

## **PQRI Steering Committee Meeting**

**Thursday, August 7, 2008**

**2:00 pm – 3:30 pm**

### **Teleconference**

Conference Call Details:

1-866-570-1041

PIN 544861#

### ***Summary Minutes***

#### **Opening**

Anti-Trust 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 Agenda**

Agenda was approved as presented.

#### **Approval of Minutes**

- Full and Summary minutes from the Feb. meeting were approved as presented with clarification noted on the usage of the PQRI logo for both sets of minutes.

#### **New Business**

**PhRMA terminating PQRI membership effective December 31, 2008 – the letter was read aloud by Bob to the group on the teleconference.**

- Chairs discussed the issue and possible impact on PQRI and then reached out to all member organization representatives and found that all other member organizations were remaining supportive of the Institute and its mission
- FDA expressed their support of PQRI and the need for continuing the work of the Institute
- No doubt that PQRI will continue work for the foreseeable future
- PhRMA members serving on Technical Committees and the Steering Committee who wish to continue their affiliation with PQRI will need to re-affiliate with another member organization by December 31, 2008.
- Questions raised and discussed included the rationale for PhRMA termination – which was given as PhRMA needed to focus their

energy and resources on more of a global effort, PhRMA's struggle to find projects within PQRI, and they currently now have other avenues of interaction with FDA; concerns about dues amount being raised back to the original amount of \$20,000; the need for PhRMA members who wish to remain active needing to re-affiliate; and the cost/benefit analysis that goes into the decision of whether or not to be involved in PQRI. The decision was made and then communicated as soon as possible to PQRI.

### **Looking forward for PQRI-**

- Need for projects in the pipe line as projects are the key
- FDA outlet for guidances has changed
- Current work being published – is that enough? What is the benefit/possibility of helping USP develop General Chapters? (i.e., the Leachables and Extractables group is helping with a chapter) Can this also be looked at for perhaps the PODP Work Group?
- Ask FDA what areas need attention to help drive some of the work projects
- Need to address the strategic implications throughout the upcoming year
- Conduct ongoing dialogue reference the PQRI Course of Action – Outlook and Outcomes

### **➤ Technical Committee Reports**

#### **○ DTC**

- Container Closure WG are currently updating their deliverables
- Stability Shelf Life WG held their webinar in July and survey results to be discussed under Old Business
- Sulfonate Esters second paper went to DTC for their approval and they are preparing their publications
- PODP is considering adding a USP rep to their committee; recently submitted an updated bulletin to Visibility committee for publication
- QbD WG is finalizing the development of the two drug product models and will hook up with the BTC to link up their work products.
- Excipient team rep from the DTC is expected to link up with NIPTE team

#### **○ MTC**

- Post Approval Changes WG project is completed and document has been publicized
- Risk Management WG has document out for review and hope to publish it in two parts
- Biological Inspections WG has been sunset
- Specification and Design WG has draft of document out for review by the WG and the TC

- OOS Work Project is still in the formulation process. A proposal should be forthcoming
- **BTC**
  - Sequential Design next step is in the works and they are writing the programming with a draft of the manuscript due by the end of 2008
  - BCS III Absorption Systems redid some of the work and new data is being analyzed and they are getting ready to publish findings with the expanded knowledge
  - QbD WG has two cases worked up and are working with statisticians with the target date still being 4Q08. They may expand committee.

**Action Item:** *SC Reps to work together to secure a candidate for BTC Chair position by December 2008*

### **Old Business**

#### **SC Vice Chair election**

- Nominating committee formed to identify candidates. No candidates presented at this time.

**Action Item:** *Nominating committee should have nominations made and ready to be voted on prior to the December face to face meeting.*

#### **Stability Shelf Life WG Webinar Survey Results-**

- webinar held in July 2008
- purpose of webinar was for vetting of WG work up to this point and get industry's input on implications/importance of work
- survey results echoed the discussions held at the Steering Committee level regarding the worthiness and applicableness of the work product
- good comments made both pro and con reference the statistical tools used, and the challenges that were presented
- FDA asked question regarding 'scattering' and asks that the WG pay attention to that and address it as they go forward
- Steering Committee will still need to reevaluate the work project and make determinations about the work progressing into 2009. A budget should be presented in early fall for the SC to consider.

**Action Item:** *Board Chair will discuss with Sc Chair so that he follows up with the Technical Committee and the Work Group to make sure they are on target with the budget presentation.*

**NIPTE – meeting held on July 15, 2008 at PDA headquarters** was productive with the TC Chairs outlining their own current work projects and looking for areas where PQRI and NIPTE might collaborate. N

- Next steps include sending RFPs to NIPTE for upcoming work projects where appropriate; offering PQRI members opportunities to take a position on the various NIPTE project teams; and co-sponsoring a workshop with NIPTE.
- FDA is currently considering two grants with NIPTE which might offer opportunities for PQRI members to get involved with NIPTE projects
- **Action Item:** *SC Reps to NIPTE should continue to engage with NIPTE and perhaps take this offline to keep the momentum moving forward.*

### **INTFG Workshop**

- Speakers being confirmed and final agenda due from committee at the end of August. Registration to open in September.

### **PQRI Financials**

- PQRI financially is in good shape but needs to maintain their financial position. Assets currently at \$663,400 + at the end of June.
- **Action Item:** *Board Chair will send a copy of June financials to all SC members*

### **Upcoming SC Meetings**

Bob Lipper

December 9, 2008      Face to Face @ DBR      9:30 am – 4:00 pm

There being no further business to be brought forward, the meeting adjourned at 3:35 pm and went directly into the Board of Directors meeting.