

research  
center  
pharmaceutical  
engineering



We make  
tomorrow's  
drugs  
possible

## A Clear Path to Technical Success



Together with the global players in the pharmaceutical industry, Research Center Pharmaceutical Engineering GmbH (RCPE) performs cutting-edge research in the field of process and product optimization.

Our focus is on the development of new drug delivery systems and on the associated production processes and their monitoring. The Center's excellent performance is due not only to its experienced interdisciplinary international team but to its location in close proximity to the universities of Graz. As a link between science and industry, RCPE carries out state-of-the-art business-oriented research.

Our performance and innovation potential ensure excellent results for our clients. We are proud of the constantly growing number of partners who trust in our competence and commitment and benefit from the expertise of our highly-qualified staff and top-level technical equipment.

Since its establishment in 2008, RCPE has won several awards, e.g. the Fast-Forward Award 2011 and the Step Award 2012. We are confident that our research efforts contribute significantly to the development of drugs of the future and look forward to tackling forthcoming challenges.



Univ.-Prof. DI Dr. Johannes G. Khinast  
Scientific Director / Leader



Mag. DI Dr. Thomas K. Klein  
Managing Director



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## Comprehensive Services at a Single Source

The most important objective of the medical and pharmaceutical sciences and technologies is to serve patients and the society. Ongoing progress in curing and managing diseases, improving health and well-being and maintaining a productive lifestyle and independent living as long as possible is based on significant and exponential advances of academic and industrial R&D. The mission of RCPE to “make tomorrow’s drugs possible” is grounded in sound science and technology, with the objective of helping patients in close collaboration with other academic and industrial partners and creating added value for the patients, society and industry.

RCPE’s highly-motivated and experienced research team assures fast and efficient execution of the R&D efforts for maximum customer satisfaction. We view ourselves as a one-stop-shop that offers package solutions for scientific and R&D challenges of the future.

RCPE’s primary goal is to establish Styria and Austria as the European region for pharmaceutical product and process development. We aim to transform the empirical approach into a rational science-based endeavor in accordance with ICH’s Quality-by-Design framework.

To that end, we combine multidisciplinary expertise in process engineering, pharmacy, chemistry, biotechnology, material science and nanotechnology. In close collaboration with national and international partners from the pharmaceutical, biopharmaceutical and diagnostic industries, we develop methods for design, optimization, scale-up and control of their new manufacturing processes. To ensure excellent staff quality in the future, we pursue targeted education and gender mainstreaming activities in the human resource development. Moreover, we act as an information center and a knowledge exchange interface between science and industry.

### **We create business advantages for our partners who profit in various ways from our wide array of services:**

- competitive, applied R&D in product and process optimization with rational, science-based methods derived from a mechanistic understanding of the relevant phenomena on all scales
- independent R&D in pharmaceutical engineering, bridging the gap between science and industrial applications
- diverse research activities, from small preparatory studies (literature reviews, initial measurements, proof of concept) to extensive multiannual research programs
- increasing the sustainability profile by reducing the costs and time requirements in the pharmaceutical development
- defined IPRs for the maximum benefit of industrial partners
- high-tech laboratory with state-of-the-art equipment (analytical and process equipment)
- additional research opportunities via national and international partner networks in science and industry create individualized complete solutions at a single source: scientific approaches and economic requirements tailored to specific needs
- distinct economy, efficiency and market orientation to maximize customer benefits



# Successful Spin-Offs

In the recent years, we have repeatedly proven that we can create added value and new jobs via innovative and marketable product development. The best examples of it are our three spin-offs, which successfully operate in the following areas:



## Pharmaceutical and Regulatory Services GmbH (PRSG)

PRSG offers services that cover all aspects of regulatory affairs and is a one-stop-shop for medicinal products, radiopharmaceuticals, medical devices class 1, nutritional supplements and wellness products. It specializes in consulting, dossier creation/maintenance, life cycle management and comprehensive support of authorizations and project registration on the European and national levels. The target group of competent consulting and individual complete solutions for the entire approval process are pharmaceutical companies.



