

PQRI Steering Committee Meeting

Pharmaceutical Research and Manufacturers of America (PhRMA)

950 F Street, NW - Suite 300
Washington, DC 20004

Thursday – September 28, 2006
9:30 a.m. – 4:30 p.m.

MINUTES

Meeting convened at 9:40 a.m., SC Chair, presiding. A quorum was reached during this meeting, with six (6) of ten (10) SC member organizations represented.

Review and Approval of the Agenda

The agenda was reviewed, times adjusted and agreed upon.

Approval of Minutes

It was agreed that the September 8, 2006 full and summary minutes will be approved electronically.

Action Items from SC Meeting of September 8, 2006

- All action items have been completed.

Discussion on Status of Projects

- **BCS Class III Drugs**
 - After discussion, it was agreed that –
 - The general impact to industry will be a higher number of compounds, which would have a substantial impact.
 - While the project is exploratory in nature, the data sought in this project is important to industry and the BTC should move forward.
- **Sulfonate Esters**
 - The WG was formed in August with AAPS, PhRMA and IPAC-RS being represented. The work plan has been drafted and four (4) steps are anticipated in completing the proposed work.
 - Partial funding from PQRI will be requested, however, outside resources will also be sought.
 - A teleconference will be scheduled to discuss the final financial needs for the WG.
 - The project is on schedule.
 - The DSTC has reviewed the proposal and they are encouraged with this project.

The FDA representative will clarify what the Agency's current position is on this work.

➤ **Specification Life Cycle**

- The MTC has selected its volunteer participants and are awaiting the final candidate selection from the DPTC.
 - A DPTC liaison has been appointed to the WG and will assist with the DPTC candidate selection.

The CHPA representative volunteered to drive the relationship between the MTC and DPTC, coordinating with the DPTC.

The FDA representative will secure Agency views/comments relating to this project.

➤ **Excipients Working Group**

- Registration has been slow
- Last minute promotions are –
 - PDA will prepare a broad distribution message to its members.
 - FDA/CDER has noted the announcement in its CDER News, which reaches about 20,000 people.
- The final survey results will be distributed in the workshop binder.
- It was also noted that the WG findings were published in the September PharmTech magazine.

➤ **Quality by Design**

- The Chair reported to the SC. Comments included –
 - There are currently six WG members.
 - The WG began meeting in early September
- It was agreed that the data will stimulate debate, but the SC questioned what it is that we are actually looking at -
 - A potential model may provide something for industry to look at for QbD for drug release.
 - This work could codify what is currently out for general industry needs.
 - Industry could be guided by the debate, which will make clear/more obvious where the next steps could be.
- The WG has started with solid dosage forms because they were the easiest; however, this work may be the guide for other dosage forms in the future.
 - This work could also create a framework as to how to identify the attributes.
- It was agreed that if it is, in fact, anticipated that the QbD WG will have a deliverable by the end of the year, the ECAS Chair investigate different venues for publication and gathering of information (for instance at the AAPS annual meeting, or other industry workshops in which the information could be shared and/or disseminated.)

AAPS Proposal for a Pilot Study

The AAPS member representative introduced the topic of “*Pilot Study to Evaluate the Variation of Bioanalytical Ligand Binding Assays Used to Support Pharmacokinetic, Pharmacodynamic and Toxicologic Assessments of Biotherapeutics.*” The following details relating to this proposal were discussed –

- There is currently an AAPS WG in place to study this area of interest.
 - Two teleconferences have been held to date.
 - All participants will receive the compiled data for their respective analysis to study the variability issue.
- A pilot study on this topic will be presented at the AAPS annual meeting in 2007.
 - The pilot study would be a very small “look” at the topic to determine the actual size of the study that would be done.
- This document is being brought to the SC in the hope that PQRI would like to work jointly to present the outcomes at that time.
- The anticipated endpoint would be a guidance to establish actual validation methods.
- The AAPS member representative will be the SC liaison to the WG and will give updates to the SC.
- Moving forward this would result in a separate proposal to PQRI to perform additional work.

It was agreed that PQRI would co-sponsor this proposal as written and will designate the AAPS member representative as liaison between the Steering Committee and the AAPS WG. The AAPS representative will regularly update the SC with the status/progress of the work.

Drug Product Technical Committee

➤ Leachables/Extractables Working Group

- The L/E recommendation will be delivered to the Agency at the close of this meeting.

