

## **Table 5: Why and How to Move New Analytical Technologies from R&D to GMP**

Facilitator: Harold Taylor, *Merz Therapeutics GmbH*

Scribe: Yasunori Watanabe, *AstraZeneca*

### **Scope and Questions for Discussion:**

We will discuss when, why and how to transfer new analytical methods from a developing to a GMP laboratory. How long can we continue optimizing a method? When do we stop and "finalize" it? How do we conduct the transfer: comparative testing, co- or re-validation? Decisions, decisions. Let's talk about how to make them.

### **Discussion Notes:**

Analytical scientists in R&D labs like to constantly develop methods to have sensitive/exciting methods. This is not always translatable to QC labs. In fact, sensitivity isn't as important for QC labs, realistically they may not want to know about every small difference.

- Small/Medium sized companies will develop methods that can be transferrable, might not necessarily be the best, but it is the most QC-friendly.
- Method transfer should ideally take place before clinical stages. Having methods in place and validated before first-in-humans use is always best.
- QC labs don't necessarily have the right equipment to transfer a method which can be a barrier.
- For a CRO, budgeting and investment in instruments can be an issue when trying to implement new analytical technologies in a GMP setting.
- Time taken to validate a method and transfer is long.
- Hard to get a QC lab to implement "newer" method. Training of personnel can also be a barrier.
- GMP labs need a method to work, therefore are resistant to change and prefer to stick to known methods.
- From a GMP lab perspective, they're accountable and audited often. They can't have a non-robust method and interpretation. So it's important for R&D labs to keep this in mind for easier transfer.
- Methods have to make sense financially – there's no point in developing a perfect method for the product to fail in phase 3. That again leads to wanting to stick with known methods.

- The cost benefit of introducing a new method can be advantageous especially in manufacturing. Having a better/more sensitive method, can in some cases, save your previously “bad” batch. But this investment isn’t proved right until a lot further down the line.
- One reasonable thing to do may be to run MAM on every 5 batches for example, or run it in parallel to the traditional methods.
- The new method doesn’t need to be filed in a report, but so long as it is characterised in an internal report it’s fine. But you have to be able to defend it since GMP labs will be making decisions based off data from a non-GMP lab. This is where data-integrity and compliance is important in R&D labs.
- There has been multiple examples of batches passing specifications by traditional QC testing but characterisation/mass spec data from a non-GMP lab has led to those batches being thrown out, since there was prior knowledge and confidence in the methods.