PRSG: Mag. Lydia Langkammer



## roombiotic GmbH

The company develops custom-made solutions for optimized hygiene in hard-to-reach areas with the help of volatile substances that spread through the air and thoroughly and safely reach surfaces and niche areas. This utterly flexible technology is effective against mold fungus, yeasts and hospital germs.



roombiotic: Mag. Dr. Stefan Liebming



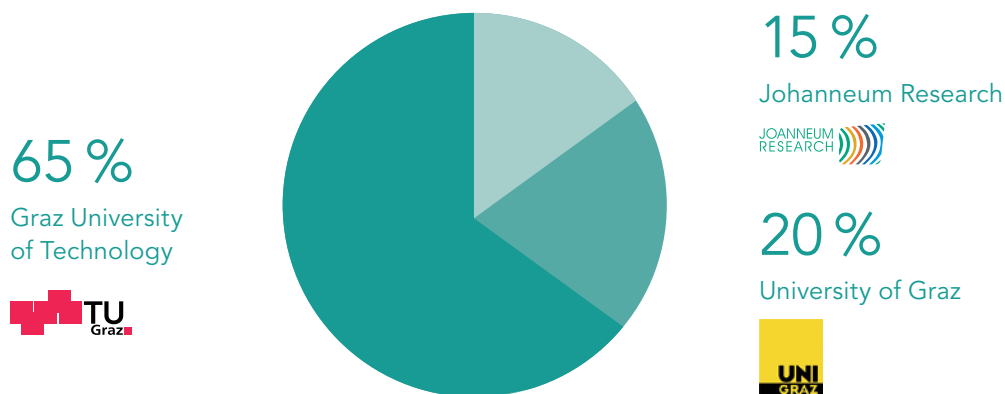
## SES-Tec OG

SES-Tec (Scientific & Engineering Simulation Technology) has excellent know-how in the area of multiphysical simulations and development of customer-specific software solutions. By integrating four flow simulation models, thermodynamics, structure mechanics and particle and process engineering, SES-Tec offers customer-specific solutions to complex problems.



SES-Tec: Dr. Dalibor Jajcevic and Dr. Wolfgang Lang (v.l.n.r.)

## Ownership and Funding



RCPE ownership structure 2014

Our success would not be possible without the commitment of the owners and funding organizations, which endorse and support us on our path. Our shareholders Graz University of Technology, the University of Graz and Joanneum Research Forschungsgesellschaft mbH meet our needs perfectly.

### Graz University of Technology


"With enthusiasm together to the international top" is the slogan of Graz University of Technology, which reflects the nature of the partnership between RCPE and its principal owner that was primarily responsible for establishing the new and promising research area in Graz. RCPE is located on the university campus, which facilitates close collaboration with the university. Apart from scientific expertise, RCPE can benefit from access to the university's equipment. Moreover, the master program "Chemical and Pharmaceutical Engineering" provides training to RCPE's future employees.

### University of Graz

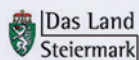
Austria's second oldest university has well-established standards that have a significant impact on RCPE. Basic and applied research based on the foundations of scientific and ethical integrity are the university's main assets. Innovative interdisciplinary research and cooperation are especially encouraged. One of the interdisciplinary research fields is "Chemical and Pharmaceutical Engineering," which was established as an inter-university master program with Graz University of Technology.

### Joanneum Research

Joanneum Research is a business-oriented innovation and technology provider, which conducts top-level research at an international level. Focused on applied research and technology development, it plays a key role in the technology and knowledge transfer in Styria. RCPE benefits from the core expertise of Joanneum Research in the fields of bio and pharmaceutical analysis, study planning, health economics as well as data management and statistics. This partnership creates a tight link between research and industry.



Various funding institutions foster worldwide co-operation between business and research institutions, making top-level research possible. RCPE is funded by the Austrian COMET Program under the auspices of the Austrian Federal Ministry of Transport, Innovation and Technology (bmvit), the Austrian Federal Ministry of Science, Research and Economy (bmwfw) and by the State of Styria (Styrian Funding Agency SFG). COMET is managed by the Austrian Research Promotion Agency FFG.



## Partnerships

Creating innovation is our daily work. We have accumulated substantial resources and have partners in various branches. By complementing specific competences and ensuring valuable synergies, we implement novel solutions.

### Partners in Science

Our partners in science comprise universities and non-university research facilities. We benefit from our partners' internationally recognized potential and have access to their extensive research infra-

structure. The partnerships focus on acquiring and exchanging of the newest scientific discoveries.



### Associated Partners

The group of associated partners includes companies, which support us in various ways. They are either scientific institutions or commercial

enterprises, with which we have established a mutually advantageous service exchange that is not commercially oriented.





### Business Partners

As an enterprise whose R&D services are strongly oriented towards the implementation of marketable products, we cooperate with a multitude of

companies. The spectrum of our business partners ranges from successful small businesses to multinational pharmaceutical corporations.







# Opportunities for Cooperation

Established as a K1 Competence Center within the COMET Program, RCPE has an overall project volume of about 4-5 million Euros per year. While maintaining a close relationship with academia, RCPE succeeded in becoming a company that provides both scientific excellence and leadership, with a highly professional management of HR, finances and business operations. As a private entity, RCPE offers its partners highly flexible business models that allow to set up particular teams and maximize the cost efficiency.

