

Summary Minutes
Joint Board and Steering Committee Meeting
December 20, 2011
1:00 pm – 3:00 pm

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

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 Oct. 2011 – comments received and minutes amended. Minutes approved as presented.

Review of Action Items – reviewed all Action Items. Those still outstanding are:

Strategic Growth Task Force-

- **Action Item:** Task Force to brainstorm ideas for moving forward. Possibility of consultant to market PQRI and solicit funding.

FDA Grants-

- **Action Item:** clarify with Jon Clark whether or not PQRI can write a proposal for FDA funding for research projects. Point to be considered is whether or not it is legal and proper for PQRI to apply for grant funding through the FDA due to the nature of our relationship?

Biosimilars Workshop-

- **Action Item:** Chair was asked to develop it further to report at the Dec. meeting. She and PQRI will develop a draft budget for the workshop once a skeleton agenda is created.

SUPAC IR-MR Guidance-

- **Action Item:** MTC Chair and team will develop the Work Plan and hopefully present it at the Dec. meeting. It is probably time to look at all SUPAC Guidance.

IQ Proposal-

- **Action Item:** QbD WG work corresponds with this topic so he will follow up with IQ President. He will prepare power point presentation for SC consideration prior to next

meeting via email. Presentation was made to IQ and he will forward that presentation along to the SC for their review.

Board of Directors Business

- **Bylaws**
 - EC approved bylaws and they will be posted effective Jan. 1, 2012 on the website. **Action Item:** During next meeting, we will address the logistics of now enforcing the new provisions in the bylaws.
- **Financial Statements/Audit**
 - Presentation was reviewed, budget looks good and on track. New statement to be received regarding investment portfolio.
- **2011 Best of Arlington Award-** PQRI has been selected to receive this honor.

Steering Committee Business

- **Nanoparticles Update/Requests**
 - Reps reviewed their presentations on the work product from the Nanoparticles Work Group. They also presented a proposal for creating a book and compensation for same. **Action Item:** Any questions should be sent directly to reps so they can be addressed prior to the next meeting. Steering Committee and Board members to consider request and relevant data so that a discussion and decision can be made during the Feb. meeting. Also, team should explore publication options and “Print on Demand” feature.
- **Strategic Growth Task Force**
 - No report given at this time.
- **IVIVC proposal**
 - Proposal was approved by SC and a planning committee has been established and is working on creating a skeleton program agenda and draft budget for approval. **Action Item:** Complete agenda and budget for consideration at the Feb. SC/Board meeting.
- **Topicals workshop proposal**
 - Concept was approved by the SC and a planning committee will be established. **Action Item:** Once planning committee formed, then a skeleton program agenda and draft budget need to be created for the next step in the approval process.
- **Biosimilars workshop proposal**
 - **Action Item:** Once planning committee formed, then a skeleton program agenda and draft budget need to be created for the next step in the approval process.
- **RWW Scoring Matrix update**
 - Reviewed suggested changes. **Action Item:** IVIVC Co-chair was asked to try to use the matrix to rank his IVIVC proposal to see if the changes help in completing the matrix and making the material more relevant.

- **Post Approval Changes WG Proposal-** reviewed presentation. **Action Item:** MTC requested that they be allowed to discuss/vet the project and then report back to the SC in Feb. They will work directly with submitter.
- **PODP Publication Request-** Work Group requested that they be allowed to publish in the PDA Journal. Basic consensus that that could happen as long as PDA can meet PQRI requirements of Open Access to article, copyright issues and no fee being charged in order to publish our research. Publication policy does indicate that we should use Member Organization Publications when appropriate. **Action Item:** PQRI to send email to Chair asking for a copy of the agreement that PDA would want PQRI to sign for this publication so that Board Chair can negotiate to make sure our interests are protected. **Post Meeting Note:** Request for agreement was made through the Work Group Chair immediately following this telecom.
- **Lung Study Request for Financial Support for Publication-** funding support requested to assist with publication of their report. They have completed work that was inspired by the PK/BE Workshop we hosted in March 2009 however, PQRI is not affiliated with the research they conducted. There was a motion to fund up to \$5,000 for publication and then discussion ensued. The final vote was unanimous in favor of denying the request for funding since this was not a PQRI project and we did not wish to set a precedent of paying for work we have not sanctioned or reviewed. **Action Item:** DTC Chair will advise the group of the SC/Board decision.

- **Technical Committee Reports**
 - **BTC**
 - No additional report at this time.
 - **DTC**
 - **SSL Co-Chairs** were unanimously approved by the SC for the Work Group.
 - **MTC**
 - **Spec Design update-** thanks to FDA reps efforts, a summary of the paper has been completed and will be ready for publication shortly, and the original paper is being updated for posting on the website.
 - **Process Drift Workshop** Planning Committee is working on a proposal for hosting a follow up workshop.

Next Steps/Upcoming Meetings

- Members will be polled regarding a date for a face to face meeting in February 2012. **Post Meeting Note:** The date selected is Feb. 2, 2012.

There being no further business to discuss, the meeting adjourned at 2:57 pm.