

**PQRI Manufacturing Technical Committee**  
**August 26, 2004**  
**Meeting Minutes**

The MTC had a teleconference on August 26, 2004. Participants included Jim Akers, Bruce Bird, Nicholas Buhay, Victor Gangi, Sylvia Gantt, Michael Glodek, John Grazal, Nicholas Maselli, Bill Mullin, Linda O'Connor, Carolyn Parziale, Jean Poulos, Gabriele Schoenberger, and Peg Szymczak,

**Antitrust Statement**

Bruce started the meeting by reading the following antitrust statement: "Our discussions today are subject to the anti-trust guidance applicable in the U.S. Nothing discussed at this meeting is intended to restrict the individual decision-making of any member company or to represent an agreement to coordinate marketing or sales conduct. Those participating in this meeting are instructed to avoid discussion of competitively sensitive subjects, including, confidential marketing, sales, and pricing information."

**Biological Indicators Work Plan**

Jim Akers then led a discussion of the Biological Indicators work plan. The MTC asked why there was a need to have a conference. Jim mentioned that it would be needed to collect information. He did suggest that we could possibly do it in conjunction with a PDA conference. Jim also stated that the laboratory work that would be needed could possibly be done at some companies or even vendors of BI's. However, there could be some sensitivities in doing it at the vendors. It may be possible to do it at the PDA Training and Research Institute also. It would be a neutral site and hopefully we could have it done for the cost of the materials. The outcome for this group would be a white paper. Jim will reformat the work plan using the latest PQRI template. Bruce will work with Jim as needed.

**ACTION ITEM:** Jim Akers to update the Work Plan and resubmit to the MTC.

**Process Robustness Working Group**

Michael Glodek updated the MTC on the status of the Process Robustness Working Group. The WG had their first meeting on Aug. 13<sup>th</sup>. Michael stated that the group discussed their charter, definitions, what does a robust process look like and metrics for a robust process. The team also began to develop the table of contents for their white paper. The MTC told Michael that the WG should use the MTC as a resource. Michael also asked that if any of the MTC had technical definitions in their companies or organizations to please forward them to the WG. The MTC asked the WG to update the timeline for the WP.

**ACTION ITEM:** Process Robustness WG to update the timeline for their work.

**ACTION ITEM:** MTC members to forward any definitions they may have to the WG.

### **Risk Workshop**

Bruce informed the team that a date that ECAS was looking for was in February. John Grazal has been talking to Stacey May (AAPS) from the ECAS on the workshop. Sylvia Gantt has also been working with Stacey on this. Nick Buhay will mention the workshop to Brian Hasselback (sp?) about possibly speaking at the workshop.

**ACTION ITEM:** Bruce to notify the MTC when a date is set. (**Post Meeting Note:** The date for the workshop will be Jan. 30 to Feb. 2.)

### **Regulatory Process Work Plan**

Nick Maselli reviewed the Regulatory Process WP. He mentioned that this WP would be finalized after the risk workshop and Process Robustness WG were completed. He also mentioned that we couldn't really put in case studies for every possible change, but should include examples for each type of change rather than each change.

### **Next Meeting**

The next meeting will be Sept. 30<sup>th</sup> at GSK in Phila. Peg had sent out an email to the team on specifics. Please RSVP to Peg if you are attending in person. The start time of the meeting will be 10 AM.