RCPE's clients can choose from a wide variety of funded and non-funded cooperation scenarios:

## **K1 projects**

The COMET program features K1 projects that offer many advantages to both scientific and industrial partners (each project consortium must have at least one scientific and two industrial partners). In contrast to other national and international funding programs, K1 funding does not require time-consuming application procedures and has no strict regulations: the project simply has to fit RCPE's scientific focus and ensure that new scientific know-how is generated. Another advantage is that the consortia of company and scientific project partners do not have to cover the entire research-related project costs.

## **NonK projects**

NonK projects are implemented within the non-sponsored project area, and project costs have to be fully covered by the project consortium. The big advantage is that NonK projects are not bound by strict regulations and can be customized to the needs of a specific client. Particularly for industrial partners that would like to reduce the publicity (e.g., publication of the results is not obligatory), performing a project within the NonK area can be highly attractive. Moreover, it can be combined with a K1 project, offering additional business flexibility.

- Funded NonK projects offer an opportunity to significantly reduce the costs of a NonK-project by applying to national and international funding programs (e.g., Framework Program of the European Union).
- Within the scope of Contractual Research Projects (Service Projects), RCPE acts as a contractor and provides specific services to one or more clients that fully cover the costs without any internal or external funding. Contractual research projects at RCPE cover a wide span of services, from small studies to long-term projects, with our clients receiving full rights to the project's results. In this case, combining K1 and NonK projects can be used as an effective tool of reducing the overall project costs.

## **Strategic partnerships**

RCPE's strategic partnerships focus on clients that are more interested in long-term cooperation rather than a specific service. In this case, RCPE provides access to its equipment and highly-qualified personnel at competitive rates. The long-term contacts between the clients and RCPE's employees are highly beneficial for our industrial partners.

Regardless of the cooperation scenario, a perfectly designed one-stop-shop that offers customized package solutions, RCPE is the ideal partner for both science- and business-oriented industries.





## Staff: The Key to Success

Although high-grade technical equipment is essential for a research facility, what is much more important are the people. With their power of imagination, personal commitment, experience and education, they make cutting-edge new developments possible.

We owe our success to our staff. More than half of our employees have university degrees and many come from abroad, highlighting our strong international alignment.

A major focus of our human resources development is creating equal opportunities for women. We are happy that with the aid of various programs and special offers more and more women choose to work with us.

In order to insure that we have well-qualified personnel in the future, we maintain contact with various schools and universities. By participating in such initiatives as "Regional Talents" and other events, we promote interest in our work and attractive jobs at the Center.

The variety of our offers is not only the result of our broad range of competences. Our project teams are made of people with diverse qualifications, ensuring a holistic view of problem definitions and a comprehensive solution development. We maintain high quality through active knowledge exchange and cooperation with the employees of our industrial and scientific partners. Many of them often work at RCPE, and our staff temporarily works at our partners' location.







## Laboratory and Technical Center: High-Tech Analysis

At our laboratory facility we investigate solid dosage forms (powders, tablets, pills, pellets, granules, capsules, etc.) relevant to pharmaceutical applications. For material characterization, comprehensive laboratory equipment is available, including typical analytical instruments, such as HPLC/UPLC and GC chromatography, and primarily, measuring systems for the characterization of particles and powder properties. Among them are, for example, devices for particle size and shape analysis, a powder rheometer and a contact angle measuring instrument.

In addition, two dissolution devices for determining the active pharmaceutical ingredient release in a mixed liquefied buffer medium and other measurement systems for the analysis of solids (X-ray diffraction, density determination, surface area and porosity analyzers etc.) are also available, as well as devices and machines for the production of solid dosage forms in lab-batch quantities in non-GMP conditions.

Our Technical Center has three laboratory extruders (MIC 27 Leistritz, ZSK18 Coperion Pharma Extruder, DE 40 Gabler), a tablet press, a compaction simulator, continuous powder dosing and mixing systems and a capsule-filling machine. The machines are not used explicitly for pharmaceutical production, but rather for process development, process understanding and the implementation of process-analytical tools for in-process monitoring, control and process optimization.











## Our Portfolio: Innovative Diversity

RCPE is the partner of choice in of pre-competitive, industrially relevant research in the field of pharmaceutical engineering.

We focus on the design of pharmaceutical and diagnostic products and the associated manufacturing processes based on a detailed understanding of the underlying effects and deductive engineering principles, while recognizing the multi-level functionality and structure of the products.

