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Drug Delivery Innovation Center

DDiC

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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.



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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







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 running PhD theses





	University	Professor	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 TU Dortmund	G. Winter C. Brandenbusch	Biopharmaceuticals: Stabilization and aggregation
5	HHU Düsseldorf U Greifswald	J. Breitkreutz 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. Breitkreutz	Printed flexible drug-loaded instillations: Manufacturing and biopharmaceutical performance

Current Academic Partners













Prof. Dr. J. Breitkreutz

Prof. Dr. h.c. P. Kleinebudde

Prof. Dr. G. Schembecker

Prof. Dr. G. Sadowski

Prof. Dr. M. Thommes

Prof. Dr. W. Weitschies

Prof. Dr. G. Winter

DDIC Membership Concept





Two options to become a member within the DDIC consortium

Tier 1 200 k€ p.a., fix for 5 years

- Member of Scientific Board (SB)
 - Definition of research topics at DDIC
- Full access to Technical Committees (TC)
 - PhD program review
- PhD mentoring
 - Individual PhD project possible
- Free technical licenses to IP
- <u>Further</u>: All rights granted to Tier 2 partners

Tier 2

25 k€ p.a., fix for 3 years*

- SB: One representative of all Tier 2 partners
- For projects with material contributions
 - PhD program review in TCs
 - Royalty-bearing licenses
- Access to
 - DDIC report data base, publications
 - DDIC facilities
 - Talent pool
 - Public funding consortia, Scientific network
 - Technology trends
- Preferred partner for community
- For Pharma company as Tier 2 partner:
 - Detailed access to one PhD work in TC

^{*}In-kind contributions possible

Current Industrial Members





- Ashland Industries Deutschland GmbH
- Bayer AG
- Haver & Boecker OHG
- INOSIM Software GmbH
- INVITE GmbH
- LB Bohle Maschinen + Verfahren GmbH
- Merck KGaA*
- Nisso Chemical Europe GmbH
- Parsum GmbH
- UCB Pharma S.A.





















The DDIC provides a range of benefits to its members





- Access to the Open-Innovation Platform at INVITE
- Unique network of partners along the pharmaceutical value chain
- Shape technology development in the area of drug delivery with partners in academia and industry in a precompetitive 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 via technical committee
- Option to run proprietary research projects as part of on-going PhD-studies or as separate PhD-studies
- 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

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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