Table 7: Implementation of USP<129>

SESSION 1:
FACILITATOR: Carl Jone, *UCB Pharma SA*
SCRIBE: Elisabeth Ruge, *F. Hoffmann – La Roche Ltd.*

SESSION 2:
FACILITATOR: Christopher Jones, *Retired from NIBSC*
SCRIBE: Bert Wouters, *Vrije Universiteit Amsterdam*

SCOPE:
USP's standards for therapeutic proteins and other biologics are based on input from global scientific experts and on specifications for FDA-approved products and are published in the United States Pharmacopeia—National Formulary (USP–NF). USP chapter <129> provides analytical procedures of recombinant therapeutic monoclonal antibodies (mAbs) and subtypes (*e.g.*, IgG1 and IgG2). This chapter includes validated procedures and system suitability criteria for purity assessments by chromatographic separation of size variants and capillary sodium dodecyl sulfate (CE–SDS) electrophoresis as well as procedures for analysis of oligosaccharides and sialic acid in mAbs. This roundtable aims to discuss both the current state of USP <129> as how it could be expanded in the future.

QUESTIONS FOR DISCUSSION:

1. What is your company's understanding of USP<129> and does your company have a strategy to address it?
2. Are you aware of the circumstances of where USP <129> is mandatory?
3. Does your company feel that USP <129> will be implemented in a similar way in developed and developing economies?
4. Is your company aware of USP policy to alternative methods?
5. How does your company view the overlap between USP<129> and other chapters in USP?
6. How does your company feel that USP<129> should develop in the future? Should it be developed?

DISCUSSION NOTES:

Topic	Discussion at Round Table (Day 1)
What is your company's understanding of USP<129> and does your company have a strategy to address it?	• General view of companies so far: wide range from taking USP129 literally to just ignore it • Not clear why this chapter has been added to USP since other chapters defining methods to control appropriate quality of antibodies already exist (glycan analysis/oligo, monosaccharides, CE-SDS, HPLC etc.). • The chapter should aim for clearly defining the minimum requirements of testing of antibodies/antibody-like products (set

	expectations), more addressing companies that have never been doing this before • Question is whether this chapter is outdated soon since many antibody formats are on the horizon with different quality/testing attributes (if this chapter still applicable for new formats)? • USP129 is seen as non-binding (no monographs) and as overlapping with other chapters. It can be used as quality standard for new companies dealing with recombinant therapeutic monoclonal antibodies. In the future, this chapter could be deleted or expanded (more mAb specific).
Are you aware of the circumstances of where USP <129> is mandatory?	• Subsequent clarification that this chapter is not currently binding was very helpful. As patents on mAbs are expiring, companies might submit monographs mentioning USP 129, which could make it binding in the future.
Does your company feel that USP <129> will be implemented in a similar way in developed and developing economies?	• Concern: Although publication came out that USP chapter is not binding USP authorities in developing countries may still take it literally and expect that USP129 is applied (similar experience gained with other USP monographs/chapters).
Is your company aware of USP policy to alternative methods?	• Yes (see Question 1 above) • Both USP and EP always has the option for applying other than compendial methods when validated (validation data need to be shown).
How does your company view the overlap between USP<129> and other chapters in USP?	• There is overlap (see Question 1 above: glycan analysis, oligo, monosaccharide etc.). USP could be changed by making it more mAb-specific, and removing certain overlap with other chapter on topics including glycoproteins.
How does your company feel that USP<129> should develop in the future? Should it be developed?	• 2 options: delete or expand to decrease overlap with other chapters. Additionally, companies should be encouraged to write monographs that could make 129 binding. • Yes, it definitely should be developed e.g. take out overlap • General question: analytical methods are evolving rapidly → how can USP deal with the developing technologies and adapt expectations accordingly (process of Pharm. updates are too slow?) • Request from Pharmacopoeia organizations: companies should push for new/better methods to be implemented → companies should share validated methods with Pharm. org.

	• Interaction of companies and Pharm. org. should improve