research
center
pharmaceutical
engineering

Research Center Pharmaceutical Engineering (RCPE)

Overview

February 2012

K1 Competence Center - Initiated by the Federal Ministry of Transport, Innovation & Technology (BMVIT) and the Federal Ministry of Economy, Family & Youth (BMWFJ). Funded by the Austrian Research Promotion Agency (FFG), Land Steiermark and the Styrian Business Promotion Agency (SFG).

RCPE - Key Facts

- **R**esearch **C**enter **P**harmaceutical **E**ngineering GmbH – **RCPE**
  - Independet research center for pharmaceutical process and product development
  - Located in Graz, Austria
  - 100% owned by research institutions

University of Graz: ***20%***

Joanneum Research: ***15%***

Graz University of Technology: ***65%***

- Our objectives:
  - Reduce costs and time in pharmaceutical development
  - Develop new science-based methods for process and product design
  - Create business advantages for our partners

Success Story

research center pharmaceutical engineering

- RCPE was founded on 1st of July **2008**
- approx. **100 employees and researchers**
- Average turnover: **6.2 M€**
- 10 Scientific Partners and approx. **50 Industrial Partners**
- Patent portfolio:.
  - A system for analyzing a granulate for producing a pharmaceutical product
  - A system and method for manufacturing a medication
  - Methods and compositions for biologically controlling microbial growth on clean room equipment
  - Synthetical Nucleic-Acid-Particle
  - Clean room suit and clean room lock for mutual cooperation in a clean room
  - …
- First **Spin-off** (PRSG) has been launched

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CUSTOMERS & PARTNERS

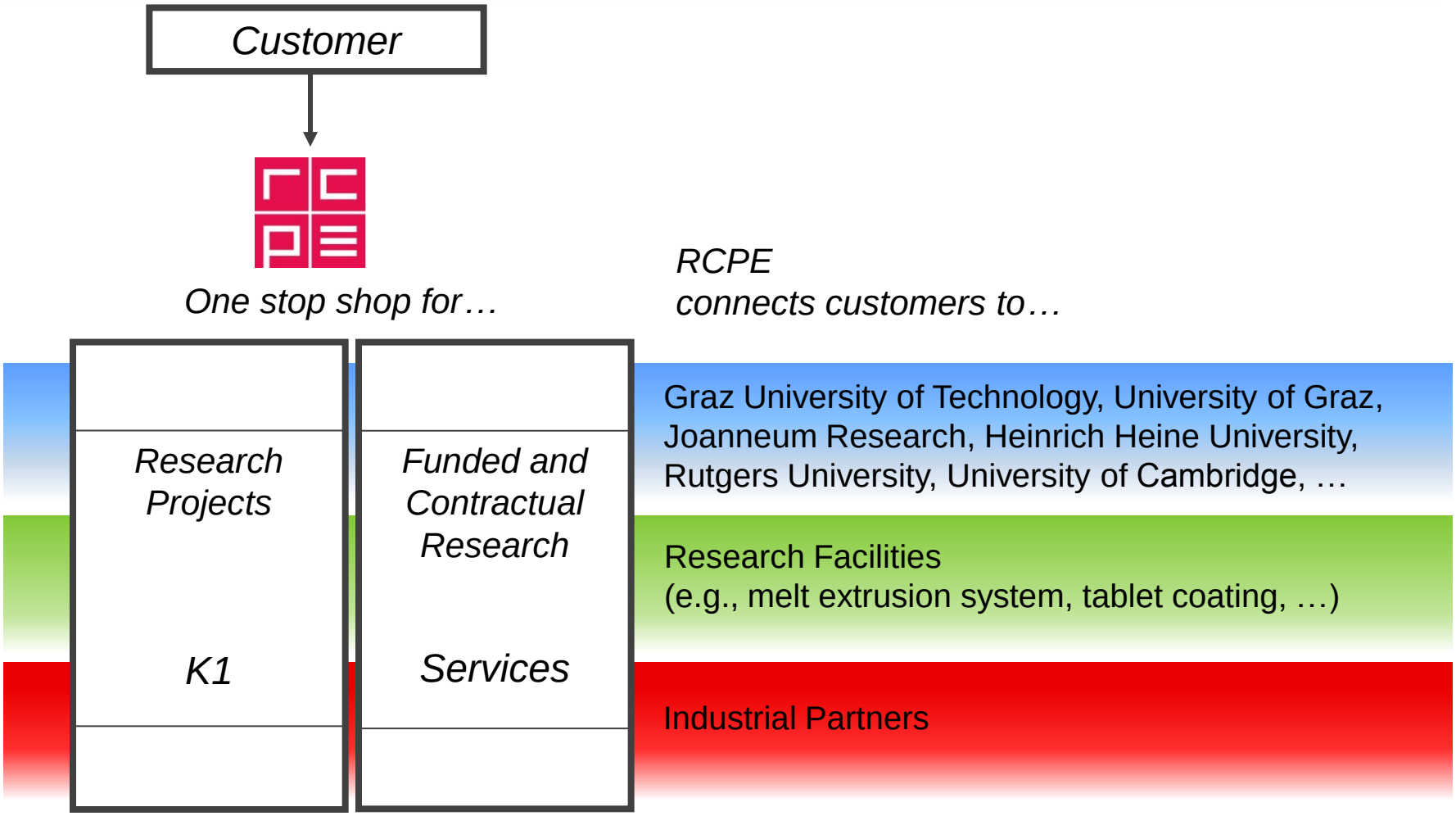
research center pharmaceutical engineering

