

Summary Minutes
Board of Directors Teleconference
May 24, 2010
12:00 pm – 2:00 pm

12:00 noon

Welcome and 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.”

12:15 pm

Financial Statements Review given by the Treasurer. Brief discussion of the current financial statements and our position which is sound. We spent about \$200,000 in FY2010 on research for the various work groups and conference.

12:30 pm

FY2011 Budget Review

As for FY2011 budget, reviewed the proposed budget and looks as though the operating budget will be fairly self-sustaining with the dues structure and a workshop revenue. It should be noted that AAPS will now be paying full member assessment dues like other member organizations.

- Member assessments will go out in June.
- Letter to past organizations offering them a limited opportunity to re-join PQRI at a reduced member assessment. Past organizations to target include:
 - GPhA—will try to meet with their Board
 - PhRMA- will explore options but advised probably will not happen
 - ISPE- will talk with Sonja about the feasibility of approaching them
 - PDA- send letter
 - BIO- send letter
- Also explore approaching ACRO; FIP- Chair will approach their Bureau of Pharm Sciences; Institute of Validation Technology; and EMEA.

Action Item; Get regulatory information on international organizations for consideration. Email Health Canada rep to try to get them to re-engage with cc to Chair.

1:00 pm

Copyright Guidelines discussion and reviewed the info from the IPAC-RS attorneys briefly and reiterated the new publication policy that all article publication agreements must now come through the Chair, Board of Directors for signature. Board made a motion, which passed unanimously to pay the \$500 permission fee for the JAMPD Mass Balance article.

Action item: PQRI to contact JAMPD and make arrangements for posting article and payment of fee.
Item accomplished directly following meeting.

1:30 pm

Bio III Work Group Contract with RIVM discussion. Board is in agreement with the Liability Limitations agreement that RIVM submitted. However, we need the complete contract from RIVM which outlines the entire work project.

Action Item: PQRI to contact WG Chair to request full contract and clinical protocol for Steering committee and Board consideration. *Action accomplished directly following meeting and WG Chair will facilitate the contract with RIVM and submit the protocol.*

1:45 pm

Steering Committee Report

- Process Drift Workshop draft agenda is being finalized and will go out to wider audience in the near future. Co-sponsorship issue to be decided in the near future. Marketing campaign to begin in early June.

Action Item; Board recommended increasing the registration fees to \$1,495 for Early Reg and \$1,595 for Onsite Reg. *Action item accomplished and changes were made to the Sign Me Up Registration form to incorporate higher fees.*

- Complex Dosage Forms Update
 - Transdermals SUPAC WG proposal was approved and the Work Plan is in development.
- Supply Chain Update
 - Excipients WG proposal was approved and the Work Plan is in development.
- Nanoparticles Update
 - CHPA rep is working with Texas A&M to adjust proposal based upon SC comments.
- Biosimilars Update
 - BTC Chair is forming committee to decide how to proceed.
- Large “N” workshop proposal
 - will be presenting at the upcoming SC meeting their proposal for a workshop on this topic

Action Item: PQRI to request that all proposals coming to the Board for funding, also contain recommendations or suggestions for possible funding sources for their project. Action item accomplished in that all TC Chairs were advised that this information should be included in the proposals they bring forward.

1:55 pm

Next Meetings

Check into week of September 13-17 for a Joint face to face meeting.

Action Item: Polling conducted and the date decided upon was Sept. 16, 2010 in the DC area.