



Agenda PDU Training Program on Product Development

## PDU-Workshop: Path(s) to transform your research into a product candidate

Day 1 | Thursday, 13<sup>th</sup> of November 2025:

Introduction, regulatory requirements and non-clinical development

Chair: Nils Lilienthal         Welcome and introduction       10:30 – 10:45       Nils Lilienthal         What is translation?       10:30 – 10:45       Nils Lilienthal         Introduction to DZIF and PDU       10:45 – 11:05       Klaus Schwamborn         Introduction of participants       11:05 – 11:30       All participants         Case study of a successful product development: Hepcludex       11:30 – 12:15       Stephan Urban         Lunch break       22:15 – 13:15       Stephan Urban         Chair: Klaus Schwamborn       Nils Lilienthal       OSRA-PEI         Noire Kirsch-Stefan       OSRA-PEI       OSRA-PEI         Nils Chaires in Germany and Europe       13:15 – 14:00       Nils Lilienthal         OSRA-PEI       Nils Lilienthal       OSRA-PEI         Nils Lilienthal       OSRA-PEI       Nils Lilienthal         OSRA-PEI       Nils Lilienthal       OSRA-PEI         Nils Lilienthal       OSRA-PEI       Nils Lilienthal         OSRA-BfArM       Thomas Hesterkamp       TPMO-DRUG         Product development towards a GMP process       14:10 – 14:15       Timur Güvercinci         Osnultant       Consultant       Consultant       Consultant	Arrival & Coffee	10:00 - 10:30	
Welcome and introduction       10:30 – 10:45       Nils Lilienthal OSRA-BFAM         What is translation?       10:45 – 11:05       Nils Lilienthal OSRA-BFAM         Introduction to DZIF and PDU       10:45 – 11:05       All participants         Case study of a successful product development: Hepcludex       11:30 – 12:15       Stephan Urban University Hospital Heidelb         Lunch break       12:15 – 13:15       Stephan Urban University Hospital Heidelb         Chair Klas Schwamborn       13:15 – 13:15       Nadine Kirsch-Stefan OSRA-PEI Nis Lilienthal OSRA-PEI Nis Lilienthal OSRA-PEI Nis Lilienthal OSRA-BFAM         Regulatory pathways and licensing procedures in Germany and Europe       13:15 – 14:00       Nadine Kirsch-Stefan OSRA-PEI Nis Lilienthal OSRA-PEI Nis Lilienthal OSRA-BFAM         Discovery process – What is a candidate?       14:00 – 14:15       Thoma Hesterkamp ThMO-DRUG Consultant         Product development owards a GMP process • Definition of GLP, GMP, GCP • Application of risk-based approach in development       14:45 – 15:05       Stebastian GOY ThMO-VAC, C         Coffee break       15:05 – 15:35       Thoma Vesterkamp TMO-VAC, The OVAC       Stebastian GOY ThMO-VAC, C         Coffee break       15:05 – 16:30       Stebastian GOY ThMO-VAC, C       Stebastian GOY ThMO-VAC, C         Coffee break       16:40 – 18:10       Andrea Teune BfArM			
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Regulatory authorities, their roles, competencies and advice possibilities       Nadine Kirsch-Stefan         • Overview of the regulatory landscape in Germany and Europe       13:15 – 14:00         • General overview of the legal framework (AMG, MPG, relevant EU regulations, etc.)       13:15 – 14:00         • Regulatory pathways and licensing procedures in Germany and Europe       14:00 – 14:15       Thomas Hesterkamp         Discovery process – What is a candidate?       14:00 – 14:15       Thomas Hesterkamp         Product development towards a GMP process       14:15 – 14:45       Timur Güvercinci         • Definition of GLP, GMP, GCP       14:15 – 14:45       Heimholtz Center Munich         • Application of risk-based approach in development       14:45 – 15:05       Wolfgang Hammerschmidt         Lab scale process development / technology transfer       14:45 – 15:05       Sebastian Goy         Case study: EB-VLP       15:35 – 16:00       Sebastian Goy         Non-clinical development, general considerations       16:00 – 16:30       Pia Empting         • Cotfse break       15:35 – 16:00       Scivii Labs       Scivii Labs         Product development       General of safety evaluation of small molecules       16:40 – 18:10       Andrea Teune         Row of the legal framework (A) or (B)       Short case study – CorA (30 min)       Andrea Teune       BfArM         Along	Lunch break	12:15 - 13:15	
Overview of the regulatory landscape in Germany and Europe       OsRA-PEI         Overview of the regulatory landscape in Germany and Europe       13:15 – 14:00       OSRA-PEI         Nils Lilienthal       OSRA-PEI       Nils Lilienthal         Discovery process – What is a candidate?       14:00 – 14:15       Thomas Hesterkamp         Product development towards a GMP process       14:15 – 14:43       Timur Güvercinci         Application of CP, GMP, GCP       14:15 – 14:44       Timur Güvercinci         Application of risk-based approach in development       14:45 – 15:05       Wolfgang Hammerschmidt         Lab scale process development / technology transfer       14:45 – 15:05       Sebastian Goy         Coffee break       15:05 – 15:35       Sebastian Goy         Non-clinical development, general considerations       0 corts & timings of preclinical studies       16:00 – 16:30       Pia Empting         SciVii Labs       SciVii Labs       SciVii Labs       SciVii Labs       SciVii Labs         Breakout Sessions (A) or (B)       Cortex setudy - CorA (30 min)       16:40 – 18:10       Andrea Teune         Marcea Schrefer       University Hospital Bonn       Chair MichaeNstefan       Nils Jost         Velogiticity testing and safety evaluation of biologicals       Nils Jost       PEI         Marea Schrefer       University Hospital	Chair: Klaus Schwamborn		
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<ul> <li>Costs &amp; timings of preclinical studies</li> <li>Intersection of animal welfare and GLP, relevance of non-clinical studies in drug development</li> <li>Breakout Sessions (A) or (B)</li> <li>Chair: Michael Schramm</li> <li>(A) Small molecules-specific non-clinical development         <ul> <li>Non-clinical safety evaluation of small molecules</li> <li>GLP toxicity testing and safety pharmacology</li> <li>Short case study – CorA (30 min)</li> <li>Q&amp;A session (30 min)</li> </ul> </li> <li>Chair: Nadine Kirsch-Stefan</li> <li>(B) Biologicals-specific quality and non-clinical development         <ul> <li>Quality and non-clinical safety evaluation of biologicals</li> <li>Non-clinical GLP toxicology, efficacy and safety pharmacology studies</li> <li>Short case study – DZIF-10c (30 min)</li> </ul> </li> </ul>	Coffee break	15:35 – 16:00	
Chair: Michael Schramm         (A) Small molecules-specific non-clinical development         • Non-clinical safety evaluation of small molecules         • GLP toxicity testing and safety pharmacology         • Short case study – CorA (30 min)         • Q&A session (30 min)         Chair: Nadine Kirsch-Stefan         (B) Biologicals-specific quality and non-clinical development         • Quality and non-clinical safety evaluation of biologicals         • Non-clinical GLP toxicology, efficacy and safety pharmacology studies         • Short case study – DZIF-10c (30 min)	<ul> <li>Costs &amp; timings of preclinical studies</li> <li>Intersection of animal welfare and GLP, relevance of non-clinical studies in drug</li> </ul>	16:00 – 16:30	
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<ul> <li>Quality and non-clinical safety evaluation of biologicals</li> <li>Non-clinical GLP toxicology, efficacy and safety pharmacology studies</li> <li>Short case study – DZIF-10c (30 min)</li> </ul>		1	
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Dinner at BfArM 18:15			





