

**Minutes of MTC Teleconference
Thursday, May 14, 2009**

Welcome and Anti-trust Statement given by the Chair.

Review of Action Items:

- send comments to Chair re Risk Management paper regarding using specific examples/case studies when they are presenting the material in the paper. Other than that, paper is ready for publication.
- MTC Chair will initiate contact with Outreach Director at AAPS, regarding options for publishing the Risk Management White Paper and the proper procedure for handling.
- FDA rep will bring ideas forward from the QbD arena as appropriate during FDA review over the next six months or so-
- MTC member will explore supply chain security issues.
- All members should continue to bring ideas forward regarding possible WG projects.
- MTC Chair did send out the current mailing list. Please check your information and advise if changes are necessary to the list.
- Member had graciously offered to host this meeting at Sanofi-Aventis. However, since not many folks could travel we opted for a teleconference.
- Reviewed proposed schedule of upcoming meetings.

Active Work Groups:

- Risk Management was not represented so no report given.
- Spec Design is hosting a face to face meeting in June to finalize the document for publication. All comments were addressed and incorporated where appropriate. After review, document should be ready to go.

Steering Committee and TC Chairs Meetings Reports:

- Periodic WG updates will now be done on the new templates; updates needed for the June 2, 2009 SC meeting.
- WG publicity is being sought in short media articles for distribution whenever there is a milestone met, or paper about to be published, etc. to promote the works of the Institute.
- Orientation packet is being developed and will be distributed once compiled; any suggestions for things that should be included in the packet are welcome.
- The MTC Vision Statement was reviewed and it will be discussed at the July TC Chairs meeting to encourage other Technical Committees to also create their own Vision Statement. MTC will look at their statement to make sure it currently aligns with the new PQRI Vision Statement.

New Work Projects

- Supply chain management- reviewed powerpoint presentation that was presented to the SC. Main issues revolve around either Raw Material Quality or Supply Chain Integrity. The SC is still exploring the issue and the MTC is encouraged to come up with their own work project in this arena. Discussion ensued about what that might entail and a

subcommittee was formed to explore this topic in more depth. Perhaps the first steps being reviewing the prior Excipients WG survey and results and looking at QbD for Excipients. A small group of members agreed to work offline on this and report back to the Technical Committee.

Action Item: PQRI will send the New Concept Template and the Work Plan Template to Peg for distribution to team members. PQRI to send the secure portal information to Chair so that she can distribute to all Work Groups and Technical Committee members. *Post Meeting Note:* Actions completed on May 14, 2009.

- Q8/9/10/11 – No ideas came forward on this topic.

New Business

SC Liaison advised that the Steering Committee is planning on hosting a conference on December 15-16, 2009 in Washington, DC to highlight where PQRI has been, and where PQRI is headed. She encouraged MTC members to plan to attend that conference if at all possible. More information about the conference should be forthcoming in the near future.

Upcoming Meetings

June 11	Teleconference	9:00 am – 11:00 am EST	
July 9	Teleconference	9:00 am – 11:00 am EST	
Aug 13	Teleconference	9:00 am – 11:00 am EST	
Sept 10	Face to Face	10:00 am – 2:00 pm EST	New Jersey @Sanofi Aventis
Oct. 8	Teleconference	9:00 am – 11:00 am EST	
Nov 12	Teleconference	9:00 am – 11:00 am EST	
Dec 3	Face to Face	10:00 am – 2:00 pm EST	Wilmington, DE @Astrazeneca

There being no other business, the meeting adjourned at 11:40 am EST.