

**PQRI Manufacturing Technical Committee**  
**February 14, 2008**  
**Summary Meeting Minutes**

The MTC had a teleconference on February 14, 2008.

**Antitrust Statement**

The Chair 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."

**Open Action Items**

Open action items from prior to the February 14<sup>th</sup> meeting:

1. Draft a response to the proposals for work plans from Rutgers and Purdue and circulate to the MTC for review.  
*Chair has exchanged emails with Rutgers rep on this. The project is in the proposals to the SC. We will wait to see what feedback we get from the SC.*
2. Draft a news brief on the PAC – Sterile Products paper for the PDA Newsletter and to communicate to the WG members the desire to have them present the data at conferences.  
*This will be in the Feb. issue of PDA Letters in addition to their electronic news letter. Chair will follow up with PQRI on whether AAPS will be doing anything also.*
3. **Chair** will draft a work plan to look at science of scale.  
*This is still open.*
4. Draft a proposal for a work shop around gaps in biologicals and biotechnology products.  
*This action item is closed. Worked with BIO to develop proposals of work plans.*
5. Draft a survey to seek ideas for work plans.  
*No update on this.*
6. Draft a work plan on how excipients should be looked at as part of QbD work.  
*This is still open.*
7. Follow up with WG Chair on submissions status.  
*WG Chair has stated that this is in progress and should be completed by the end of the year.*
8. Look into getting a presentation on PAC Sterile Products group at PDA Annual Meeting and/or PDA/FDA meeting and reach out to DIA contacts.

*PDA rep has gotten a slot on the agenda for the Risk Management of Sterile Products conference the 15<sup>th</sup> and 16<sup>th</sup> of May. This would be for a presentation of the risk management tool. He's also gotten a slot for one case study on the use of the tool. MTC members along with the WG, will look to get someone to present a case study. (POST MEETING NOTE: PDA rep has been in touch with WG Chair on this and he is contacting work group members on this.)*

9. Draft work plans for the proposed topics.  
*Will review with the BIO manufacturing group and will work with them to draft a work plan. No update at this meeting.*
10. Send wording for revisions to the OOS work plan to PDA rep.  
*This is still open.*
11. Add additional language from FDA rep into the OOS work plan and then forward on to TC Chair.  
*Needs FDA's revisions to complete.*
12. Forward the work plan on OOS to the SC for endorsement.  
*The OOS work plan is in the proposals to be presented at the SC strategic meeting. Once PDA rep completes the document it will be forwarded to the SC.*
13. Speak with others about chairing the work group on OOS.  
*PDA rep spoke with Lynn on this and he can not do this at this time. He will recommend someone for chair of this WG.*
14. **MTC Members** to let Chair know if they are interested in being Vice Chair of the MTC.  
*This is still open.*
15. **MTC Member** to volunteer to represent the MTC at the SC meeting in Washington, DC on Feb. 26<sup>th</sup> and 27<sup>th</sup>.  
*Three MTC reps will be at the SC meeting.*

### **Risk Management Work Group**

WG Chair had sent an update to TC Chair. The work group has drafted a paper with one of the case studies. The group is now writing the remaining case studies in the same format. The paper should be ready for review by the MTC the end of February.

### **Biologicals Inspection Survey Work Group**

Chair mentioned that there was no update. The work group has not been able to get onto any conference agendas. Chair will talk to the head of Team Bio to see about trying to get on the agenda for GMP by the Sea.

### **Post Approval Changes for Sterile Products**

There was no update during the teleconference. However, after the teleconference WG Chair updated TC Chair on the work group. As mentioned in the Action Items, the article on the work group will be in the next PDA Letter. WG chair stated that the paper has been submitted to the dockets. TC Chair will try to get a list of dockets it was submitted to. WG Chair is presenting on the work group at the PDA Risk Assessment conference.

### **Steering Committee Update**

As mentioned in the action item updates, three MTC reps will attend the SC strategic meeting. Chair previously shared with the MTC the work group update and work plan proposals for the SC meeting.

### **Work Group Ideas**

As mentioned in the action item updates, PDA rep will update the OOS work plan once he has FDA's revisions.

Trying to get some people from BIO to work on preparing the work plans on Enabling Manufacturing Changes for Well Characterized Proteins and Manufacturing Novel Dosage Forms.

### **Other Business**

FDA rep mentioned that he has gotten a potential new member for the MTC from FDA Compliance. He will confirm this and let TC Chair know once it's confirmed.

### **Specification Design & Lifecycle Management Work Plan**

There was no update on this work group.

### **Next Meeting**

The next meeting is a teleconference on Thursday, March 6th. An agenda and call in information will be issued prior to the teleconference.

The date for the April 10<sup>th</sup> face to face needs to be changed. Chair will solicit the best time for the MTC to get together.

Schedule of meetings:

#### **2008**

March 6 <sup>th</sup>	Teleconference
April 10 <sup>th</sup>	Face to Face (Pfizer, Peapack)
May 8 <sup>th</sup>	Teleconference
June 12 <sup>th</sup>	Teleconference
July 10 <sup>th</sup>	Face to Face (TBD)
August 14 <sup>th</sup>	Teleconference
September 11 <sup>th</sup>	Teleconference
October 9 <sup>th</sup>	Face to Face (TBD)
November 13 <sup>th</sup>	Teleconference
December 11 <sup>th</sup>	Teleconference