

PQRI Steering Committee Meeting

Friday, March 9, 2007

9:30 a.m. – 4:30 p.m.

Consumer Healthcare Products Association

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SUMMARY MINUTES as amended

Opening

- * The meeting convened at 9:35 am, with Gordon Hansen, Chair presiding. A quorum was reached with 7 of 9 Steering Committee member organizations represented.
- * The SC Chair read the admonition statement relative to anti-trust issues.
- * The agenda was reviewed and agreed upon, with one addition by John Lisack to discuss limitations on FDA resources and potential impact on participation in PQRI.
- * Both the Full Minutes and Summary Minutes were approved as presented.
- * The goal of this meeting is 2007 planning.

Action Items from the December 13, 2006 meeting

FDA Member Representative-

A FDA rep is still needed for the Sulfonate Esters WG and a FDA Compliance rep for the Spec Design WG

PhRMA Member Representative-

All action items were handled.

PQRI Leadership-

All action items were handled.

ECAS Chair-

ECAS was to conduct a telecon to discuss producing a workshop on QbD. It is not believed that telecon has taken place. (Following the SC meeting, it was advised that a 'focused' workshop is being discussed on the topic of QbD for Drug Release, using the work completed thus far by the PQRI QbD CQA team. Discussion will follow at the next SC meeting.)

SC Member Representatives-

Action item accomplished.

PQRI Executive Secretary-

All action items were handled.

Report from PQRI Board of Directors-

Chair of the Board of Directors reported the following:

- hiring of PQRI Executive Secretary
- contract with Absorption Systems was signed off on Feb. 6, 2007 for the WG BCS III
- contract with John Wiley & Sons signed re L&E book;
- increase awareness of PQRI's Accomplishments through the Excipient workshop; Gold Sheet approval to distribute 150 copies of the pdf version, and purchased 50 hard copies; let PQRI know if you would like some of the materials to use for promotional purposes
- DSTC request for PQRI contribution on sulfonate esters project
- as a part of PQRI outreach, it was arranged for Bob Lipper and Gordon Hansen to present at the PhRMA Leadership Technology Meeting in April 2007
- Academic Travel Reimbursement Guidelines need to be reviewed and perhaps amended to reflect current costs; Board will review and make adjustments as necessary to make sure policy is reasonable; Guidelines will be posted on the website for member use
- discussed the policy of who among the Board should be the person to sign all contracts; decided that the Chair is the appropriate signator
- PQRI Accomplishments document that was created by ECAS for use at AAPS Annual meeting should be sent to all member organizations as PR tool;
- Discussed creation of brochure type document for future PR use;
- Discussed the financial impact of loss of one member organization in 2006; Board doesn't see a significant financial impact on PQRI,
- but GPhA has been requested to pay their dues for FY07 that they were in arrears for prior to their resignation from PQRI

Report from Adhoc Working Group

* Two proposals were presented.

* First proposal, recommendation from the working group re the reorganization of the technical committee structure; combine the DPTC and the DSTC into one TC - Development Technical Committee; unanimous approval by the SC on the agreement to restructure and the acceptance of the recommendation; copy of slide presentation attached to minutes; discussion about how to transition to the new model of TCs,

* Second proposal, recommendation presented to use workshops- both focused and general- to explore ideas/topics that PQRI should focus on and perhaps explore further; an example, the slide presentation of The New Frontier, which is attached to these minutes highlighting the topic of chemometrics

Key Points of Discussion to the second proposal:

- 1) 'focused' workshops would involve a relatively small number of "thought leaders" on a given topic area who would explore the need for further study and the direction of that study for consideration by PQRI;
- 2) 'general' workshops would be those similar to what PQRI has done in the past which are used mainly as a public education forum to disseminate information;
- 3) discussion concerning the need for flexibility to allow the process to be fluid so that if a topic does not apparently fall under one of the TCs area of expertise, then an Adhoc WG could be established;
- 4) the normal role of a TC is that of technical oversight of a project; the role of an Adhoc WG would be a compressed group that would be able to handle both the TC and WG functions; a SC rep would need to be on the Adhoc WG for accountability and procedural guidance

