Table 1: Platform Approaches for Control Strategies in Submissions

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Scope:

ICH Q8: Pharmaceutical Development describes the expectations for control strategies, which ensure that products of required quality are produced consistently. ICH Q8 provides some suggestions for control strategy elements but also allows leeway for customization. This roundtable is designed to facilitate discussion about various approaches to control strategy, along with ways to make the process more efficient and enable leveraging of knowledge from product to product.

Questions for Discussion:

1. Does your company use a platform approach to control strategy? Are there examples when it is appropriate/necessary to deviate from a platform approach? What kinds of templates and tools can make the process more efficient?
2. When do control strategy discussions take place? Are there differences in timing for traditional mAb programs versus alternate product types? Is control strategy simply an integral part of your company's product development, which is then documented in the commercial application, or is it an explicit work product with reports or spreadsheets generated at defined times during product development?
3. What types of elements are typically included in a platform control strategy? Are the same elements leveraged across all products or are there any differentiations among various product types?
4. Do you generate separate control strategies for DS and DP or is a single overarching control strategy generated for the product as a whole? If the final product is a combination product incorporating a device, do you follow the same paradigm for documenting device control or is the control strategy documentation process different for drug versus device? Where in the CTD are DS, DP, and device/combination product control strategies typically filed?
5. Given recent FDA requests for summary tables of process parameters and in-process controls for each unit operation and summary tables of quality attributes and process and product related impurities (in addition to traditional control strategy writeups), are tables of these types being incorporated into your control strategy discussions and documentation?

Discussion Notes:

- What does it mean by platform approach? QTPP, Risk Ranking Filter, CQAs within a modality (ie. monoclonal antibodies) are similar so platform knowledge, analytical approaches,

platform analytical methods and tools can be applied. Prior knowledge helps in building platform strategies, which are then foundation to establishing control strategies.

- When do control strategy discussions take place? Many chimed in that initial control strategy assessment takes place prior to pivotal in the development and then again prior to the start of PPQs. Control strategy evaluation is an iterative process and many companies employ platform approach as their framework. Not a lot of companies perform rigorous CQA assessment during Ph1. Most begins the control strategy assessment in preparation for the PPQ. Most handle problems as they arise along the way.

- Some questions around documenting control strategy for a combination product and how the information is filed in the dossier. Some shared their experiences that the device development and control strategy are provided in Regional Section of the eCTD and the FDA product reviewer in attendance said the Agency greatly appreciates the device information consolidated in one section since Agency often reaches out the CDRH to get their input and it's easier when all information is in one dedicated section.

- Regarding the recent FDA requests for the summary tables of process parameters, in-process controls and CQAs connecting all in a E2E summary, FDA hopes that this table helps the sponsor just as much as the Agency. This table helps provide the Agency with a final big picture of the CPPs, how they are controlled, what are the impacting CQAs, how are these CPPs and CQAs supported by. PPQs, clinical experience, etc. Did the sponsor challenge them in PPQs or representative small scale runs.

- We also talked about the placement of information in the dossier and perspective on how to holistically present control strategy and justification clearly with ease of review for HAs in mind. Regardless of the placement, what is important is for the reviewer to be able to find information easily.