PQRI Steering Committee Meeting

Thursday – May 19, 2005
10:00– 11:30 a.m.

Teleconference

SUMMARY MINUTES

Meeting convened at 10:10 a.m., Gordon Hansen, Chair, presiding. A quorum was not reached during this meeting (items requiring approval were subjected to an off-line electronic vote).

Approval of Minutes
The minutes of the April 6, 2005 meeting were approved by those present, with an electronic vote to be taken due to the lack of a quorum.

The summary minutes of the March 11 and April 6 meetings will be revisited to summarize more fully. The SC Chair will assist with the summaries.

Summary of Actions taken: Committee reports.

Biopharmaceutics Technical Committee (BTC)
Dr. Alan Parr, Co-Chair, reporting.

- **Sequential Design Working Group**
  Final draft document to be submitted to the BTC/SC in the June/July time frame.

- **Development of Biorelevant Dissolution Methods Working Group**
  A work plan is being drafted and will be submitted to the SC in July 2005.

- **Extension of BCS Waiver Guidelines Working Group**
  A draft work plan is being drafted and will be submitted to the SC in July.

Drug Product Technical Committee (DPTC)
Dr. Terry Tougas, Chair, reporting.

- **Radio Frequency Identification (RFID) Working Group**
  It is anticipated that the WG will report back to the DPTC in June, as to whether there is no impact, or additional information is required.

- **Container/Closure working Group**
  This WG remains inactive.

- **Excipients Working Group**
  The SC has voted to make a recommendation to the Board for funding of the on-line survey. Deadline for Board approval is May 23, 2005.

- **Profile Comparisons Working Group**

The document has been submitted to the SC for approval, with a deadline of May 27, 2005.

- **Leachables/Extractables Working Group**
  The L/E Workshop has been scheduled for December 5-6, 2005.

- **Mass Balance Working Group**
  This WG has met an impasse. A resolution is being sought among the DPTC, WG and SC. and proposals,

Drug Substance Technical Committee (DSTC)
Dr. Pat Tway, Chair, reporting.

- **Specifications Working Group**
  Still awaiting comments on BACPAC II from the Agency.

- **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 sent to the Pharma Science Journal, which is an approved ECAS publication.

New programs and projects have been discussed by the WGs with the DSTC and will be recommended to the SC at a future date.

Manufacturing Technical Committee (MTC)
Dr. Bruce Bird, Chair, reporting.

- **Process Robustness Working Group**
  - The WG has drafted the overview for process robustness, which will be finished by next. week.
  - It is anticipated that it will be submitted to the SC for final approval in late June or early July.

- **Post Approval Changes for Sterile Products Working Group**
  - Team members are being selected. SC member representatives were requested to send names of candidates to the MTC Chair, or PQRI office. Upon full population of the WG, work will begin.

- **Risk Management Case Studies Working Group**
  - The suggested work plan has been drafted and is being reviewed by the MTC.

- **Process Analytical Technology Working Group (PAT)**
  - The work plan is being rewritten.

- **Regulatory Process Working Group**
  - Work has not yet begun, as the output of the Process Robustness WG is required.

- **Biological Indicators Working Group**
  - A work plan is being drafted.

- **Project Manager**

- The MTC Chair is awaiting additional information on the proposed candidate. A decision is expected within a week's time.

Education, Communication and Assessment Subcommittee (ECAS)
Ms. Stacey May, Chair, reporting.

- **PQRI Web Site Redesign**
  - The ECAS is reviewing the final outcome within the next six (6) weeks.

- **L/E Workshop Planning**
  - The Workshop has been set for December 5-6, 2005 at the North Bethesda Marriott in Bethesda, Maryland.
  - A site inspection is scheduled for June 6th.

New Business

- **Membership Request** – Synthetic Chemical Manufacturer's Association (SOCMA)
  - The Bulk Pharmaceuticals Task Force of SOCMA requested participation on the DSTC and PQRI membership. Discussion included –
    - SC requested PQRI office to send the requester the criteria for membership on the SC, with additional information on the Institute.

- **Distribution Lists for E-Mail Messages**
  - SC member representatives requested that when responding to requests for meeting availability, or other general type messages, that they "reply" only, instead of "reply to all."
  - TC/WG Chairs will confirm to whom messages relative to their respective committees will be sent.

Next Scheduled Meeting – The next meeting is an in-person meeting at FDA (5515 Security Lane, Rockville, Maryland) on June 9, 2005.

There being no further business of the SC, the meeting adjourned at 11:34 a.m.