

# Manufacturing Technical Committee Meeting

February 3, 2005 PQRI

## Minutes

Participants: Mark Altman, Bruce Bird, Nicholas Buhay, Bob Dana, Victor Gangi, John Grazal, Bill Mullin, Linda O'Connor, Carolyn Parziale, Jean Poulos, Fred Razzaghi, Gabriele Schoenberger, Peg Szymczak, and Glenn Wright,

### Anti-trust Statement:

Bruce started the meeting by reading the anti-trust statement.

### Post Approval Change Guidance for Sterile Products:

Glenn reviewed the draft PAC for Sterile Products with the MTC. Glenn did ask others for comments on the draft. Glenn will revise the document and circulate to the committee by Feb. 15<sup>th</sup>. (**Post Meeting Note:** Glenn did send the revised document out. It is attached to the minutes, Work Plan Draft feb152005 PAC-S.DOC). In revising the document Glenn should consider if money will be required to complete the work.

Nick suggested some other possible routes for making changes. He will send some wordings to Glenn.

The MTC also talked about team members for the WG. The MTC recommended 10 to 15 members only. We also mentioned that members for the WG should participate.

As with other WG's, the MTC will have a liaison with this WG. The liaison will be Jean Poulos. Glenn has proposed several team members. (attached Potential Working Group Members.doc).

**Action Item: MTC** to review work plan and be prepared to discuss/approve at next teleconference.

### Risk Management Workshop:

The MTC first reviewed the summaries from the three day workshop. I have attached the presentation we used for Day 1 and 2 summaries (PQRI Breakout Session Day 1.ppt, Day2 Risk Mgmt Workshop.ppt) and a summary of the workshop that I gave to the SC meeting which includes the comments from Day 3 at the end (Risk Management Workshop.ppt). It was agreed that we should polish up the wording of these prior to putting on the website. It would also be helpful to list the tools and where they can be used.

Since some of the team members have not seen the ICH 9 draft, it was agreed to send out with the minutes. (Attached 11294a1 guideline ICH Q9 DRAFT 4 Dec 1 2004.pdf).

The MTC then discussed next steps. We could set up a WG to develop case studies for different applications. Peg and Bill agreed to draft a Work Plan for this. The plan should include a plan for training. We could also put references on the PQRI web site. This could be a deliverable from the WG.

**Action Item: Peg and Bill** to draft a work plan for development of case studies of risk assessment.

We then discussed conference feedback. There was a favorable response by those who attended with a lot of interest in the topic. Most people were engaged and participated in the breakout sessions. The group agreed that Ajaz's presentation was provocative. The general feeling was that the workshop was better than they thought it would be.

We then discussed why the turnout was low.

1. The fact that it was only for solid dosage forms could have hurt.
2. Lack of advertising was a key issue. The advertising should have had more of the agenda with speakers.
3. Definitions of roles for the organizers would have been very helpful. This should include timelines, especially for advertising.
4. There wasn't a sense of urgency on the number of attendees until right before the conference. This was late.
5. The web site was shut down a week before the conference. It should have had a note that people could still register at the workshop.
6. We agreed to look at the questionnaire results when it is completed. Hopefully there will be questions about how they heard about the conference and when did they decide to attend? (**NOTE:** John or Linda did you see the questionnaire yet?)

It was agreed that the presentation by Gaedekal was very good, but it wasn't what was asked for.

The auditorium seating was very good, although the temperature control was not good. Also questioners did not use the microphones when asking questions, so it made it hard to hear.

Nick suggested that the MTC prepare a report to the FDA on unresolved questions from the workshop, the interest in this area and areas that the FDA may want to address in some way.

**Action Item: Bruce** to draft a report to the FDA.

#### **Steering Committee Strategic Planning Meeting:**

The MTC then discussed potential work groups for the upcoming year which will be discussed at the upcoming SC meeting on strategic planning.

Those already on the list include:

1. PAC Sterile Products
2. Process Robustness
3. Biological Indicators for Isolators
4. Case Studies for Risk Management

Potential work groups include:

1. Items from the specifications workshop, such as Specifications Lifecycle
2. Regulatory Process (follow up to Process Robustness)
3. New Process Validation Paradigm (i.e. Continuous Quality Verification) - Nick mentioned that the FDA is rewriting the validation guidance, so timing would be appropriate.
4. PAI Implementation plan
5. Biosurvey for Team Bio
6. Process Control - control of specific steps in processes, i.e. mixing. Recommended controls to assure these processes go well.

It was agreed that it would be a good idea to set up a subcommittee to develop ideas for 2006. Everyone should be thinking of areas where work groups would be helpful and appropriate.

**Action Item:** MTC members to think of ideas for future workgroups. Submit your name to Bruce if you'd like to work on the subcommittee.

**Project Manager:**

The MTC then reviewed the draft job description for a project manager for the MTC. The revised job description is attached (Description of Project Management Services fro PQRI.doc).

**Product Robustness WG Update:**

The MTC then reviewed the update that Mike Glodek made at the Workshop.

**MTC Tracking Form:**

Bruce then reviewed the MTC tracking form that was sent in for the SC meeting. (Attached MTC Tracking Form Jan 05.doc).

**New Business:**

It was mentioned that it would be beneficial if everyone introduced themselves and their background and responsibilities.

Bruce also agreed to send out the list he has for MTC members and their associations (Attached Manufacturing Technical Committee Members.doc).

**Next Meeting:**

The next scheduled MTC teleconference is Friday, March 4<sup>th</sup> from 10 to 12 AM (EST). I will send out an agenda as we get closer to the meeting.