



## Agenda – EBF Training Day

in collaboration with the C&GT community (AAPS)

### Bioanalytical Strategies for Cell & Gene Therapies

BRU	NY	DAY 1 - 15 SEP 2020	DAY 2 - 16 SEP 2020	DAY 3 - 17 SEP 2020	Tokyo	LA
13:00	07:00				21:00	04:00
14:00	08:00	BM Session 1	BM Session 3	BM Session 6	22:00	05:00
15:00	09:00		BM Session 4a		23:00	06:00
16:00	10:00	16:00 – 18:00 (BRU Time) C&GT Session 1: General Overview of C&GT / Bioanalytical Challenges	16:00 – 18:00 (BRU Time) C&GT Session 2: Therapy Immunity and Immunogenicity	16:00 – 18:00 (BRU Time) C&GT Session 3: Addressing the Bioanalytical Challenges	24:00	07:00
17:00	11:00				01:00	08:00
18:00	12:00		BM Session 4b		02:00	09:00
19:00	13:00	BM Session 2	BM Session 5		03:00	10:00
20:00	14:00				04:00	11:00

#### Day 1 - 15 SEP 2020

**timezone = CET (Brussels time zone)**

#### 16:00 – 18:00 Session 1 – General Overview of C&GT and the Bioanalytical Challenges

- 16:00 – 16:10 Coming online – Welcome and introduction  
*Philip Timmerman, on behalf of the EBF*
- 16:10 – 16:30 An overview of Cell and Gene Therapies and how they differ from traditional biologics  
  
*Fraser McBlane (Novartis)*
- 16:30 – 16:50 Regulatory overview  
*Manuela Braun (Bayer)*
- 16:50 – 17:10 Understand how to measure and demonstrate exposure during the development of cell therapies  
*James Munday (Covance)*
- 17:10 – 17:30 Am I Biomarker or am I PK?  
*Thomas Emrich (Roche)*
- 17:30 – 17:50 How to approach the development and validation to measure the expression of the transgene product.  
*Chris Cox (PsiOxus)*
- 17:50 – 18:00 Q&A and closing remarks for Session 1

**End of Day 1 – for Biomarker FW delegates, go to session 2 of the FW (18:30 – 20:00)**

#### Day 2 - 16 SEP 2020

**timezone = CET (Brussels time zone)**

#### 16:00 – 18:00 Session 2 – Therapy Immunity and Immunogenicity

- 16:00 – 16:10 Introduction to the session  
*Chris Cox (on behalf of the EBF)*
- 16:10 – 16:30 Bioanalytical approaches to assess the immunogenicity in C&GT  
*Arno Kromminga (on behalf of the EBF C&GT team)*

- 16:30 – 16:50 Assessing cellular Immunogenicity for CGT  
*James Munday (Covance)*
- 16:50 – 17:10 Pre-clinical challenges and translational solutions  
*Philippe Ancian (Charles River Laboratories)*
- 17:10 – 17:30 Pre-Existing Antibodies: Considerations for Cell & Gene Therapy Products  
*Kelli Phillips (PPD)*
- 17:30 – 17:50 Integrated summary of immunogenicity  
*Jo Goodman (on behalf of the EBF)*
- 17:50 – 18:00 Q&A and closing remarks

**End of Day 2 – for Biomarker FW delegates, go to session 5 of the FW (18:30 – 20:30)**

### Day 3 - 17 SEP 2020

**timezone = CET (Brussels time zone)**

#### **16:00 – 18:30 Session 3 – Addressing the bioanalytical Challenges**

- 16:00 – 16:10 Introduction to the afternoon sessions  
*Johannes Stanta (on behalf of the EBF)*
- 16:10 – 16:30 qPCR applications and how to approach the method development and validation  
*Milena Blaga (on behalf of the EBF qPCR Team)*
- 16:30 – 16:50 Case Study: Measuring transgene product activity as a demonstration of therapeutic efficacy  
*Paula Miranda (UniCure)*
- 16:50 – 17:10 Case Studies: The use of ELISpot in CGT  
*Julia Ober-Blöbaum (BioAgilytix)*
- 17:10 – 17:30 Current industry standards and expectations for reliable Flow Cytometry Assays to support cell and gene therapies  
*Daisy Yuill (UCB Biopharma)*
- 17:30 – 17:50 Feedback and comments from a recent EBF survey on regulatory challenges for BA in C&GT  
*Johannes Stanta/Chris Cox (on behalf of the EBF)*
- 17:50 – 18:30 Q&A and closing remarks – Bioanalytical in support of C&GT in practice  
Based on Question from survey, live-pols (?) during the sessions and open questions from the experts

**18:30 Adjourn**



#### **Meeting Organisation**

**Focus Workshop:** Ulrich Kunz (Boehringer-Ingelheim), Linda Terry (GlaxoSmithKline), Lars Karlsson (Ferring), Robert Nelson (Covance), Kyra Cowan (Merck KGaA), Joanne Goodman (AstraZeneca), Michaela Golob (Nuvisan) and Philip Timmerman (EBF).

**Training Day:** Johannes Stanta (Covance) and Chris Cox (PisOxus)

**Cybermeeting logistics:** Magnus Knusson (for EBF)

With collaboration from the AAPS, JBF and CBF