

Summary Minutes
Joint Board and Steering Committee Meeting
December 14, 2012
9:30 am – 2:00 pm
Hosted by PQRI

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

Call to Order by SC Chair.

Admonition Statement read by 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 Agenda- PQRI added the Call for Nominations Packet to the agenda.

Review of Minutes from September 2012 – comments received and minutes amended. Minutes approved.

Review of Action Items

Action Item: The Finance Committee, was charged with working with Campion to refine the proposal for PQRI and creating and Investment Statement. Proposal to be presented at the December meeting. **Post Meeting Note:** Treasurer provided the Campion proposal to SC and Board members for their review prior to the December meeting.

Action Items: AAPS rep to provide PQRI with the AAPS nominees immediately following the EC meeting on Oct. 14th so that they can be prepared for everyone to look at prior to voting. All member organizations may also still send in nominees up until Oct. 28th. PQRI will set up a telecom in early November so that SC members can discuss the candidates prior to voting with each member org representative to introduce their own candidates.

- **Election Procedures/Policy**

- **Action Item:** PQRI to look at AAPS’ procedures and policies for how to set up the election process for future elections, and try to adjust them accordingly for PQRI’S use.

Post Meeting Note: All Action Items accomplished and voting took place in November with notification of selection of candidates made on November 19, 2012.

Action Item: the IVIVC paper’s corresponding author will advise planning committee of the PQRI decision. **Post Meeting Note:** Board Chair and SC Chair decided to bring the matter back before the SC to re-consider proposal. AAPS’ Publication Department Director will address the SC on Dec. 14th to explain the publication policy.

Action Item: Erika will refine the BCS III proposal requesting a grad student's assistance with the project if it is needed; FDA will check with one of their employees who has done some extensive work in this area and put her in contact with BTc Chair (*Post Meeting Note:* Completed as stated) and also suggests the possibility of connecting with NIPTE on this project.

Action Item: DTC Chair will forward CVs for PODP WG to PQRI for SC consideration. *Post Meeting Note:* CVs distributed and approval obtained by SC members.

Action Item: DTC Chair to request formal proposal from the Container Closure WG for work continuation.

Action Item: PQRI to work with Planning Committee for the Nanotechnology Workshop to set budget for workshop. Planning Committee will need to formalize and finalize their agenda for the next step in the approval process. If the workshop wishes to happen in Spring 2013 then the Planning Committee will need to commit to an expedited process. FDA rep will inform members of the Planning Committee and will work with the group to move it forward. We also need to look at other groups that may have events that will conflict with our dates. Suggestion was made to contact Nanoparticles WG Chair to enlist her participation as well on the Planning Committee and utilize her PQRI work during the workshop. *Post Meeting Note:* No response from FDA as of November 28, 2012 after a couple of attempts to get this moving forward.

Award Presentations by PQRI to SC Chair and Treasurer for their dedication and service to PQRI. SC Chair will remain an ex-officio member of the Steering Committee for a period of two years. Treasurer is still currently involved in multiple projects for PQRI. PQRI is extremely grateful for their service.

Installation/Introduction of Officers by SC Chair

- **New Director for the Board and Chair and Vice Chair of Steering Committee**
New Chairs and Director installed.
- **Call for Nominations Packet** will be sent out to all member organization primary representatives in the month of January to facilitate nominations for the positions of Chair, Board of Directors and Director, Board of Directors. The deadline for nominations will be May 31, 2013 and elections will take place in July/August so that we can have the selection for AAPS' EC to review by their September meeting for Chair of the Board of Directors.

Board of Directors Business

- Financial Report was given by Treasurer. Slide presentation was reviewed and discussed.
- Campion Proposal was and then they turned the presentation over to Campion representatives- Discussion about the proposal and a vote of confidence and concurrence was given by all members present. **Action Item:** Any members having questions or concerns about the proposal should voice them by no later than December 31, 2012. We will address the concerns and seek answers where appropriate from Campion prior to the next Board meeting. Board will arrange to meet in January to discuss and vote upon proposal and if proposal is accepted, to

determine the asset allocations. **Post Meeting Note:** We were able to secure the answer to the questions raised about what happens in the event of the demise of either the owner of Campion, or the firm. The response from Campion was provided to all SC and Board members for their clarification.

