

**Summary Minutes  
Steering Committee Meeting  
February 20, 2009  
8:30 am – 4:00 pm**

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

**Call in Information:  
1-866-570-1041  
544861 passcode**

Opening and Welcome was made by the Vice Chair  
Admonition Statement was read by the Vice Chair  
Review of Agenda with no additions noted.

**Bioequivalence Workshop** update was given. Workshop is currently at 147 total attendees. There are numerous international folks and a good mix between academia, industry and regulatory agencies. Should be a good workshop.

**New BTC Chair** has been found at USP. She has worked with current BTC Chair and is familiar with the work of the BTC.

**Action Item:** USP rep will send contact information for new Chair to PQRI and then PQRI to draft a letter from SC Chair welcoming her and promoting contact with former Chair.

*Post Meeting Note:* Letter sent via email and they have set up a teleconference.

**Sulfonate Esters WG** was given by the Chair, via a power point presentation. (Presentation is attached to the minutes.) He advised that he is in the process of drafting a white paper in conjunction with PhRMA and other publications have already been submitted. A motion was made that PQRI needed to address PhRMA to reaffirm that the intellectual property belongs with PQRI. Motion carried unanimously.

**Action Items:** DTC Chair will help facilitate a means of communicating with FDA and/or Health Canada to promote the work group's findings through a webinar or such vehicle. AAPS rep will talk with FDA to facilitate FDA involvement with the project and its results to find avenues moving forward. SC Chair will contact PhRMA to advise them that the intellectual property derived by the WG belongs to PQRI, and that a white paper with their name on it is not appropriate.

**Stability Shelf Life WG** update presentation was given via power point. (Presentation is attached to the minutes.) No research monies forseen for 2010 calendar year. However, WG is considering the possibility of doing a workshop and will work with SC to further that idea.

2009 SSL WG Budget Request was reviewed and unanimously approved by the Steering Committee for furtherance onto the Board for approval.

**Action Items:** UN-L will draw up Research Agreement as in years past. PQRI Secretary to send 2009 Budget Request onto Board of Directors.

*Post Meeting Note:* Board unanimously approved the 2009 SSL Budget.

**L&E in Parenteral Ophthalmic Drug Products (PODP)** update was presented via a power point presentation. (Presentation attached to the minutes.) Chair also requested guidance on the PQRI approval process for presentations made regarding the work of the WG. DTC Chair advised that the DTC liaison could help with those decisions, but when approval is necessary, they should be submitted to the DTC for review and approval. When possible, the PQRI slide template should be used to advertise that the material is the work of PQRI.

**12:30 pm**

Adjournment