Minutes

Steering Committee
Friday - June 27, 2003
12:00 p.m. - 4:00 p.m.

Parenteral Drug Association (PDA)
3 Bethesda Metro Center - Suite 1500
Bethesda, MD

Attendees: * denotes acting Chair

Academia/Industry Representatives:
Steve Bende - GPhA
Bruce Bird - PhRMA (by telephone)
Don Burstyn - BIO
Mary Devlin Capizzi - IPAC-RS
Paul Fackler - GPhA
Edmund Fry - PDA
Sylvia Gantt - PQRI
Gordon Hansen - IPAC-RS (by telephone)
Gordon Johnston - GPhA
Ashok Katdare - IPEC Americas
* Tobias Massa - PhRMA
James Polli - AAPS
Richard Poska (for Sid Goldstein) - PhRMA
Fred Razzaghi - CHPA
Frederick Sexton - ISPE (by telephone)
William Stoedter - PDA
Patricia Tway - PhRMA
Gillian Woollett - BIO

FDA Representatives:
Jon Clark
Joseph Famulare (by telephone)
Helen Winkle

Meeting convened at 12:14 p.m., Dr. Tobias Massa, Chair, presiding. A quorum was reached during the meeting with ten of eleven SC member organizations in attendance.
Introductions
Mr. Gordon Johnston, VP of Regulatory Affairs (GPhA) and Dr. Paul Fackler, new Biopharmaceutics Technical Committee Co-Chair (GPhA) were introduced.

Approval of Minutes
A motion was made, seconded and passed, with two abstentions, to approve the minutes of the May 15, 2003 Steering Committee meeting with one spelling correction.

Education, Assessment and Communication Sub-committee (ECAS)
Mr. William Stoedter, Chair, reporting.

- **GMP Workshop**
  Dr. Massa thanked FDA for sharing sponsorship of the Workshop with PQRI, in order to generate revenue for the Institute. Additional Workshops have been proposed for the future.

- **PQRI Workshop**
  - **Speakers**
    - Dr. Steve Galson, Deputy Director, CDER, has confirmed that he will speak in place of Dr. Woodcock.
    - Dr. David Horowitz's office is in the process of finding a replacement for him.
    - Mr. Clark has agreed to follow up with Dr. McClellan's office to confirm his speaking.
  - **Program**
    It is anticipated that the program will remain as previously planned for the April Workshop, but updates to presentations, etc., will need to be made.
  - **Budget**
    No revisions appear to be necessary for the August Workshop.

- **Logistics**
  AAPS has agreed to perform the services (registration, logistics, etc.) for this Workshop. Mrs. Pichon (AAPS) has agreed to draft a proposal describing services and fees.

- **Blend Uniformity Workshop**
  - The BUWG’s proposed program has been submitted to the DPTC, but final approval has not been determined. DPTC to review, vote electronically and notify the SC of its agreement/approval with the program.
  - Program will include the economic assessment for industry done by FDA on the BUA recommendation. Ms. Winkle will supply a draft and executive summary of the outcome of this study to the SC for reporting at the Workshop. The results are very positive, in that it revealed that $140-150 million dollars could be saved by industry. These savings would be realized mainly on the generic side, but some also on the innovative side.
- It is anticipated that the draft guidance will be released by the end of summer 2003. A September/October time frame is expected for scheduling the workshop.
- Proposed dates are in the September 22nd to 23rd time frame.
- Discussion took place relative to whether a tradeshow should be considered for this Workshop. It was agreed that there is not sufficient time to contact companies to exhibit. It should, however, be considered for future workshops. Sample contracts to be obtained from PDA and AAPS.
- PDA has offered to handle the logistics for this meeting. A proposal for services and fees will be drafted and supplied for review by ECAS and the SC.
- Mr. Stoedter will prepare a budget for this Workshop and submit to the SC for review/approval.