RCPE - Key Benefits

research center pharmaceutical engineering

- RCPE provides independent R&D in the field of pharmaceutical engineering, bridging the gap between science and industrial applications
- Diversity in research activities: small preparatory studies (literature review, initial measurements, proof of concept) up to extensive multi-year research programs are possible
- Defined IPRs provide maximum benefit for industrial partners
- Long-term cooperation with the RCPE possible
- No time-consuming project application procedures; project work plan can be defined bilaterally and the project can be started immediately
- RCPE can provide additional scientific partners if required
- RCPE can provide additional industrial partners if industrial cooperation is desired

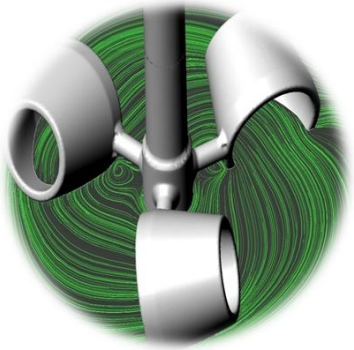
Single Point of Contact



RCPE – Fields of Expertise

research center pharmaceutical engineering

Area I



ADVANCED SIMULATION TECHNOLOGY

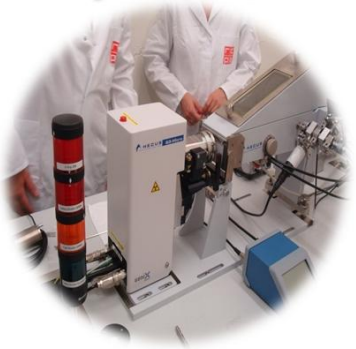
- Pharmaceutical process simulation
- Granular flows
- Fluid Mixing and multiphase flows
- Molecular simulations and structure optimization

Area II

PRODUCTS AND STRUCTURES

- Protein drugs
- Formulation development and optimization
- Novel drug delivery systems
- Nano technology

Area III



PROCESS ENGINEERING

- Process control and PAT
- Process optimization
- Quality-by-Design
- Continuous processing
- Hot melt extrusion

Innovations for our partners

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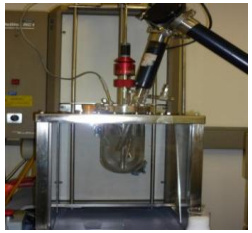
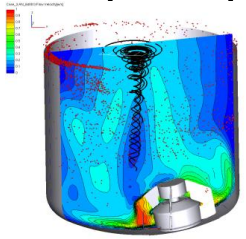
Area I – Fields of Expertise

research center pharmaceutical engineering

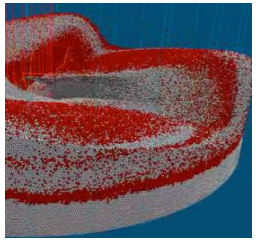
- Pharmaceutical process simulation
- Granular flows
- Fluid Mixing and multiphase flows
- Molecular simulations and structure optimization

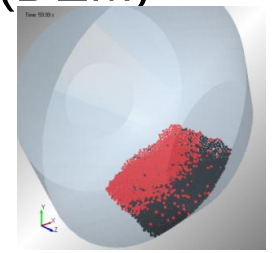
Computational Fluid Dynamics (CFD)



