

PQRI Manufacturing Technical Committee
March 15, 2007
9:00 am – 10:00 am
Summary Meeting Minutes

Antitrust Statement

Chair read the following:

"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 Feb. 15th meeting:

1. Need 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.
2. Check with FDA Compliance about getting a member for the Specification WG.
3. Need to discuss putting the Process Robustness paper on the PQRI web, and about writing an article to get publicity for the article with ECAS and WG Chair.
The article is on the PQRI web and the possibilities of other articles is being explored.
4. PQRI Secretary to do the summary /redaction requirement of TC minutes and then post on website. PQRI is exploring possibility of member only link so that members have access to full minutes, etc.

New Action items from Feb. 15th meeting:

5. MTC to review the article (attached to the minutes) and see if a work group is warranted.
It was agreed to discuss this paper at our April face to face meeting. It was felt that the area of environmental monitoring, not just active air monitoring vs. settling plates would be a good area to do some work. It was also felt the area for the paper may be too narrow of a focus for a work group. We will also discuss at PDA to get comments on possible work in this area.
6. MTC to review the proposals (attached to the minutes) to see if the MTC would support recommending funding of these proposals.
We agreed to discuss this at the April face to face meeting.

Risk Management Work Group

WG Chair was not able to participate in the teleconference. We will try to get an update from WG to share with the MTC.

Specification Design & Lifecycle Management Work Plan

Reported that the WG had their first face to face meeting, which went very well. Rep stated that given the nature of the work that this work group is working on they will probably have more face to face meetings than normal work groups. They were surprised that there was so much harmony among members on their thoughts on this topic.

Biologicals Inspection Survey Work Group

Chair stated that the manuscript was accepted for publication, with some minor edits. The WG is meeting on Monday to revise the manuscript. They have until the 26th to resubmit the revised manuscript. They target getting it back well prior to this date. The article is targeted for the May/June issue.

Post Approval Changes for Sterile Products

Chair gave an update on the work group. All of the comments on the draft have been reviewed and the editing of the document completed. It is currently circulating with the WG for final agreement. This should be done in the next week or so. They will then forward the final document to the MTC.

Biological Indicators for Isolators Work Group

There was no update for this WG at this meeting.

Steering Committee Update

The SC has agreed to reduce the number of Technical Committees to three from the current four. The MTC and BTC will remain unchanged. The DPTC and DSTC will be combined into one TC which will probably be referred to as the Development TC.

Also mentioned that the SC is looking at using focused conferences with 50 or so invited “thought leaders” on a topic to discuss gaps in an area that lead to work groups to close those gaps. There was one proposal for such a workshop on Chemometrics. More work was asked for developing the topic for a workshop. More information from the SC will be coming shortly regarding the changes they are instituting.