

Topic Teams 24

Tissue Analysis

**Presented at 3rd EBF Focus meeting,
12-13 June, 2012**

Nathalie Mokrzycki, on behalf of TT-24

TT-24: Tissue Analysis

Topic Team started: new - 2012

➤ Background

- Hot topic in many BA labs,
- Continued scientific challenge to perform in correct/smart/efficient way
- No clear guidance and risk of over-validation
- GLP or not?

➤ Deliverables

- Share procedures to come up with best practices
- Host session @ Barcelona 14-16 November 2012
- EBF recommendation on the extent of **method establishment*** for tissue analysis at different stages of drug development (incl. GLP)

** refers to the combined process of method development followed by method qualification or method validation*

➤ Members (bold = TT-L):

- Irène Lenthéric (Harlan), Philip Timmerman (Janssen R&D), **Nathalie Mokrzycki (MSD)**, Pascal Delrat (Servier), Pawel Dziegel (Roche), Morna McIntosh (CRL), Marc De Meulder (Janssen R&D) and Eva Erbach (Bayer)

➤ Sponsor:

- Philip Timmerman

TT-24: detailed plans on deliverables

Scope:

- Provide guidance for tissue analysis for PK, PD or TK in addition to regular plasma analysis (primary matrix)
 - Includes Metabolites or Biomarkers

TT-24: detailed plans on deliverables

Deliverables: *at 2 levels*

- Science
 - What and how?
- Process
 - What and how?

Science: What?

- Share scientific procedural details on wet and solid tissue analysis
 - o Sampling: how to get a representative and homogenous sample
 - o Sample preparation:
 - Homogenization processes and challenges
 - Sample extraction after homogenization
 - Extraction efficiency/recovery
 - o Stability, specificity, robustness, matrix effects, ISS
 - o Scarce/surrogate matrix, others...

Science: How?

- Use broad experience and Use *Open meeting* to report back
 - Use broad experience within current TT to provide initial insights and prepare a slide deck
 - In addition team will reach out expert in EBF (can be based on survey « in process »)
 - @Barcelona 14-16 Nov. 2012,
 - report back
 - reach out to other experts to gauge and include additional scientific insights and approaches
 - Currently no intention to publish on science related to tissue analysis of individual compound

Process: What?

➤ Share current practice on process of our member companies

- o Extent of Method Establishment required

- o GLP or not, and why (or why not?)?

- And if not: how to include non GLP data in a GLP environment? Best practices

Process: How?

- Use survey(s) to gauge current practice in EBF
 - o Propose best practices from survey outcome(s) and TT discussion
 - o Present @ Barcelona, 14-16 Nov. 2012
 - o If deemed valuable and adding value, publish our thinking as Recommendation Paper in Q1-2013

Acknowledgment

- Eva Erbach, Bayer
- Irène Lenthéric, Harlan
- Pawel Dzygiel, Roche
- Pascal Delrat, Servier
- Morna McIntosh, CRL
- Marc De Meulder, Janssen R&D
- Nathalie Mokrzycki, MSD (Lead)
- Philip Timmerman, Janssen R&D (Sponsor)