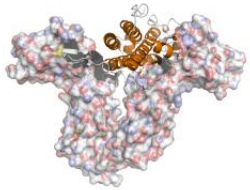


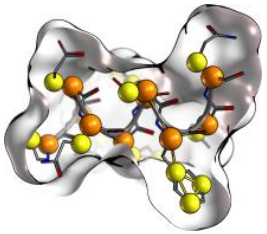
Discrete Element Method (DEM)

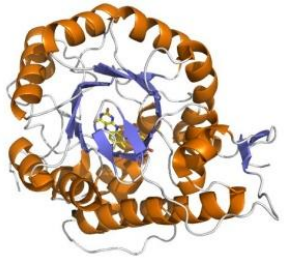




Molecular Dynamics (MD)







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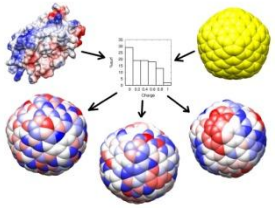
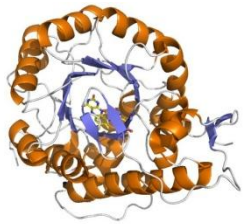
Area II – Fields of Expertise

research center pharmaceutical engineering

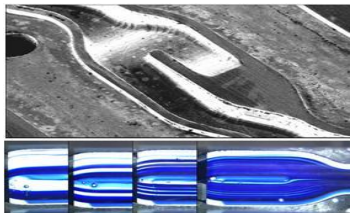
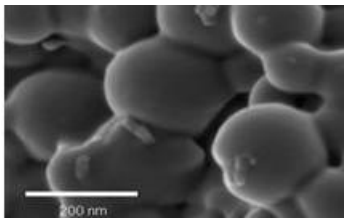
- Protein drugs
- Formulation development and optimization
- Novel drug delivery systems
- Nano technology

Biopharmaceutical Proteins

Formulation Development


Nanoparticles

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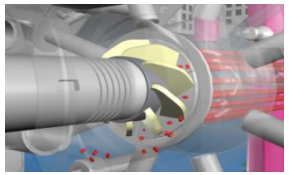
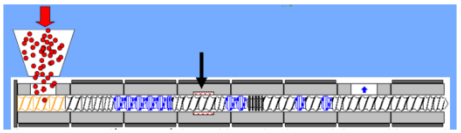
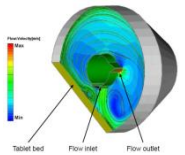
Area III – Fields of Expertise

research center pharmaceutical engineering

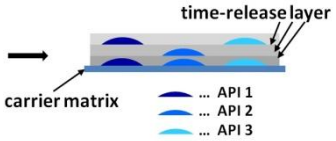
PROCESS ENGINEERING

- Process control and PAT
- Process optimization
- Quality-by-Design
- Continuous processing
- Hot melt extrusion

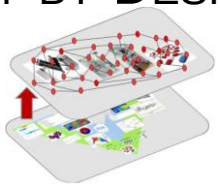
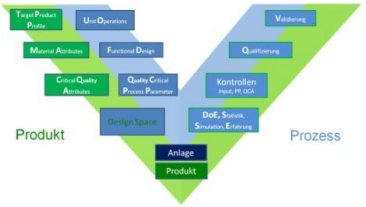
Continuous Manufacturing (e.g. Extrusion)

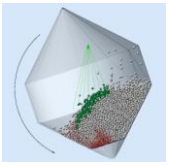
Printable Formulations

Quality-by-Design (QbD)

Process Analytical Technology (PAT)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Analytical Services
Laboratory Equipment I

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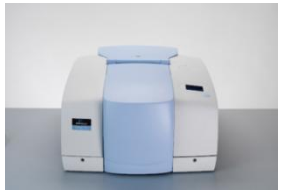
SPECTROMETER

