

Summary Minutes MTC Teleconference
Thursday, February 18, 2010
9:30 am – 11:00 am

Admonition statement read by the Chair.

Review of Action Items from Jan. 14, 2010:

- FDA approved their rep becoming the SC liaison to the MTC
- FDA rep made presentation to the SC on 2/8/10 for the Process Drift workshop
- MTC Chair secured copy of the paper on transdermals and sent to MTC
- Chair got update regarding Risk Management paper, which will need to go through Board once an agreement is obtained; she also sent him info regarding presenting an abstract at the AAPS meeting in Nov. 2010

Steering Committee Report

- PQRI is healthy financially
- Reviewed the approved membership dues structure and intent to invite new memberships with a graduated fee structure (\$5,000 first year, \$10,000 second year, and \$20,000 third year); will also invite past organizations to rejoin with a one shot offer of the graduated dues structure (PDA, ISPE, PhRMA, BIO, GPhA); MTC rep is willing to serve as intermediary for ISPE invite back into PQRI and she suggests using the historical article along with the letter from the Board to showcase all the PQRI successes
- Reviewed survey results
- Several WG proposals are being explored- nanoparticles, large 'n' sample size; OOS, biosimilars, and complex dosage forms
- Discussed Volunteer contract and asked that all MTC members sign and return to PQRI

WG Proposal on Complex Dosage Forms is being considered by the MTC in the area of transdermals. Members were given the paper to use as a starting point to decide how to proceed; still a timely topic. FDA rep suggested involvement with OPS, ONQA and OND at the FDA as the FDA is very interested in this topic

Action Item: SC rep will compile ideas/notes and send them to Chair for MTC consideration

WG Proposal on SUPAC guidelines to explore how multiple changes at one time can/do impact final output. Maybe do a survey to see how folks are using QbD, PAI and SUPAC and is quality as good or being compromised? How big a problem is this?

WG Proposal on Supply Chain is being explored. He is going to use the template provided by PQRI to develop the presentation to the SC for this concept proposal.

Action Item: MTC rep will take info from the Oct. 2009 meeting of the MTC and plug it into the presentation to have it ready for the next SC meeting.

Process Drift Workshop Proposal workshop was approved in concept by the SC

- budget estimate needs to be prepared for the SC and Board to approve
- FDA rep is working with some members of the planning committee to further develop the agenda
- Time frame is for Sept/Oct. 2010 if possible
- Goal is to do international workshops if the first is successful
- Narrowed focus to include only small chemical molecules
- MTC members can help by bringing forward case studies, serving as moderators at the breakout sessions and volunteering to serve on the planning committee

Next meeting of the MTC is the Face to Face on March 11, 2010 at the PQRI/AAPS offices in Arlington, VA. Directions were sent to Chair for distribution.

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

Meeting adjourned at 11:10 am