## Tuesday, 17 March 2020

## 9:00 Welcome and Theory 1

- Introduction into eukaryotic DS manufacturing process
- Virus Filters in biopharmaceutical manufacturing
- Sources of virus load
- Reason/necessity for virus removal from DS
- Virus realm
- Sources of viruses
- Examples of virus contaminations (plasma, biotech)
- Outline of how to control the risk
- Relevance of virus safety in ATMPs and potential applications

## 10:50 Coffee Break

11:20	<ul><li>Theory 2: Case Study</li><li>Up- &amp; Downscaling of a virus filtration step</li></ul>	Franz Nothelfer
12:50	Lunch Break	
13:50	<ul> <li>Hands-on 1: Set-up and Handling of Filters</li> <li>Set-up in lab-scale: hands-on</li> <li>Display of production scale filters</li> <li>Integrity tests: hands-on</li> </ul>	Sebastian Teitz
15:20	Coffee Break	
15:50	<ul> <li>Theory 3:</li> <li>Mechanistic principles of (Parvo-) Virus retention</li> <li>Designing a virus filtration process – assumption and points to consider</li> </ul>	Sebastian Teitz
17:00	End of Day 1	
18:00	Networking Dinner	

## 9:00 - 17:00

Sebastian Teitz Andrew Bailey

Wednesday, 18 March 2020 9:00 - 15:3		
9:00	Wrap-up Day 1	All
13:50	<ul> <li>Hands-on 2:</li> <li>Set-up of filtrations with different protein solutions</li> <li>Documentation</li> </ul>	All
10:30	Coffee Break	
11:00	<ul> <li>Theory 4:</li> <li>Introduction/background part for viral clearance - methods, guidelines</li> <li>How to organize a virus clearance study</li> <li>Challenges in VC studies</li> <li>Historical data</li> <li>Case studies for VC studies</li> <li>Continuous manufacturing aspects in combination with virus filtration</li> </ul>	Michael Lasse, <i>TBC</i>
12:30	Lunch Break	
13:30	Revisit Filtration Results	Sebastian Teitz
13:30	Interactive session: Bring your own case/topic/question/problem/challenge for discussion! Participants have the opportunity to address real-life challenges during the implementation of a virus filtration process – from bencht-top development through to commercial scale-up.	All
15:00	Wrap-up, Q&A	All
15:30	End of Course	