

**Summary Minutes**  
**Joint Board of Directors and Steering Committee Meeting**  
**December 16, 2009**  
**1:30 pm – 4:30 pm**

**Face to Face Meeting**  
**Hilton Executive Meeting Center**  
**1750 Rockville Pike**  
**Rockville, MD 20852**

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

### **Opening and Welcome**

#### **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.”

### **Review of Agenda**

#### **PQRI Conference**

- Good publicity needs to continue to highlight the successes of PQRI
- Excellent ideas for possible areas for PQRI to become involved in:
  - **Process Drift**
    - Possibility of workshop and/or follow-up work group
    - Training courses
    - Co-sponsorship with FDA

**Action Item:** FDA rep will explore possibilities and discuss with MTC for taking this forward

- **Sample Size**
  - Specification setting for large 'n' sample sizes
  - Pick up where PhRMA group left off
  - Do work group first, then possible to do workshop on results
- **Supply Chain**
  - Can we find a PQRI niche?
  - Possible area is EMA potentials (economically motivated adulterations) and/or fingerprint authenticity to link ingredient to supplier

- **Maintenance of Prior PQRI Projects**
  - i.e., aseptic processing- update the research
- **Biosimilars**
  - Develop proposed framework of elements necessary for follow-on biologic to be considered equivalent
  - Fundamental considerations for the comparability of biologics

**Action Item:** BTC Chair to take matter to BTC to explore getting started

- **Complex Dosage Form**
  - Revisit SUPAC guidelines
    - If you make multiple changes, how do you make customer comfortable?; what kind of DOE is required?; what level of SUPAC change leads to what level of change?...
    - Look at creating guideline for transdermal products; previously only done to the white paper stage of research

**Action Item:** Treasurer to discuss with MTC Chair to engage them in SUPAC update in view of recent use of DOE and QbD principles

- **Nanoparticles**
  - Compile already existing capabilities and identify technical gaps
  - Possibility of funding PhD student to create the compilation
  - Have advisory committee oversee grad student
  - Nano presentation was made to support creating the compilation

### **PQRI Conference Survey**

**Action Item:** A committee will create a survey to be distributed to all attendees of conference for their feedback

**Post Meeting Note:** Survey was created and distributed with the help of AAPS' Marketing Department. Results were obtained and will be presented to the SC and Board.

**PQRI Financial Statements** were stated by the Treasurer. Then there was a short discussion concerning the development of PQRI's financial model moving forward. Treasurer had provided some written proposals which people were asked to look at, and consider for discussion at the next SC/Board meeting.

### **BTC**

Replacement for member- okay to go with their recommendation

### **Intellectual Property Rights Statement in Volunteer Contract**

PQRI Secretary made the motion for the SC to insert the proposed wording into the Volunteer Contract to address protecting PQRI's research and the acknowledgement of their research efforts. Motion was unanimously approved. Contract will be amended.

### **Inclusion of Discussion Groups as a Member of PQRI**

SC Chair proposed that PQRI consider including a couple of past PhRMA Expert Teams as Discussion Groups for PQRI. PhRMA has terminated the groups, and the groups wish to continue. They are currently in the areas of Drug Product, API, Quality, and Technical. This could be a win-win for both the teams and PQRI.

**Action Item:** Chair to provide a charter proposal/rules of engagement for PQRI to consider at that next meeting. **Post Meeting Note:** Guidelines were obtained and sent to all SC and Board Members for their consideration at the Feb. 8<sup>th</sup> meeting.

### **3:00 pm**

#### Next Steps/Upcoming Meetings

Joint Board and Steering Committee Meeting- to be in PQRI office in Feb. 2010

- Business model needs to be established
- Discussion group inclusion needs to be considered
- Ideas for Projects and moving them forward need to be fleshed out

### **4:30 pm**

Adjournment