Table 10: Validation

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Scope:

From method development, through qualification to method validation and transfer, it is a continuous process from early research and development to QC and release. The objective is to demonstrate that methods are fit for their intended purpose. Method knowledge, experience, and advanced techniques are critical to establish efficient, accurate and fit-for-purpose analytical methods that can be subsequently qualified, validated and transferred to release testing, while improving efficiency and reducing cost, time and resources.

Questions for Discussion:

1. Setting requirements for a method to be validated:
    a. What are the challenges?
    b. How to effectively plan validation studies?
    c. What are the most common method validation approaches?
2. For qualitative and semi-quantitative methods:
    a. What are the major validation challenges?
    b. Is there sufficient guidance for qualitative and semi-quantitative methods?
    c. How to define terms ‘qualitative’ and ‘semi-quantitative’?
3. What are the requirements for test methods used during biopharmaceutical development at early stages when complete assay validation may be unnecessary?
4. What method performance criteria are expected as method development moves through Ph 1, Ph 2, and Ph 3?
    a. Increasing the level of performance rigor (e.g. going from wider to more narrow performance acceptance criteria)?
    b. Increasing the number of replicates/runs for intermediate precision?
    c. Adding specific method performance data (e.g. forced degradation for stability-indicating methods)?
5. Confirming method robustness ranges defined in the procedure?What are the current phase-specific strategies utilized by companies for method validation to support clinical development? Are sponsors submitting similar method validation packages for Ph 1, Ph 2, Ph 3?

6. General discussion: Leveraging data from previous validations (e.g. use of a validation of a platform method) rather than executing all new validation experiments for each product for each assay?

a. For certain product types (e.g., Mabs)?

b. For some method technologies (e.g., protein concentration, HPLC)?

c. For selected method parameters (e.g., procedural robustness)?