

## ***Technical Committee Restructuring and Solicitation of Members for New Technical Committee***

The Steering Committee and Technical Committee Chairs have reviewed the past and current activities of each Committee and agree that the Biopharmaceutics and Manufacturing Technical Committees should continue to function in their current form while the Drug Substance and Drug Product Committees should be replaced by one Committee to be known as the Development Technical Committee. The Chairpersons of the Drug Substance Technical Committee and Drug Product Technical Committee, Dr. Pat Tway and Dr. Terry Tougas, respectively, will develop a concise mission statement for the new Technical Committee in consultation with the Steering Committee and current members of their respective Technical Committees.

The Development Technical Committee will focus on research projects that help to more clearly define through technical examples and applications the Quality by Design (QbD) concepts. The Steering Committee is seeking nominations from member organizations to populate this new Development Technical Committee. Committee members must be technically strong, constructive team players, and have a good understanding of QbD and the desired regulatory flexibility from this initiative. All PQRI member organizations are encouraged to nominate individuals with strengths in one or more of the following skill sets/background:

- Drug Substance development, scale up from lab to pilot plant to full scale
- Drug Product development and scale up
- Drug Product formulation, impact of excipients
- Physical properties assessment both for excipients and drug substance
- Specifications/analytical
- Development Regulatory Affairs, including CMC and traditional filing requirements
- PAT and related tools to assist in product and manufacturing understanding

The activities of this new committee will complement those of the existing Manufacturing Technical Committee, as both will focus on applications of QbD but from slightly different perspectives. Coordination of activities of these committees will be critical to maintain consistency and to identify opportunities for collaboration.

Leadership of the new Committee will be determined after the initial members are identified. **Committee nominations will be accepted through Monday, July 23, 2007 and should be submitted to the respective member organization Steering Committee representatives.** The member organization Steering Committee representatives, including contact information, are as follows:

| <b><u>Member Organization</u></b> | <b><u>Representative</u></b> | <b><u>Email</u></b>  |
|-----------------------------------|------------------------------|--|
| AAPS                              | Mario Rocci                  | <a href="mailto:mrocci@prevalere.com">mrocci@prevalere.com</a> |
| BIO                               | Don Burstyn                  | <a href="mailto:dburstyn@altus.com">dburstyn@altus.com</a>     |

|               |                     |  |
|---------------|---------------------|--|
| CHPA          | Fred Razzaghi       | <a href="mailto:frazzaghi@chpa-info.org">frazzaghi@chpa-info.org</a>               |
| FDA           | Helen Winkle        | <a href="mailto:helen.winkle@fda.hhs.gov">helen.winkle@fda.hhs.gov</a>             |
| IPAC-RS       | Mary Devlin Capizzi | <a href="mailto:mary.devlincapizzi@dbr.com">mary.devlincapizzi@dbr.com</a>         |
| IPEC-Americas | Bob Wiens           | <a href="mailto:wiens_robert_e@lilly.com">wiens_robert_e@lilly.com</a>             |
| PDA           | Richard Levy        | <a href="mailto:levy@pda.org">levy@pda.org</a>                                     |
| PhRMA         | Scott Boudreau      | <a href="mailto:scott.boudreau@astrazeneca.com">scott.boudreau@astrazeneca.com</a> |
| USP           | Ron Manning         | <a href="mailto:rgm@usp.org">rgm@usp.org</a>                                       |

### ***PQRI Workshops***

The PQRI Steering Committee has agreed to aggressively pursue and promote focused workshops, a new means to facilitate PQRI discussion of timely regulatory and scientific topics. These workshops will foster the Institute's ability to lead collaborative and timely discussions on emerging product quality regulatory topics. While PQRI has long sponsored conferences (and will continue to do so) as a means to highlight PQRI's work, including recommendations and conclusions of various Working Groups, these new focused workshops will primarily seek to generate information and ideas. The distinctions between workshops and conferences are summarized in the table below.

The PQRI Steering Committee is currently accepting proposals for focused workshops. All member organizations are encouraged to submit proposals for innovative, well-focused workshops on important product quality and regulatory topics. Workshop themes and formats can be diverse and may focus on a new PQRI topic or derive from ongoing PQRI projects. The PQRI Steering Committee will review workshop proposals against the following criteria:

- **Significance:** Does the proposal argue convincingly for the importance of the workshop topic?
- **Relevance:** Is the theme of the workshop appropriate for PQRI? If there exist other workshops on the same theme, what is the novelty introduced by the proposed workshop?
- **Workshop Format:** Is the format clearly described and does it encourage a high level of interaction between the participants?
- **Organizers:** Are there at least two organizers? Do the organizers have the requisite background knowledge and experience?
- **Completeness:** Does the proposal cover all the information specified in the guidelines stated above?

Workshop Submissions should be made as early as possible to allow for effective timing and publicizing of the workshops. Submission of proposals must be in electronic format and submitted to Vicki Penn, PQRI Executive Secretary at [pennv@pqri.org](mailto:pennv@pqri.org) or via the

PQRI web site at [www.pqri.org](http://www.pqri.org). The workshop proposal submission form is located at <http://www.pqri.org/workshops/index.asp> .

*Comparison of PQRI Conferences and Workshops*

| <b>PQRI Workshops</b>   | <b>PQRI Conferences</b>  |
|---|--|
| <ul style="list-style-type: none"><li>• Highlight an emerging regulatory or scientific issue of import to FDA and industry</li><li>• Facilitate generation of information and ideas that will feed into timely recommendations and potential projects</li><li>• Encourage broader PQRI engagement by facilitating member organization submission of proposal of interest to that organization</li><li>• Generally require less time to plan as these events will be smaller, more focused and led by relevant experts</li></ul> | <ul style="list-style-type: none"><li>• Highlight developments and achievements of PQRI Working Groups and projects</li><li>• Organized by Steering Committee, Technical Committee or Working Group</li><li>• Generally require long-term planning</li><li>• Seek to attract large number of attendees</li></ul> |