

**Summary Minutes
Joint Board and Steering Committee Meeting
February 8, 2010
9:30 am – 4:00 pm**

Teleconference due to weather

**Call In Information:
1-866-570-1041
544861 passcode**

Opening and Welcome

Admonition Statement was read by the SC 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.”

Review of Minutes from December 2009 were approved as presented.

Review of Financial Statements was given by the Treasurer.

- Presentation was given of current status and projected needs for FY2011

PQRI Conference Results

Survey/Comments were reviewed. Survey results were compiled and indicators are that the mission of PQRI is clear and favorably received. The conference is considered an overall success and PQRI needs to act upon the suggestions made during the conference to keep the momentum moving forward.

Projects :

- **Process Drift Workshop Proposal** was given by rep from the MTC. The SC approved the workshop concept and asked that Raj develop the agenda further and create a budget estimate for the SC and Board to review.
Action Item: PQRI will work with MTC to prepare a budget estimate for review once the program is a little better established. **Post Meeting Note:** Budget is in the works to be reviewed by the Planning Committee prior to submission to the SC.
- **Supply Chain-Excipients WG** is being worked on by MTC and should be ready for presentation to the SC at their next meeting.
- **Sample Size for large ‘n’** is being explored and will be developed further for review by the SC.

- **Nanoparticles** is being developed with the idea of supporting a grad student to do the compilation for a characterization tool kit as a first step.
Action Item; CHPA rep will contact Texas A&M Health to see if they are interested in creating the grant for a grad student to undertake this assignment. PQRI will send sample grad student contract from the Stability WG to rep for her reference. **Post Meeting Note:** Sample sent so she could begin the process.
- **Complex Dosage Forms** in relation to transdermals is being explored by the MTC. They will decide how to proceed once they review the transdermal document. SC Liaison will participate on their next teleconference to facilitate discussion.
- **Biosimilars** project will be explored under the BTC.
Post Meeting Note: BTC Chair and PQRI sent an email to all PQRI conference attendees asking for their input and participation in a discussion group to move this concept along and define an appropriate work project.
- **Out of Specifications** work project was proposed in concept to see if there is an acceptance rate for OOS, and what is the anticipated effect?
Action Item: SC Chair will refine the proposal concept and consider whether or not it should be rolled into the discussion on large 'n' sample size project or be handled separately.

Technical Committee Reports

BTC update was given.

- BCSIII WG report is being reassigned to get the report finished.
- Orientation Class set for 2/16/2010

DTC update was given.

- **SSL request for extension**-Board approved extension so that grad student can take advantage of leftover funds to attend the ENAR presentation in March 2010.

MTC update was given.

- **Working on Supply chain WG proposal; Process Drift Workshop Proposal; exploring WG proposal on transdermals.**
- **Invited Risk Mgmt.** speaker to participate in FDA Training Session in March 2010 to present findings from their WG.
Action Item: PQRI to contact Chair of WG to try to get an answer for FDA ASAP.
Post Meeting Note: Reply to FDA was too late and another speaker was inserted in their place.
- **Specifications WG** is still in need of assistance to finish up work project.
Action Item: PQRI to contact MTC Chair to see how we can help get this moving to finalize the paper and finish work plan.

PK/BE Workshop in April 2010 currently has 45 registered attendees.

Volunteer Appreciation Efforts have started and we are acquiring the lists of those to whom we should be addressing letters.

Orientation Class for BTC is being held on Feb. 16, 2010 and open to any and all PQRI volunteers.

Publication Policy Update was given. SC and Board reviewed and approved the revised Publication Policy to highlight that all agreements must now go through the Chair, Board of

Directors for signature to try to protect PQRI's right to place the articles in full on our website for use in the public domain.

Action Item: PQRI to have IT post new pub policy. *Post Meeting Note:* Accomplished.

Quality Leader Discussion Groups/Membership Proposal and Guidelines was reviewed by the SC and Board members. Discussed pros and cons of having a formalized discussion group. General concern over the lack of transparency and lack of opportunity for member organizations to become discussion group members.

Action Item: SC Chair withdrew her proposal based upon the concerns of the SC and Board.

Financial Model Discussion

Dues Structure was discussed and the feasibility of offering a graduated dues structure to new incoming member organizations to give them the opportunity to try PQRI. The graduated schedule for dues would be \$5,000 for the first year, \$10,000 for the second year, and then the full \$20,000 for year three and on. We would also send a letter to previous member organizations and offer them a one shot opportunity to return to PQRI during FY2011 (July 1, 2010 – June 30, 2011) at the graduated dues structure to try to encourage them to re-engage with PQRI. The discussion also revolved around whether or not member organizations felt that the \$20,000 annual dues were reasonable. The opinion of the members was unanimous in that the dues are reasonable, and in favor of offering the graduated dues structure to new and returning members. There was some discussion concerning AAPS' reduced membership dues and whether or not that needs to be revisited.

Action Item: The AAPS representatives to the Board and SC opted to have a discussion with AAPS' Executive Director regarding the current structure and whether or not that should be revised. They will report back to the Board and SC on their meeting. PQRI to draft a letter from Board Chair and Treasurer to previous member organizations to offer them the one shot deal for FY2011 and the reduced dues.

Treasurer will draft a written proposal regarding the graduated dues structure and submit it to all SC and Board members for their official vote. *Post Meeting Note:* That revised proposal went out for comments on Feb. 8, 2010.

Next Steps/Upcoming Meetings

PQRI will contact SC Chair for dates/times for next Steering Committee meeting, and the Board will schedule their next meeting for mid-late May 2010 to address the budget.

There being no further business, the meeting was adjourned at 3:30 pm.