

Minutes

BIOPHARMACEUTICS TECHNICAL COMMITTEE

January 22, 2003
10:00 am – 2:00 pm
FDA – Woodmont
1451 Rockville Pike
Rockville, MD

AAPS/Industry Representatives

Leon Shargel (Chair)	GPhA
Andrew Dahlem	PhRMA
Paul Fackler	GPhA
Ron Manning	USP
Joel Sequeira	PhRMA

FDA Representatives

Ray Baweja	Jon Clark	Wallace Adams
Dale Conner	Lawrence Yu	

PQRI

Sylvia Gantt

Guests

Tobius Massa	Chair, PQRI Steering Committee (PhRMA)
Helen Winkle	FDA
Steve Bende	GPhA

Meeting started at 10:00 am with an introduction of attendees.

PQRI Steering Update

Tobius Massa, Chair, PQRI Steering Committee (PhRMA) discussed general issues concerning PQRI projects and WGs. Funding for PQRI projects is not available. PQRI is looking for financial support from the industry.

PQRI has established a new technical committee on the GMP initiative. The GMP initiative is of primary interest to industry and FDA. This issue is a major focus of PQRI. Current projects of the BTC are unlikely to be funded in the near future. BTC should consider projects that relate to GMPs.

FDA Priorities

H. Winkle stated the BTC is important to FDA. Ms. Winkle also stated that FDA is working on topical and inhalation drug products and does not see the need for any activities on these issues by the WGs. The respective WGs will therefore be inactive. FDA has limited resources and personnel time to devote to all of the PQRI activities.

Oral Immediate release products WG

Lawrence Yu stated that the dollar costs of the current projects can not be funded. Projects of the WG should be part of FDA priorities. It was suggested that a consideration of dissolution specifications might be a possible topic for the WG to consider.

WG volunteers -- Richard Mountfield and Bruce J. Aungst were formally approved as members of the oral immediate release products WG.

PQRI Workshop

Sylvia Gantt and Leon Shargel gave an update of the PQRI workshop scheduled for April 3-4, 2003 in Crystal City, VA.

A BTC Roundtable discussion is planned for the PQRI Workshop. In preparation of the roundtable discussion, we need to know the 'hot button' biopharmaceutic issues that are affecting our industry. BTC members were asked to submit a list of any topics that they or their colleagues think are key biopharmaceutic issues that should be addressed by our committee and/or FDA or USP.

New Business

Several topics for consideration by the BTC were suggested and discussed:

Should dissolution specifications be based on QC or in vivo bioavailability?

Can sequential design be used more efficiently to demonstrate BE?

Can upstream testing predict downstream dissolution testing?

The first item, 'dissolution specifications' has direct impact on GMPs. In addition, USP Project team #6 has been discussing this issue. The interaction of the BTC with USP will be discussed more fully at the next BTC meeting.

It was also suggested that a 'white paper' could be published on some of these topics,

Action items:

BTC members were asked to submit a list of any topics that are important biopharmaceutic issues that should be addressed by our committee and/or FDA or USP.

Next BTC Meetings:

The next BTC meetings will be held on February 12, 2003 and March 5, 2003.