

PQRI Steering Committee Meeting

Thursday – June 9, 2005
10:00 a.m. – 2:00 p.m.

U.S. Food and Drug Administration (FDA)
Rockwall II – Room 112
5515 Security Lane
Rockville, MD

MINUTES

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 May 19, 2005 meeting were approved, along with the summarized action items from the March 11, April 6 and May 19 SC meetings.

Summary of Actions taken: Committee reports.

Biopharmaceutics Technical Committee (BTC)

- The BTC Co-Chairs will contact the Agency to secure guidance to move forward with plans for the PQRI WG.
- SC Chair to report these discussions to the BTC and request them to delay starting any work as a larger view is needed.
- It was suggested that the BTC review the transcript from the Advisory Committee meeting previously mentioned.
- The SC will explore dissolution and the DIA meeting.

Drug Product Technical Committee (DPTC)

- **Radio Frequency Identification (RFID)**
 - A risk assessment has been conducted to look at field effects on biologics.
 - The RFID Co-Chair will perform additional research, securing the last pieces of information required.
- **Excipients Working Group**
 - The on-line survey has received all of the required approvals. The WG is moving forward with the posting of the survey.
- **Container/Closure Working Group**
 - Efforts will resume in this area in the near future.

- **Profile Comparisons Working Group**
 - The SC has approved the recommendation and the WG is now ready for the publication of this interim report.
- **Leachables/Extractables Working Group**
 - This WG has reached a completion point.
 - A Workshop will be held on December 5-6, 2005 where findings of the WG will be presented to the public.
- **Mass Balance Working Group**
 - There was discussion surrounding the impasse previously reached by this WG. The two opposing views will be presented to the DPTC for a technical assessment.

Drug Substance Technical Committee (DSTC)

- **Specifications Working Group**
 - Awaiting comments from the Agency relative to BACPAC II.
- **Impurities Working Group**
 - Awaiting publication of the survey results in the *Pharm Research Journal*.
- **Particle Size Working Group**
 - The recommendation draft (“*PQRI Guidance on Drug Substance Particle Size Analysis of Oral Dosage Forms*”) will be submitted to the Journal of Pharmaceutical Science.

Discussions continue relative to new DSTC projects.

Manufacturing Technical Committee (MTC)

- **Process Robustness Working Group**
 - The white paper will be submitted to the SC by the end of June or July.
 - This WG is also considering where best to publish the paper.
- **Post Approval Changes Sterile Products Working Group**
 - The SC has approved the work plan and the WG is being populated.
- **Risk Management Case Studies Working Group**
 - A work plan is receiving final MTC approval.
- **Bio Indicators Working Group**
 - A new chair is being sought.
- **PAT Working Group**
 - A work plan is being drafted.

➤ **Bio Inspections Working Group**

- The work plan and survey have been developed and are under review.

New Business

➤ **Cross-Review of TC Projects and Work Plans**

- It was determined that cross-review of other TC projects/data would not be required.

Old Business

➤ **Project Manager**

- A confidentially agreement and “consultant” contract will be drafted and circulated to SC for review.

➤ **Macher/Nickerson April Presentation to the SC**

- To date no further contact has been made with the PQRI office relative to their request for PQRI.

2005 SC Meeting Schedule

- The July 14 meeting has been cancelled due to scheduling conflicts. The next meeting is a teleconference on August 11th.

There being no further business of the SC, the meeting adjourned at 11:50 a.m.