

PQRI Drug Substance Technical Committee  
Minutes of Meeting, December 6, 2001  
Nicholson Research Center, Kensington, MD

Present:

Ira Berry

John Carrano

John DeFoe

Angelos Dovletoglou

Frank Etzler

Robbe Lyon

John Smith

Kasturi Srinivasachar

Terrence Tougas

Reports of the Working Groups

Specifications and BACPAC WG - Angelos Dovletoglou

It was reported that the WG had two major initiatives:

- 1) to develop a "changes" document to outline all possible changes to manufacturing operations, route of synthesis, packaging and suppliers - and to use this to determine the process for defining the testing and acceptance criteria that should be used to evaluate changes.
- 2) 2) to identify cases of API and/or drug product failures that were attributable to inadequate specifications for the API.

After some discussion of the difficulty of obtaining meaningful data for the second initiative, it was suggested to focus on cases in which failure of a drug product (dosage form) in the market could be attributed to a situation in which the specifications/testing of the API were inadequate. Data on US recalls of drug products over some selected period would serve as the starting point.

Physical Properties / Particle Size - Frank Etzler

It was reported that the WG had conducted a survey of common particle size instrumentation used. A review of literature and available data indicated poor correlation among various types and even within the same type. The WG intends to attempt to define appropriate use criteria for particle sizing instrumentation. Prior to this, they needed additional expertise and had previously proposed a technical symposium for the WG and other interested PQRI groups, but funding was not available. Alternates to that approach for the requisite expertise could be an alliance with other industry group(s), consultants, and/or additional WG members with the appropriate expertise. A name of one industry expert interested in participating was proposed and with the recommendation of the DSTC will be advanced to the PQRI Steering Committee. It was also agreed to investigate whether IFPRI (International Fine Particle Research Institute, a non-profit consortium) might be a suitable alliance candidate.

Impurities - John Carrano

It was reported that the WG had developed a survey questionnaire regarding the instrumentation being used to determine impurity levels both during development and post-approval. This questionnaire is being finalized for the Jan PQRI meeting. There was discussion regarding the need to insure that the survey is directed to the appropriate individuals to obtain the necessary meaningful responses. Since it would be directed to US API manufacturers, and the most meaningful data is expected from innovator companies, it has been proposed to attempt to use the PhRMA bulk committee and work groups to help identify the appropriate individuals within each company.

Discussion of WG Activities

The general discussion of the current activities of the Working Groups both during the presentations and afterwards did not indicate any significant changes were deemed necessary

## Administrative Matters

### Membership

With the exception of the Physical Properties WG as noted above, the WGs felt that they had appropriate membership at this time. In the case of the Impurities WG, there were two members shown on the PQRI roll as members who had never participated. It was agreed that they would be contacted to determine their interest.

### Management of WGs

Since each of the WGs currently had one or more members of the DSTC participating, it was agreed to continue that practice. The WGs would copy in all members of the DSTC on minutes of the WG meetings. At all subsequent meetings/conference calls of the DSTC, the Chairs of the WGs (or a designee) would participate. At this time, the WGs did not feel the need for further involvement by the DSTC.

### January Meeting

The DSTC/WGs participation would include:

- a general presentation (estimated to be approx 15 minutes) on the activities/progress of the 3 WGs given by the DSTC Chair to the general meeting
- meetings of each of the WGs individually to progress their activities (timing to be determined, but estimated to be approx 2 hours)
- a meeting of DSTC and WGs to discuss activities
- report to the general meeting (format and timing to be determined)

### 2002 Meeting Schedules

The WGs would submit their respective schedules of meetings directly to PQRI.

The DSTC meetings would be:

- Jan 29 (at the PQRI general meeting)
- Apr 24 (conf call 9:00-10:30)
- Jul 24 (location to be determined)
- Oct 23 (conf call 9:00-10:30)