

PQRI Steering Committee Meeting

Thursday, May 31, 2007

9:30 a.m. – 4:30 p.m.

Drinker, Biddle & Reath LLP

1301 K Street, NW, Suite 900

Washington, DC 20005

SUMMARY MINUTES

Attendees:

Academia/Industry Representatives

Gordon Hansen, Chair – IPAC-RS

Vicki Penn – PQRI

Bruce Bird – MTC

Chris Allen – CHPA

Terry Tougas – DPTC

Mario Rocci – AAPS

Scott Boudreau – PhRMA

Rich Levy – PDA

Mary Devlin Capizzi – IPAC-RS

Nakissa Sadrieh – FDA

Fred Razzaghi – CHPA

Stacey May – AAPS

Mary Oates, Vice-Chair – PhRMA

Alan Parr – BTC

Bob Wiens – IPEC-Americas (by phone)

Bob Lipper, Chair B of D – AAPS (by phone)

Dennis O'Connor – AAPS/ITFG (by phone)

Pat Tway – DSTC (by phone)

Kumudini Nicholas, Health Canada (by phone)

Sultan Ghani, Health Canada (by phone)

Helen Winkle – FDA (by phone)

Absent:

Gail Sherman – PDA

Ron Manning – USP

Todd Cecil – USP

Sara Radcliffe – BIO

Don Burstyn – BIO

Jim Polli – BTC

Opening

- The meeting convened at 9:35 am, with Chair presiding. A quorum was reached with 7 of 9 Steering Committee member organizations represented.
- The SC Chair read the admonition statement relative to anti-trust issues.
- The agenda was reviewed and agreed upon, with several additions. They are:
 - PQRI participation in USP conference
 - Committee members whose org. has withdrawn from PQRI. Their continued participation on TCs and WGs
 - How members get selected for TCs and WGs
 - Paperless SC meetings
- Both the Full Minutes and Summary Minutes were approved as presented. It was requested that Action items be shown in different font and linked to the discussion.

Action Items from the April 4, 2007 meeting

FDA Member Representative-

It was reported that FDA rep for Sulfonate Esters has been appointed, FDA contact is working on rep for Specification Design WG and an FDA employee will assist Stability WG with representation. *Action item accomplished.*

PQRI Leadership-

The doc on restructuring was reworked; QbD committee withdrew their proposal for a workshop at this time; mission statement for the new TC was sent to all SC members. *Action items accomplished.*

ECAS Chair-

ECAS Chair to work on using media outlets to facilitate distribution of information in the PQRI Accomplishments document. It is too large to send as is, perhaps using the brochure once it is created, at the least, info will go out to all member organizations. *Action item accomplished.*

SC Member Representatives-

ITFG rep to be on call re the ITFG workshop proposal; dropped the item for getting the article into Pharm. Manuf magazine for Process Robustness WG. *Action items accomplished.*

PQRI Executive Secretary-

Info re workshop proposal submission form to be sent to USP for chemometrics workshop; Mission statement re restructuring sent to all SC members; hotel directions sent re SC meeting. *Action items accomplished.*

Report from PQRI Board of Directors-

SC Chair reported for Board of Directors:

- SC and Board Chairs presented to the PhRMA TLC group in April. Very favorably received and they are willing to take the “show” on the road to any organization who requests same.

- Financials are solid at the end of April with approximately \$330,000 allocated towards research funding projects throughout FY08
 - \$100,000 to Absorption systems
 - \$50,000 Stability Shelf Life contract with UNL
 - \$150,000 Sulfonate Esters contract with RIC
 - \$30,000 Sulfonate Esters contract with Ed Delaney
- Board meeting set for June 1, 2007 from 9:00 am – 12:00 pm
 - Discuss assessments for FY08
 - Academic Reimbursement Guideline

Current Projects

DPTC – Tracking form was completed

- **Stability Shelf Life WG:** discussed possibility of creating brochure to outline the upcoming work of the WG. SC decided that brochure was not the appropriate format to advertise their work at this time. Their work outline can and should be contained in the PQRI Accomplishments brochure which is being created by SC. All ongoing projects should be highlighted.

MTC – Tracking form was completed

- **Post Approval Changes WG:** submitted to docket @ FDA; PDA Journal doesn't fit for publication due to size of article (100+ pages); trying to come up with another strategy to publish article; suggested that the WG write a summary of the article for PDA Journal and then the full document could go up onto the website.

MTC Chair will advise WG to create a summary and then submit article to Stacey for insertion on website. It was suggested that we create a spot in each member organization's newsletters, etc. to insert PQRI articles or pertinent information.

PQRI Secretary to solicit names/emails of contacts at member orgs for this purpose.

- **Risk Management- Case Studies WG:** discussed possibility of a workshop to address concerns/gaps; discussed the possibility of establishing discussion boards

PQRI Secretary to explore Communities of Practice software with AAPS' IT folks for use by Work Groups. Earlier discussions indicated that this may be possible in Fall '07.

DSTC – Tracking form was completed

BTC – Tracking form was completed

- Co-chair of the BTC was appointed
- Since IPAC-RS member no longer on SC; do we need to appoint another SC rep as liaison to BTC? Would like to expand the number of reps on the TC to help divide work load.

