

Development Technical Committee Meeting
17 January 2008
Teleconference
2:00 pm – 4:00 pm

Summary Minutes

Opening

The meeting was brought to order and the Chair read the following Admonition Statement:

“Our discussions today are subject to the anti-trust guidance applicable in the U.S. Nothing discussed at this meeting is intended to restrict the individual decision-making of any member company or to represent an agreement to coordinate marketing or sales conduct. Those participating in this meeting are instructed to avoid discussion of competitively sensitive subjects, including, confidential marketing, sales, and pricing information.”

Agenda

Review of communications

Clarification and review of WGs under the DTC umbrella

Discussion/Approval of the SSL WG 2007 year summary and the 2008 work plan and budget

PQRI Strategic Vision Meeting

Follow-up to QBD discussion topic from December teleconference (see attachment)

Communications

The Chair reviewed communications sent to the committee members since the last Committee meeting. These included the 2007 summary and 2008 proposal from the SSL WG, recently approved PQRI Bylaws, and ITFG (inhalation technology focus group) workshop committee request.

Working Group Review

The Chair reviewed the WG which will report into the DTC:

- Container Closure
- Stability Shelf Life (SSL)
- Genotox Impurities/Sulfonate esters
- Reporting and Qualification Thresholds for Leachables in Parental and Ophthalmic Drug Products (PODP)
- Specification Design and Lifecycle Management (joint with Manufacturing TC)

The Excipients and Leachables & Extractables WGs are sunset and will not be part of the discussions. However, the L&E WG is preparing a book manuscript which will be reviewed by the Committee.

The Committee was also made aware of some proposed external technical presentations by the SSL WG which will need to be reviewed. There was some discussion regarding a turn-around time commitment for these types of reviews. The Committee felt that 2 weeks would be a reasonable commitment to provide a review for technical presentations.

The committee members were also solicited for interest in working with specific WGs as a liaison to the DTC as has been done in the predecessor TCs. Interests should be directed to the Chair.

SSL WG

The committee discussed the 2007 summary. The SSL WG will be asked to revise this summary to clearly emphasize the accomplishments versus yearly and overall goals of this WG. (Post meeting note: The summary which was circulated for review was not intended to serve as a summary of accomplishments versus goals for 2007. Such a summary is available and will be circulated to the Committee shortly.)

There was much discussion concerning the 2008 budget proposal. In particular, the Committee was not comfortable recommending funding for the Data Warehouse component of the proposal. The Committee recommended splitting the proposal into two parts. The research component, which continues work performed in 2007, would comprise the first proposal. The Data Warehouse work would be presented as a second proposal which may be submitted later this year as a supplemental request. The Committee requested additional details on costs, likelihood/timing of need based on data harvesting from participating companies, and consideration of alternatives for cost effective management of the data collection process. The Committee agreed to provide additional specific recommendations to the Chair which would be collected and given to the SSL WG. (Post meeting note: The DTC Chair met by teleconference with the SSL WG Co-chairs to debrief them on the outcome of the Committee discussion. The Co-chairs stated that they would begin work on refining the 2007 summary as well as separating the existing 2008 proposal as directed by the Committee.)

Strategic Vision Meeting

The committee briefly discussed the upcoming PQRI Strategic Vision meeting at the end of February. Generally, this meeting will review the project portfolio for 2008 and will consider new proposals. A request for suggestions for new topics was made to the committee.

Along the lines of new topics, a discussion on QBD was generated by a DTC member. The discussion ranged from suggestions of project synergy and coordination within PQRI to collaboration with ongoing work with external organizations (i.e., ASTM, ISPE, etc.). For example, should PQRI reorganize the WGs currently investigating this area to increase the overall effectiveness and influence? The DTC member will continue to collect discussion ideas and suggestions on this topic from committee members off-line and will prepare a summary document for consideration.

The meeting concluded at 4:00 PM