**Biopharmaceutics Technical Committee (BTC)**

The SC has approved, by electronic vote on June 16, 2003, the appointment of Dr. Paul Fackler of TEVA (GPhA) as Co-Chair sharing responsibilities with Dr. Andrew Dahlem of Eli Lilly (PhRMA). Dilip Sanvordeker, currently serving on the WG, has been approved as GPhA's representative on the BTC.

- **Immediate Release Oral Drug Products Working Group**
  - Dr. Polli is retiring as Chair of this WG. Bruce Aungst has been suggested as his replacement. Aungst's CV will be reviewed/approved by the BTC, then submitted to the SC for informational purposes.
  - The WG has not met recently and does not seem to be coming to any closure on its project. A determination must be made as to whether to move ahead on its work.
  - Two new dissolution projects recently added to the tracking form, but on hold, seem to have more relevance than the current dissolution project underway. More information, however, needs to be developed by the BTC and then brought to the SC for consideration prior to moving forward with anything new. If it is determined that work should be done, WGs can be created.

- **Inhalation and Nasal Drug Products Working Group**
  While this WG is not currently active, exploration of additional BA/BE projects was discussed. It was determined that before formally establishing and activating the WG, more discussion and work must be done on a work plan before submission to the SC.

Dr. Fackler agreed to update the tracking form to include project management milestones.

**Drug Product Technical Committee (DPTC)**

Dr. Richard Poska of Abbott Laboratories (PhRMA) reporting for DPTC.
• **Blend Uniformity Working Group**  
  Workshop - previously discussed under ECAS.

• **New Technologies Subcommittee**
  • This committee has been in existence for quite some time, but has never officially been activated. There appears to be an overlap with the PAT group.
  • It was agreed that this committee should be sunset at this time.

There was a general discussion relevant to how the DPTC and Manufacturing Technical Committee (MTC) are similar/different and how projects will be defined and assigned. It had been thought that projects would be assigned from the FDA/OPS Advisory Committee to the MTC, but project assignments will be assigned on a case-by-case basis to any of the appropriate technical committees. It is anticipated that this topic will be addressed at the August Workshop.

After additional discussion, it was the consensus of the SC that the New Technology-type issues would more appropriately be addressed under the MTC.

• **Container/Closure Working Group**
  • While this project is on going (originally approved in November 2002), there was nothing new to report at this time. An update is expected at the July SC meeting along with milestone dates established on the tracking form.

• **PSD Mass Balance Working Group**
  • While, the article on Good Cascade Impactor Practice will be published in late summer/early fall in the Journal of Aerosol Medicine, it was questioned whether the WG was pursuing any other avenues of publication (e.g., through FDA/USP), in addition to other scientific publications.
  • Data mining continues and deliverables need to be determined.
  • The WG is working on protocols that significantly overlap work between this WG’s project and the Profile Comparisons Working Group.
  • The SC questioned whether once the publication of the work is submitted, if this group would be disbanded. After publication, the WG will continue to work through the remainder of the work plan.

• **PSD Profile Comparisons Working Group**
  • The project is on going and on schedule.
Leachables/Extractables Working Group
  - By electronic vote of the SC on June 4, 2003, it was approved that Mr. Norwood, Chair of the WG, could present at the RDD conference.

The Steering Committee recognized the importance of in-kind contributions to PQRI by member organizations such as IPAC-RS. Organizations providing contributions in-kind were encouraged to assess the appropriate value of such contributions in order to be recognized appropriately by PQRI.

Drug Substance Technical Committee (DSTC)
Dr. Pat Tway, Chair, reporting.

Impurities Working Group
  - The survey results have been compiled and reflect that industry chooses to do more work in the early stages of their research, even though it is not required. Full results will be presented at the August workshop
  - The HPLC columns equivalency
    - The general consensus was that the PQRI perspective was the best overall of the approaches offered, however, it is believed that it is an issue of system suitability.
    - A subgroup of the PQRI WG will work with USP in the hope of combining and implementing a single approach. Once a final approach is determined, it will be brought to the SC.
    - It was questioned as to how it was possible, if USP is a member of the WG, that they have a different approach than the PQRI WG.

