

Meeting Summary
 PQRI Aseptic Processing Working Group
 January 9th, 2003

Working Group Members Present:

X	James P. Agalloco Agalloco & Associates		Carol M. Lampe Baxter Healthcare Corporation
X	James E. Akers, Ph.D. Akers Kennedy & Associates	X	John Lindsay Aseptic Solutions Inc.
X	Barbara Bassler Bridge Associates International	X	Russell E. Madsen PDA
X	Martyn Becker Merck & Co.		Andy Minor Eli Lilly & Co.
X	Susan Bruederle FDA	X	Leonard Mestrandrea Pfizer Inc.
X	Don Burstyn Alkermes		Kenneth Muhvich, Ph.D. Micro-Reliance.
X	Roger Dabbah USP	X	Terry Munson KMI/PAREXEL, Inc.
X	Roger Deschenes Astra Zeneca	X	Rainer F. Newman Johnson & Johnson
X	Joseph Famulare FDA	X	Jean I. Olsen GlaxoSmithKline
X	William R. Frieben, Ph.D. Pharmacia Corporation	X	Robert Sausville FDA
X	Rick Friedman FDA	X	Neal Sweeney FDA
X	John G. Grazal AstraZeneca Pharmaceuticals	X	Ian D. Symonds GlaxoSmithKline
X	Klaus Haberer Compliance Advice & Services		Laura Thoma, Ph.D. University of Tennessee
	Nigel Halls, Ph.D. GlaxoSmith Kline (ret.)	X	Debbie Trout FDA
	Karl L. Hofmann Bristol-Myers Squibb Co.	X	Martin Van Trieste Abbott Laboratories
X	David Hussong FDA	X	Brenda Uratani FDA
X	Richard M. Johnson Abbott Laboratories		Richard T. Wood, Ph.D. Pfizer, Inc.
	Kunio Kawamura Otsuka Pharma. Co., Ltd.	X	Glenn E. Wright Eli Lilly & Co.
	Lee Kirsch, Ph.D. University of Iowa	X	Jeff Yuen Jeff Yuen and Associates
X	Joe Lasich Alcon Laboratories, Inc.		

Summary:

- The meeting began with a general discussion regarding the PQRI process, its purpose, and the role of the working group member in that process.
- The ground rule provided with the agenda were discussed and agreed to.
- The PQRI work plan, timeline, and deliverables were reviewed. A question was raised regarding the ability to add topics to the work plan. A review of the work plan process and the need to adhere to the approved work plan was discussed. To address this question a suggestion was made that when topics, which are outside of the work plan, arise they will be collected for possible use in future work plans.
- The status of the Aseptic Processing Survey was reviewed and several questions as to the industry's awareness of the survey were asked. A review of the different methods used to communicate the survey was provided. No additional actions regarding the communication of the survey were made.
- The first working group topic (clarifications) was reviewed and discussed. Leaders and backups were assigned for each clarification as follows:

Clarification #1

Leader: William Friebe (e-mail address: william.r.friebe@am.pnu.com)
Back up: Leonard Mestrandrea

Clarification #2

Leader: Martyn Becker (e-mail address: martyn_becker@merck.com)
Back up: Glenn Wright

Clarification #3

Leader: John Lindsay (e-mail address: jlindsay@asepticsolutions.com)
Back up: Jim Agalloco

Clarification #4

Leader: John Grazal (e-mail address: john.grazal@astrazeneca.com)
Back up: Jim Akers

Clarification #5

Leader: Richard Johnson (e-mail address: richard.m.johnson@abbott.com)
Back up: Terry Munson

Clarification #6

Leader: Don Burstyn (e-mail address: don.burstyn@alkermes.com)
Back up: Martin Van Trieste

Clarification #7

Leader: Jim Akers (e-mail address: AKAInckC@aol.com)
Back up: David Hussong

Clarification #8

Leader: Roger Deschenes (e-mail address: roger.deschenes@astrazeneca.com)
Back up: Terry Munson

The following actions were developed and agreed to by the group:

- Working group members are to prepare redlined versions of the concept paper text (see work plan) for each clarification and provide them to the assigned clarification leader. Redlined versions should be sent no later than Tuesday January 14th but preferably sooner.
- Each clarification leader is to compile the redline versions into a single redline text draft. If this is not possible due to widely differing positions several redline text drafts may need to be developed.
- Once the clarification draft(s) are completed the leaders are to e-mail the redline draft(s) to all working group members for discussion at the upcoming meetings.
- We will work on the first 2 clarifications at our next teleconference and possible, if time permits, clarification 3.

To more easily work with the concept paper text a suggestion was made to make the Word version of the document available to the working group members. The document will be sent out with the meeting minutes. It was noted that the line numbers on the word version are different than the line numbers of the PDF version. The line numbers referenced in the work plan are for the PDF version.

- A suggestion was raised to continue by making assignments for the Recommendation section. The following discussion leader assignments were made:

Process Simulation

Leader: Richard Johnson
 Back up: Terry Munson

Environmental Monitoring

Leader: Carol Lampe
 Back up: Klaus Haberer

Aseptic Processing Isolators

Leader: Don Burstyn
 Back up: Jim Akers

Sterilization Options

Leader: Jim Agalloco
 Back up: Russ Madsen

- A question was asked about the meeting planned for the January 30 and 31 regarding the location of the meeting. A general location has been set (Washington DC). The exact meeting location will be provided on Friday.
- The meeting was adjourned at approximately 1:00 PM with the next meeting being scheduled for January 16th.