

Summary Minutes of the PQRI Steering Committee and Board of Directors
December 4, 2014

Hosted by
CHPA
1625 Eye St. NW
Washington, DC

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

The meeting was brought to order at 9:32 am in the conference room at CHPA.

Admonition Statement read by the Chair of the Board.

Review of the Agenda – request by Treasurer to handle financial review first up as he is traveling via car while on the call.

Review of Minutes from the Oct. 2014 meeting. Minutes were unanimously approved as amended.

Financial Review led by Treasurer.

- Discussed the results of the quarterly financial review as done by AAPS Finance Director. New practice initiated to review at the end of each quarter; Elemental Impurities Workshop to be added to the budget for FY15. **Action Item:** PQRI to send budget to accounting for inclusion. Post Meeting Note: budget sent to accounting for inclusion in the FY15 budget.

Addition of New Members to PQRI Steering Committee-

- Results of email vote to admit PDA into PQRI was passed unanimously.
- Member organizations also voted on the interest intent letter submitted by ISPE to join PQRI. Vote to approve ISPE membership with a motion and 2nd. Unanimous approval to admit ISPE to PQRI. Board also addressed a motion and 2nd to prorate membership dues for ISPE since they are coming in mid-year. Vote was passed unanimously.
- Discussed proposal to admit IQ Consortium to PQRI as members. Board and SC reps attended the IQ meeting in early October and during that time, a discussion was had with IQ leadership on whether or not it might be valuable for the organizations to collaborate since we perform much of the same type of work. Discussion ensued concerning using an MOU, or requiring full membership, and the decision made was to offer IQ Consortium a full membership to the Steering Committee which means that they would need to pay dues like all other member organizations. Board Chair and SC Chair will re-address the issue with IQ after preparation of the updated slide presentation. **Action Item:** AAPS will help prepare a piece with Key Messages in it

to use in their discussions with IQ. Once they are ready, Board Chair will request a conference call with IQ to discuss the proposal and how we can move forward.

PQRI Scientific Advisory Board Proposal

- Idea was tabled at this time. It might be a good idea to undertake in the future, but there will be a need to make sure it stays science based and not become a political board so that it does not create conflict for the FDA.

Strategic Growth Task Force

- Membership campaign has been successful and we now have two new members. Recommendation made that each Member Organization utilize the PowerPoint presentation created by SC Vice Chair, and then tweak it occasionally to make it relevant to their specific organization. This could help keep PQRI in the limelight within their organization and also helps promote the good work that is taking place in the Institute. **Action Item:** PQRI to re-send the PowerPoint presentation so that folks can use that in discussions with their Boards and committees. ***Post Meeting Note:*** Presentation was re-sent to all SC and Board members.
- Treasurer has had preliminary discussion with GPhA who is interested in having PhRMA back in PQRI; PhRMA is not interested at this time as their attention is being spent elsewhere and they have dissolved most of their technical groups. **Action Item:** Treasurer to request to be on the GPhA agenda for their next Board Meeting, and the Task Force should look at any other means of moving forward with this candidate.

Installation of New SC Chair and Vice Chair

- Board Chair officially thanked outgoing SC Chair for her service, and her award will be mailed to her following the meeting; He then welcomed the new Chair for the Steering Committee. She then ran the voting for a new Vice Chair for the SC. USP rep volunteered to assume that responsibility with the support of his leadership at USP and he was unanimously elected to that position. No other volunteers came forward for that position and we are grateful to him for stepping into that role.

ISPE Collaborations-

- ISPE CEO gave an overview of his role at ISPE and their excitement at being a part of PQRI once again. He offered the opportunity to PQRI to co-sponsor the upcoming June 2015 ISPE/FDA Quality Conference which is being held in Washington, DC June 1 – 3, 2015. Motion made and 2nd to co-sponsor this event and to allow a PQRI volunteer to serve on the Planning Committee for the meeting. The motion passed unanimously and Treasurer volunteered to be on the Planning Committee for this conference. **Action Item:** PQRI to send sample co-sponsorship agreement to John and also contact information for Louis so that he can participate on the Planning Committee. ***Post Meeting Note:*** Both items accomplished and agreement signed.
- ISPE named an interim representative to the Steering Committee until the Vice President for Regulatory Issues is selected at ISPE. They are in the process of hiring at this time, and also of creating a DC based office for ISPE. ISPE advised that the new person is welcome whenever they arrive, and that the interim can also remain as an observer on the SC once the new primary rep is seated. We welcome their participation on the Steering Committee.

2nd FDA/PQRI Conference on Advancing Product Quality-

- Budget will be voted on once the comp registration issue is discussed and decided upon with FDA; Treasurer asked for an estimate of how many comps we think there might currently be according to the agenda in place at this time; discussed the PQRI Comp Policy and the importance of sticking with that policy unless specific allowances are requested and then approved by the Board of Directors. Also discussed the opportunity for each PQRI Member Organization to have their logo on the program materials for the conference to show their endorsement of the conference. That will also show the various members of PQRI so that the public can see the breadth and reach of PQRI. In addition, FDA advised that they will not be utilizing thumb drives to store the speaker presentations. The assumption is that this is due to security policy at the FDA which forbids any use of outside devices on FDA computers. **Action Items:** AAPS rep to obtain AAPS' policy of issuance of comps, and ISPE CEO to provide ISPE's policy on comps for moderators so that the Board can examine our policy in light of what others are doing in this realm. PQRI to send email requesting logos if each Member Organization is interested in having theirs on the materials.

Reports from Technical Committees-

BTC- as reported by Vicki Penn.

- All Work Groups are moving forward and the Sequential Design and the BCS III groups are getting ready for publication as their work is completed. The BCS Update is currently in progress and they are waiting for the draft from the professor in Sao Paulo to begin the next phase of the project.

DTC- no report at this time.

MTC- overview given by PQRI as to work projects that are moving forward.

- Process Validation topic has been added to the FDA/PQRI Conference for inclusion; the Excipient Variability survey is almost ready to go out with a target date of early December; the Compounding project is being addressed and may go forward with assistance from PDA
- Outgoing MTC Chair was thanked for her many years of service to PQRI and especially to the MTC and we hope she will continue to be a member of the MTC in the future; a new Vice Chair will be selected in early 2015. **Action Item:** PQRI to send the award to Jean directly following the meeting.

Key Words/Metadate Search for Website-

- PQRI has worked with IT and this project has now been completed

Website Re-Design-

- PQRI spoke with AAPS IT and they said that if PQRI wished to have a re-design done they suggested having it done by someone else, and then PQRI take over maintenance of the website. PQRI has asked some of her family members to look at

what it would take to create a new website, and whether or not we would need a Content Management System to host it, and what the potential costs would be and what it might look like. She is hoping to have something to show the SC and Board in the spring.

Elemental Impurities Workshop-

- The timing for this workshop is superb due to the Training Materials for this new requirement should be released around the same time as this workshop- Spring 2015. The program agenda is being developed and finalized and the deadline for having a confirmed final agenda is the end of December so that we can get out the Preliminary Program Brochure in early January 2015. The Planning Committee may need to ask for an additional travel reimbursement for one Japanese speaker. Two have already been approved for up to \$10,000 of expenses, and if a third becomes necessary we will seek approval from the Board at that time. Since USP is co-hosting this meeting, and not charging PQRI for the use of the Meeting Center, the potential for profit for this meeting is considerably higher. **Action Item:** Chair to send to PQRI the list of AAPS Sections/Focus Groups that might benefit from a targeted email broadcast regarding this workshop. All others are asked to share the Save the Date promotional piece you received to help get the word out about this meeting.