

Table 1: Experience Implementing New Technologies including Quality and Regulatory Considerations

Scope:

Use of new analytical technologies can help to expand our understanding of a therapeutics critical quality attributes, as well as allow collection of this data more efficiently and / or reliably. These new analytical technologies are especially important for new modalities where the knowledge base is still being established. However, there are many practical challenges associated with implementing new analytical technologies, especially for product release testing. This round table will focus on experiences implementing new analytical technologies, including challenges faced as well as solutions.

Topics for Discussion:

- How does your company implement new analytical technologies?
- Experience training on new analytical technologies in your organization.
- Advice on building new methods and qualifying them
- Quality and Regulatory considerations for implementation of new analytical technologies
- Challenges of new methods with limited publication history
- Costs of implementing new analytical technologies
- Timing for implementing new analytical technologies
- Transition of methods from characterization to release

Table 2: Future Technologies: Needs and Transitioning from Academia to Industry

Scope:

Development and implementation of new technologies has always been forefront of modern pharmaceuticals. Recent success of novel modalities (mRNA, cell and gene therapy, live biotherapeutics) and speed to develop new therapies, there is a growing need of new technologies, more than ever. Academia has always played a crucial role in pioneering new technologies. These novel technologies typically enter regulated biopharma world with characterization testing followed by IPC and/or release testing. This round table will be focused on need and challenges of transitioning future technologies from academia to industry.

Topics for Discussion:

- What technologies are we missing? What attributes are we not measuring?
- What are open problems/challenges
- Why we need new tech – throughput/robustness/new modalities?
- Pitfalls and advantages of transfer from academia
- Implementing technology from other industries
- Encourage early career scientists thinking about biopharma

Table 3: Practical Aspects of Implementing of New Technology: IQ/OQ, Reference Standards, Acceptance Criteria

Scope:

Adopting new technologies for improved product assessments has been encouraged by the agency; however, few new technologies have been implemented and then primarily for characterization. What are the challenges to implementation of new technologies?

Topics for Discussion:

- Instrument qualification and performance criteria
- Regulatory feedback for new technologies
- Parameter reporting and setting specifications
- Critical reagent strategy
- Establishing critical quality attributes