FT-NIR/MIR
PerkinElmer
Spectrum 400

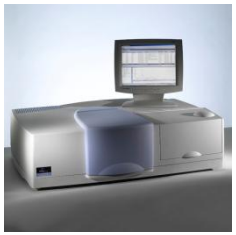
Raman
PerkinElmer
RamanStation 400

React IR
ASI ReactIR 1000



Infrared Spektrometer
PerkinElmer
Spectrum 400

NIR SentroPAT FO
Sentronic, Probes:
DR LS 300, Dynisco



UV/VIS spectrometer
PerkinElmer
PE 950

POROSIMETER

Porosimeter
Micromeritics
Tristar II 3020

Porosimeter
Micromeritics
ASAP 2000

SPRAY DRYER

spray dryer
BÜCHI Labortechnik
Nano Spray Dryer B-90

Analytical Services
Laboratory Equipment II

research center pharmaceutical engineering

CHROMATOGRAPHY

UPLC + MS
Waters
Acquity UPLC + MS

GC
PerkinElmer
Clarus500

HPLC
HP-Agilent 1090

SIZE AND SHAPE

QicPic Sympatec
Size and Shape
Image Analysis

Helos Sympatec
Laser Diffraction
Size Analysis

Zetasizer
Malvern
NanoZS

DENSITY MEASUREMENT

Gas Pycnometer
Micromeritics
AccuPyc II 1340

DSA
Anton Paar
DSA 5000 M

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Analytical Services
Laboratory Equipment III

research center pharmaceutical engineering

RHEOMETER

Freeman FT4
Powder Rheometer

Rheometer
Anton Paar Physica MCR 300

X-RAY DIFFRACTION

SWAXS
Hecus S3-Micro

DISSOLUTION

Dissolution Tester
Erweka

FRIABILITY TESTING

Friability Testing
Copley AS 400

CONTACT ANGLE MEASUREMENT

Krüss Easydrop
Contact Angle Measurement

LAB TECHNIQUES

Microscope
Leica DM4000 DFC290 Camera

Stirring Device
Heidolph RZR 2102

Refrigerated Centrifuge
Hettich Universal 320 R

Scale
Sartorius High Precision Scales

Analytical Services
Process Equipment

research center pharmaceutical engineering

MIXING

Spinning Wheel Mixer
Engelsmann
RRM 100

Shake Mixer
WAB
Turbula T2F

High Shear Mixer
Diosna
P25

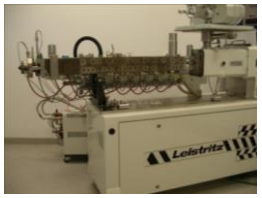
COATING

Batch Fluid Bed System
Glatt Process
TechnologyGPC G1

STABILITY TESTING

Conditioning Cabinet
Binder
Stability Studies

EXTRUSION



Extrusion System
Leistritz
Micro 27

Extrusion System
Coperion
ZSK 18

Downstream Equipment
Automatik
Strand Granulator P60E

TABLETT PRESSING

Laboratory Tablet Press
Fette Compacting
102i

Compaction Simulator
MedelPharm
STYLCAM 200R

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Simulation Tools

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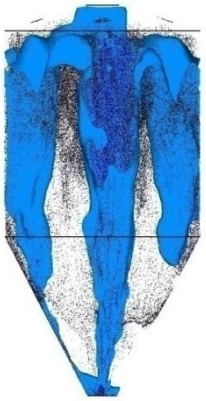
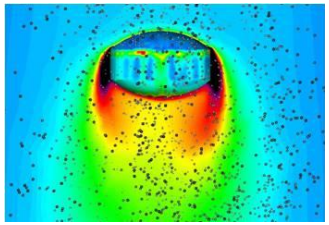
Multiphase flow

CFD (Computational Fluid Dynamics)

