

**PQRI Manufacturing Technical Committee**  
**September 30, 2004**  
**Meeting Minutes**

The MTC had a face to face meeting on September 30, 2004 at GSK in Philadelphia. Participants included Mark Altman, Bruce Bird, Nicholas Buhay, Jon Clark, Bob Dana, Victor Gangi, John Grazal, George Millili, Linda O'Connor, Carolyn Parziale, Jean Poulos, Gabriele Schoenberger, and Peg Szymczak, with Kurt Van Scoik on the telephone.

**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."

**Steering Committee Meeting**

Bruce reviewed the last Steering Committee meeting and what was discussed there regarding potential future work plans.

**Nick Buhay Presentation**

Nick gave the presentation that he made the previous day on the GMP initiative, "A Risk-Based Approach to CGMP: Are We Ready?". The presentation was distributed by Peg to the team members.

**Process Robustness Working Group**

George gave an update on the Process Robustness WG. He stated that their next meeting will be at the AAPS meeting. They are working on robustness in development, scale-up and manufacturing. The new timeline has a draft being completed in Feb. 2005.

George mentioned that the team was working well together. Frank Ye, a statistician, has left the WG and needs to be replaced by another statistician. The MTC stated that the WG should recommend replacements for members to the MTC for approval, if they need them. George did mention that the team would like more FDA support. Jon will contact Chris Watts to insure that he can still participate on the team. Nick stated that he has two people to work on the team, Grace McNally and Nikal Thakur. The MTC approved their participation on the WG.

**Risk Workshop**

John and Linda then walked us through the agenda for the Risk Management workshop. We talked about having a speaker from the FDA (Greg Claycamp) and Industry (Greg Guyer) give an overview of risk to start the meeting on day 1. It was mentioned that it was difficult to get someone for Risk Matrix, Preliminary Hazard Analysis and Fault Tree Analysis presentation. Jon mentioned Robert Menson to give a presentation on all three.

**(POST MEETING NOTE:** Bruce and Jon ran into Dr. Menson at the CHPA meeting and asked if he would be willing to speak at the workshop. He tentatively said yes. We said that the organizing committee would follow up with him on specifics.) The combining of these into one presentation would facilitate the additional speakers on day 1.

The speaker for FMEA will be Tom Hutchinson, Pfizer. (**Action Item:** Bruce to confirm with Tom). For HAZOP, Llew Williams from Bayer HC will be the speaker. For HACCP, Nick will get someone from the FDA. (**Action Item:** Nick to get a speaker on HACCP.) If Nick can't find someone, Bob Dana has a potential person.

On day 2, the speaker on risk in other industries is someone Carolyn has in mind. He previously worked at GE. Carolyn will speak with the person to insure that the person is speaking on a topic he is familiar with from outside the pharmaceutical industry. (**Action Item:** Carolyn to verify the topic and expertise of the person she had in mind.)

For the FDA presentation on risk management/mitigation Jon will get a speaker from CMC review risk. (**Action Item:** Jon will get a speaker for this topic.)

John has an AstraZeneca speaker for speaking about industry examples of risk.

On day 3, David Horowitz has agreed to speak on the site selection criteria inspections. Fred Razagghi will present on the status of ICH Q9.

John and Linda will continue will continue to work with ECAS on the planning for the Workshop.

### **Approach to Implement a Process Analytical Technology**

Kurt walked the group through the draft work plan. Kurt mentioned that the attempt is to develop a protocol for implementation of PAT technology. Bruce mentioned that this should probably be a little clearer in the document as an outcome. The group also mentioned that this is written as requesting quotes for performing work, with not enough information as to what work is being requested. The document should state what is necessary to achieve the desired protocol. RFP's will be written later to conduct the work.

Kurt will edit the document for further review. (**Action Item:** Bruce will send Kurt the Work Plan template for his use.)

### **Next Meeting**

The next meeting will be a teleconference on October 28<sup>th</sup> at 10:00 AM (ET).

The team also planned the schedule for next years meetings/teleconferences. The schedule for the remainder of this year and next year is:

October 28 <sup>th</sup>	Teleconference
December 9 <sup>th</sup>	Teleconference
January 13 <sup>th</sup>	Teleconference

Feb. 3 <sup>rd</sup>	Face to Face (after the Risk Management Workshop)
March 3 <sup>rd</sup>	Teleconference
April 7 <sup>th</sup>	Face to Face
May 12 <sup>th</sup>	Teleconference
June 9 <sup>th</sup>	Teleconference
July 14 <sup>th</sup>	Face to Face
August 11 <sup>th</sup>	Teleconference
September 15 <sup>th</sup>	Teleconference
October 13 <sup>th</sup>	Face to Face
November 10 <sup>th</sup>	Teleconference
December 8 <sup>th</sup>	Teleconference