

Summary Minutes of the Steering Committee Teleconference  
April 12, 2010  
12:30 pm – 4:00 pm

Chair read the Admonition Statement.

Minutes from the February 2010 meeting were approved as presented.

Action Items:

**Sample Size for large 'n'**- reported work is still in process

**Nanoparticles** –discussed proposal from Texas A&M and the SC members comments to the proposal. Discussion around comments and decision was reached to ask Texas A&M to develop further the proposal specifically outlining Intentions 1 and 2 for a work project with the possibility of also addressing Intention 3 at a later date.

**Action Item:** SC rep will work with Texas A&M to incorporate the comments and direction given by the SC members into the proposal and have an adjusted detailed proposal ready for the June SC meeting.

**Out of Specifications** – conclusion was drawn that there is not enough substance at this time to warrant a work project in this area

**Complex Dosage Forms** –MTC has a proposal to present today to the SC

**Biosimilars** –Chair is forming a work group to explore the specific area that they should tackle as a work project. She is looking for volunteers to add to the group she currently has and will send request out.

**Action Item:** Chair will send a synopsis of the volunteer type needed, and a short description of the project they will be asked to explore. PQRI will then send out a solicitation for volunteers to all member organizations. Chair is specifically trying to find some individuals with generic companies or GPhA.

**Risk Management WG** – FDA rep found another trainer for their workshop since the WG Chair did not respond in time for the request.

**Specifications Life Cycle Design WG** – MTC members are working on putting the current draft into a final format for the MTC to approve. Their timeline is to hopefully have that completed by June 2010.

### **Proposed/Upcoming Work Projects**

**Process Drift Workshop-** workshop executive committee have prepared a draft preliminary agenda, and will seek support for speakers, topics, breakout session leaders and planning committee members from the SC membership.

**Action Item:** FDA rep will send out draft to SC members and seek their suggestions and support for the various roles in the near future.

**Supply Chain/Excipients WG** – reviewed power point presentation from the MTC. Discussion ensued concerning collaboration with other groups that are currently doing work in this arena. IPEC rep offered to work with MTC to coordinate efforts to make sure there is no duplication of ongoing efforts.

**Action Item:** SC approved the concept of the WG and asked that the MTC prepare a detailed Work Plan and consult with IPEC rep regarding direction for the WG.

**Transdermals WG** – reviewed power point presentation from the MTC. Discussion concerning scope of work project and unanimous approval of the concept by the SC.

**Action Item:** MTC to prepare a detailed Work Plan on the project and present to the SC hopefully by fall 2010.

#### Technical Committee Reports

##### **BTC-**

- BCS III paper will be composed by compiling the generated data. BTC members volunteered to perform this task for the WG.
- Sequential Design is moving forward with expanding their research building on the previous results. Programming is already taking place and a paper should be generated in the near future.
- Bio III contract is in formulation at this time; University of Mainz will actually perform the study so that is the hold up currently. Work should begin around January 2011 so funding will not be needed until that time.

##### **DTC –**

- Bioequivalence Workshop scheduled for April 30, 2010 in Orlando currently has 143 registrants.

##### **MTC-**

- Process Robustness Case Studies are still looking for venues to present their work.
- Specification Life Cycle paper is in review
- Excipients proposal will move to next phase and develop work plan
- Transdermals proposal will move to next phase and develop work plan
- Risk Management paper needs to be published
- FDA nominee received unanimous approval from the SC for her appointment to the MTC as the new FDA representative.

#### **Volunteer Appreciation Efforts**

- week of April 19-23 is Volunteer Appreciation Week
- letters to all Board, SC and TC members will go out next week

#### **Next Steps/Upcoming Meetings**

- polling for next meeting to be held in June
  - best time frame is around June 14
- CHPA has offered to host the next face to face meeting in September 2010.
  - Polling will take place to determine best date.

There being no further business, the meeting adjourned at 2:10 pm