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## Drug Delivery Innovation Center

DDiC

Drug Delivery innovation Center

Info Package, June 2022



# Drug Delivery Innovation Center



- The **Drug Delivery Innovation Center (DDIC)** which aims to bridge basic research and industrial applications officially started on **September 1st, 2017**.
- **Founding Tier 1 members** of the **open consortium** are the companies **Bayer AG, LB Bohle GmbH, Merck KGaA\*** (all Germany) and **UCB S.A.** (Belgium), together with the university partners **TU Dortmund** and **HHU Düsseldorf**.
- The **consortium is complemented** by several **Tier 2 members** who support the work with material, equipment, software and know how.
- The **INVITE GmbH**, which is located in the CHEMPARK Leverkusen, Germany, **leads the consortium and builds the legal frame**.
- The consortium expands and we are looking forward to **discuss the opportunities of the DDIC with new members**.



Contact: INVITE GmbH, Dr. Werner Hoheisel (DDIC Operation Director,) CHEMPARK Bldg. W32, D-51368 Leverkusen, [hoheisel@invite-research.com](mailto:hoheisel@invite-research.com)

# Vision and Mission

## Drug Delivery Innovation Center (DDIC)



The DDIC is based on partnership and close collaboration between academia, industry and public stakeholders to become a world-class Center of Excellence in Drug Delivery Innovation. Based on established research platforms at the universities of Düsseldorf and Dortmund as well as at INVITE the DDIC will foster international, multi-disciplinary research networks.

### ■ Science

- Advance pharmaceutical science and innovation in close collaboration of multi-disciplinary networks with pharmaceutical industry (focus on pre-competitive research)
- Increase fundamental process understanding as the base of advanced process control, modelling and prediction

### ■ Education

- The center supports the “master of industrial pharmacy” program at HHU Düsseldorf and offers a unique doctoral training program to develop a highly skilled talent base for industry and academia

### ■ Products & Innovation for Patients (better healthcare for patients)

- The center will accelerate patient-centric innovation, enabling the development of new technologies and advanced healthcare products and services

# DDIC – a consortium of partners in academia and industry



A broad world-wide network of partners builds the basis for successful research as well as education and talent development to meet the needs of the pharmaceutical sector.

- **Multi-disciplinary research collaborations and consortia:**  
network of universities / research institutes from different disciplines
- **Pharmaceutical industry:**  
pre-competitive basis oriented research and proprietary applications
- **Equipment Manufacturer:**  
new technologies for manufacturing and testing of pharmaceutical products
- **Pharmaceutical Suppliers:**  
excipient manufacturer, medical device industry (e.g. delivery technologies)

# DDIC – innovative solutions for current challenges in the pharmaceutical industry



## Modeling and Prediction

- Rationale formulation design / pharmaceutical material science
- In-silico testing / prediction of biopharmaceutical properties
- Process modeling and simulation (DoE process optimization and scale-up)

## Drug Delivery Technologies

- Oral, solid dosage form: Overcoming low solubility / poor bioavailability
- Inhalation technologies and ocular drug delivery (incl. medical devices)
- Advance formulations for biologics
- Drug Delivery for special patient groups (pediatrics & geriatrics)

## Process Engineering

- Down-scaling (equipment & processes)
- Continuous Processing
- Advanced Process Understanding (incl. Design Space and Process-analytical technologies (PAT))

## Future Technologies

- Nano-medicine, Nano-technology
- 3D-printing
- Drug delivery for cell-based / gene therapy

# DDIC Research Clusters

Seven research clusters have been defined by the Scientific Board



## Research Cluster

- 1 Low solubility / Poor bioavailability of oral drugs
- 2 Drug delivery forms for special patient groups / Personalized medicines
- 3 Continuous processing
- 4 Fundamental process understanding / PAT / Scalability
- 5 Models for predicting biopharmaceutical properties
- 6 Drug formulations for biomolecules (focus: mAbs and ADCs)
- 7 Nanomedicines / Nanotechnologies