Chung Chow Chan of Eli Lilly has been suggested as Chair for the WG, replacing John Carrano upon his retirement. His name will be submitted to the DSTC for review/approval, then submitted to the SC for informational purposes.

Particle Size Working Group
- The AAPS Particle Size Workshop of May was discussed. It was noted that the issues that were highlighted at that meeting were the same issues that the WG has been attempting to address.
- The issue of the DSTC Chair not being able to determine the current status of the WG was discussed. In spite of numerous attempts to contact the WG Chair, she has been unsuccessful. The SC instructed the DSTC Chair that if she cannot make contact, that the WG should be disbanded.
• Mr. Hansen also agreed to try to reach the WG Chair to address this matter.

• **Specifications (BACPAC) Working Group**
  • This WG has been very active. They are still attempting to bring the PhRMA, GPhA and PQRI WG draft documents into agreement, or reach some type of compromise.
  • A decision tree was sent electronically to the DSTC and the SC for review and comment. Approval is pending in July 2003.
  • Formal requirements will be drafted at the August Workshop because there will not be sufficient time to secure prior SC approval.
  • It was reported that a PDA group is also working with FDA. The outcome is not known at this time.

**Manufacturing Technical Committee (MTC)**
Mr. Bruce Bird, Chair, reporting.
• The MTC held its first meeting in New Jersey on June 19, 2003, at which time it drafted a mission statement, discussed the work of the Aseptic Processing WG, the presentation to be made at the upcoming August Workshop, along with possible projects under the MTC.
• The TC will solicit possible projects from the attendees of the Workshop.
• The two projects proposed previously for the APWG were discussed
  o Biological Indicators - a proposal may be prepared and submitted.
  o Adjunct Processing - more definitive information is required. No proposal is to be prepared until the SC has an opportunity to review the additional information.

More discussion is to take place prior to drafting work plans for the proposed projects.

• **Aseptic Processing Working Group (APWG)**
  • The survey results are still being compiled. It is anticipated that they will be submitted to the SC at its July meeting.
  • The FDA continues to meet and discuss the PQRI recommendation. FDA would like to move as quickly as possible with the publication of its recommendation in order that it can adhere to the schedule originally set.

**FDA Manufacturing Technical Subcommittee**
Ms. Winkle reported -
• The Subcommittee met for the first time on May 21, 2003.
• The purpose of the meeting was to discuss areas that the Subcommittee may be covering. Those areas could include PAT, some GMP, as well as Aseptic Processing.
A question arose as to industry representation on the Subcommittee. It was explained that guests from industry could participate and may even be sitting at the table; however, it will be in a non-voting capacity.

FDA will supply areas of expertise that are needed on the Subcommittee.

Members of industry could be represented on the Manufacturing Technical Committee.

The next meeting will be in mid-September.

**Old Business**

**Protocol Governing Data Collection, Access and Use**

- It was agreed that the raw and compiled data would be held indefinitely in the PQRI files.
- Ms. Capizzi will revise the Protocol procedure to reflect that decision.

