

Table 7: CE Method Lifecycle Management

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Scope:

Method lifecycle management is a critical component of product development and commercialization. Elements of analytical quality by design (AQbD) can be adopted to gain long-term efficiencies in method lifecycle management. Additionally, platform approaches can be developed for monitoring development stage products while advancing to product specific methods as programs move to commercialization. This roundtable aims to discuss the challenges and opportunities for CE method lifecycle management as a project progresses through clinical development to commercialization and beyond. Attendees to this roundtable will increase their understanding of CE-specific method lifecycle issues including what has worked, or not worked, in the past and potential/emerging issues to watch out for in the future.

Questions for Discussion:

1. What CE based methods are in your control strategy?
2. Do you use AQbD approaches to CE method development and lifecycle management? Are there success stories that can be shared from using AQbD elements?
3. Do you use platform methods at early clinical phases while developing product specific methods in preparation for commercialization?
4. What differences are there between qualification and validation of platform vs. non-platform methods?
5. Are there high throughput CE methods used for early clinical vs. late phase development or product/process characterization? How do you bridge between methods?
6. Are there different approaches to managing a method lifecycle when the method is performed by a CRO vs. in-house?
7. What are some common CE method issues encountered during the commercial phase of a product? How have you overcome these issues?
8. Are there any success stories or lessons learned that could be shared from instances of CE based method updates post commercialization?
9. How do you approach specification setting for CE-based methods? Does the approach change through the product lifecycle?