

PQRI Manufacturing Technical Committee
June 10, 2005
Meeting Minutes

The MTC had a teleconference on June 10, 2005. Participants included Bruce Bird, Nicholas Buhay, Jon Clark, Victor Gangi, Sylvia Gantt, George Millili, Bill Mullin, Linda O'Connor, Jean Poulos, Fred Razagghi, Gabrielle Schoenberger, Peg Szymczak and Glenn Wright.

Antitrust Statement

Bruce 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."

Minutes Review

The team reviewed the minutes from the May 13th meeting and approved the minutes.

The MTC then reviewed action items from previous meetings:

1. **MTC members** to provide any comments on Risk Management Work Plan to Peg or Bill.
Completed.
2. **Bruce** to complete draft report on risk management workshop.
Still an open Action Item.
3. **MTC members** to provide comments on Biological Inspections Survey Work Plan to Bruce or Vic.
Still an open Action Item.
4. **MTC members** to review specification workshop break out session reports and develop ideas for potential work groups in the future.
Completed.

Action items from the May 13th meeting:

1. **Robustness WG** to issue final version of white paper.
2. **Glenn Wright** to provide the resumes of the people above in bold italics to Bruce Bird.
Completed.

3. **Bruce Bird** to obtain the resumes for these two candidates and send out to the MTC for evaluation. (**Post Meeting Note:** Joe Rinella's resume was received and is attached to this email.)

Completed.

4. **Gangi** to seek members for the work group from BIO.

Completed.

5. **Carolyn Parziale** to see if there is anyone from Centocor who is interested in being a member on the work group.

Completed.

6. **Jon Clark** to look into the participation of David Husong and Laurie Norwood and someone from OGD.

Completed.

7. **MTC members** to provide comments on the Work Plan to Bill and/or Peg by June 3rd.

8. **Bruce Bird** to forward information on the company doing the survey for the DPTC work group to Victor.

Biologicals Inspection Survey Work Plan

Victor Gangi reviewed the comments provided on the Biologicals Inspection Survey Work Plan. The MTC approved the work plan. It was agreed to separate the work plan and the survey and call it a draft survey since the Work Group will finalize this.

We will send the Work Plan to the Steering Committee in June for approval.

We also discussed obtaining members for the Work Group. Keith Webber already has the FDA membership in mind.

Action Item: Bruce Bird to send the Work Plan to the Steering Committee for approval.

Action Item: MTC to begin to solicit members for the work group.

Risk Management Work Group

Peg and Bill mentioned that they had received some positive feedback on the draft work plan. Since part of the work plan is to conduct a survey to obtain case studies, money will be requested for this survey. Bruce mentioned that they should include \$10,000 in the

work plan for this. Peg will make these revisions. The MTC approved the work plan. It will now be sent to the Steering Committee for approval.

Bill mentioned that he had a name for the chair of the work group. He will forward the name to Bruce and we will have the MTC approve the person electronically. Bill will be the MTC liaison for this work group.

Action Item: Bruce Bird to send details on the consultant for surveys to Peg and Bill.

Action Item: Peg Szymczak to make final revisions and forward the work plan to Bruce. (**Post Meeting Note:** this has been completed.)

Action Item: Bruce Bird to forward the work plan to the Steering Committee for approval.

Action Item: Bill Mullin to send the name of the candidate for the chair of the committee to Bruce. (**Post Meeting Note:** this has been completed.) **Bruce Bird** to forward the resume to the MTC for approval.

Action Item: MTC to begin to look for members for the work group.

Process Robustness Working Group

George mentioned that the work group was getting a lot of comments from various sources. Several of the MTC members distributed the report to their trade associations for review. The work group will consider all of these comments prior to finalizing. They will make the minor changes at their scheduled June 30th meeting. We will then get this back and forward to the Steering Committee for approval.

Action Item: Process Robustness WG to make minor modifications and forward final report to Bruce Bird.

Action Item: Bruce Bird will send the report to the Steering Committee for approval.

The work group has agreed to develop and is currently working on the addenda for oral solid dosage forms. They will evaluate which other dosage form addenda they feel comfortable working on at their June 30th meeting.

Action Item: Process Robustness WG to draft oral solid dosage form addenda and let MTC know which other dosage form addenda they will prepare.

The work group will also discuss where they want to publish the report after it is approved and make a recommendation after their June 30th meeting.

Action Item: Process Robustness WG will make a recommendation to the MTC on where they would like to publish the report.

We also discussed various team members making presentations on the work at various conferences. There is no issue with members presenting at conferences, however, the presentation of PQRI work needs to be approved by the Steering Committee. The work group was told to draft a standard presentation on the work that could be submitted to the Steering Committee for approval.

Action Item: Process Robustness WG to prepare a presentation on their work that may be given by members at conferences for Steering Committee approval.

Project Manager

Bruce mentioned that a Rafik Bashira who is retired from Eli Lilly was interested in the project manager position for the MTC. People who know Rafik mentioned that he was a good person. Bruce mentioned that things still had to be worked out for this.

Steering Committee

Bruce reviewed items from the Steering Committee meeting that was held the 9th of June. He was requested to be sure to send out the minutes from the Steering Committee meetings to the MTC.

Specification Design & Lifecycle Management Work Plan

Peg mentioned that she was drafting a work plan on Specification Design and Lifecycle Management. She hopes to have a draft for this by the July meeting of the MTC.

Post Approval Changes for Sterile Products

The MTC discussed the final list of members for the work group. The groups decided to include Joe Rinella, Donna Gulbinski, John Pavlik and Thomas Dolan on the work group. Bruce will send out a final list of work group members and those not placed on the work group. Sylvia will then send letters to both groups.

Action Item: Bruce Bird to send out a list of work group members and also those not selected for the work group.

Action Item: Sylvia Gantt to send out thank you letters to those not selected and congratulations letters to those selected.

Jean Poulos will be the MTC liaison for this work group.

Glenn Wright hopes to have his first face to face meeting with the group in early August.

Next Meeting

The next meeting will be a face to face meeting scheduled for July 19th at Pfizer's Peapack facility.

The schedule for the remainder of this year and next year is:

July 19 th	Face to Face (at Pfizer in Peapack, NJ)
August 11 th	Teleconference
September 12 th	Teleconference
October 13 th	Face to Face (at IVAX in Miami)
November 10 th	Teleconference (need to change this date or time)
December 8 th	Teleconference