

PQRI Manufacturing Technical Committee
February 15, 2007
Teleconference at 9:00 am EST

Opening

Reading of the Antitrust Statement

Risk Management Work Group

MTC was updated on the progress of the work group via a powerpoint presentation. The group is progressing. The WG will add the J&J rep to the team. Team was asked to consider whether a conference should be held after publication of the white paper as an educational tool. If the WG feels one should be held they will draft a tentative agenda to help decide on number of days for the conference.

Biologicals Inspection Survey Work Group

Manuscript for the white paper was completed and sent to the PDA editors for publication.

Post Approval Changes for Sterile Products

MTC was updated on the progress of the work group. The WG has teleconferences scheduled for February to review comments and a face to face meeting scheduled for March.

Specification Design & Lifecycle Management Work Plan

No update given on this WG at this meeting.

Biological Indicators for Isolators Work Group

No update given on this WG at this meeting.

Steering Committee Update

Presentation being given at the PDA Annual meeting on the MTC by the chair. Chair will forward PDA presentation to the MTC.

Old Business (Action Items to be done are in italics)

1. Obtained the contact information for a Merck participant on a teleconference to discuss the Biological Indicators for isolators work plan, then need to arrange a meeting for the discussion of the need for this work. *Call needs to be scheduled.*
2. *Need to circulate the final version of the specifications development and lifecycle work plan to the MTC.*

3. Presentation of the Risk Management work group's progress was made at this teleconference via power point presentation.
4. *Follow up needed on commitments for publication of the Process Robustness White Paper and check with ECAS on possible other routes to get the article out.*
5. The report on Biological Inspections was completed and submitted.
6. *Follow up with FDA about getting a member for the Specification WG from Compliance.*
7. *Follow up needed to put the Process Robustness paper on the PQRI web, and write an article to get publicity for the paper.*
8. *Share the MTC WG metrics with the MTC.*
9. *Follow up on redaction requirement of TC minutes.*

New Business (Action Items to be done are in italics)

1. There was an ad hoc committee to review the PQRI TC structure.
2. It was mentioned that there was an article in the PDA Journal of Pharmaceutical Science and Technology by Barbara Andon on "Active Air vs. passive Air (Settle Plate) Monitoring in Routine Environmental Programs" and a question was raised as to whether there might be an idea in this for a work group. *MTC to review article.*
3. Fernando Muzzio of Rutgers forwarded some proposals for work to be funded by PQRI to MTC reps for review. *MTC to review proposals.*