The FDA member representative will discuss the process with the OPS Director and report findings to the SC.

- The recommendation is the result of approximately five years of effort by the WG.
- The individual members have been recognized by a certificate and letter from the SC.
 - An article will also be placed in the PQRI newsletter, including mention of in-kind contributions, which will also receive a certificate and letter from the SC.
 - All SC member organizations were requested to highlight the work of this group in their respective publications and send letters in congratulations/appreciation.
 - Contact information for the WG Chair is to be provided to the SC member organizations for press releases.
- The recommendation should now be made public and added to the PQRI web site.

- A flyer is to be prepared and distributed at the AAPS annual meeting regarding the accomplishments of PQRI over the years.
 - Flyers should also solicit volunteers for committee work.
 - ECAS Chair will assist with distribution of flyer from the press office and non-profit table.

- **L/E Training Course**
 - This training was very successful.
 - Book publication
 - Contract with publisher is still under consideration by attorneys.
 - The book publication would be considered as a separate project and not part of the original work plan.
 - Technical papers are also being drafted, targeting toxicologist publications and other scientific journals.

- **Profile Comparisons Working Group**
 - There is an interim and final report that the WG is working to complete.
 - The interim report is in the editing cycle and will be published in the AAPS PharmSci Tech magazine.
 - The final report is anticipated by the end of the year and will also be published in the PharmSci Tech publication.

- **Mass Balance Working Group**
 - The final recommendation has been sent to the SC Chair and is ready for submission to the Agency.
 - The only additional deliverable is the final paper, which was delivered yesterday to the Journal of Aerosol Medicine.
 - This WG will now be sunset.
 - A letter of appreciation will be sent from the SC, along with a certificate.

PQRI Executive Secretary will draft a cover letter for submission of the recommendation to the Agency.

- **Stability Working Group**
 - There are currently five core members on this WG.
 - There has been a great deal of interest from industry and the first challenge to be faced is to finish populating the WG, as there are many excellent candidates coming forward.

- **Terms of Leadership Service**
 - The DPTC Chair requested discussion relative to the succession of committee leadership.

- **IPAC-RS Request for Posting of November Workshop on PQRI Web Site**
 - A request has come from the IPAC-RS Secretariat that the Institute post information relative to their upcoming workshop on the PQRI web site.
 - It was agreed to allow posting of this meeting on the web site.

Posting of a link to the IPAC-RS web site on this matter to take place at the earliest opportunity.

Biopharmaceutics Technical Committee

➤ Sequential Design

- A paper has been drafted and will be forwarded to the PhRMA statisticians within a week.
- It was reported that this undertaking will save industry significant amounts of money.

➤ Quality by Design – BIO Segment

- The BTC Chair is attempting to schedule a meeting in the near future.

National Institute for Pharmaceutical Technology and Education (NIPTE)

- A NIPTE representative will be invited to participate in the next face-to-face SC meeting.
- The PDA member representative will invite a representative from NIPTE for the December SC meeting.

Sample PDA Ballots

- After discussion of the sample ballots, it was agreed that all future requests for approvals/voting would be accompanied by a cover sheet noting the information provided on the PDA sample ballots.

Informational Items

➤ August PQRI Financials

- Modifications, as requested by SC member representatives were completed.

➤ PQRI Annual Audit

- The Institute again received a clean audit.
- The audit report provides valuable information about the Institute moving forward.
- The audit firm will provide a summary of the new Pension Reform Act.

PQRI Executive Secretary to provide a copy of the audit to PDA.

➤ PR for PQRI

- The Board Chair requested additional visibility for PQRI and what it has accomplished.
 - A year end report to the PQRI volunteers should be made stating accomplishments and how we are looking forward to 2007.
 - Letter will be sent from the Board on this subject.

ECAS will take the lead with the year-end listing of accomplishments.

- The December SC in-person meeting will be a year-end review meeting.

➤ **Annual Report**

- The PDA member representative suggested the PQRI prepare an annual report such as corporations provide to shareholders.
 - This would give volunteers something to take back to their companies and would also be placed on the PQRI web site.
 - This would include outcomes of things that have been done in the past.

PDA will provide a template of the PDA annual report.

➤ **Project Tracking Forms**

- PDA requested the reinstatement of the tracking forms.
- SC to revisit this request at its December meeting.

There being no further business of the SC, the meeting adjourned at 3:00 p.m.