

**Development Technical Committee**  
**Teleconference/WebEX Meeting Summary Minutes**  
**October 16, 2008**

**Opening**

Chair read the Admonition Statement and welcomed all participants. Apologies for the WebEx teleconferencing issues in getting everyone connected. The Chair also thanked PQRI Secretary for offering to take minutes of the DTC meetings.

**NEW BUSINESS**

**Specifications Design & Life Cycle Management Work Group** – WG Rep gave a brief overview of the purpose of the WG and their structure. It was set up to be a joint project between the former DPTC and the MTC. However, most of the work to date has been accomplished by MTC members on the WG. The WG would like to involve the DTC (formed through consolidation of the former DPTC and the DSTC.) The DTC members are being asked to review the White Paper that is currently going through revisions and offer their input to the WG. The White Paper is intended to be a new way of looking at things, and hopefully a starting point of serious discussion for setting specifications design. WG Rep gave an overview of the White Paper (see attached slide presentation) and encouraged questions from folks on the teleconference. Some questions raised included:

- Where will the White Paper be published?
  - Hopefully, in a journal such as *Pharmaceutical Technology* when it is in its finalized format. There is also the possibility of doing presentations to promote this different way of doing things.
- How do you get clinical relevance?
  - Discussion ensued about how that can be achieved.
- Is the White Paper a description of the ‘new world’ or actually the way that things are handled currently?
  - The introduction to the paper needs clarification to make sure the reader understands that the paper is proposing something brand new, and how that might be implemented.

The group agreed that the DTC members will have until November 7, 2008 to send in their comments on the White Paper. Comments should be directed to WG rep who will collate them for the WG, but the DTC members should be copied in on one another’s remarks. DTC members are encouraged to discuss the paper’s premise with their business associates, stressing that this is just a draft at this point (the current draft is #12.)

**Action Item:** *PQRI Secretary to send WG rep’s email address to all DTC members. Also, send a copy of the slide presentation to all DTC members directly following the teleconference.* Post meeting note: both action items accomplished by October 17, 2008.

### **New Member Addition to the C/C Work Group**

The C/C Work Group is asking for the endorsement of candidate to be added as a member to their team. Candidate's CV is attached to these minutes, and he brings a wealth of experience and expertise in package development to the team. After a brief discussion, John's nomination was unanimously approved as an addition to the team. DTC liaison will report back to the WG on the endorsement.

### **Co-Chairs for C/C Work Group**

The Chair has asked for consideration of a three way leadership team for this work group. The Steering Committee suggests that they have one Chair, and then have two Vice Chairs who can assist the Chair as needed. That way there is still just one point of contact for the Steering Committee and DTC, but they are able to divide duties as appropriate within their team.

### **Tracking Forms for Work Groups**

DTC Chair asks that each WG liaison have their respective WG Chair send a update to him by no later than November 26, 2008 so that he can prepare the Tracking Forms needed by the Steering Committee for their December meeting.

### **Development Technical Committee Face to Face Meeting**

A polling took place of members on the teleconference call to see who could participate in a face to face meeting on December 8, 2008 at the PQRI office. With five members indicating they could make the face to face, and a couple of others who can call in, it was decided that the meeting would go forward. The meeting will start at noon in order to give folks time to get into DC area, and west coast participants an opportunity to participate. Lunch will be ordered in for the meeting. The Steering Committee meets face to face in the District the day following the DTC meeting.

**Action Item:** *PQRI Secretary to make arrangements through the AAPS office for use of their conference room for the meeting.* Post meeting note- action item accomplished.

### **OLD BUSINESS**

#### **FDA Representation on PODP Work Group**

The PODP Work Group is asking to add an FDA representative as a liaison to the team. DTC FDA rep has agreed to serve in this capacity, and his addition to the team is endorsed by the DTC. He will join the current DTC liaison and offer regulatory guidance.

#### **NIPTE Excipient Team Member**

DTC Chair has asked for a volunteer to serve on the NIPTE Excipient Team as a liaison from PQRI. To date, no one has volunteered for that position. Some discussion took place about the recent article written by NIPTE that was in the RPM Report which has caused some concern among various PQRI members. The article will be addressed at the upcoming Steering Committee meeting.

**Action Item:** *PQRI Secretary to send article to DTC Chair for his perusal and distribution.* Post meeting note- action item accomplished.

### **WORK GROUP REPORTS**

**PODP** – has an upcoming face to face meeting in November. Work is progressing.

**C/C** – getting ready to do three things: future work plan; interim report for publicity purposes on work results; and collaboration with ASTM for a test method

**SSL**- two day face to face recently occurred. WG is preparing a White Paper outline for review by mid November. They will also include their status report and projections for the next couple of years of work to be done by the work group. They have finalized an adhoc method which looks promising for establishing shelf life. They have come up with a working definition of “shelf life.” They have/or will have presented several abstracts/posters by the end of the year- Joint Statistical meeting, IPAC-RS conference, and at the AAPS Annual Meeting. WG was reminded that the next payment to UN-L is tied to the presentation they were to do at the Joint Statistical meeting, and subsequent presentation to the DTC and Steering Committee.

**Sulfonate Esters** – currently has two papers in the review process.

**QbD for CPPs and CQAs** – WG Chair has been unavailable for several months so work has slowed, but they are ready to pick back up the work and get back on track. They have not yet presented their work to the Biopharmaceutical Technical Committee. DTC Chair will maintain contact with them and assist with keeping them moving forward.

There being no further business, the meeting was adjourned at 3:35 pm. The next teleconference is scheduled for Thursday, November 20, 2008.