

Steering Committee Teleconference
April 20, 2009
Summary Minutes

Opening and Welcome was made by the Chair.

Admonition Statement was read by the Chair.

“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.”

Reports of Topic Areas/ Proposals for PQRI Work Projects- Each subgroup was asked to report on their collective decision regarding the following:

The most important scientific question/problem that PQRI can address in this arena...

Supply Chain Management Key discussion centered around two concepts- Raw Material Quality and Supply Chain Integrity. These topics fit well with the earlier research completed by the Excipients Work Group, and in fact IPEC is performing several projects along this vein. The MTC is working with IPEC to try to develop an area that they might contribute to, but it was felt there is also a need to do something on the drug development side.

The supply chain proposal consists of two aspects, specifically data mining and development of analytical methods. The goal of the data mining exercise will be to determine if better material characterization would prevent repetitive drug product/process issues arising from use of common excipients. Information on such issues for a selected list of common excipients would be solicited from interested parties. If the hypothesis that materials should be characterized more fully is confirmed, then work could be done to identify methods that are most suitable for these analyses.

Complex Dosage Forms did not report as their rep joined in late to the call. He will report at the June SC meeting.

Nanoparticles was reported on with basically two areas of interest to explore for projects. One, creating a Steps/Flow Chart for Characterization of Nanoparticles which would be a paperwork exercise gathering all relevant data on hand. Secondly, then do the actual lab work to fill in the gaps that are found in exercise #1, or the building of the Chart.

Comparability of Biologics was reported on and he advised that the subgroup has developed four adhoc groups to look into four possible areas of biologics to develop a work proposal. Their adhoc groups will meet again in May and then report back to the Steering Committee in June on their collective findings. One topic of discussion revolved around the fact that the EMEA has guidance currently in effect, but that the U.S. does not have a regulatory framework for this area

of expertise. It might be beneficial to help create that framework in conjunction with what has already been established in Europe.

New Concept Proposals from Technical Committees

BioThree proposal was submitted and presented and supported by the BTC Chair. The presentation is attached to these minutes and was well received by the SC. BTC rep was asked to develop it further and report back to the SC so that it might consider it in detail in order to possibly recommend financing to the Board. The RIVM would like to know if we will provide financial support for the project by July 2009 if at all possible.

Action Item: PQRI to assist with next step preparation of Work Plan.

Post Meeting Note: PQRI provided the example from the BCS III Work Plan and the Absorption Systems contract so that he could begin the process of creating those documents and presentation for the SC to help move this along at a fast pace.

Sulfonate Esters Webinar The DTC Chair is working with WG Chair to try to get this event to happen in the near future. They are looking at early June possibly. The Steering Committee supports the event, but would like to see budget estimates for costs before they approve and recommend to the Board for financing. They would also then discuss and decide upon whether or not to charge any registration fee for the webinar.

Action Item: PQRI will prepare estimated budget for DTC based upon cost with GoToWebinar and SignMeUp.

Post Meeting Note: PQRI provided budget to DTC on April 22, 2009.

The discussions that took place surrounding all topics were positive and each group was asked to move onto the next phase of the proposal process, and be prepared to come back to the Steering Committee with more definitive plans at the June meeting.

New Business

Co-sponsorship of Workshop with AAPS/FIP was requested. The Steering Committee agreed to co-sponsor this workshop in name only.

Action Item: PQRI to acquire agreement from AAPS for Board Chair's signature.

Post Meeting Note: Document and signature acquired on April 22, 2009 and sent to AAPS for their counter ratification. Marketing has already begun for this meeting.

Reception/Event at the PSWC 2010 in New Orleans

Discussion tabled due to time constraints until the next Steering Committee meeting.

FDA Guidances in the Works for 2009

Discussion tabled due to time constraints until the next Steering Committee meeting.

Old Business

PQRI Conference was reviewed by PC Chair and she offered a new draft agenda which was briefly discussed. Dates in December 2009 are offered for SC members to vote on.

Action Item: PQRI to send polling to SC members to decide which date they prefer in December.

Post Meeting Note: The overwhelming preference was for the date of December 15-16, 2009. PQRI notified PC and secured that date with USP on April 22nd.

Bioequivalence Workshop and the subsequent ideas for follow up activities was reported on by PC Chair. Several members of their Planning Committee are addressing the various topic/project areas and will try to have presentations ready for the June SC meeting.

Next Steps

SC Chair thanked everyone for their input and work that was done to make this meeting successful. The Steering Committee is looking forward to hearing back for the various groups at the next SC meeting in June.

Upcoming Meetings

Face to Face requested for the early part of June 2009 to keep the momentum going.

Action Item: PQRI to poll members for date in the first week in June.

Meeting adjourned at 12:04 pm.