# DDIC Research Projects

Overview on 1<sup>st</sup> generation PhD theses, already finished (2017 – 2020)



|   | University                     | Group of                         | Title of PhD thesis                                                                               |
|---|--------------------------------|----------------------------------|---------------------------------------------------------------------------------------------------|
| 1 | TU Dortmund                    | G. Sadowski                      | Thermodynamic and kinetic stability of amorphous solid dispersions (ASDs)                         |
| 2 | TU Dortmund                    | M. Thommes                       | Comparison of spray drying, hot melt extrusion and single pot technology in manufacturing of ASDs |
| 3 | TU Dortmund                    | G. Schembecker                   | Disturbance prediction in continuous manufacturing of oral solid dosage forms                     |
| 4 | LMU Munich<br>TU Dortmund      | G. Winter<br>C. Brandenbusch     | Biopharmaceuticals: Stabilization and aggregation                                                 |
| 5 | HHU Düsseldorf<br>U Greifswald | J. Breitzkreutz<br>W. Weitschies | Customized solid drug-loaded 3D-printed implants                                                  |
| 6 | HHU Düsseldorf                 | P. Kleinebudde                   | Evaluation of PAT tools for defining control strategies                                           |
| 7 | HHU Düsseldorf                 | P. Kleinebudde                   | Regime maps for twin-screw granulation (TSG)                                                      |
| 8 | HHU Düsseldorf                 | J. Breitzkreutz                  | Printed flexible drug-loaded instillations: Manufacturing and biopharmaceutical performance       |

# DDIC Research Projects

Overview on 2<sup>nd</sup> generation PhD theses, currently running (2021 – 2023)



|   | University     | Group of        | Title of PhD thesis                                                                                                                      |
|---|----------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | TU Dortmund    | G. Sadowski     | Controlling Quality and Kinetics of Drying Processes for amorphous solid dispersions (ASDs)                                              |
| 2 | TU Dortmund    | M. Thommes      | Comparison of numerical approaches in modeling of pharmaceutical hot melt extrusion processes for ASD production                         |
| 3 | HHU Düsseldorf | J. Breitzkreutz | Fate of amorphous particles in the GI-tract                                                                                              |
| 4 | HHU Düsseldorf | J. Breitzkreutz | In vitro and in silico physiology based pharmacokinetic (PBPK) modeling of pediatric drug formulations                                   |
| 5 | HHU Düsseldorf | J. Breitzkreutz | Small matrices (Minitablets) with extended drug release properties                                                                       |
| 6 | HHU Düsseldorf | M. Hacker       | Amino acid-derivatized amphiphiles for stabilization and release of highly concentrated and low viscous formulations of protein/antibody |
| 7 | HHU Düsseldorf | A. Seidlitz     | Gel printing of clinical batches for early clinical phases                                                                               |
| 8 |                |                 | <i>in preparation, coming soon</i>                                                                                                       |



# Current Academic Partners



Prof. Dr. J. Breitkreutz  
Prof. Dr. Dr. h.c. P. Kleinebudde  
Prof. Dr. M. Hacker  
Prof. Dr. A. Seidlitz



Prof. Dr. G. Schembecker  
Prof. Dr. G. Sadowski  
Prof. Dr. M. Thommes  
Dr. C. Brandenbusch



Prof. Dr. W. Weitschies



Prof. Dr. G. Winter

# Current Industrial Members

- Ashland Industries Deutschland GmbH
- Bayer AG
- DFE Pharma GmbH & Co KG
- INOSIM Software GmbH
- INVITE GmbH
- Janssen Pharmaceutica N.V.
- LB Bohle Maschinen + Verfahren GmbH
- Merck KGaA\*
- Nisso Chemical Europe GmbH
- Parsum GmbH
- Phoenix Contact GmbH
- Siemens AG
- Solid-Chem GmbH
- UCB Pharma S.A.