RCPE has three areas: Area I for modeling, simulation and prediction, Area II for advanced drug products and delivery systems with a strong focus on small molecules and novel solid drug products, and Area III for innovation in the process and manufacturing science. RCPE tackles various challenges associated with process design, scale-up, control, automation and optimization. Four integrating technology thrusts (ITTs) connect the areas and address emerging issues in the field.

Reducing costs, time-to-market and failure rates associated with new product development while establishing novel design and manufacturing approaches is one of the Center's goals.



## Modeling and Prediction

This area deals with modeling and simulation of fluid and granular/powder form media using a broad spectrum of industrial and scientific simulation tools. Coupled simulations of fluid-particle-interactions to study movement, substance exchange and heat transfer are performed, as well as simulations of processes/single unit operations. In addition, special models are developed.

### Our services:

- customer-specific special model development for (partial) processes of relevant production methods in the pharmaceutical and other branches
- process design assistance through advanced simulation and evaluation of the results
- optimization analysis of existing processes through simulations
- visualization of latent (hidden), invisible process sequences
- improving process understanding through structured modeling approaches
- storage, suitable visualization and evaluation of data from simulations and/or experiments in parametric studies (DoE)
- multiscale modeling and simulation of pharmaceutical microstructures in relation to the process, performance and quality, e.g., modeling of nucleation/crystallization of small/large molecules, molecular dynamics simulation and atomistic modeling of diverse physical and chemical interactions/transitions in complex formulation matrices

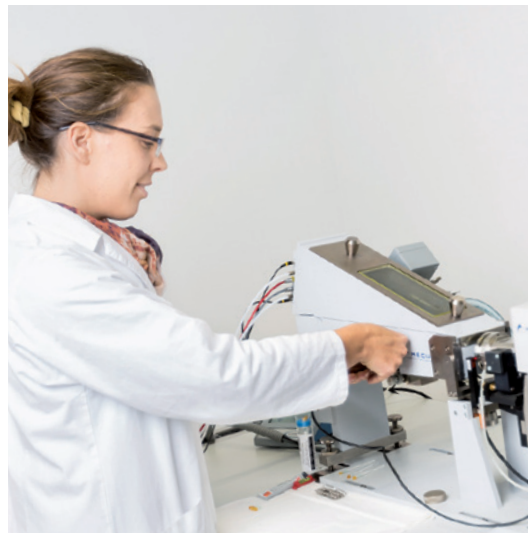


# Material Science

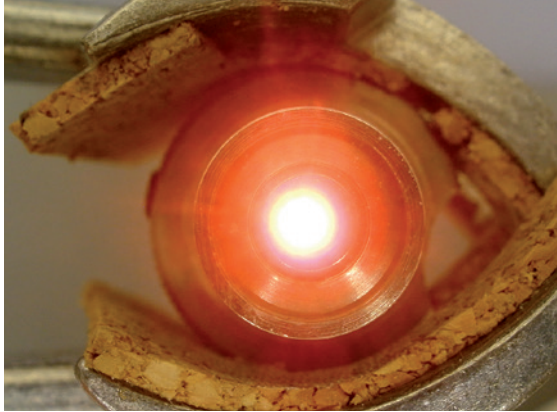
This service area focuses on characterization/identification of raw materials, intermediate and end products. The goal is to provide assistance with various product development activities, e.g., hot-melt extrusion, wet extrusion, tableting and capsule filling.

## Our services:

- micromeritics: particle size/shape and distribution, density, porosity, etc.
- rheology of powders/pellets: flowability, segregation tendency, cohesivity, flow energies, etc.
- surface properties: roughness, topography, charge, heterogeneity, energetic, wettability, etc.
- solid-state characterization: thermal, spectroscopic, melt-rheological, diffractometric, microscopic characterization of solid forms of API, excipients and drug products (amorphous, polymorphs, hydrates/solvates, crystallinity, disorder, miscibility, phase transitions, hygroscopicity, etc.)
- solubility, dissolution and disintegration, drug release
- assay, impurity/degradant profiling using HPLC and UPLC with multiple detector options
- physical/chemical stability studies (standard and accelerated conditions)



