



## **ICH M10 - BMV**

### **Public Consultation & Industry Feedback**

**20-22 May 2019, Barcelona, Spain**

*Meeting in collaboration with the AAPS, JBF and CBF*

## **New or Alternative Technologies**

Breakout Workshop Moderator – Scott Summerfield, on behalf of the EBF

# Workshop

## New or Alternative Technologies

### Excerpts from Section

- *This outcome can occur when one platform generates drug concentrations that differ from those obtained with another platform.*
- *The data generated from the previous platform/technology should be cross validated to that of the new or alternative platform/technology.*
- *The use of new technology in regulated bioanalysis should be supported by acceptance criteria established a priori based on method development and verified in validation.*

# Workshop

## New or Alternative Technologies

- Hi-Res MS (superseding tandem MS)
- Protein LC-MS (superseding immunoassay)
  
- Immunoassay (Ella, SQIDlite)
  
- qPCR
- Flow Cytometry
  
- Acoustic Dispensing (calibration curves, liquid transfers)
- 'Inkjet' Liquid Dispensing
  
- Near-Patient Sampling