

Manufacturing Technical Committee Meeting Summary Minutes
October 9, 2008

- ***Antitrust Statement***

Vice-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***
 - Have a resolution on the OOS Work Plan by next meeting.
 - Present the work plan to the SC at their next meeting. *On hold until the work plan is updated.*
 - Circulate the latest draft of the Specification Design & Lifecycle Management White Paper to the DTC & the MTC after the WG's meeting on 10 Oct 2008. The WG will present to the DTC on 16 Oct 2008.
 - **MTC Members** to provide comments on the Risk Management paper to WG Chair by the end of August. *Follow up needed on this.*
 - Follow up on publication of the Risk Management paper in Pharmaceutical Technology. *When the paper is finalized it will be sent to Pharm Tech.*
 - 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.*
 - Follow up with BIO reps as to whether they wish to stay on the MTC. *Follow up still needed on this.*

- ***Risk Management WG***

It was mentioned that WG Chair gave a presentation on risk management at a recent meeting that got a good response. A featured speaker at that meeting might be a good person for the proposed PQRI Risk Management Workshop. Send information on the speaker to the MTC.

Post-meeting note: Chair reported that the comments received on the White paper were easily addressed & a revised paper will be distributed in 2-3 weeks.

- ***Specification Design & Lifecycle Management WG***

Comments received from the MTC have been incorporated into the White Paper. The presentation on the White Paper has been postponed to the DTC's Oct TC.

- ***New Work Group Ideas***
 - **QbD Implementation**

Understanding of how QbD is being implemented & if there are any hurdles may uncover some ideas for new WGs. MTC member companies may be interviewed regarding this subject.

FDA rep to develop a list of possible question by 17 Oct 2008 to

distribute to the MTC members.

All will develop additional questions by the next TC.

- **Security of Supply Chain**
Excipients & APIs with higher metal contaminants, bioburdens, presence of objectionable organisms, related compounds & heavy metals are starting to be seen. The heparin adulteration and melamine contamination incidents are two recent examples.
Action Item: Put together some ideas regarding management of external suppliers for the next TC and speak to IPEC and draft a plan on auditing for authenticity for the next TC.
- **Counterfeit Drugs**
After discussion, the MTC decided not to look into this subject at this time.
- **Risk Management in Aseptic Processes**
The use of risk management for media fills & other areas as outlined in Annex 1 can be evaluated for information gaps.
Action Item: Put together some ideas for the next TC.
- **Implementation of New USP Test for Residual Solvents**
Difficulties in obtaining information regarding residual solvents from suppliers was discussed.
- **SC Update** – PQRI Secretary
There is a SC FTF meeting to be held on 09 Dec 2008. At this meeting, the new Chair will be installed.
- **Other New Actions**
 - **All** to check the 2009 dates below for any conflicts & let Chair know by next TC.
 - Update the MTC mailing list & distribute to all.
 - Contact regarding the questionnaire that was developed.
 - **PQRI** will invite Health Canada to send a representative to the MTC.
 - Talk to Rachael Roehrig re: liaison to MTC.

Schedule of meetings

2008

November 13 th	Teleconference
December 11 th	Teleconference

2009 (tentative)

Jan 15th	FTF at PDA, Bethesda, MD, 10:00 AM - 2:00 PM ET
Feb 12th	Teleconference, 9:00 - 11:00 AM ET
Mar 12th	Teleconference, 9:00 - 11:00 AM ET
Apr 16th	FTF at Pfizer, Peapack, NJ, 10:00 AM - 2:00 PM ET
May 14th	Teleconference, 9:00 - 11:00 AM ET
Jun 11th	Teleconference, 9:00 - 11:00 AM ET
Jul 9th	FTF at GSK, Philadelphia, PA, 10:00 AM - 2:00 PM ET

Aug 13th	Teleconference, 9:00 - 11:00 AM ET
Sep 10th	Teleconference, 9:00 - 11:00 AM ET
Oct 8th	FTF at ?, 10:00 AM - 2:00 PM ET
Nov 12th	Teleconference, 9:00 - 11:00 AM ET
Dec 10th	Teleconference, 9:00 - 11:00 AM ET