# Continuous Process and Quality Control

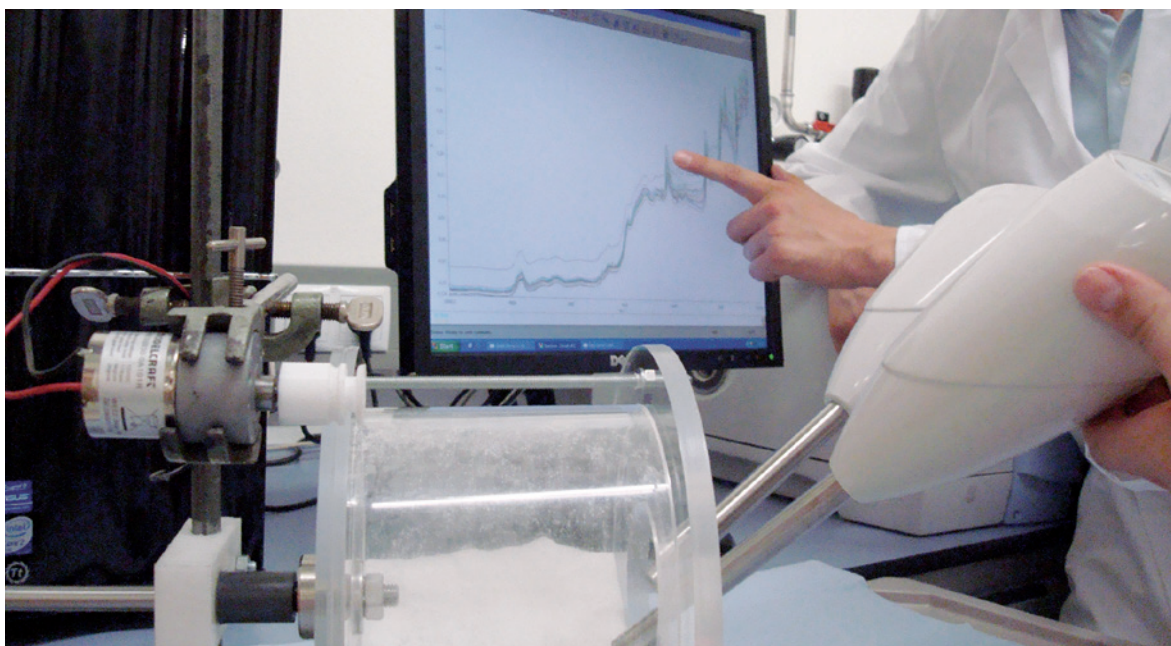


We offer in-line process monitoring using the latest technology, adapt established approaches and develop innovative Process Analytical Technology (PAT) and Optical Coherence Tomography (OCT) methods. To implement existing processes, we apply the Quality-by-Design principle. In addition, we further develop new process-analytical technologies, multivariate sensor technology and multivariate evaluation and analysis of process

data. Finally, we develop solutions for process risk evaluation and achieving process understanding (based on the collected process data).

## Our services:

- implementation of process analysis according to the requirements of our customers' processes
- development of monitoring strategies for existing and new processes
- evaluation of critical process variables and steps via process data analysis
- development of algorithms and analytical tools for real-time evaluation of process data
- process risk management







## Continuous Manufacturing

Our expertise in this area includes the development of continuous process routes and control strategies involving process analyses based on process understanding. To that end, we focus on inline monitoring tools and control strategies embedded into the Quality-by-Design framework in order to implement product quality within the processes. Moreover, we perform economic profiling of continuous processes under development and compare them with established batch processes to evaluate the economic benefit.

### **Our services:**

- process parameter sensitivity analysis
- developing control strategies for continuous processes to assure product quality and achieve real-time release
- transforming batch processes into continuous processes
- selecting appropriate basic operations and processing units for continuous production
- process development to establish the process-specific design space
- economical evaluation of alternative process routes
- process evaluation, critical process step reporting and development of concepts for improvement



# Formulation Engineering

In this area we focus on creating formulation designs for solid medication forms in the early development phase and on innovative strategies for improving active ingredient solubility in solid medication forms for oral administration. With regard to inhaled medication forms, we offer services in the context of particle engineering for increasing the carrier load capacity for carrier-based dry powder inhalers (DPI). Our other competences include personalized and population-oriented formulation development (e.g. for pediatrics and geriatrics) and model-based design, development and processing of formulations through Quality-by-Design (QbD) and *in silico* simulations.

## Our services:

- manufacturing multiparticulate systems for pellets (wet or hot-melt extrusion) and granulates (compacting or fluid bed granulation) for diverse applications
- developing taste-masking multiparticulate systems with quick release profiles as “easy to swallow and dose-tailored” medications, e.g., in geriatrics and pediatrics (methods: fluid bed coating or matrix formation via hot-melt extrusion)
- developing multiparticulate medications with modified release for improving patient compliance by reducing the amount of the administered medication (methods: fluid bed coating or matrix formation via hot-melt extrusion)
- improving solubility of poorly soluble medications using hot-melt extrusion, spray-drying, milling (particle engineering via nanotechnology, cocrystal engineering, manufacturing of solid solution or amorphous solid dispersion systems)
- developing and improving formulations via *in silico* simulations taking into account the pharmacokinetics of the released active ingredient, and prediction of in vivo properties and bioavailability (GastroPlus™)
- particle technologies for tailoring carrier, active pharmaceutical ingredient (API) and formulation properties intended for the carrier based dry powder inhalation (DPI) product development using spray drying, micronization, interactive mixing
- developing and manufacturing personalized low-dose pharmaceutical dosage forms, poorly soluble APIs and their combinations through liquid printing technology





