

PQRI Manufacturing Technical Committee
May 17, 2007
Summary Meeting Minutes

The MTC had a teleconference on May 17, 2007.

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 April 19th meeting:

1. Follow up for a Merck participant on a teleconference to discuss the Biological Indicators for isolators work plan, then to arrange a meeting for the discussion of the need for this work.
PDA is currently drafting a document on indicators for sporicidal gases. We may want to wait for this document to be issued prior to doing any work.

Action times from the April 19th meeting:

2. Draft a response to the proposals for work plans from Rutgers and Purdue and circulate to the MTC for review.
This is still open.
3. Draft a cover letter to submit the PAC – Sterile Products document to the FDA.
a letter was sent to the MTC
4. Look into submitting the PAC – Sterile Products document to the post approval changes docket.
this will be discussed during the Work Group review below
5. Work on submitting the PAC – Sterile Products document to PDA for publication in some format.
*forwarded the document to the PDA for publication
working with the PDA to determine how best to publish the work*
6. Forward a list of current members of the PAC – Sterile Products work group to Chair. **PQRI** will send letters of thanks to the work group once she has the list of members.
(Post Meeting Note: This action item has been completed.)

7. See if we can get a presentation on the PAC Sterile Products at the PDA/FDA joint conference in the fall.
This is still being explored
8. 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 action item is still open
9. Provide contact information for the Chair of the PDA risk management support group.
This action item has been completed.
10. Send a list of the current Biologicals Inspections Survey work group members to Chair MTC. PQRI will send out thank you letters to the work group.
This action item has been completed.
11. Explore the option of having a presentation on the biologicals inspection survey included on this falls PDA/FDA conference agenda.
This action item is still open
12. Be on the lookout for conferences where presentations on the biologicals inspections survey work group results could be made.
This action item is still open

Risk Management Work Group

Reviewed the progress the work group has made to date. Chair visited the FDA Office of Compliance to discuss the work of the Risk Management Work Group. Chair felt the meeting was a good meeting and that they were very interested in what the group is doing and feel the group is on the correct path. They supported the structure of covering all six of the quality systems with risk management examples. Chair mentioned that two new examples have been submitted to the team, however, they still need examples for laboratory systems and asked if the MTC members could help here.

Action Item: MTC to seek examples for risk management in laboratory systems for the Risk Management WG.

Chair will also update the matrix of models and send to the MTC.

Action Item: Chair to update matrix of risk models and send to MTC.

There was also a discussion on whether we need to publish something soon, even if the work is not complete, so the work stays relevant. There could possibly then be an additional publication of work or workshop with updated materials and additions added. Chair will discuss this with the Work Group.

Action Item: Discuss preliminary publication of work with the work group.

Specification Design & Lifecycle Management Work Plan

Updated the MTC on the progress of the Specifications work group. The work group had a teleconference and worked on the glossary. They have a face to face meeting scheduled for June. The MTC approved the addition of a clinician to the work group to provide support on clinical relevance for specifications.

Biologicals Inspection Survey Work Group

Updated the team that all of the revisions to the paper have been completed and proofs approved. The paper should be published in the May/June PDA Journal. It was mentioned that the May PDA Letter had a note in it on the Biological Inspection Survey work group and paper.

Post Approval Changes for Sterile Products

FDA rep mentioned that he discussed the document with several others at the FDA. They supported the idea of filing to dockets and guidance documents. He is working to identify where all of the document should be submitted. It was mentioned that the docket for post approval changes (#314 70) is closing for public comment and it would be good to submit the document prior to this. FDA rep advised that even if the docket is closed we can submit comments and the agency will review them. We will draft a letter for the submission to the PAC docket.

Action Item: develop list of dockets and guidance documents that the PAC for Sterile Products should be submitted to.

Action Item: draft cover letter to submit document to the 314 70 docket.

(Post Meeting Note: The cover letter was drafted and the document submitted.)

Steering Committee Update

Gave an update on the Steering Committee. There was some concern raised on the DTC draft around the fact that they would be doing scale up and PAT and that this was an overlap with the MTC. MTC Chair said he would raise these concerns at the SC meeting the end of May.

Next Meeting

The next teleconference is scheduled for June 21st from 9:00 to 11:00 AM (EDT). An agenda and call information will be issued prior to the teleconference.

Also note we have changed the date for the July face to face meeting to July 12th it will be at Pfizer's Peapack, NJ facility.