

**PQRI Manufacturing Technical Committee**  
**September 11, 2008**  
**Meeting Minutes**

The MTC had a teleconference on September 11, 2008.

**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."

**Action Item Update**

1. Revise the OOS work plan as soon as possible.  
*This is still open.*
2. Present the work plan to the SC at the August meeting.  
*Since the work plan was not updated, it was not presented to the SC.*
3. **MTC Members** to send any comments they have on the Specification Design and Lifecycle Management paper to Peg as soon as possible.  
*Some comments have been received. FDA rep will send his comments to the team.*
4. Circulate the document to the DTC after revision with comments from MTC.  
*Rep has contacted the DTC and the WG will possibly present to the DTC at their meeting on Sept. 18<sup>th</sup>. The WG will try to revise the document prior to the meeting.*
5. **MTC Members** to provide comments on the Risk Management paper to Chair by the end of August.  
*Follow up with Chair on this.*
6. Follow up with Visibility Chair on publication of the Risk Management paper in *Pharmaceutical Technology*.  
*When the paper is finalized it will be sent to Pharm Tech.*
7. Discuss with the SC the possibility of holding a conference on Risk Management.  
*The WG will have to work out details for the conference and complete the form on the PQRI web site for submission to the SC.*
8. Follow up with PhRMA reps as to whether they wish to stay on the MTC.  
*Action item not completed yet. One member wishes to stay, still need commitment from other member.*

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

This was covered during the discussion on action items. The WG is awaiting comments back on the draft white paper so it can be finalized.

### **Risk Management Work Group**

There was no update on this WG at the meeting. MTC Chair will follow up with WG Chair on this.

### **Work Group Ideas**

MTC Chair will follow up on the survey being prepared to seek input on work groups.

FDA rep mentioned that there are new cGMP amendments that were put out in the Federal Register for comment. We may be able to get some ideas from these for work groups. Rep sent the links to the MTC. We can discuss these at the face to face in October.

### **Steering Committee Update**

With CHPA primary rep terminating, he has replaced at CHPA. We're not sure if she will be on the SC or not. And we're not sure who will be the SC liaison to the MTC. This will be discussed at the next SC. The next SC is in December, but there could be a teleconference prior to that.

### **Next Meeting**

The next meeting is a face to face meeting on Thursday, October 9<sup>th</sup> at GSK in Philadelphia. Please let GSK rep know if you will be attending in person or not. An agenda and call in information will be issued prior to the teleconference.

Schedule of meetings:

#### **2008**

October 9 <sup>th</sup>	Face to Face (GSK, Philadelphia, PA)
November 13 <sup>th</sup>	Teleconference
December 11 <sup>th</sup>	Teleconference