Agenda PDU Training Program on Product Development

# PDU-Workshop: Path(s) to transform your research into a product candidate

## Day 2 | Friday, 14<sup>th</sup> of November 2025: Clinical development and funding sources

Start	8:30	
Chair: Thomas Hesterkamp		
<ul> <li>Clinical trial design</li> <li>Phases of clinical development</li> <li>Design of clinical studies (in early development of drugs)</li> <li>Complex study designs (e.g. adaptive, umbrella and basket studies)</li> <li>Regulatory requirements and early steps</li> </ul>	8:30 – 9:15	<b>Thomas Sudhop</b> BfArM
<ul> <li>First-in-human clinical trials</li> <li>Planning and implementation</li> <li>Budgeting and timelines</li> <li>Statistical considerations</li> </ul>	9:15 – 10:00	<b>Ullrich Bethe</b> CTO
Coffee break	10:00 - 10:30	
Clinical trial application (CTA) <ul> <li>Process and timelines</li> <li>Frequent questions on CTAs</li> </ul>	10:30 – 11:00	<b>Saskia Borregaard</b> Consultant
Case study: TherVacB <ul> <li>Lessons learned on conducting clinical trials</li> </ul>	11:00 – 11:45	<b>Marian Wiegand</b> Helmholtz Center Munich
Coffee break	11:45 – 12:15	
Chair: Nils Lilienthal		
<ul> <li>FlexFunds process</li> <li>Application process and parties involved</li> <li>Important considerations and documents</li> <li>Recommendations for the application / Things to consider</li> <li>Involvement of TIs</li> <li>Q&amp;A session</li> </ul>	12:15 – 12:45	<b>Klaus Cichutek</b> PEI, DZIF-IAB
Introduction to TI BBD	12:45 – 13:00	<b>Anna Wronska</b> TI BBD
Other sources for support and funding <ul> <li>INCATE</li> <li>CARB-X</li> <li>Others</li> </ul>	13:00 – 13:20	<b>Silke Alt</b> TPMO-DRUG
Wrap-up and feedback	13:20 – 13:30	Nils Lilienthal OSRA-BfArM
End	13:30	

### Venue

Federal Institute for Drugs and Medical Devices (BfArM) Hörsaal 1 und 2 Kurt-Georg-Kiesinger-Allee 3 53175 Bonn

### Germany

## Organizers

Product Development Unit (PDU) German Center for Infection Research (DZIF) Contact: <u>osra@dzif.de</u>