

## **PQRI Steering Committee Meeting**

### **Generic Pharmaceutical Association (GPhA)**

*(Law Firm of McKenna Long & Aldridge LLP)*

1900 K Street, NW  
Washington, DC 20006

Wednesday – December 7, 2005

10:00 a.m. – 2:00 p.m.

### **MINUTES**

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Meeting convened at 10:05 a.m., Gordon Hansen, Chair, presiding.

#### **Re-creating PQRI**

The meeting of November 29<sup>th</sup> was discussed with the SC. Items discussed at that meeting included –

- The mission and function of PQRI
- Where the Institute is today and from where it has come.
- What should the expected outcomes/deliverables be from the WGs?

The newly revised function statement will be –

“PQRI rapidly advances science-based pharmaceutical product quality by:

- Providing a forum to address relevant pharmaceutical quality topics
- Collecting, analyzing and interpreting data
- Conducting research and testing
- PQRI facilitates scientific consensus among regulatory authorities, industry and academia.

#### **Publication Policy**

The Policy was approved with edits and will be initiated immediately.

- The matter of SC member organization review of documents for finalization/approval was also discussed. SC member organizations will provide the PQRI office with a listing of those contacts within their respective organizations to which documents should be forwarded for review; that is to say, those organizations which do not have an official representative on the specific TC that is reviewing the document.

#### **Organizational Structure**

- An ad hoc group will be set up to review all of the discussion items mentioned today, as to whether bylaws changes will be required.
- TCs will continue to evaluate, among themselves, whether cross-functionalization for specific projects may be appropriate.

Summary of action items taken: Committee reports.

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

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

- The latest revisions made were a result of the FDA study.
- The revised document is now being circulated among the DPTC for approval, with a deadline for comment being January 6, 2006.
- The report indicates that there are no significant thermal effects. This has been confirmed by other studies, as well as the PQRI research; that is, negligible risk has been found.
- The draft report has been shared with the CDER/OPS at FDA.

### ➤ **Mass Balance Working Group Impasse**

- At the direction of the SC, the two factions met in-person on November 4<sup>th</sup> to discuss the science behind their views.
- The DPTC Chair was requested to return to the DPTC to determine whether they would be willing to discuss the differing views in a more public forum.

## **Leachables and Extractables Working Group (L/E)**

### ➤ **L/E Workshop**

- The Workshop concluded yesterday (12/6/05)
- The draft recommendation is currently being reviewed by the DPTC with a deadline for comment being February 1, 2006.
- The ECAS Chair agreed to contact the Gold Sheet to request review of their article on the Workshop prior to their going to press.

### ➤ **Profile Comparisons Working Group**

- Currently, a Profile Comparisons document is being reviewed for publication by the Journal of Aerosol Medicine, which has asked the WG for some clarifications.
- It is anticipated that the final recommendation will be submitted to the FDA in early 2006.
- Another document, a white paper currently being drafted, will also be submitted both to the FDA and for publication.

### ➤ **Container/Closure Working Group**

- A document in summary of the findings of the WG has been published.
- Additional members for the WG are being sought.

### ➤ **Excipients Working Group**

- Their survey was just completed and the deliverable will be publication of the results of the survey.
- It is believed that drafting of the final document of findings will take about 4-5 months to complete.

- The DPTC will be meeting in early 2006 to brainstorm and discuss possible new projects. The DPTC Chair will invite the MTC Chair to participate in order to discuss cross-functional projects for the coming years.

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

- **Specifications Working Group**
  - A BACPAC II white paper was submitted to FDA.
- **Particle Size Working Group**
  - Their research has been completed and findings are ready for publication.
- **Impurities Working Group**
  - There were two main projects for this group, a survey for which results have been published and work on column equivalency.

All DSTC projects should be completed by the first quarter of 2006. At this point there do not seem to be any new projects exclusively in the drug substance area that have been identified for next year.

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

- **Process Robustness Working Group**  
A draft document has been reviewed and comments are being incorporated. A decision is to be made as to whether all addenda should be published in one or two sections.
- **Post Approval Changes for Sterile Products Working Group**  
Suggested changes were drafted, sent out to PQRI volunteers and posted on the web site. In effect, this WG is just getting started and will be moving forward in 2006.
- **Case Studies for Risk Management Working Group**  
This WG is being populated.
- **Biologicals Inspection Survey Working Group**  
The survey is almost ready to go on-line with responses done electronically. The survey questions will be evaluating the “science of compliance.”
- **Biological Indicators for Use in Isolator Systems Working Group**  
There is no standard indicator(s) for VHP. A team leader is being sought.
- **Implementation of PAT Working Group**  
The work plan is currently being rewritten to reflect this change in direction.
- **Regulatory Process Working Group**  
This work will not be done.
- **Specification Design and Lifecycle Management Working Group**

A draft work plan has been shared with DSTC and DPTC. This will be a cross-functional project, if the project moves forward.

➤ **Possible New Projects for 2006**

- Quality verification to be continued.
- How do we develop biorelevant test methods?
- Science around statistics for pharmaceutical sciences.
- Possible new projects coming out of GMP product quality.
- Quality by Design.
- Review of current/future projects in terms of whether they may be appropriate for workshops.

**Biopharmaceutical Technical Committee (BTC)**

➤ **Sequential Design Working Group**

- A white paper on how to combine multiple PK studies will be ready for review by the BTC by the end of December 2005 and SC review by the end of January 2006.

➤ **BCS Compounds for Biowaivers**

- It was agreed that the SC will have to further discuss how this project meets PQRI's mission and portfolio.
- SC Chair will discuss funding levels with the Board Chair to determine to what level projects may be funded and whether a "formula" could be designed for such funding; i.e. –
  - A percentage of funds on hand
  - Whether a partial funding by the Institute could be established with funding from interested industry parties.

**Metrics of PQRI Success**

- There was discussion relative to how PQRI will be able to measure its success as an organization in the coming year was discussed.
- Mary Oates will draft the ideas discussed and distribute to the SC (by December 12) for their comments (by December 26).

**SC Member Organizations' Expectations for PQRI**

- All SC member organizations were requested to bring a listing of their respective organization's expectations for PQRI; *e.g.*, what they expect to "receive" from PQRI, as an organization.
- Member organizations were also requested to bring ideas for any new projects that their organizations would like to see addressed in 2006.

**Vice Chair Position**

- A nominating committee comprised of Jeffrey Blumenstein, Christopher Allen and Gordon Hansen will establish a slate by which candidates for the position may be selected.
- Election for the position will take place by the February SC meeting, date to be determined.

**PQRI Web Site Redesign**

- ECAS Chair will provide the demonstration link to the newly designed web site to Terry Tougas, Christopher Allen and Scott Boudreau for review and comment.

There being no further business of the SC, the meeting adjourned at 2:25 p.m.