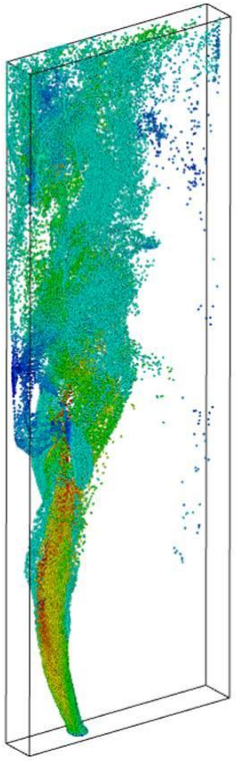
Spray drying/ granulation



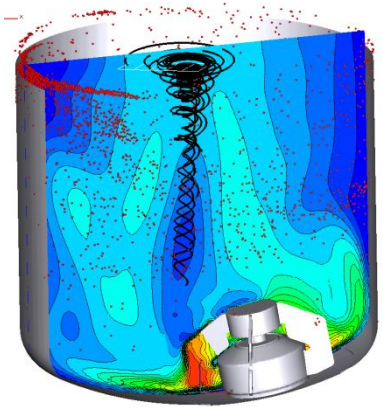
Spray and coating



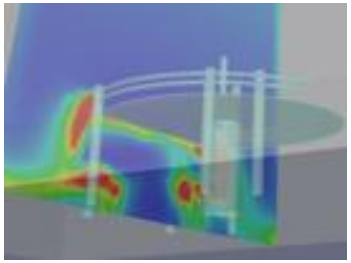
Bubbly flows



Mixing



Room flow

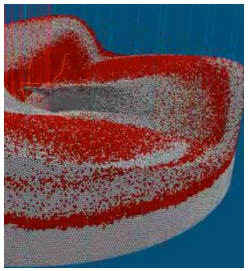


Softwares: FIRE, OpenFOAM

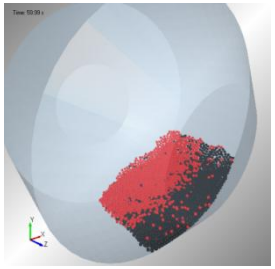
Particle flow

DEM (Discrete Element Method)

Blending



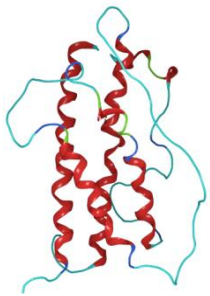
Coating

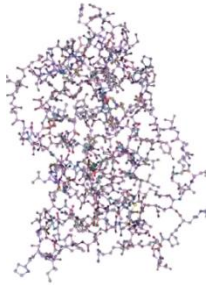


Software: EDEM, RPD

Molecular dynamics

MD (Molecular Dynamics)





Software: MOE

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PROCESSING OF HIGH RISK SUBSTANCES

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List is based on Occupational Exposure Band (OEB) type substances

- **RCPE-Laboratory is equipped for the following substances:**
  - Class 1 (low danger potential) / OEL limit: > 1000 µg/m³
  - Class 2 (moderate danger potential) / OEL limit: 100 – 1000 µg/m³
  - Class 3 (high danger potential) / OEL limit: 10 – 100 µg/m³
    - Exceptions: very small particles, very low solubility (hard to clean)
    - Class 3 Substances have to be discussed on a case-by-case basis
- **RCPE-Laboratory NOT equipped for the following substances:**
  - Class 4 (very high danger potential) / OEL limit: 1 – 10 µg/m³
  - Class 5 (extremely high danger potential) / OEL limit: < 1 µg/m³
  - Substances that are:
    - radioactive
    - mutagenic
    - cancerogenic (e.g. cytostatica)
    - reproductive toxic
    - hormones
    - microbiological

THE PROCESS ENGINEERING CENTER

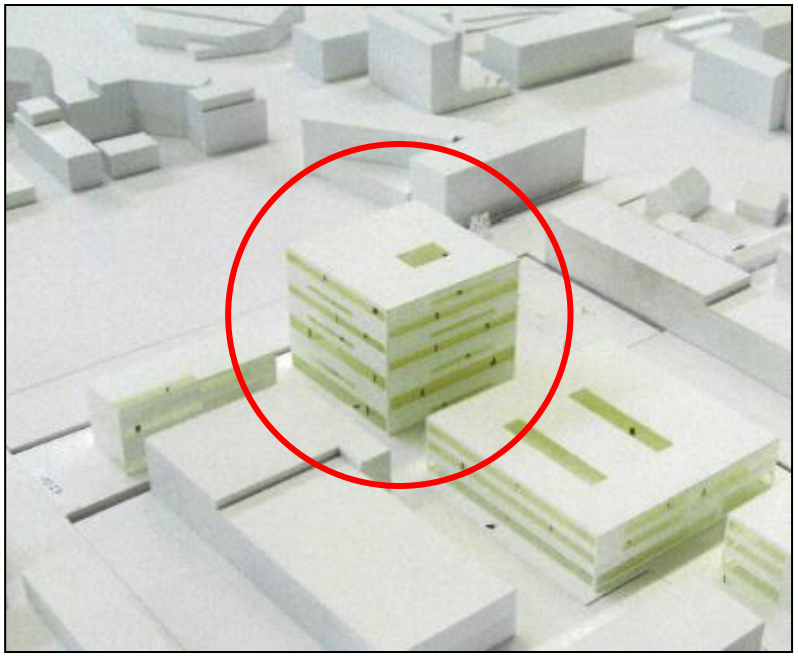
research center pharmaceutical engineering

Office building with state-of-the-art laboratory facilities

Start of construction: 2009

Scheduled for completion: 2011

Footprint: 1000 m² / 7 stories + basement



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