# The DDIC provides a range of benefits to its members



- Access to the Open-Innovation Platform at INVITE with a unique network of partners along the pharmaceutical value chain
- Unique opportunity to work on pharmaceutical and process engineering issues simultaneously and jointly with recognized university chairs
- Shape technology development in the area of drug delivery with partners in academia and industry in a pre-competitive environment
- INVITE offers the capabilities and experience (e.g. F3-factory) to set-up and successfully run publicly funded projects. Partners of DDIC will have the opportunity to join the (international) consortia for these projects
- First-hand insights into all joint research projects (20-30 PhD and master programs in steady state envisioned together with partner universities), thus substantially increasing return on own research investment
- Option to run proprietary research projects as part of on-going PhD-studies or as separate PhD-studies with option to use Invite facilities
- Temporary staff exchange (to DDIC or from DDIC to company) for training and development of new capabilities.
- Access to talents (i.e. graduates of PhD and master programs)
- Technical non-exclusive, world-wide license to IP developed at the DDIC

# Lab facilities open for use by members

## Currently available facilities

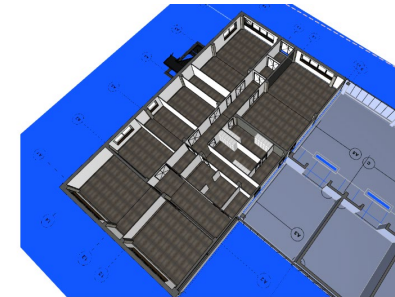
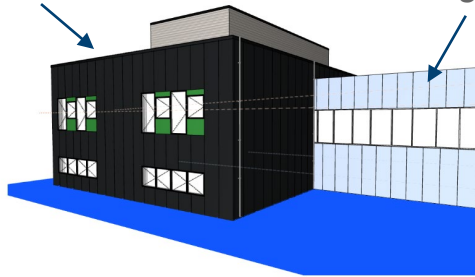
- 3 labs with  $\sim 70 \text{ m}^2$  for handling active ingredients of OEL 3

## New lab and pilot plant facilities under construction (opening in March 2023)

- Additional lab area of  $\sim 600 \text{ m}^2$  for handling active ingredients up to OEL 4

*Building extension  
(opening in 2023)*

*Existing building*



# DDIC Membership Concept

Two options to become a member within the DDIC consortium

*Trial membership possible*

## Tier 1

**200 k€ p.a. for 3 years**

- Member of Scientific Board (SB)
  - *Definition of research topics at DDIC*
- Full access to Technical Committees (TC)
  - *PhD program review*
  - *Steering the content of running theses*
- PhD mentoring
  - *Individual PhD project possible*
  - *Test technologies with your own materials*
- Free technical licenses to all IP
- Opportunity to use Invite facilities
- Further:  
All rights granted to Tier 2 partners

## Tier 2

**in-kind or cash contribution for 3 years**

- SB: One representative of all Tier 2 partners
- For projects with material contributions
  - *PhD program review in TCs*
  - *Test your product in a highly visible environment*
    - *Results are later part of publications*
  - *Royalty-bearing licenses*
- Access to
  - *DDIC report data base, publications*
  - *DDIC facilities*
  - *Talent pool*
    - *observe your future employee over a long period of time*
  - *Public funding consortia, Scientific network*
  - *Technology trends*
- Preferred partner for community

# Executive Summary



- The Drug Delivery Innovation Center (DDIC) builds on strong academic research and many companies in the pharmaceutical sector and will expand to create an international, multi-disciplinary network in the area of Drug Delivery Innovation.
- The center aims to bridge basic research and industrial applications, strengthen pharmaceutical education (master of industrial pharmacy and PhD-programs) and ultimately deliver patient-centric innovation for better healthcare.
- The location – directly connected to INVITE and the CHEMPARK Leverkusen - provides the optimal infrastructure for research and can be easily reached by private and public transportation.
- The DDIC offers a privileged membership to a broad range of players in the pharmaceutical industry along the value chain.

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# invite.

## DDiC

Drug Delivery **innovation** Center

INVITE GmbH  
CHEMPARK • Building W32 • 51368 Leverkusen • Germany  
Phone: +49 214 31 2030 • Email: [info@invite-research.com](mailto:info@invite-research.com)  
[www.invite-research.com](http://www.invite-research.com)

Research Center  
Otto-Bayer-Straße 32  
51061 Cologne • Germany  
**51°01' N 6°99' E**