

**MINUTES**  
**Manufacturing Technical Committee**  
May 27, 2004  
Pfizer Inc.  
Peapack, NJ

**Attendees List**

**Industry Representatives:**

Mark Altman - CHPA  
Bruce Bird – PhRMA  
Robert Dana – PDA  
Sylvia Gantt (by phone) – PQRI  
John Grazal – PDA  
Nicholas Maselli – GPhA  
George Millili – ISPE  
Linda Evans O’Connor (by phone) - GPhA  
Gabriele Schoenberger – IPAC-RS  
Margaret Szymczak – AAPS

**Process Robustness Work Group:**

The Work Plan was approved by the Steering Committee. I’ve attached the final version.



Microsoft Word  
Document

The MTC then selected members for the WG. The following names were submitted for consideration:

Kim Assini - GPhA  
Rakesh Grover – GPhA  
Dave Hedden – PhRMA  
Stephen Liebowitz – PhRMA  
Randal McCarthy – PhRMA  
Rajeev Mohan – GPhA  
Cynthia Oksanen – PhRMA  
Saurabh Patel – PhRMA  
Thomas Schultz – AAPS

Mani Sundararajan – PDA  
Robert van Osdel – ?  
Rod Vorkapich – CHPA  
Chris Watts – FDA  
Feng Ye – PhRMA

The team discussed all of the proposed members and decided on nine members along with Michael Godek the Chair. The nine selected were Kim Assini, Stephen Liebowitz, Randal McCarthy, Cynthia Oksanen, Thomas Schultz, Mani Sundararajan, Rod Vorkapich, Chris Watts and Feng Ye.

Sylvia will send a letter to all the members selected with an overview of PQRI and welcoming them to the team. (Post Meeting Note: The letters have gone out.) She will also a letter to those not selected asking if they would like to be considered for a future WG (Post Meeting Note: The letter has been drafted.)

George Millili will be the MTC liaison with this WG.

**Workshop on Risk Management:**

The volunteers for the workshop committee were Mark Altman, Bruce Bird, John Grazal, Linda O'Connor and Fred Razzaghi. John and Linda agreed to act as co-chairs for the workshop committee.

Bruce reviewed his teleconference with the ECAS team on the workshop. One concern was the timing. ECAS felt that the only time to do it would be early Dec. The MTC felt that this would not be good since it is the end of the year and if there are budget constraints in various companies they would not allow members to attend. So the MTC recommended the meeting be held the second week in January if possible.

The MTC reviewed the agenda for the meeting to review potential presenters for the workshop. The following attachment is the result of this discussion.



Microsoft Excel  
Worksheet

The ECAS is looking for more detail and definition on the sessions and take aways. A marketing blurb/hold the date notice also has to be developed.

Sylvia will send out an example to John Grazal for him to develop this. (Post Meeting Note: John has written a draft for the Workshop committee to review.)

### **Work Group Proposals:**

The MTC then reviewed various new work group proposals.

- Biological Indicators for Use in Isolator Systems. The comments on this Work Plan were:
  1. It needs to be placed in the Work Plan template format that is currently being used.
  2. The MTC questioned whether there really is a need for a two day workshop to collect information on this topic. We felt it would be quicker and more economical to do the data collection electronically.
  3. There was a question as to what if 3 biological indicators are not identified for further analysis. Then what?
  4. We need to minimize the costs for the final analysis as much as possible.
  5. With respect to the timing, the MTC felt it was too long to complete the work. Not sure why a literature search would take 6 months.
  6. We will need more detail on the resources required to complete this Work Plan (money and personnel).

The MTC agreed that Jim Agallaco would be a good Chair for this Working Group if it is approved. Bruce will work with Jim and Glenn Wright to revise the work plan.

- Reporting of Post Approval Changes for Sterile Products. The comments on this Work Plan were:



PQRI PC  
comments.doc

1. Peter Calcotts comments were:
2. Need to make sure that we have proper FDA representation from all the appropriate divisions.
3. The actual deliverable would be a white paper.
4. Needs to be placed into the new Work Plan Template.
5. Need resources, etc.

6. Should use similar language as to what was used in the Change Management Work Plan.

Bruce will work with Glenn Wright to revise the work plan.

- Regulatory Process Work Plan. The MTC briefly talked about the latest version that Nick had. There was discussion of changing the title to Regulatory Change Management. We agreed to send out the latest version and discuss at the next meeting. The version is attached.



Regulatory Process  
Work Plan.doc

- Specifications Lifecycle. Bruce and Peg agreed to work on drafting a work plan for this topic.

### **PQRI Quarterly Newsletter:**

Bruce mentioned that he had to write an update for the quarterly PQRI newsletter. The following is what was submitted.



MTC Update 6 2  
2004.doc

### **MTC Contact List:**

Bruce asked everyone to look at the contact list and let him know of any updates. I do need some information from Carol Parziale and Nicholas



Microsoft Word  
Document

Buhay.

### **Meeting Schedule:**

1. Next meeting is scheduled as a teleconference on Thursday, June 24<sup>th</sup> from 10:00 to 12:00 EDT. I will send out a reminder and call in information next week. Let me know of any agenda items.
2. The following is the schedule for MTC meetings for the remainder of the year:

July 29 <sup>th</sup>	Teleconference
Aug. 26 <sup>th</sup>	Teleconference

Sept. 30 <sup>th</sup>	Face to face meeting – Peg has agreed to hold this meeting at GSK’s Franklin Plaza facility in Philadelphia.
Oct. 28 <sup>th</sup>	Teleconference
Dec. 9 <sup>th</sup>	Teleconference