

And Pharma R&D?



ICH M10 - BMV

Public Consultation & Industry Feedback

20-22 May 2019, Barcelona, Spain

Meeting in collaboration with the AAPS, JBF and CBF

Dried Matrix Methods

Breakout Workshop Moderator – Enaksha Wickremsinhe, Ph.D.

Overview of Dried Matrix Methods (section 7.6.1)

- Recommendations in this section are limited to addressing dried matrix microsampling methods only (including experiments that need to be evaluated during the validation of DMM)
- Describes requirement to cross validate the DMM with traditional liquid method (for both clinical and non clinical studies).
- Cross validation needs to meet the requirements in section 6.2.
- Non clinical studies should meet requirements in S3A Q&A (section 4.1)

Aim of the Workshop

- Identify challenges and agree on proposed recommendations for section 7.6.1
- Areas of discussion:
 1. Is the verbiage too restrictive?
 2. Are all wet microsamples exempt?
 3. Should the section be broader and/or renamed?
 4. When is cross validation needed?
 5. What statistical tests and acceptance criteria for cross validation?
 6. Does this section “accommodate” future technologies and needs?
 7. Have we missed something?

Focus Workshop

- Tuesday, 21 May 2019, 8:30 – 10:00
- Room: **AQUILA**