

Draft MINUTES  
**Manufacturing Technical Committee**  
June 19, 2003  
Pfizer Inc.  
Morris Plains, NJ

**Attendees List**

**Industry Representatives:**

Bruce Bird – PhRMA  
Peter Calcott - BIO  
Robert Dana – PDA  
Sylvia Gantt – PQRI  
John Grazal – PDA  
Greg Guyer – PhRMA (by telephone)  
Steve Lane – USP  
Nicholas Maselli – GPhA  
George Millili – ISPE  
James Mitchell – IPEC (by telephone)  
Gabriele Schoenberger – IPAC-RS  
Margaret Szymczak – AAPS  
Ken Warner (CHPA) (for Mark Altman)

**FDA Representative:**

Jon Clark

**Introductions**

Everyone introduced themselves giving their company and trade association affiliation. The current mailing list was circulated for corrections/updates. It is attached with the minutes.

**PQRI Background**

Sylvia Gantt provided an overview of PQRI, it's structure (Steering Committee, Technical Committees and Working Groups), working plan outline, Protocol Governing Data Collection, publication/presentation policy, and the PQRI Bylaws.

## **Manufacturing Technical Committee**

Bruce Bird then led the team through some committee logistics. He mentioned that the members need to remember that they are representing their trade associations and not themselves or their company only. As such there is a need to insure that when documents are reviewed that the members get their associations comments included. This will be difficult given the speed which the committee will need to operate on many topics.

The committee also agreed to meet face to face at least quarterly. We will try to rotate the location of the meeting between Washington D.C. and the Northeast. To accommodate travel we will try to hold the meeting schedule from 10 AM to 3 PM. Members who can't make the meeting in person are encouraged to phone in to participate. The frequency may be adjusted if the need arises.

Between the face to face meetings we will hold a monthly teleconference. We will try to keep the teleconferences as short as possible to accommodate the agenda. Due to the various locales of the committee members we will start the teleconferences at 10 AM Eastern Time.

It was also suggested that all of the members share with the committee position papers that their trade associations issue on topics of concern to the committee. This would be after they have been made public. This would facilitate all the members knowing the various positions taken.

The committee then discussed the Manufacturing Technical Committee's mission. It was suggested that we should be sure our mission aligns with the FDA Advisory Committee's Manufacturing Sub-Committee mission once it is written.

Greg Guyer proposed the following mission statement: "Leverage our Manufacturing Expertise to define science-based guidances that appropriately integrate risk assessment that will encourage innovation and continuous quality improvement in pharmaceutical manufacturing and flexibility in the associated regulatory processes." The team agreed to review this and make comments. Our goal would be to adopt a mission at our next meeting in July so it can be presented at the August Conference.

### **Aseptic WG Report**

Bruce Bird, with the help of John Grazal who was on the WG, went through a presentation from Glenn Wright, the Chair of the Aseptic WG. The TC then discussed the two proposals that were put forward by the Aseptic WG for future work. One was on the establishment of biological indicators for qualification of isolators using VHP. And the other was on adjunct processing as a concept to increase sterility assurance.

While normally these proposals would have been reviewed and approved by the Manufacturing Technical Committee prior to going to the Steering Committee, since the MTC had not met yet, it was taken directly to the Steering Committee. The SC endorsed developing a working plan for the BI project, but asked for more definitive information on adjunct processing before endorsing a project in this area.

**ACTION ITEM:** Bruce Bird to follow up with Glenn Wright on the preparation of a working plan for the BI project.

### **August PQRI Conference**

PQRI had planned a conference in April of this year on “Good Regulation Through Good Science”. The conference was postponed due to the war in Iraq. The conference has now been rescheduled for August 4 – 6. The afternoon of the first day the conference will have four breakout sessions, one for each of the Technical Committees. Originally the Manufacturing TC session called for a presentation on Aseptic Processing, Good Manufacturing Practices and then a Round Table Discussion.

The TC agreed that there should be an update by the Aseptic WG.

**ACTION ITEM:** Bruce Bird to discuss with Glenn Wright who should make this presentation.

**ACTION ITEM:** Jon Clark will check on the timing for the Aseptic Guidelines issuance. It's timing could affect the presentations content.

It was then agreed that we should use this Round Table discussion as a way of gathering information on areas that the committee should work on for the GMP Initiative. It was agreed that we would give a presentation on our mission, articulating what it means. It was then proposed that we present a menu of science based ideas to work from during the Round Table

discussion. The team will collect ideas for development of this menu for the presentation.

Members of the TC were encouraged to attend the conference if possible.

### **GMP Initiative and MTC**

The conference discussion led the TC into a discussion of where we as a team feel we should devote our efforts. We discussed the four areas covered during the FDA/PQRI conference and the summaries generated at that conference. These were Changes Without Prior Approval, Integrating CMC Review and Inspections, Risk Based cGMP's, and Manufacturing Science.

Bruce Bird also mentioned four areas that Toby Massa and Helen Winkle suggested the team look at. These are OOS, cleaning validation, process validation and technology transfer.

The team agreed with Grey Guyer that the number one priority of the Manufacturing TC is to support the FDA's initiative.

The TC then reviewed the Manufacturing Science and Risk Based cGMP's summaries from the FDA/PQRI workshop.

It was agreed that we would use the Manufacturing Science summary as a basis to start our Round Table discussions at the conference. It was proposed that the presentation start with a "strawman" position followed by the Manufacturing TC mission, then a synopsis of the summaries for Risk Based cGMP's and Manufacturing Science, followed by some ideas to start the discussion and the round table.