

## **PQRI Steering Committee Meeting**

Wednesday – April 6, 2005  
10:00 a.m. – 2:00 p.m.

**Pharmaceutical Research and Manufacturers of America (PhRMA)**  
1100 15th Street, NW  
Washington, DC

### **MINUTES**

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#### **Guests:**

Jeffrey Macher – Georgetown University  
Lee Nagao – IPAC-RS (by telephone)  
Jackson Nickerson – Washington University in St. Louis  
Dan Norwood – IPAC-RS (by telephone)

Meeting convened at 10:05 a.m., Gordon Hansen, Chair, presiding. A quorum was reached during this meeting, with nine (9) of eleven (11) SC member organizations represented.

#### **Approval of Minutes**

The minutes of the March 11, 2005 meeting were approved.

Summary of Actions taken: Committee reports.

#### **Drug Substance Technical Committee (DSTC)**

##### **➤ Particle Size Working Group**

- The recommendation draft (“*PQRI Guidance on Drug Substance Particle Size Analysis of Oral Dosage Forms*”) was approved electronically by the SC on March 31<sup>st</sup>.

#### **Research Overview**

- Drs. Macher and Nickerson presented their overview, goals and findings to date.
- The request for PQRI’s assistance includes –
  - Funding for two years for hiring an analyst to refine the collected data.
  - Possible assistance in data collection.

The SC requested a formal proposal of the request for assistance with a detailed approach to the work. Upon receipt of the information, further discussion will take place.

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

#### **➤ Dissolution Working Group**

- BTC Chairs will consult with the OPS Director to ensure that their conception of the project is in alignment with FDA's views.
- It was agreed that there be representation of the BTC at a FDA Advisory Committee meeting on dissolution scheduled for May 3<sup>rd</sup> and 4<sup>th</sup>.

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

#### **➤ Excipients Working Group**

- The SC requested that they receive a full copy of the PRA proposal.

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

#### **➤ Post Approval Changes Sterile Products Working Group**

- It was requested that the SC member organizations offer candidates for participation on the new WG. Names and CVs of proposed candidates should be forwarded to the MTC Chair and PQRI office.

#### **➤ PAT Working Group**

- It was agreed that the documents for establishing this WG would be redrafted as a work plan, rather than a RFP.

### **New Business**

#### **➤ Barnett Conferences**

- The SC agreed not to pursue co-sponsoring workshops with for-profit organizations.

### **Old Business**

#### **➤ Project Manager**

- The MTC Chair will move forward with filling the position and will discuss details of establishing this position with the PQRI office.

### **2005 SC Meeting Schedule**

- The July 14 meeting has been cancelled due to scheduling conflicts and will be noted on the annual schedule.

**Next Scheduled Meeting** – The next meeting is a teleconference on May 19<sup>th</sup>.

There being no further business of the SC, the meeting adjourned at 1:15 p.m.