The second proposal dealing with the workshop concept, was accepted and approved as presented; criteria for setting up this formal organizational structure for PQRI and the justification behind it, as well as the avenue for soliciting new ideas/projects for consideration by PQRI will be developed and submitted for SC consideration at the April 4 SC meeting. Following the SC discussions on 4 April, an explanation of the restructuring should be provided to current DPTC and DSTC members. The process for populating the new TC will also be addressed. The SC is hoping to have a couple of topics/ideas to address through the workshop model by May 2007. The initial topics addressed using the workshop model will allow the SC to assess the model's flexibility and efficiency.

The overall goal of this restructuring should allow PQRI to reshape its work to help it become more of a robust pipeline from industry to regulatory agencies.

SC Discussion and Review of 2007 Project Portfolio

New Projects/Issues for Consideration

- discussed limited FDA/CDER resources and potential impact on FDA participation in PQRI activities; SC will monitor the situation and work to ensure the continued participation of FDA members in PQRI functions
- PDA highlighted a proposal on leachables and extractables
- USP representative reiterated proposal for consideration on the topic of Chemometrics; he will refine his proposal and narrow the scope of same and have it available for consideration by the May 31 SC meeting;
- Representative from the Inhalation Technology Focus Group within AAPS proposed PQRI consider a workshop on Guidance for BA/BE for Nasal Sprays and Inhalation Products. There is a link here with the Profile Comparison WG. SC asked ITFG rep for further clarification on whether they believe a 'focused' workshop or a 'general' workshop would be more in order at this stage and what the expectations of ITFG are for this workshop.

Current Projects

DPTC – Tracking form was completed

- **Profile Comparison WG:** report forthcoming to SC for submission to FDA
- **Container/Closure WG:** making headway
- **Excipients WG:** draft guidance in the works; meeting set with FDA to discuss topic; WG asked to come up with expectations from meeting
- **L & E WG:** upcoming training course in April 2007 and Sept. 2007; book contract signed
- **Specifications Design WG:** need FDA compliance person on WG;
- **Stability Shelf Life WG:** held two day face to face in Feb.; would welcome FDA rep on their WG;
- **Mass Balance WG:** waiting for FDA response

MTC – Tracking form was completed

- **Process Robustness WG:** paper on PQRI website, PharmEng put article on their website;
- **Post Approval Changes WG:** received comments on first draft, should have it ready for SC April 2007
- **Risk Management- Case Studies WG:** compiling case studies; need more case studies for consideration
- **Bio Inspections WG:** paper submitted to PDA for publication
- **Bio Indicators WG:** set meeting to discuss what is needed to proceed
- **Specifications Design WG:** group is getting started; FDA member needed;

DSTC – Tracking form was completed

- **Sulfonate Esters WG:** need status of contract and FDA rep for WG

BTC – Tracking form was completed

- found co-chair for the BTC; looking for additional people to populate the BTC
- **BCS III WG:** contract signed with Absorption Systems and work has begun

QbD WG

- met a couple of times
- studying CQAs and CPPs
- two case studies

Old Business

Only post redacted minutes onto the public domain on the PQRI website. Note that PQRI is exploring a 'back door' to the website for member only access, via one password, so that members and member organizations can have access to detailed full minutes, committee members, publications, etc.

New Business

Upcoming SC Meeting – Schedule

April 4, 2007 Teleconference at 1:00 pm

May 31, 2007 Face to Face at 9:30 am – 4:30 pm

hosted by DBR, 1301 K Street, NW

Dec. 6, 2007 Face to Face at 9:30 am – 4:30 pm
hosted by TBD

Informational Items

Referred members to the financial statements as presented in the binder for February 2007; statements accepted as presented.

The meeting adjourned at 2:40 pm.