

Summary Minutes
Steering Committee Face to Face Meeting
June 2, 2009
9:30 am – 4:00 pm

Hosted by:

CHPA Headquarters
900 19th Street, NW Suite 700
Washington, DC 20006

Opening and Welcome

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.”

Review of Minutes from April 2009 were approved as presented.

Review of Agenda with no new items for the agenda.

Review of Action Items from Past SC meetings

PQRI Article being written. Historical data sent to authors in early 2009 for article.

Action Item: Get article by the end of June to distribute to all SC members for comments so that it can be finalized and ready for August newsletters, the first week in August. *Post Meeting Note:* Article requested by June 30th.

CHPA weblink for PQRI was reviewed.

Action Item: Send weblink along with logo template letter to all SC members for their organizations websites. CHPA link to be made active.

Post Meeting Note: PQRI sent link and template to all SC members.

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. FDA’s input on this project is now completed, and FDA is interested in receiving PQRI’s recommendation, or the group’s findings and work product. Rep from FDA/ONDQA will no longer participate on the WG. He may be contacted on a very limited basis only, if necessary, towards completion of PQRI’s work product.

Action Item: Meet with IPAC-RS legal counsel, to review her recommendations for copyright issues.

Post Meeting Note: Teleconference set up and held on June 11th. SC members have until mid July to get questions/concerns to legal counsel for their review and integration where appropriate. Final document will then be resent for final review by SC and Board.

BioThree Work Proposal is still in the works. We should have Work Plan available for SC review by next SC meeting in August.

Assessment of Progress in Achieving PQRI's 2009 Mission/Vision

“The Product Quality Research Institute (PQRI) is a non-profit consortium of organizations working together to generate and share timely, relevant, and impactful information that advances drug product quality and development.”

- Productivity Task Force has worked diligently to form processes to help move things forward more expeditiously
- We need to execute on those things that we have made decisions on
- We need to get more member organizations and address who we should solicit
- We need to get update from the Board on efforts they have made in the past several months

New Concept Proposals for PQRI Work Projects (using template)

Nanoparticles

- Reviewed template presentation and discussed physical characteristics/properties i.e., size, function, solubility, surface, etc.

Action Item: Member org reps should solicit folks from their ranks who might be interested in serving on a formative discussion group to further explore where to take this topic in terms of a PQRI project that is within our scope and be doable with our timeframe and be beneficial/advantageous to all member orgs.

Post Meeting Note: Member names solicited and supplied to Chair on June 29th for her to directly contact them. Four individuals volunteered to serve.

Comparability of Biologics topic area had not report for the SC.

Complex Dosage Forms

- Discussed need to create better understanding of complex dosage forms
- What parameters best reflect BA and BE?
- PQRI co-sponsorship of workshop with AAPS and FIP in this arena in October 2009.
- Discussed possible overlap between QbD WG and this topic.

Action Item: Chair and DTC Chair will review the QbD models to see if we can find an extension to take this into the complex dosage forms realm.

Extension of Ongoing Work Projects

Bioequivalence Workshop Future Projects

- Three areas for future projects:
 - Publication of white paper with *Journal of Aerosol Medicine and Pulmonary Delivery*; possible cost could run as high as \$15,000 if it needs to run as a supplement. Steering committee motion seconded and approved to support up to \$15,000 for white paper publication, with the caveat that the planning

committee explore possibility of running and executive summary with links to the full paper on PQRI website.

- PK/BE Workshop in the Spring 2010.
- Proposals for Risk Management (IPAC-RS)
- Reviewed the PowerPoint presentation and cost estimates of hosting a PK/BE Workshop
- Possibly in conjunction with RDD in Orlando, FL in April 2010.
- SC motion seconded and approved to host workshop in Spring 2010 with cost estimates of approximately \$80,000 to follow same guidelines as BE Workshop that was held in Spring 2009.

Action Items: Take both SC recommendations to Board for their consideration at the June 8, 2009 meeting.

Post Meeting Note: Board approved the white paper publication for up to \$15,000 if necessary, and approved the workshop with the projected \$80,000 budget.

MTC Work Group Updates

- Peg reported that two work groups are still active
 - Risk Mgmt. is in the process of getting paper published with possibility of requesting a workshop on topic in the near future.
 - Spec Design and LifeCycle Management WG will be meeting on June 8th to finalize the last couple of items on their paper and discuss where to publish. Paper needs to be brought back before the TC and SC prior to publication.

- TC is exploring the topic areas of supply chain integrity and raw materials for possible work projects.

Action Item: MTC Chair will try to generate a specific proposal from the MTC in the near future. No need to wait for task force input. Also, she will solicit WG rep to discuss the Spec Design paper with the SC when appropriate.

New Business

Reception/Event at the PSWC 2010 in New Orleans

- Discussed possibility of hosting event in New Orleans to capture the international audience and highlight PQRI.

Action Item: Committee to further explore what type of event would be appropriate, set goals and prepare proposal for SC review.

FDA Guidances in the Works for 2009

- Document attached as copied from *The Gold Sheet* was reviewed and presented for members to refer to for use in making suggestions for future PQRI projects.

Old Business

Sulfonate Esters Webinar

- Set for July 23rd from 10:00 am – 12:00 pm ET
- AAPS has offered use of their software to run webinar to save PQRI cost of subscription
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PQRI Conference

- Date set for Dec. 15-16, 2009 at USP for rate of \$125/person per day cost. Includes all AV, food and meeting room rentals.
- Reviewed agenda and suggestions made for changes
- SC motion seconded and approved to host PQRI Conference at USP if survey comes back positive for outlook of conference

Action Item: Conduct survey with PQRI volunteers to solicit their expected rate of participation. Take recommendation to Board for consideration.

Post Meeting Notes: Survey came back with almost 2 to 1 ratio of people in support of conference and with strong desire to attend so recommendation was taken to Board on June 8th. Board approved cost of conference for up to \$50,000.

Productivity Task Force Report

- Discussed the following documents:
Real, Win, Worth Scoring Criteria Matrix; Work Plan Templates; and the Volunteer Contract

Action Items: Each TC should try to populate the matrix now to see if it's feasible using information from at least one current WG. The Nano group will also complete for their project. Comments/evaluations due to PDA Rep by the end of July so that he can make adjustments to present to the SC at August meeting. In regards to the Work Plan Template, PQRI Secretary should send a couple of past Work Plans to IPAC-RS rep so she can review and compare to the template to see if there should be adjustments made. She will then report back to SC in August. *Post Meeting Note:* TC Chairs were sent the matrix again, and asked to perform their review and send comments to PDA rep. Several past work plans were sent to IPAC rep for her use in reviewing the template.

Upcoming Meetings

August 11, 2009	teleconference	1:00 pm – 3:00 pm ET
September	face to face	TBD
Oct/Nov.	teleconference	TBD
December	face to face	immediately following PQRI conference 1:00 pm – 4:00 pm with Board

There being no further business, the meeting adjourned at 3:55 pm.