

## **PQRI Steering Committee Meeting**

Thursday – August 11, 2005  
2:00 – 3:30 p.m.

### **Teleconference**

### **MINUTES**

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Meeting convened at 2:05 p.m., Gordon Hansen, Chair, presiding. A quorum was reached during this meeting, with ten (10) of eleven (11) SC member organizations represented.

#### **Approval of Minutes**

The minutes of the June 9, 2005 meeting were approved.

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

There were no action items requiring the attention of the SC.

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

All working groups appear to be on schedule. The date for the next DPTC meeting is being sought. PQRI Executive Secretary will inform the Agency when an agreed upon date has been found.

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

The work of this group is on-going, with some additional information still needed.

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

There was no report relative to this Technical Committee.

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

Two work plans (Biological Inspections and Risk Management Case Studies) have been submitted for the review and approval of the SC.

#### **➤ Process Robustness Working Group**

- The WG is incorporating MTC comments into the white paper, which will be submitted to the SC at its September meeting for approval.

#### **➤ Project Manager**

Candidates are still being sought to fill this position.

#### **➤ New TC Participants**

- New members are being sought from within the SC member organizations.

#### **Education, Communication and Assessment Subcommittee (ECAS)**

- **Web Site Redesign**  
The SC member organizations were requested to view the demo and offer comments to the ECAS Chair.
- **Publication Policy**  
The ECAS Chair will continue to follow up with the publication of the Particle Size document to obtain the necessary approvals.
- **PQRI Newsletter**  
The ECAS is currently working to identify articles for the next newsletter.

### **New Business**

- **Tunnel Consulting Symposium**
  - Two motions were made and seconded, with vote being taken electronically.
- **Strategic Planning Meeting in September**  
Steering Committee member representatives were requested to offer suggestions to the SC Chair relative to the upcoming Strategic Planning meeting.
- **Retirement of Dr. Tobias Massa**  
Dr. Massa (PhRMA) announced his retirement as Steering Committee Member and Board of Directors Chair. A replacement will be sought to fill the vacancy. Dr. Massa was thanked for his long-time service and many contributions to PQRI.

There being no further business of the SC, the meeting adjourned at 3:40 p.m.