

**Summary Minutes
Joint Board of Directors and Steering Committee Meeting
January 15, 2009
9:30 am – 4:00 pm**

**Hosted by PQRI
2107 Wilson Blvd. Suite 700
Arlington, VA 22201**

**Call in Information:
1-866-570-1041
10695500 passcode**

Opening and Welcome

Chairs opened the meeting and welcomed all members.

Admonition Statement

Chair read the following 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 Agenda

Chair reviewed the agenda and it was accepted with one addition – DTC request to approve nominee placement on the PODP Work Group.

Approval of Minutes

Board/Steering Committee Minutes from December 9, 2008– Motion made to approve minutes as presented. Motion passed unanimously with no corrections. Suggestion was made that PQRI Secretary take minutes that are not in great detail. Rather that she highlight those areas discussed and what the final outcome/decision is that is reached by the Board and/or Steering Committee.

PQRI Financials

Treasurer provided an overview of the current financial position. He recommends that although PQRI is currently in a good financial position, it will be important to monitor our investments as they are short term investments and may need to be adjusted in accordance with market fluctuations and/or research funding requests. Treas. commended the Accounting Department’s excel spreadsheet that shows the return on investments that was supplied. There was a discussion about what liability either the

Board of Directors members have, and what do Steering Committee members have in regards to financial liability.

Action Item: PQRI Secretary to request a D&O Policy review by our legal representative and also ask whether they believe it is necessary to insure the Steering Committee members as well as Board members?

Post Meeting Note: D&O policy sent to our legal review team at Winthrop, Pillsbury and Shaw for their review and legal opinion.

Development Technical Committee Request

The DTC, in support of the PODP requests that the Steering Committee approve their nomination to the WG. Steering Committee unanimously approved the nomination.

Bylaws Change re SC Past Chair Position

In accordance with the unanimous email vote, the following will be adopted as part of our bylaws.

Steering Committee Immediate Past Chair- The Chairperson may elect to remain on the Steering Committee as Past-Chair, once they relinquish their position as Chair, for a period of up to one year in order to provide continuity and assistance to the new Chair, as long as they are affiliated with a current PQRI member organization. As an ex-officio, they can offer input into discussion, but may not vote on any issue before the Steering Committee.

Action Item: Immediate Past Chair is requesting that IPAC-RS allows him to affiliate with their organization for this purpose. IPAC-RS rep will confirm with IPAC-RS their approval, and report back to the SC.

PDA Announcements-

PDA rep advised that current secondary rep is no longer with PDA. There will be a new secondary representative for PDA to the SC. They will appoint someone to take his place where appropriate on the various TCS, and WGs where he currently serves.

Action Item: PQRI Secretary to send thank you on behalf of the Steering Committee to member for all of his hard work on the various projects. He has truly been a valuable resource on many levels.

Post Meeting Note: Letter sent by PQRI on Steering Committee's behalf.

Strategic Visioning for PQRI Discussion – Task Force Reports

- 1) **Mission Statement** – reviewed their draft statement and after much discussion, a consensus was reached on the new Mission Statement for PQRI. It is as follows:

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.

By virtue of its diverse membership, PQRI provides a unique forum to focus critical thinking, conduct research, exchange information, and propose methodology or guidance to pharmaceutical companies, regulators, and standard setting organizations.

- 2) **Productivity** – reviewed their minutes from December call and they advised that their group was to meet on January 16th in PQRI office to address issues they saw as pertinent.
- 3) **Relationship to Regulators** – reviewed their power point presentation of the relationship at the SC, TC and WG levels. PQRI should consider outreach to build interactions with other regulators besides the FDA, as well as to strengthen the involvement of academics. The Task Force was asked to additionally consider to whom and how we should make the approach. Tony DeStefano agreed to work with this Task Force on this particular issue.
- 4) **PQRI Outreach/ Scientific Forum** – discussed the feasibility of hosting a PQRI Conference in early summer. Task Force will work on dates with USP and put together a planning committee to formulate a program agenda. There was consensus on the concept of hosting the conference.

Action Item: Rep to contact USP about dates.

Post Meeting Note; Dates were acquired, polling was done to get members input on the most preferable dates and a call for planning committee volunteers was put out. Three volunteers for the planning. They will report back to SC on Feb. 19, 2009.

The Outreach Task Force also reported that they are in the process of creating a weblink template that all member organizations can use to bring PQRI into the member websites.

Action Item: Rep creating template and will request logo permission from PQRI.

Post Meeting Note: A permission request template letter was drafted so that all member organizations can utilize it, and also a permission form for PQRI to sign to authorize use of the PQRI logo. CHPA requested the logo usage, and Board Chair signed off on it so they could finish creating the template and install it on their website.

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

Action Item: PQRI to send them background info for article.

Post Meeting Note: Vicki sent CD with several historical files and information on it for use in the article.

Nominations for Chair of the Biopharmaceutical Technical Committee-

The skill matrix example was received, but has not established the matrix in regards to the BTC. Also not found anyone for the BTC Chair position, but may have a candidate at PDA who is interested. Board Chair offered to search AAPS for a candidate if unsuccessful within PDA.

Action Item; SC rep to follow up on BTC Chair search, as well as create the skill matrix for populating the BTC. PQRI Secretary will assist to clarify how the process worked when we populated the DTC.

Post Meeting Note: Set up the process for how this should transpire.

Mission Statement and Establishing Objectives

The group broke down the new mission statement into five objectives. Each objective had members assigned to their subcommittee, and charged with addressing the strategies and tactics necessary to meet the objective by the Feb. 19th meeting. See attached Objective sheet-

Post Meeting Note: PQRI Secretary prepared document outlining the objectives and their respective committee and sent information to all SC members, TC Chairs and Board members via email on January 21, 2009.

Upcoming Meetings

February 19, 2009 Joint Board/Steering Committee Meeting
February 20, 2009 SC Review 2009 Portfolio

Adjournment

There being no further business to bring before the Board or Steering Committee, the meeting adjourned at 3:55 pm