## Platform Technologies: Hot-Melt Extrusion, Injection Molding

In the area of platform technologies, we have comprehensive material characterization know-how, especially of thermal processes, and extensive knowledge of pharmaceutical pellet manufacturing via hot-melt extrusion. On this basis, we develop the concept and design of hot-melt extrusion processes, including downstream processes, in close cooperation with our wide network of equipment manufacturers. Furthermore, our spectrum includes solid state evaluation of the processed active ingredients throughout the entire process cycle (raw material/intermediate/products), process development/optimization and manufacturing of advanced delivery systems via injection molding.

### **Our services:**

- feasibility studies for clarification of formulation system processability via hot-melt extrusion
- state-of-the-art characterization of the products and materials used (solid state, release, stability)
- complete process development of production lines, including implementation of in-line process monitoring
- optimization and transformation of existing processes
- rheological evaluation of polymer/active ingredient systems
- developing alternative dosage forms (IVR, implants etc.)
- identifying and adapting production technologies for application in the pharmaceutical industry





## Drug and Drug Product Profiling

Pre-formulation activities related to the drug product development include understanding and qualifying the interactions between the physico-chemical properties, the drug administration delivery system and the drug's bioavailability. The overall profiling of active pharmaceutical ingredients (APIs) and dosage forms is a complementary approach that integrates scientific expertise in various disciplines, such as material science, analytical science, modeling and simulation and physical chemistry.

### Furthermore, we offer:

- solid form screening and API characterization (polymorphs, salt, hydrates/solvates, amorphous, etc.)
- multi-methodological determination of various physicochemical properties, such as wettability, surface charge, hygroscopicity, micromeritics, molecular and mechanical properties, etc.
- investigation of the dissolution behavior of solid oral dosage forms under bio-relevant test conditions, including wettability assessment,
- evaluation of dissolution rate and solubility of APIs and their potential effect on the related in vivo performance
- application of dissolution testing and hyphenated techniques (USP I, II, III, IV apparatus and modified dissolution systems) as tools for in vitro characterization of API and drug product behavior in selected bio-relevant media (i.e. simulated physiological fluids)
- proven experience with in silico and in vitro predictive technology applications, e.g. GastroPlus™

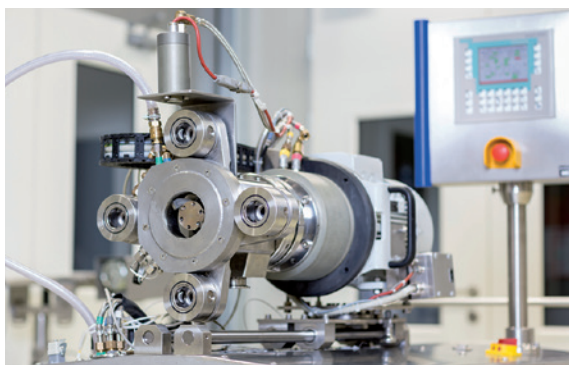




## Project Example

### SIPAT Integration

RCPE has developed a hot-melt extrusion line consisting of a twin-screw extruder, a die face pelletizing system and an NIR process spectrometer for the production of micropellets. The equipment was incorporated into SIPAT, a soft-



ware architecture from Siemens AG, which allows gapless traceability of production parameters of all involved aggregates and active, independent control of the entire line (autonomous automatization).

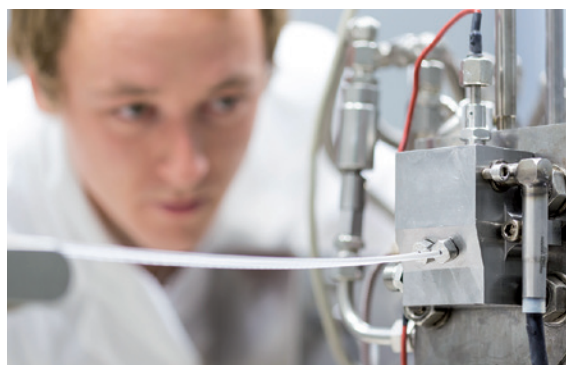
SIPAT uses the design space of a specific process to assure a proper process. In case of deviations in the critical process parameters, the system adjusts the settings according to pre-defined rules without the operator's intervention.

SIPAT offers fast and gapless evaluation of the critical process- and product-specific parameters and represents a very efficient component in a real-time release strategy.

