

PQRI Steering Committee Meeting

Wednesday, April 4, 2007

Teleconference

SUMMARY MINUTES

Opening

- * The meeting convened at 1:10 pm, with the Chair presiding. A quorum was reached with 6 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.
- * Both the Full Minutes and Summary Minutes were approved as amended.
- * The goal of this meeting is to review action items from last meeting and finalize the restructuring plans for the technical committees.

Action Items from the March 9, 2007 meeting

FDA Member Representative-

- FDA members are still exploring the possibilities of finding a FDA rep for the Stability Shelf Life WG and also an FDA Compliance rep for the Specifications Design WG as well as, who the best FDA rep would be to assist with the Sulfonate Esters WG. Trying to determine the exact role that the FDA reps will play on each of the WG.

PQRI Leadership-

- Action item accomplished with document outlining the new formal organizational structure for PQRI and the justification behind it, as well as the avenue for soliciting new ideas/projects for consideration by PQRI;
- Action item accomplished with cover letter to accompanying the PQRI Accomplishments document being sent to all member organizations; favorable feedback received re documents from some of the organizations

ECAS Chair-

- Action item accomplished with QbD Adhoc committee making a proposal to SC for their consideration re exploring possibility of QbD workshop.
- Unknown status on this action item. Draft press release to utilize media outlets for PR purpose using the PQRI Accomplishments document to highlight achievements

SC Member Representatives-

- Action item accomplished with work on brochure design highlighting PQRI Accomplishments. They are reformatting the document at this time.
- Action item accomplished as a mission statement for the new TC;

- Unknown status on this action item. Need info from ITFG for further clarification on whether they believe a ‘focused’ workshop or a ‘general’ workshop would be more in order at this stage and what the expectations of ITFG are for this workshop.
- Unknown status on this item. Offer to help get the article into the *Pharm Manufacturing* magazine for the Process Robustness WG
- Advise on the status of the contract for the Sulfonate Esters WG. PQRI advised that the contract has been through review with the attorney and is back to RIC for their review and signatures.
- Unknown status on this item. Discuss with FDA for a rep for the SSL WG.

PQRI Executive Secretary-

- Action item accomplished. Posted reimbursement guidelines on the PQRI portal so that all SC, TC and WG members can review and familiarize themselves with the policy so they can relate it to those academics that they invite to meetings
- Action item accomplished. Posted PQRI Accomplishment document on website
- Action item accomplished. Cover letter to accompany the PQRI Accomplishments document; send document to all pertinent organizations;
- Action item accomplished. Set up telecon between to draft mission statement for the new TC model
- Send criteria information to USP once it has been adopted by SC so they can make their presentation re the Chemometrics proposal fit the model
- Action item accomplished. Sunset Process Robustness WG with letters and certificates going out to members.
- Action item accomplished. Explore the security that the PQRI site will have via AAPS’ IT section when the ‘back door’ is created, and we will send a template for the page and links to all SC members for their consideration prior to the April 2007 SC meeting.
- Action item accomplished. Updating the portal to delete old information, and asks that SC members take a look at it prior to the April meeting to advise if anything else needs to be updated.

Current Projects-

Tracking forms completed and in packet for your informational purposes only. No discussion on technical committees.

Old Business

- New TC structure- document offered for consideration and discussion. It was suggested that a letter of goals and the skills that PQRI is looking for in establishing the new TC should accompany the announcement
- SC will accept nominations for this new TC; nominations will be vetted by the SC and the SC will be charged with repopulating the TC

- Discussion about deciding leadership roles for the new TC; can be handled either by the SC or by the TC members themselves once it is formed
- Need to include a paragraph in the announcement document outlining that the BTC and the MTC are not being affected by this restructuring. ONLY the DSTC and DPTC are being reorganized. WGs will continue on the path they are currently on-
- Discussed the PQRI workshop models and the differences between the topical workshop and the conference type workshop. The topical workshop will involve “thought leaders” and be charged with establishing information or topics that PQRI should consider addressing, and the conference type workshop will be charged with disseminating information to a general audience. A workshop proposal submission form draft was created for review and use on the website.

New Business

- discussed the criteria for proposals as offered in the announcement document and requested changes be made to the document. We will rework document to include all the recommended changes/additions, and send it out via email for review to move the process along in a more timely manner.
- QbD workshop proposal sent in for SC review. SC has requested that the meeting submission form be completed so that SC has more information in order to make a decision about this proposal. Send form to et al and then will forward completed form onto SC members for their review prior to the next SC meeting.
- Discussed the Mission statement that was offered and was accepted as presented with no comments. Current TC chairs will help set up new TC and get it running, but have no interest in chairing the new TC after it is formed. Forward copy of mission statement so that it can be distributed to all SC members.

Upcoming SC Meeting – Schedule

May 31, 2007 Face to Face at 9:30 am – 4:30 pm

Informational Items

Referred members to the financial statements as presented in the binder for March 2007.

The meeting adjourned at 2:20 pm.