Steering Committee Business

- IVIVC workshop totals are now final. We made ~\$22,000 profit from this workshop. All expenses have been paid.
 - Publication approval for paper issue discussion was led by the AAPS Publications Dept. He discussed the consensus agreement and how it might be applied in this instance. He advised that if there were further questions, it would be best to talk to the Editor of the *AAPS Journal*. **Action Item:** Teleconference to be scheduled with the Pubs Committee to address PQRI concerns. If author is satisfied with the results/answers he receives then he is to proceed with the publication in the *AAPS Journal*. **Post Meeting Note:** arranged this teleconference.
- Topicals workshop has a current registration total of 16, with 14 of those as comp registrations. Registrations should pick up after the first of the year. **Action Item:** Member Organization reps are encouraged to seek avenues for advertising this workshop within their respective organizations.
- Biosimilars workshop has had a recent development in that the FDA has withdrawn their speakers, moderators, and planning committee personnel from the workshop. They do not feel that they can participate in a discussion on this topic at this time. FDA rep clarified their position and advised that the FDA had concerns about the topics being addressed and felt there was too much emphasis on USP and on a monographs approach for Biosimilars. FDA also does not wish to speak publicly on the topic until they have experience, data and applications to discuss their position. Not sure when that might happen - Right now the FDA is still formulating their policies on the topic of Biosimilar drugs, and not ready for discussion at a workshop. The concern was raised that the week prior to the PQRI workshop the FDA is heavily involved in the WCPB 2013 conference dealing with the exact same issues PQRI has asked them to speak on. The explanation is that the FDA's Biosimilar Implementation Committee (BIC) and CDER's Biosimilar Review Committee (BRC) are yet to develop policies on the topics of PQRI program and therefore cannot participate at the February 5-6, 2013 meeting. It should be noted, that prior to this meeting PQRI had not known about the BRC and BIC committees and their role within the FDA. The Steering Committee, along with the recommendations of the workshop Planning Committee, have opted to postpone the workshop until such time as the FDA feels it can get on board with a public discussion surrounding this topic. **Action Items:** PQRI will work with FDA and their appropriate personnel to try to get this workshop back on track so that the workshop is only being postponed and not cancelled. PQRI will send out notices to all of the Planning Committee members, speakers, moderators, etc. as well as handle all the reimbursements for registration and penalty costs for cancelled airline reservations for speakers. Cancelling hotel reservations should not incur any costs. PQRI will also work with USP to try to reschedule a workshop within

12 months at their facility so that we do not lose the \$5,670 deposit we have already paid.

- **USP/PQRI Joint Meeting** as a co-hosted event for December 2013 was discussed and approved in theory. The Board will need to address the financials of the arrangement. The workshop is currently slated for December 2013 with the first day being USP issues on the topic and the second day dedicated to the results of the research done by the PODP Work Group on Leachables and Extractables. **Action Item:** The PODP Work Group will work with USP to develop the agenda. The FDA would like to make sure that they are involved in the program to the extent necessary to address their issues. Their representative on the Work Group should work with colleagues at the FDA to make sure that happens.

Technical Committee Reports

- **Biopharmaceutics** as reported by Chair
 - **BCS Guidance Update WG-** group has submitted two proposals for consideration in their powerpoint presentation. Proposal #1 is for grad student in Sao Paulo and professor in Canada to work jointly to complete extensive literature search within 12 months time frame for a cost of \$8,000. Proposal #2 is for grad student at UCONN to complete literature search on BCSII drugs and create database of solubility characteristics for a total cost of \$90,000. The WG members are asking that the SC approve Proposal #1 now, and if appropriate they will come back later with a work plan around Proposal #2. The Steering Committee discussed the merits of each proposal and approved Proposal #1 for submission to the Board for their approval. **Action Item:** Board will vote on Proposal #1 at their next meeting in January.
 - **BCSIII paper-** still in review process with **Action Item:** comments from BTC members to be compiled and sent to WG Chair in January for his consideration in incorporating the comments into the document. This paper has been in the works for over 2 years so we would like to get this resolved and published in the near future if at all possible. PQRI will reach out to WG Chair to see how/where we can help make this happen.
 - **Sequential Design WG-** still working on completing the research. The grad student completed his portion of the project and now the other members of the team are adding to that work.
- **Development** as reported by Chair
- Request for 'Please Review' software proposal for the SSL Work Group needs to be postponed as we have not yet received the cost estimates for the software. This should be forthcoming in the near future.
 - Nanotechnology Workshop proposal, second step was reviewed by the SC and approved. The budget now needs to be developed and brought before the Board for approval of financials. **Action Item:** PQRI will work with the Planning Committee to answer some logistical questions so that the budget can be drafted. This needs to happen within the next few weeks in order to even attempt to have this workshop in the Spring 2013. The Planning Committee will need to make assurances that they are willing to commit to work within PQRI time frames and deadlines in order to try to host this

meeting this spring. We are very short on time which will impact marketing and logistical efforts. **Post Meeting Note:** PQRI and DTC Chair spoke with PC organizer, at the FDA to try to get a call set up for the week of Dec. 17-21 to move this forward.

- **Manufacturing** as reported by Chair.
 - **Excipient Variability Work Group-** Member agreed to Chair the Group and is finalizing the work plan for the MTC review in January.
 - **IR/MR SUPAC paper-** paper is in the works and is currently looking to be about 60 pages in length which may necessitate it being split into multiple articles; 1Q2013 should see the MTC review the document
 - **Life Cycle Management Workshop-** solidifying the Planning Committee, topics and possible speakers. **Action Item:** PQRI to work with Planning Committee to set logistics and finalize the agenda so that it can be sent to the SC and a draft budget can be created and then sent to the Board for their consideration.
 - **PAC for Sterile Products Work Group-** WG Chair is re-starting work on re-drafting the work plan to include suggestions made by the MTC and FDA for deliverables.

Other New Business: none

Next Steps/Upcoming Meetings – to be determined at later date

Adjournment of Joint Meeting at 2:00 pm

****Board Meeting following conclusion of Joint meeting to select Treasurer for the Board.**

- Signing of signature cards/paperwork for transfer of Treasurer duties
- Conflict of Interest paperwork for new Director
- Need Volunteer for Treasurer position on the Board
 - Member volunteered to assume those duties. No other volunteers noted. **Post Meeting Note:** Board members not present were polled following the meeting and said member is confirmed as Treasurer.

Appendix to Minutes

Location of Meeting: PQRI

2107 Wilson Blvd. Suite 700
Arlington, VA 22201

Attendance for Meeting: reflected in full minutes