the development and validation of processes under real production conditions. This innovative technology accelerates the validation of recipes and the detection of potential faults as early as the development phase. Unlike simulators, the systems work without conversion steps and loss of time.



FE CPS Process Emulator:

- + Precise emulation of the dosing process in the FE CPS as the basis for homogeneity
- + Systematic tests of different refill configurations
- + Optimization of dosing parameters for different base materials
- + Identical HMI control for direct transferability of dosing recipes
- + Versatile applicability in development and production environments

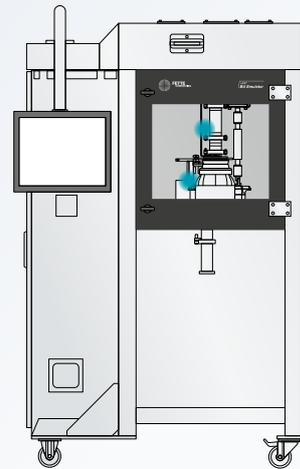
ePAT Emulator



ePAT Emulator:

- + Near-infrared (NIR) spectroscopic analysis under real production conditions
- + Exact emulation of the Tablet Uniformity (TU) measurement in the tablet press
- + Optimization of spectrometer settings and measurement speed
- + Calibration and validation of chemometric models
- + Optional Blend Uniformity (BU) sensor for comprehensive powder analysis

ePAT BU Emulator



ePAT BU Emulator:

- + True-to-original filling device as in the tablet press
- + Development of spectroscopic methods under real filling conditions
- + Integrated BU sensor for homogeneity analysis
- + Authentic simulation of powder dynamics in the filling system
- + cGMP-compliant software integration for direct method transfer

FE CPS

Continuous process excellence in every phase

Development and scale-up:

- + Minimal use of materials in early development (from 5 kg/h)
- + Generic design and flexible adaptation of ingredient concentrations as well as integrated real-time analysis
- + Direct transferability of development results
- + Efficient scale-up without process adjustments
- + Up to 90 % material savings compared to batch development

Process integration:

- + Processing of up to six starting materials or premixes
- + Precise dosing and innovative two-zone mixing technology
- + Special powder transport system without segregation
- + Installation on just one level with a small footprint

Production:

- + Continuous Direct Compression
- + Significantly reduced process costs compared to granulation
- + Flexible throughput rates from 5 to over 200 kg/h
- + Processing of a wide range of powder properties
- + Closed system for high operator and product safety
- + High energy efficiency and compact footprint
- + Simple operation, quick cleaning and changeover

Quality assurance:

- + Embedded process analytical technology (ePAT) at all critical points
- + Continuous NIR spectroscopy
- + 100 % tablet inspection in real time
- + Automatic rejection in the event of deviations
- + cGMP-compliant overall system



F
E | CPS

TU sensor

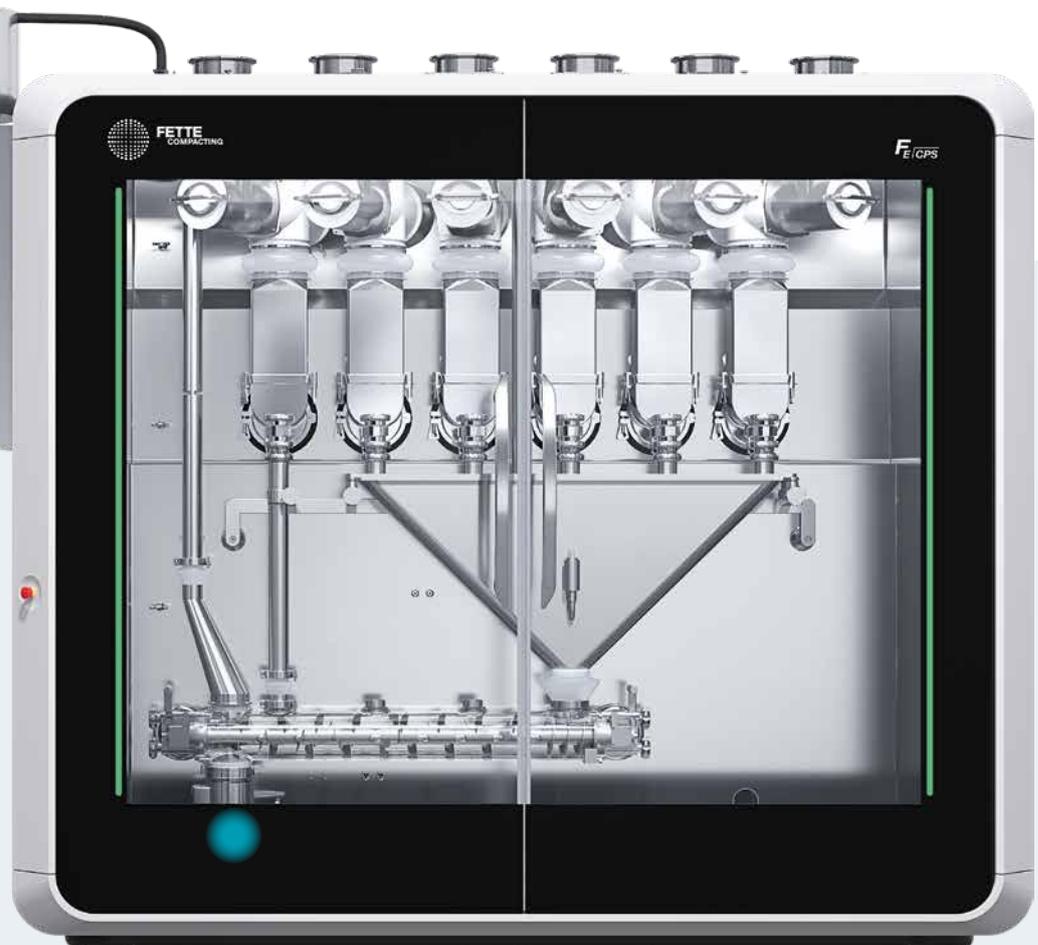


BU sensor



ePAT

ePAT (embedded Process Analytical Technology)



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