ObD WG

- Looked at 71 Quality attributes to review process parameters

- Called a meeting of Steering team to review next steps; mtg. set for June 28, 2007

Old Business

- Reviewed letter to Member Org re restructuring. Comments and corrections noted. Nominations for appointment to this TC must be submitted by July 23, 2007 through the primary rep on the SC from each Member org. Committee should be up and running in Sept. 2007. SC will review all nominations to make sure all skill sets are covered, and decisions made re selection on the August 17, 2007 teleconference.

PQRI Secretary to add corrections to letter and the website posting article re the primary rep contact information as well as the nomination process info. Letter will then be sent to all Member Org reps with hard copies following email.

- PQRI Website Update discussed. Back door to portal created and password handed out to all SC members. Several documents are already up for review, SC members should pass along the password to their respective groups for their use. PQRI Secretary is maintaining the site so all documents for posting must go through her office.
- Bylaws and Policy and Procedure Documents need to be reviewed and merged with the new additions that were made last year to make sure the most current version is what is on the website. Adhoc committee formed to accomplish this task.

Adhoc committee to review various versions of the documents and compile an updated version for use. PQRI Secretary to send old and new docs to members for their perusal.

- PODP Proposal submitted by DPTC member and endorsed by PDA. Discussion ensued around the need for the information and whether or not it is a goal to come to a consensus with FDA; can the project move any faster than the 3 year projected timeline?; SC approved WG in principal, and asked for a budget and work plan to be created for review

DPTC Chair to relay information to the submitters about the next steps.

New Business

- Discussed the proposed work plan for the SSI WG that was submitted for comments. PDA asked for two additional weeks. All comments should be submitted by June 15, 2007. No objections noted at this time to work plan. WG mentioned that they will be submitting cost projections for a data warehouse to be considered by the SC.

- Excipient paper was submitted in parallel to both the DPTC and SC for review. Comments need to be in June 18, 2007. WG will compile and rework document on their June 21st telecom. All comments should go to both co-chairs for incorporation into document, with cc to DPTC Chair.
- PQRI participation at the USP consortium being held on June 11, 2007. CHPA rep volunteered to go and represent PQRI.
- ITFG Proposal was resubmitted. Discussion re the timing for the meeting, requested for 1st Quarter 2008; discussed offering AAPS the opportunity to sponsor in name only as it is their Focus Group offering the proposal – *AAPS' rep will work through AAPS to make this offer*; FDA is working on guidances in this arena, and is amenable to working with the workshop on topic. Concern raised by PhRMA reps re the generic slant of the material, and they asked if ITFG can reframe the topic to be more inclusive of PhRMA as well as generics.

ITFG to address some of the issues raised, and to reframe the scope of the topic. DPTC Chair offered to assist with this task as they are colleagues at Boehringer.

- Discussed the need for a submittal/approval process be created for these new type of workshops. Issue should be addressed in the policy and procedure document, but will be discussed within the SC further to clarify the correct procedure.
- PQRI Accomplishment brochure being pulled together by CHPA rep. Document to be sent to all SC members electronically so they can respond with their comments.

PQRI Secretary to send document to SC members and TC Chairs. CHPA rep to compile comments and rework document based on feedback. PQRI Secretary to obtain pricing information from Lettercomm re printing.

- Discussed the proper protocol for selection of new members onto either a TC or a WG. Results of discussion were that all nominations for a TC must come through the official primary member org. rep to SC Chair, with copy going to the PQRI Secretary. The selection process is handled by the SC and selection of a Chair for the TC is also made by the SC. As for replacement of members whose member org has withdrawn from PQRI, the member must be removed from the TC, and then if appropriate, they may seek to be nominated by a fellow member org rep.
- Discussed the proper protocol for selection of new members onto a WG. The current method was explored and it was decided that the TC for that WG selects members to populate a WG based on the skill sets that are needed; if nominees get turned down for selection onto the WG, it is important to try to offer them another means of volunteering with PQRI (i.e., serving as a reviewer for the final paper/product that is produced by the work group)

The PQRI Secretary should maintain the files of all nominees, and issue letters under the direction of the SC Chair and/or TC Chairs regarding the selection process. SC Chair

will create a descriptive paragraph outlining the process for distribution to all SC members.

- BTC Chair brought up the possibility and advisability of going paperless for upcoming SC meetings due to time commitments, cost factors and waste of paper. The motion was discussed and voted upon, and it was decided that SC meetings will be paperless in the future. All documents and attachments will be sent to SC members and TC Chairs, via email, for their use during the meetings. Each member is responsible for either bringing their own hard copy of the documents, or computer so they have access to the documents for discussion points.
- Discussed the starting times of SC meetings. Voted on whether or not to have meetings begin at either 9:30 am or 10:00 am. By a vote of 7 to 2 in favor of starting times of 9:30 am the SC decided the matter.

Upcoming SC Meetings

August 17, 2007	10:00 am – 11:30 am	Teleconference
December 6, 2007	9:30 am – 4:30 pm	Face to Face meeting

PQRI Secretary to send email to all SC members re the upcoming teleconference in August, with a reminder that the teleconference will be to discuss and decide upon the selection of nominees for the new Development TC.

Informational Items

Referred members to the financial statements as presented in the binder for April 2007; statements accepted as presented.

There being no further business before the Steering Committee, the meeting adjourned at 3:40 pm.