

Summary Minutes DTC Teleconference
January 27, 2010
2:30 pm – 4:00 pm

Admonition statement read by the Chair.

Sulfonate Esters WG- comments are still being collected on the chapter that was written on genotoxic impurities. Deadline for comments was extended to Feb. 5th.

Stability Shelf-life WG-

- latest telecom on Jan. 26, 2010.
- Subgroup is working on the white paper which was to have been completed last year; should have something for DTC to review within a couple of months
- WG submitted proposal for participation at the JSM 2010 meeting of several abstracts; DTC was okay with the abstracts to be used
- Short Course Proposal was submitted for consideration to participate in the FDA/Industry Statistical Meeting
 - Concern raised over the format of the presentations proposed. If they are going to be delivering the final product from the WG research, then they must first present that to the DTC and SC for their endorsement. If they are simply providing an update to their research, then that can be considered differently by the DTC

Action Items: Liaison will clarify with the WG what their intent is and their expected outcomes and advise them that if they are planning on giving definitive results from their work project then that must happen first within PQRI before it is taken outside the Institute. Liaison will also encourage the group to consider putting together a workshop on the results from the research, and hopefully within 2010 to get the information out faster. PQRI is willing to help facilitate a speeded up process if it can be put together and receive SC approval. Liaison will ask the WG if they can be prepared to present their update to the DTC at the next teleconference scheduled for Feb. 18th.

PhRMA Stability Expert Team is looking for a home now that PhRMA has abandoned their teams. This is the same type of arrangement that the SC is considering regarding the expert teams that SC chair recommended PQRI have as Discussion Groups. Team was advised of the consideration that will take place at the Feb. 8th SC meeting.

Action Item: PQRI will send the guidelines that the SC is considering to Chuck so that he can see what is being talked about on the 8th. **Post Meeting Note:** Information sent to member directly following the conclusion of the teleconference.

Upcoming Joint Board and Steering Committee meeting is set for Feb. 8th and there will be discussion of the Process Drift proposal as well as the Sample Size for large 'n' topics that were discussed during the recent PQRI conference. Pfizer rep has been involved with moving the sample size topic forward with the FDA, and it appears that the FDA is going to recommend combining the two topics into one workshop which would be co-sponsored by the FDA and PQRI. She provided an overview to the DTC of what all

is involved with the sample size for large 'n' topic and how that might be appropriate for a DTC work project.

Action Item: PQRI to send the agenda and call in information for the Feb. 8th so that she could participate in that discussion. **Post Meeting Note:** Information sent directly following the conclusion of the teleconference.

PK/BE Workshop set for April 2010 in coordination with RDD is progressing smoothly and there are currently 36 registrants. Outlook is good for having at least 100 participants.

Meetings for 2010:

DTC Chair will send schedule for meetings on every third Thursday at 2:00 pm, the same as last year's schedule. The next meeting will be on Feb. 18th.

There being no further business, the meeting adjourned at 3:30 pm.