

## **PQRI Strategic Planning Meeting**

Thursday – September 15, 2005  
10:00 a.m. – 3:00 p.m.

### **International Pharmaceutical Aerosol Consortium for Research and Science (IPAC-RS)**

*(Law Offices of Gardner Carton & Douglas)*  
1301 K Street, NW – Suite 900E  
Washington, DC 20005

## **MINUTES**

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Meeting convened at 10:05 a.m., Gordon Hansen, Chair, presiding. A quorum was reached during this meeting, with all SC member organizations represented.

Summary of action items taken: Committee reports.

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

There are three projects that are under discussion by the BTC and which were presented -

- **BA/BE**
  - Comments from the BTC will be solicited and any edits will be incorporated into the work plan, which will then be resubmitted for a final review by the BTC.
  
- **Biowavers**
  - The WG will modify the work plan and will resubmit drug groups to more long-term strategic groups and will coordinate the proposed work with the other TCs.
  
- **Dissolution – Evaluate development of \_\_\_\_\_.**
  - There is a FDA Advisory Committee meeting next month (October 25-26). It was recommended that the BTC members attend this meeting.

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

- **Radio Frequency Identification (RFID) Working Group**
  - A form will be drafted for WG debriefing purposes to set forth what is good and what is bad about the work of the group. A form should be completed for each project; i.e., success and failures.
  
  - Gordon Hansen will draft a dispute resolution policy for resolving conflicts in a more timely manner.

- **Mass Balance Working Group**  
The DPTC Chair will draft a document articulating the stance and key points of the two opposing views of the WG, which will be forwarded to the Director, Office of Pharmaceutical Science at FDA.
- **Profile Comparison**  
Work is on going and on target.
- **New Projects**  
Work will be proposed for a project in collaboration with Nebraska University regarding collecting and evaluating statistics around stability testing.

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

The majority of the projects of DSTC are completed and awaiting further action.

The four TC Chairs were requested to work closely together to develop a harmonized approach to future projects, in which they would attempt to get ahead of the needs of industry.

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

- **Process Robustness Working Group**
  - The white paper has been reviewed by the MTC, with some minor edits being included. It will be submitted to the SC in October.
- **Post Approval Changes Sterile Products Working Group**
  - The WG has been populated.
  - The WG will draft a white paper looking at possible changes and risk language.
- **Bio Inspections Working Group**
  - A survey has been completed and approved for funding.
- **Risk Management Case Studies Working Group**
  - The MTC will publish the outcomes at the completion of the project.
- **Bio Indicators Working Group**
  - A work plan has been drafted and a chair is being identified.
- **PAT Working Group**
  - Implementation was previously anticipated by a RFP but now a different tact will be taken.
- **Specification Design and Life Cycle**
  - A work plan has been submitted to the MTC, has been reviewed and comments are being incorporated.

## **New Business**

### ➤ **Training Initiatives**

Fred Razzaghi volunteered to work with a small group to develop the above ideas further, in order that we may better understand and discuss at our next meeting.

### ➤ **Leachables/Extractables Workshop**

A motion was made, seconded and passed, with one SC member organization opposed, to make a recommendation to the PQRI Board of Directors to fund travel expenses and an honorarium for Dr. Kroes.

### ➤ **Succession Procedures**

#### ○ SC Vice-Chair Position

A nominating committee will be established for the purpose of appointing a vice-chair.

#### ○ Board of Directors Vacancy

A replacement for Dr. Tobias Massa will be discussed at the next SC meeting.

### ➤ **What is the purpose of PQRI for the future?**

- An ad hoc committee will be established to look at different aspects of the Institute and will report to the SC at its December meeting.

There being no further business of the SC, the meeting adjourned at 3:00 p.m.