

Summary Minutes
PQRI Steering Committee
Teleconference
August 11, 2009
1:00 pm – 3:00 pm

Opening and Welcome given by Chair.

Admonition Statement was read.

“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.”

Review of Minutes from June 2009 - Motion made and seconded to accept the minutes as presented. Motion passed unanimously.

Review of Action Items from Past SC meetings

From January 2009 Meeting

The Outreach Task Force recommended a PQRI Review Article to highlight past, present and future PQRI perspectives. Past Chair volunteered to spearhead this article.

Action Item: Item accomplished. Article is in the review process. TC Chairs need to do a critical review of the Table in the article relating to their specific Work Group products. IPEC rep will provide contact information for *Pharm Tech* for publication of the article.

Post Meeting Note: Email sent to TC Chairs to request their review by August 14th. IPEC rep sent contact information directly following meeting.

From February 2009 Meeting

Sulfonate Esters WG update was given by the Chair. Chair advised that he is in the process of drafting a white paper in conjunction with PhRMA and other publications have already been submitted.

Action Items: Item accomplished. Webinar was held on July 23, 2009 with approximately 170+ attendees. A total of 6 FDA participants viewed the webinar. The webinar has been archived and sits on the PQRI website.

From March 2009 Meeting

BioThree proposal was submitted and presented by the BTC Chair, Erika Stippler. The presentation is attached to these minutes and was well received by the SC. They were 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: Action item accomplished. PQRI Secretary sent presentations and work plans out to SC members and TC Chairs for their review and subsequent vote at the end of August on whether or not to support the proposal to the Board for financing.

From June 2009 Meeting

Sulfonate Esters WG white paper with PhRMA was discussed with PhRMA President through SC Chair. PhRMA agreed to give PQRI credit for workshop results where appropriate. Intellectual Property Right Issues explored via legal counsel at IPAC-RS.

Action Item: Follow up with IPAC rep to finalize the documents and resubmit to SC for their consideration of adoption.

Post Meeting Note: Email sent to IPAC rep requesting status report of document revisions.

PQRI Event at PSWC 2010

Action Item: Still outstanding. Committee needs to consider ideas for what type of event will be most beneficial to PQRI.

Extension of Ongoing Work Projects

Bioequivalence Workshop Future Projects was given with an update on the PK/BE Workshop which it appears will be held in conjunction with the RDD Conference in April 2010 in Orlando, Florida if all the details can be worked out. Chair and PQRI are working with RDD to try to accomplish this goal. Planning committee for workshop has developed their agenda and is moving forward with setting up workshop.

DTC – Container Closure WG update was given, powerpoint presentation is attached. Chair reviewed the current status of the Work Group and their projections for work continuing into 2010.

New Projects

BioThree Work Group Proposal by BTC was presented powerpoint presentation is attached. Review of the presentation was made by the SC members and a discussion of points was held.

Action Item: The Work Plan and the presentations to be sent to all SC members and TC Chairs for their input, with a vote expected by the end of the month on whether or not to approve the project and request Board funding for the Work Group.

Post Meeting Note: Information was sent out to all SC members and TC Chairs and input was requested by the end of August when a vote will be taken on support of the project.

Biogenerics/Comparability of Biologics was given, powerpoint presentation attached. Review and discussion took place following the presentation.

Action Item: Icon ee to go back to subcommittee and ask them to develop one idea or area where PQRI could be most effective. To consider either immunogenicity, PD or 5052b plan. Report back to SC in Oct/Nov timeframe.

PQRI Conference update was given by PC Chair with discussion and review of the proposed Recognition Ceremony nomination form and process. Three awards will be given for “Excellence in Research” and nomination forms will be reviewed by a committee of individuals to determine best candidates. Speakers are being confirmed and confirmation is needed by August 27th along with their Speaker Contact forms and bios for inclusion in the brochure that is being produced. AAPS rep volunteered to assist with the Recognition Ceremony team and secondary AAPS rep volunteered to moderate the Session to work with the Closing Speaker and handle the recognition ceremony details. President with USP will be the Closing Speaker.

Action Items: PQRI to send flyer out to all SC members on work groups, past and present to invite them to the conference. Need to contact speaker at USP to set up and confirm participation. Need to revise the nomination form with the addition of the criteria for the award and add the name of the award to the form. PQRI will then send out the revised form to all SC members, TC Chairs and WG Chairs for their completion. Forms are due back to committee by mid October for the selection process.

Next Steps/Upcoming Meetings

Action Item: Members are asked to reply to the polling that was sent out to select the best date for the September face to face meeting.