

## PQRI Steering Committee Meeting

Thursday – October 20, 2005  
10:00 – 11:30 a.m.

### Teleconference

### MINUTES

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Meeting convened at 10:10 a.m., Gordon Hansen, Chair, presiding. A quorum was not reached during this meeting, with five (5) of eleven (11) SC member organizations represented.

#### **Review and Approval of the Agenda**

The agenda was presented and agreed upon.

#### **Approval of Minutes**

The minutes of the August 11 and September 15, 2005 meetings were distributed. A vote will be taken electronically.

#### **Biopharmaceutics Technical Committee (BTC)**

##### ➤ **Biowaivers for BCS Class III Drugs**

It was agreed that the voting deadline relative to the work plan would be extended until October 27<sup>th</sup>.

#### **Drug Product Technical Committee (DPTC)**

##### ➤ **Mass Balance Impasse**

- A meeting of the DPTC has been set for November 4, at which time both sides of the issue will present their views on the Mass Balance question.

**Dr. Sadrieh agreed to follow up on the status of the review, as well as secure a response from those at the FDA with the minority opinion for their availability on November 4<sup>th</sup>, and report back to the DPTC and SC Chair.**

##### ➤ **Radio Frequency Identification (RFID)**

- A draft report from the WG will be given to the DPTC this week. If approved, the report will be presented to the SC for final approval, then passed along to the FDA.

#### **Manufacturing Technical Committee (MTC)**

The MTC met last week, at which time they discussed all on-going projects.

- **Post Approval Changes for Sterile Products Working Group**  
This new WG met for its kick-off meeting last week and approved the anticipated time lines for presentation of materials for this project.
- **Process Robustness Working Group**  
The work has been completed, approved by the MTC and is now ready for SC approval.
- **Specifications Life Cycle**
  - A draft document has been completed.
  - The MTC Chair will contact the other TC Chairs to determine whether they would be interested in participating in this work.

### New Business

- **Re-creating PQRI Subcommittee**
  - The meeting of this subcommittee has been scheduled for Tuesday, November 29<sup>th</sup> at the IPAC-RS Secretariat office in DC.
  - **SC Chair will request that the DPTC appoint a designee to participate in the 11/29 meeting.**
- **Succession Policy**  
A proposal for addition of a Vice Chair (Chair-Elect) to the SC was offered. –  
  
**This proposal will be forwarded to the SC for an electronic review and approval. Once approved by the SC, a recommendation will be sent to the Board of Directors for their review and comment.**

### Old Business

- **RFP Policy**  
Some clarifications in the language of the policy were requested.  
  
**The PQRI Executive Secretary will forward the questions to Dr. Polli for his review and response.**

### 2005 SC Meeting Schedule

- The November meeting has been cancelled due to scheduling conflicts. The next meeting is scheduled for December 7, 2005 at the GPhA's law firm (McKenna Long & Aldridge LLP, 1900 K Street, NW, Washington, DC 20006).

### Informational Items

- SC and TC future meeting schedules.
- PQRI financials as of September 30, 2005.
- Project status timeline of all PQRI work.

There being no further business of the SC, the meeting adjourned at 10:55 a.m.