**Fundraising**

- As a result of Dr. Massa’s solicitation letter, contributions have been received from Abbott Laboratories and Proctor and Gamble. The documentation included with the checks indicated that the funds would be restricted for work on GMPs.
- Two additional checks are expected from Pfizer and F. Hoffmann-La Roche.
- Dr. Massa will follow up on other letters that he sent soliciting funds for PQRI, along with a separate letter to Mr. Sexton’s new company.
- Ms. Gantt will send a listing to the SC of all companies to which the Massa/PhRMA solicitation letter was sent.
- Operating Funds for PQRI –
  - Due to the lack of funding that has been received by the Institute for research and/or administrative costs, a proposal was put forth to the SC member organization representatives. Member representatives were requested to query their companies/organizations to ask whether they would be willing to fund PQRI administrative costs.
  - It was proposed that the annual operating costs of the Institute would be divided evenly among the SC members, excluding FDA and AAPS. (As a government agency, FDA cannot contribute funds and AAPS funded much of the start-up costs of the Institute.) Further discussion will take place on this matter at future SC meetings.
  - An electronic ballot will be sent to SC members for return to the PQRI office by July 16th. Upon determination, the SC will make a recommendation to the Board.
  - A statement of financial standing will be supplied to the SC at each meeting.
New Business

• For-Profit Entity Participation in PQRI
  It was agreed that the policy of no participation of for-profit organizations within PQRI would stand. It was further noted that allowing such companies to participate could jeopardize PQRI’s non-profit status.

• Pharm Tech Supplement on Solid Dosage Forms
  It was noted that the DPTC and BUWG Chair were interested in submitting article(s) for the supplement. It is anticipated and hoped that this may be one of many opportunities to contribute to this publication.

• Adding New Members to Working Groups
  - When a new SC member organization is added, they will be permitted to add members to any WGs on which they believe that they have expertise.
  - BIO will submit names of candidates to Ms. Gantt for distribution to the appropriate WGs.

• PQRI Newsletter
  - Receipt of article contributions for the current newsletters have been few.
  - Technical Committee Chairs will be reminded that articles from their respective TCs are expected.
  - Suggestions for future articles were –
    - PQRI Workshop Wrap up.
    - Draft report on blend uniformity and the economic assessments done by FDA.
    - Draft report on aseptic processing.
    - Listing of PQRI Contributors.

• Future PQRI Workshops
  - Questions for planning future workshops were discussed –
    - Should they be annual meetings?
    - Should we alternate years between internal participant meetings and allowing public participation?
    - When are project milestones being met, so that we can promote announcements of project results?
    - Specific workshops to be held on individuals projects (e.g., blend uniformity)?
    - PQRI should show more of the science we are achieving in our research projects.
    - If more in-depth scientific reporting is done, then it may be necessary to limit public attendance.
    - Should a registration fee be charged? (This item is to be added to the September SC meeting agenda.)
• Prepare an evaluation form to discuss different formats, content and other specific questions regarding future meetings.

• **New SC Chair**
  - During the nomination period, two nominations were received for the position of SC Chair - Gordon Hansen and Ed Fry - that were put forward to the SC for vote.
  - Currently there is no formal procedure in place for election of the Chair, but the process will be made a part of the revised policies and procedures. Clarifications might include -
    - Whether the SC Chair should always be a member of the Board of Directors.
    - Should the SC Chair have a vote?
    - Should the current Chair and immediate past Chair be the two SC representatives to the Board?

  After discussion, a motion was made, seconded and passed to make a recommendation to the Board of Directors that the two SC representatives to the Board of Directors be the current and past Chair of the SC.

  - Electronic voting for the SC Chair position will take place, with a July 7, 2003 deadline for voting.

• **SC Meetings for 2004**
  Schedule of meetings for 2004 will be added to the July agenda to make a determination of whether the meetings should be held -
  - Monthly
  - Bi-monthly
  - Quarterly

• **TC and WG Member Participants**
  - It has been reported that a number of TC and WGs are having difficulty in keeping some members active. After discussion it was agreed that if members are absent three (3) meetings in a row, the Chairs might replace them.
  - Letters may be sent to those individuals who have not been active and/or participating, notifying them that they will be replaced.
  - Ms. Gantt to verify whether there is already a policy in place in the draft policies and procedures manual.

**Next Meeting**
The next scheduled meeting is Thursday, July 24, 2003 at CHPA (1150 Connecticut Avenue, NW, Washington, DC 20036).
There being no further business of the SC, the meeting adjourned at 3:50 p.m.