## Project Example

### NanoExtrusion

Due to the increase in the number of poorly soluble active pharmaceutical ingredients (APIs), pharmaceutical scientists focus more and more on innovative formulation platforms for such molecules. Although the emerging field of nanoscience and the application of nanosuspensions in particular offer novel possibilities, there are several issues associated with nanosuspensions: they have stability problems and are typically delivered parenterally, which is an undesired and invasive delivery route. As such, it would be beneficial to transform the nanosuspensions into solid oral dosage forms. However, since the manufacturing of solid-nanoparticle formulations requires several challenging steps, is time- and cost-intensive. Hence, we aimed at developing a one-step nano-extrusion process with the nanosuspension (prepared via wet media milling and/or high pressure homogenization) directly fed into a hot-melt



extruder\*. The de-aggregated nano-crystals are homogeneously distributed in the extrudates, and the drug release rate of the poorly soluble drug can significantly be enhanced.

\* NanoExtrusion: a one-step process for manufacturing solid nanoparticle formulations directly from the liquid phase.



## Project Example

## Combining CFD\* and DEM\*\*



The goal of this project is to develop a computer simulation of particle flow and coupling with gas and fluid flows in complex devices.

Computer simulations can help to control and predict the product quality in complex processes, such as fluidized bed drying of powdery material and tablet coating. For realistic resolutions of industrial devices, numerical methods must handle extremely high particle numbers.

Since commercial programs can only manage 100,000 particles, we used the software prototype Xtended Particle System (XPS) within the project. This software implements the DEM with the newest GPU/CUDA technology and can process significantly higher particle numbers (up to 120 million).

While XPS simulates solid particles or sprays, the gas phase (e.g. the incoming drying air) is calculated with the flow simulation software AVL FIRE® with a complete two-way coupling of momentum, heat and mass transfers.

Another outstanding feature of the XPS software is that XPS + AVL FIRE® need a single workstation, rather than maintenance-intensive cluster hardware or a data processing center.

\* Computational Fluid Dynamics

\*\* Discrete Element Method

## Project Example

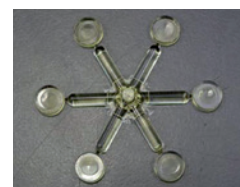
## Hot-Melt Extrusion and Injection Molding

Since 2009, RCPE has been involved in adapting technologies from other industries to manufacturing of pharmaceutical dosage forms. To date, two promising technologies used in the plastics industry have been identified: hot-melt extrusion and injection molding.

Hot-melt extrusion allows the transformation of poorly soluble active ingredients into their amorphous forms, which significantly increases their solubility and bioavailability. By selecting suitable downstream processes, various dosage forms can be produced, such as pellets that can be filled directly into capsules.

Injection molding combines melt extrusion with direct shaping, allowing a one-step-production with the raw materials transformed into the final product within

one unit operation. The short processing time (e.g. 2 minutes from powder into tablets) and the freedom of geometry make this technology a powerful tool of increasing the efficiency and decreasing the complexity of solid dosage forms production.





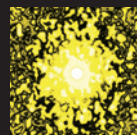
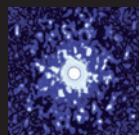
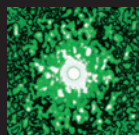
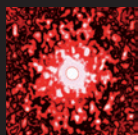
OUR STRONG PARTNERS

*Innovation Needs Partnerships.  
We Thank Our Partners:*



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## PARTIKELMESSTECHNIK PARTICLE MEASUREMENT



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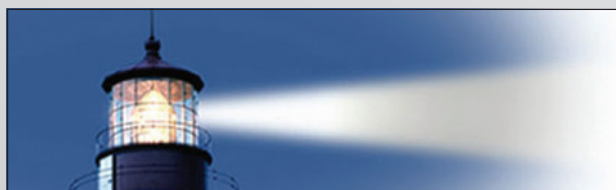


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### Pharma Applications - Focusing On

- Solubility enhancement of poorly soluble API's
- Taste masking of bitter tasting API's
- Adjustment of prolonged drug release with reduced risk of dose dumping
- Monolithic and multiparticulate dosage forms
- Film extrusion as strips or patches
- Wet extrusion
- Wet granulation

### Features & Benefits

- From table top unit up to stand alone solutions
- Suitable for early development (PTSE 12/36 EC) of clinical and sample production (PTSE 12/36, PTSE 20/40)
- Clamshell barrel design, allowing easy cleaning and trouble shooting
- Suitable for PAT



