

**DZIF / CARB-X / PEI Webinar**

**Webinar Series:  
 Biologicals “From R&D to GMP”**

**19.11.2020 – 17.12.2020**

**Thursdays starting at 2 pm (CET)**

**Thursday, 19.11.2020**

**Series 1: Introduction and overview**

<i>Topic</i>	<i>Referent</i>	<i>Time</i>
Welcome and Introduction	TPMO/PEI	5 min
DZIF – German Center for Infection Research <ul style="list-style-type: none"> <li>• Introduction of the organization</li> </ul>	<b>Dr. Thomas Hesterkamp,</b> Head DZIF-TPMO	15 min + 5 min discussion
CARB-X – Combating Antibiotic-Resistant Bacteria <ul style="list-style-type: none"> <li>• Introduction of the organization</li> <li>• Funding opportunities for early development projects</li> </ul>	<b>Tbd,</b> CARB-X Organisation	15 min + 5 min discussion
Overview of the Regulatory Framework in Germany <ul style="list-style-type: none"> <li>• From bench to bedside and what is required</li> <li>• Competent authorities and advice possibilities</li> </ul>	<b>Dr. Nadine Kirsch-Stefan,</b> PEI	15 min + 5 min discussion
From target to market – How modern project management tools help to achieve the goal	<b>Dr. Bernd Eisele,</b> Consultant	45 min + 15 min discussion
From GSP (Good Scientific Practice) to GMP (Good Manufacturing Practice) <ul style="list-style-type: none"> <li>• Case study from DZIF</li> </ul>	<b>Prof. Dr. Gerd Sutter,</b> LMU Munich, DZIF	45 min + 15 min discussion
		<b>3 h 5 min</b>

## Thursday, 26.11.2020

### Series 2: Product development towards a GMP process

<i>Topic</i>	<i>Referent</i>	<i>Time</i>
Reminder/Overall context	TPMO	5 min
qTPP – quality Target Product Profile <ul style="list-style-type: none"> <li>• Things to consider</li> <li>• Implications of the various properties for development</li> <li>• How does a typical development process look like</li> </ul>	<b>Dr. Sebastian Goy,</b> DZIF-TPMO	45 min + 15 min discussion
Cell line development <ul style="list-style-type: none"> <li>• Do's/Don't Do's</li> <li>• Optimization</li> <li>• Reference cell bank (RCB) generation</li> <li>• Documentation</li> </ul>	<b>Dr. Simon Schröder,</b> DZIF-TPMO	45 min + 15 min discussion
Upstream- and Downstream Processing (USP/DSP) <ul style="list-style-type: none"> <li>• Principals of process development in preclinical and clinical development phases</li> <li>• Scale up – development or just engineering?</li> <li>• From process development to process risk assessment</li> <li>• Definition of process parameter and quality attributes</li> </ul>	<b>Dr. Andreas Neubert,</b> IDT Biologika GmbH	45 min + 15 min discussion
		<b>3 h 5 min</b>

## Thursday, 03.12.2020

### Series 3: GMP Cell Banking

<i>Topic</i>	<i>Referent</i>	<i>Time</i>
Reminder/Overall context	TPMO	5 min
Master- and Working cell bank generation (technical) and characterization	<b>François Nicolas,</b> Texcell S.A.	45 min + 15 min discussion
Importance of suitable raw materials / Product characterization and candidate screening	<b>Tbd,</b> Bioreliance	45 min + 15 min discussion
		<b>2h 5 min</b>

**Thursday, 10.12.2020**

**Series 4: Manufacturing Process**

<i>Topic</i>	<i>Referent</i>	<i>Time</i>
Reminder/Overall context	TPMO	5 min
Lab scale Process Development <ul style="list-style-type: none"> <li>• What can be done?</li> </ul>	<b>Prof. Dr. Wolfgang Hammerschmidt,</b> LMU Munich, DZIF	45 min + 15 min discussion
When is a process considered controllable?	<b>Dr. Konrad Stadler,</b> DZIF	45 min + 15 min discussion
Risk-based approach in biologics development	<b>Timur Güvercinci,</b> Consultant	45 min + 15 min discussion
		<b>3 h 5 min</b>

**Thursday, 17.12.2020**

**Series 5: Adventitious agents, frequent findings and manufacturing contracts**

<i>Topic</i>	<i>Referent</i>	<i>Time</i>
Reminder/Overall context	TPMO	5 min
Regulatory Aspects of Viral Safety	<b>Dr. Astrid Schwantes,</b> PEI	30 min + 10 min discussion
Applied adventitious agents testing	<b>Tbd,</b> Bioreliance	30 min + 10 min discussion
Frequent findings in Clinical Trial Applications (CTAs) <ul style="list-style-type: none"> <li>• Focus on Quality and CMC (Chemistry, Manufacturing, Control) aspects</li> </ul>	<b>Dr. Nadine Kirsch-Stefan,</b> PEI	20 min + 10 min discussion
Business Development	<b>Andreas Wendt,</b> Eurofins	45 min + 15 min discussion
		<b>2 h 55 min</b>

Abbreviations:

- CARB-X - Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator
- DZIF - German Center for Infection Research
- LMU - Ludwig-Maximilians-University Munich
- PEI - Paul-Ehrlich-Institut
- TPMO - Translational Project Management Office