

PQRI Steering Committee Meeting

Teleconference

Monday – June 26, 2006

2:00 – 3:00 p.m.

MINUTES

Meeting convened at 2:05 p.m., Gordon Hansen, SC Chair, presiding. A quorum was reached during this meeting, with seven (7) of ten (10) SC member organizations represented.

Purpose of the Meeting

The purpose of this teleconference is to evaluate whether we are on the right track with the new and on-going projects.

Review and Approval of the Agenda

The agenda was presented and agreed upon.

Approval of Minutes

A motion was made, seconded and approved to accept the May 12, 2006 full and summary minutes as presented.

Quality by Design (QbD)

- Members for the two teams (BTC and CQA) have received CVs of interest for participation on the Working Group.
- A teleconference has been scheduled for July 5, 2006 to select the WG members.
- The project is moving along as planned.

Sulfonate Esters

- This group is in the process of collecting CVs for the Working Group.
- The decision on populating the WG will be made in mid-July.
- A key deliverable for this project (3rd quarter of 2006) is to secure funding to complete this work.
- The SC agreed that once the WG determines a final amount to perform this project, the total will be taken to the Board to consider the extent to which PQRI would fund.

BCS

- The PQRI Board of Directors has committed partial funding for this project.
- Additional in-kind services from the partnering company will be needed to complete the project.
- This proposal will be shared with the OTC within the next two weeks.

Sequential Design

- The WG is currently completing the final paper and it is anticipated that it will be completed by July 18, 2006.

Manufacturing Technical Committee (MTC)

- **Specification Design**
 - All comments have been returned and are now being incorporated into the document.
 - The WG is starting to solicit and review CVs to populate the Working Group.
- **Post Approval Changes Working Group**
 - This WG will be finalizing their position paper by the end of the summer.
 - This position paper will not be discussing firing systems as FDA is reviewing its procedures on this issue for low/high risk.
- **Process Robustness**
 - Some comments were received and have been considered.
- **Risk Management**
 - This WG has several meetings and is currently collecting risk assessment statistics from industry.
- **Bio Inspections**
 - This WG did not receive the anticipated level of responses.
 - The WG will be analyzing data.
- **Specification Design**
 - A time line will be established on this project.
 - A model for dosage forms should be completed by early 2007.

Action Items

- All action items from the May 12th meeting were reviewed
- A thank you letters to WG members who have completed their work was approved and is now ready for certificates and letters to go to all volunteers.

Informational Items

- PQRI financial reports through May 31, 2006 were supplied to the SC member organizations.
- SC member operating funds are being received.

There being no further business of the SC, the meeting adjourned at 2:45 p.m.