MINUTES

PQRI Board of Directors Meeting

November 1, 2001
9:00 p.m. – 2:00 p.m.

CHPA
1150 Connecticut Avenue, NW
Washington, DC

* Denotes chair

Participants:
William W. Bradley – CHPA
Jack Cox – AAPS
Edmund Fry - PDA
Sylvia Gantt - PQRI
* Kenneth R. Heimlich – AAPS
Robert Lipper – AAPS
Jerome Skelly - AAPS

The meeting convened at 9:15 a.m., Dr. Kenneth Heimlich, Chair, presiding.

Welcome and Opening Remarks
Dr. Robert Lipper, newly appointed Board member for AAPS was welcomed. He fills the vacancy created with the retirement of Dr. Gilbert Banker.

Approval of Minutes
A motion was made, seconded and passed that the minutes of the conference call of June 5, 2001 be approved as edited.

Treasurer’s Report
Mr. Bradley reported on the financial status of the Institute. At the present time there is a contract under way for data analysis for the Blend Uniformity Working Group. The information will be used to validate the computer-simulated information regarding stratified sampling at a cost of up to $15,000. Approximately $7,000 has been expended for this work to date.

The issue of contributions to PQRI was discussed. There have been only four companies that have stepped forward to contribute, over and above the one-time assessments from the Steering Committee members. One of those contributions, $50,000 from Eli Lilly, was originally earmarked for process mapping. Further clarification of the specific use of these funds is needed.
The FY02 numbers (July through September 2001) were discussed, along with the FY02 budget and the need for increased funding needs. Mr. Bradley reported that approximately $156,000 per year is required to keep the Institute operating, exclusive of any research funding. The meeting among Dr. Heimlich, Dr. Massa and Mr. Cox of June 20th relative to PQRI expenses was discussed.

Details regarding the incorporation and operation of PQRI were reiterated, wherein Mr. Cox stated that American Association of Pharmaceutical Scientists (AAPS) had supported PQRI with funding in the Institute’s start-up phases, but due to the requirement that PQRI and AAPS maintain totally separate organizations in every way, it could no longer support the Institute in the manner it had done in the past.

Fund raising possibilities were discussed. One option was the hiring of a professional fundraiser. While the process and hiring of outside fundraisers are expensive, they can be productive. The biggest concern with this option is that Board Members have been approaching companies with which they have a personal relationship and they have not had the anticipated outcome, as yet. If an outside fundraiser is hired, what success can be expected from someone not knowing any of the player organizations?

A second option for fundraising was holding workshops. Due to the success of the previous year’s workshop on blend uniformity, it was felt that this was a viable opportunity. Delete There Concern was expressed, however, that much of the planning would have to be outsourced, due to PQRI staffing limitations.

Other options included the use of CRADAs for the funding of upcoming projects. The use of funds set aside by FDA for PQRI projects is also an option. The Board requested that the Steering Committee make every effort to use the FDA-allocated funds whenever possible.

A final point of discussion involved the previously Board approved $20,000 allocation for academic reimbursement. Due to the current PQRI financial situation, it was questioned whether this amount should be eliminated. After consideration, it was agreed to retain this line item in the budget, as deleting it could result in the loss of all academic involvement in PQRI projects. The possibility of holding meetings at academic sites was discussed, but no resolution on that issue was reached.

Lengthy discussion relative to the need of securing funding from the pharmaceutical industry took place. It was believed that there is a correlation between the work produced and released to the public and the amount of funding contributed to the Institute; that is, what benefit will the contributor be receiving for its money?

A motion was made, seconded and passed to accept the Treasurer’s report as presented.

**AAPS Update**
Mr. Cox reported that during the presentations given at the recent AAPS annual meeting in Denver, comments relative to PQRI were noted in the speeches of the incumbent President, the President-elect, as well as his own presentation. There was also a featured workshop at the meeting noted under “Hot Buttons” which gave an opportunity for the BUWG to present its findings on the stratified sampling proposal currently under comment on the PQRI website.

It was questioned whether there was any recognition of PQRI contributors on the exhibit floor of the AAPS meeting. To date, no resolution has been reached on how contributors may be formally recognized. Previously, it had been discussed that a special banner would be made with the names of all exhibitors who have contributed, or whether special signage at the individual booth might be an option. Further discussion to take place on this issue.

**Steering Committee (SC) Update**

Mr. Fry reported as the acting Steering Committee Chair during Dr. Massa’s recuperation from surgery.

- International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) has been admitted as PQRI’s newest Steering Committee member. It is managed by a secretariat located in the law firm of Gardner, Carton & Douglas in Washington, DC.

- The Steering Committee voted to abolish the Science Management Technical Committee (SMTC). Some Board members expressed concern that it had been disbanded, especially in light of the fact that every pharmaceutical company has science management issues. It was noted, however, that when projects are identified the SMTC would be reinstituted.