PTSE 20/40

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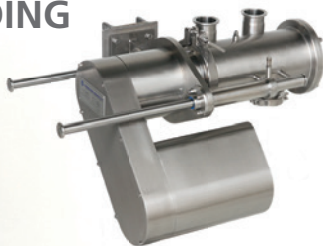
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FROM LAB TO  
PRODUCTION  
SCALE



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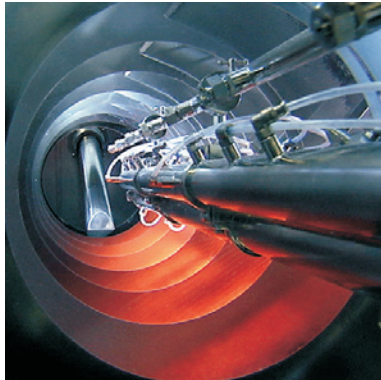


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# DRIACONTI-T pharma<sup>®</sup>

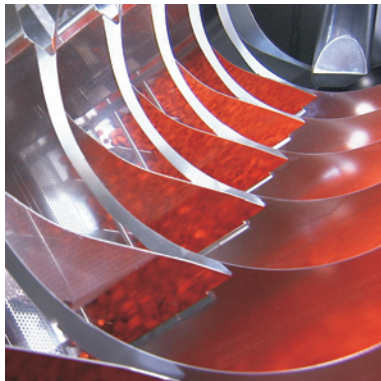
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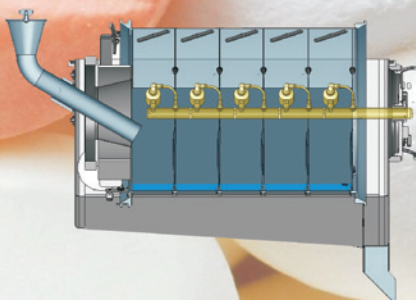


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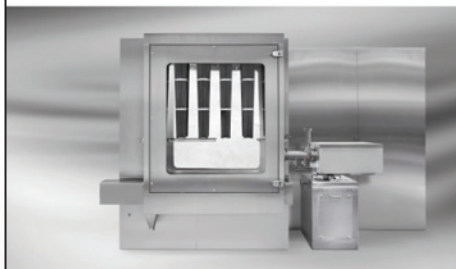
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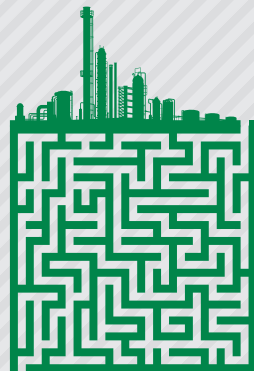
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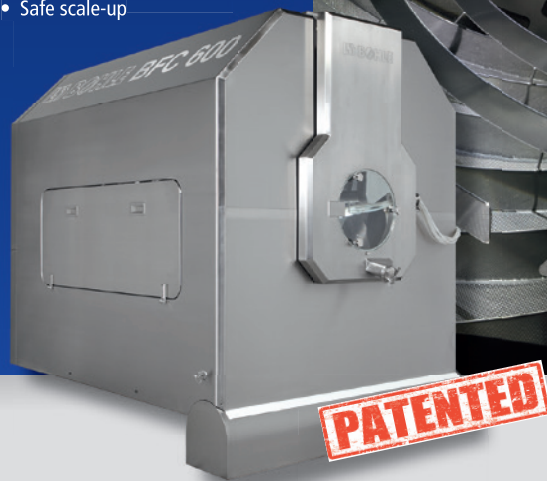
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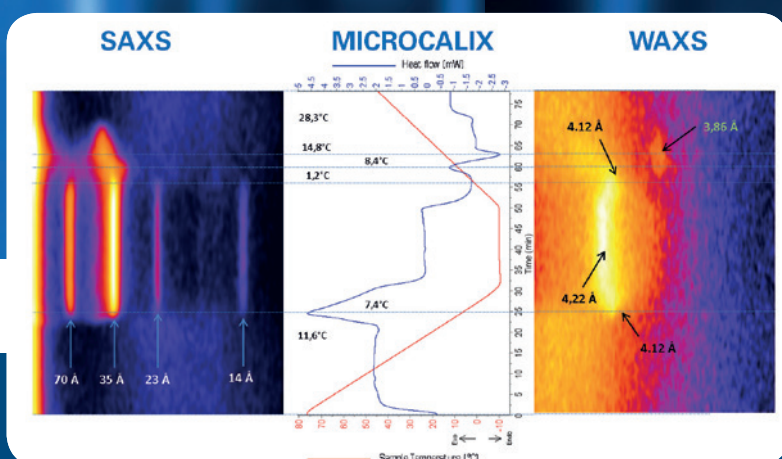
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