

Summary Minutes MTC Face to Face Meeting
Thursday, March 11, 2010
10:00 am – 2:00 pm

Admonition statement read by the Chair.

Review of Action Items from February 18, 2010:

Action Item: Rep to compile ideas/notes regarding the possibility of a WG to explore transdermals and send them to Chair for MTC consideration. Item Accomplished

Action Item: Rep will take info from the Oct. 2009 meeting on supply chain- excipients, and plug it into the presentation to have it ready for the next SC meeting. Item accomplished. MTC reviewed the presentation and suggestions were made which will be incorporated into the presentation for review at the next MTC meeting on April 8th prior to the April 12th SC meeting.

Steering Committee Report

- Process Drift Workshop was approved by both the SC and Board and a contract is in the works for the dates of December 1-3, 2010.
- Discussed trademark issue with other PQRI group- Physicians Quality Reporting Initiative.

WG Reports:

- **Risk Management-** no update from Chair

Action Item- MTC Chair will contact WG Chair to get paper status update.

- **Specifications Life Cycle** – SC Chair has asked for a report on what needs to be done to complete this WGs project.

Action Item: MTC Chair and rep will take a look at the current version of the document to see what needs to happen to finalize the paper. It will be brought back to the MTC for their review and finalization of the paper is desired by the June MTC face to face meeting. The paper will then be sent to the SC for their informational purposes. The SC does not need to approve the final product, but the MTC does.

WG Proposal on Complex Dosage Forms is being considered by the MTC in the area of transdermals. Rep prepared a presentation on the topic for the MTC consideration. A suggestion was made to prioritize topics to be researched- i.e., adhesivity of patches is a major concern. Considerable work has been done by USP personnel that perhaps PQRI could collaborate with them to complete the project.

Action Items: PQRI to send rep the concept template for presentation to the SC as well as the skill set matrix for their consideration of who would be needed to complete the work project. Items accomplished.

Rep will collect MTC comments by March 25, 2010 and incorporate them into the powerpoint presentation for the MTC to review at the April 8th meeting.

WG Proposal on Supply Chain presentation proposal was reviewed and discussed. There will be 3-4 excipients explored for their correlation factors and not causation. **Action Item:** Rep will add the suggestions to the presentation for finalization at the April MTC meeting to then go to the SC in April as well.

Process Drift Workshop Proposal

- Solicited help with a breakout session and/or speaker selection
- Meeting held at FDA on 3/9 to further develop draft agenda
- Workshop committee and Planning Committees are being formed. An MTC member will be asked to serve on the Planning committee. If you wish to volunteer, let MTC Chair know by March 18th.
- Planning Committee members will be asked for their input into developing the program agenda and soliciting the appropriate speakers
- All speakers will be required to present at least one case study to illustrate their point
- Possible co-sponsorship with FDA, AAPS, ISPE

Action Item: MTC members should communicate to Chair their desire to serve on the workshop planning committee and a decision will be reached by the end of March.

Other Business

- MTC Chair will send out a current contact list for people to update accordingly
- MTC is looking for a new IPAC-RS member.
- MTC member is now affiliated with AAPS as their representative.

Next meeting of the MTC is the teleconference set for April 8, 2010 from 9:00 am – 11:00 am.

Rep will check on June Face to Face meeting in Peapack, NJ.

Meeting adjourned at 1:30 pm.