The issue of how projects are approved was discussed. Previously the projects were either assigned directly from the SC or a working group could bring a project to their respective technical committee for approval, then forward to the SC for final approval. However, the most recent projects came directly from a SC member (IPAC-RS), which had three clearly defined projects, fully formed working groups in place and a willingness to fund all administrative expenses of the working groups. A fourth proposed project (Development of Risk Management Approach to Bioequivalence Studies Requirements for Locally Acting Nasal Drugs), however, may not be work that PQRI can promote as there is a definite division between SC members as to the appropriateness of it as an Institute project. It is currently assigned to the Biopharmaceutics Technical Committee (Biopharm TC) for determination as to whether it is a viable project.

This specific proposal was approved by the SC for referral to BTC only for suspensions. This will alleviate the concerns of GPhA that there is no adequate scientific base for beginning a project on solution products. This issue does, however, highlight the need for a formal process for bringing projects to PQRI.
• Other items reported by Mr. Fry included:

  • Parenteral Drug Association (PDA) will be bringing a new proposal on steam quality to the upcoming SC meeting of November 8th. Discussion will take place at that time as to whether it is an appropriate project for PQRI in relation to its mission.

  • The SC has assigned the Education, Communication and Assessment Subcommittee (ECAS) the task of preparing a policy on how PQRI should manage the public dissemination of WG output. The draft policy will be ready for presentation at the January Workshop.

  • The current informal status of WG projects was also provided by Mr. Fry.

  • Mr. Fry gave a presentation relative to PQRI and its status before the CDER/OPS trade association briefing on October 31st.

  • On November 16th, CDER will be making a presentation to the FDA Science Board on on-line analytical technology. This will potentially provide a mechanistic understanding of how the process and formulation changes drug products. In the past, manufacturing was considered an art, now it is considered science and may require a complete rethinking of regulation. This subject is not currently earmarked as a PQRI project, but consideration could be given as a long-term potential project for the Institute, as well as the topic for a PQRI workshop.

    Further discussion will take place with FDA regarding the possibilities of PQRI working in this area with FDA. The Board requested that this subject be added to the November 8th SC agenda for additional discussion.

Old Business

• Fundraising.

  Board Members reported their progress relative to contacting their assigned companies, as well as their outreach success. While calls have been made and letters sent, the fundraising efforts have been relatively unsuccessful. It was agreed, that this will remain an on-going effort for the Board. Dr. Lipper agreed to take responsibility for the companies formerly assigned to Dr. Banker prior to his retirement.

• Additional discussion included:

  • The Institute needs projects that companies within the industry can get behind and will help to gain their financial support.
• It was suggested that TC and WG members approach their respective companies concerning funding of PQRI.

• The January Workshop was offered as a platform to get the message out about PQRI and its need for funds. The subject must be very visible during that meeting.

• In the short-term the Board must determine how to improve the financial status of PQRI.

• In the long-term, the Board needs to think about various avenues for bringing in funds, such as professional fundraising, assessment of SC members, dividing the operational budget among the SC members, funding from FDA and continued searching for the correct individual with whom to talk in each company.

• PQRI must concentrate on projects which will receive broad support across the industry, especially as concerns FDA guidances and regulations.

• The possibility of holding workshops again was suggested. The Board to charge the SC with the assignment of putting together two or three workshops. Some concern was expressed, however, because it often takes six to nine months to prepare for a workshop; that is, advertising, registration, securing speakers, hotels, etc.

New Business

• Academic Reimbursement

Mr. Bradley reviewed with the Board the reimbursement guidelines that are currently being observed within PQRI.

• PQRI Executive Training Workshop

Mr. Fry reported that an e-mail has been distributed to all possible Workshop participants to save the date. PQRI is currently waiting for final approval of the hotel contract by AAPS attorneys, as well as availability of dates for the University of Maryland through FDA. Immediately following final approval of the hotel and meeting site, the Workshop invitations will be mailed to participants.

The program and agenda remain identical to the postponed Workshop that was to take place in September. All speakers are being confirmed.

• Set Board Meeting Schedule for Future Months
Board Members were requested to supply Ms. Gantt with their “black-out” dates for the mid-April to mid-May time frame, along with the September/October time frame in order to keep to a quarterly meeting schedule. Once the dates are determined, then meeting locations will be set.

It was also agreed that the Board would meet January 30th immediately following the Workshop.

- **Action Items**
  
  - Board Members will continue on-going contact with their fundraising assignments.
  - Mr. Fry will discuss with the SC the possibility of PQRI holding workshops (e.g., on-line analytical technology). He will also report that the Board requests a joint meeting with the SC and the Board to specifically discuss fundraising needs.
  - Dr. Heimlich will follow up with PhRMA regarding the outcome of its meeting relating to support of PQRI and its activities.
  - There will be a plea at the Workshop for funding support, as well as an attempt to obtain the names of specific individuals who should be contacted regarding financial support within the companies of those already participating in PQRI working groups and technical committees.
  - Follow up with FDA regarding how to best utilize their available funds and whether the Institute may obtain money through the use of CRADA’s.

There being no further business of the Board, the meeting adjourned at 1:45 p.m.