

Meeting Summary  
 PQRI Aseptic Processing Working Group  
 January 16<sup>th</sup>, 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		Carolyn Renshaw FDA
X	Rick Friedman FDA	X	Robert Sausville FDA
X	John G. Grazal AstraZeneca Pharmaceuticals	X	Neal Sweeney FDA
X	Klaus Haberer Compliance Advice & Services	X	Ian D. Symonds GlaxoSmithKline
	Nigel Halls, Ph.D. GlaxoSmith Kline (ret.)	X	Laura Thoma, Ph.D. University of Tennessee
	Karl L. Hofmann Bristol-Myers Squibb Co.		Debbie Trout FDA
X	David Hussong FDA	X	Martin Van Trieste Abbott Laboratories
X	Richard M. Johnson Abbott Laboratories	X	Brenda Uratani FDA
	Kunio Kawamura Otsuka Pharma. Co., Ltd.		Richard T. Wood, Ph.D. Pfizer, Inc.
	Lee Kirsch, Ph.D. University of Iowa	X	Glenn E. Wright Eli Lilly & Co.
X	Joe Lasich Alcon Laboratories, Inc.		Jeff Yuen Jeff Yuen and Associates

**Summary:**

- The meeting began with a review of the previous meeting summary. An error in an e-mail address was noted in the summary. The summary was approved with the e-mail address correction.
- The group began discussions on Clarifications 1,2, and 3 as summarized below:

➤ Clarification #1

The discussion was lead by William Friebe . The group actively discussed how the text should be clarified and came to an agreement on the text changes. Listed below is the agreed upon text clarification:

Concept Paper Line Number Reference: 637

**Original Text**

“Subsequently, routine semi-annual revalidation runs should be conducted for each shift and processing line to evaluate the state of control of the aseptic process.”

*Clarification:* What clarification should be provided in regards to each shift to help the reader understand that the process simulation needs to represent the various shifts but that a separate media fills for each shift may not be required.

**Clarified Text**

Subsequently, routine semi-annual revalidation should be conducted for each processing line to evaluate the state of control of the aseptic process. Activities and interventions representative of each shift and shift change over should be incorporated into the design of the semi-annual revalidation.

➤ Clarification #2

The discussion was lead by Martyn Becker. The group actively discussed how the text should be clarified and came to an agreement on the text changes. Listed below is the agreed upon text clarification:

Paper Line Number Reference: 984

**Original Text**

“Written procedures should include a list of locations to be sampled. Sample timing, frequency, and location should be carefully selected based upon its relationship to the operation performed. Samples should be taken throughout the aseptic processing facility (e.g., aseptic corridors; gowning rooms) using appropriate, scientifically sound sampling procedures, standards, and test limits.”

*Clarification:* What clarification should be provided for the term “test limit” so that it is not confused with a specification?

**Clarified Text**

Written procedures should include a list of locations to be sampled. Sample timing, frequency, and location should be carefully selected based upon its relationship to the operation performed. Samples should be taken throughout the aseptic processing facility (e.g., aseptic corridors; gowning rooms) using scientifically sound sampling procedures.

➤ Clarification #3

The discussion was lead by John Lindsay. The group actively discussed how the text should be clarified and came to an agreement on the text changes. Listed below is the agreed upon text clarification:

***Original Text***

“Disinfectants should retain efficacy against the normal microbial flora and be effective against spore-forming microorganisms. Many common sanitizers are ineffective against spores, for example, 70%isopropyl alcohol is not effective against *Bacillus* spp spores. A sporicidal agent should be used regularly to prevent contamination of the manufacturing environment with otherwise difficult to eradicate spore forming bacteria or fungi.”

*Clarification:* What clarification should be suggested regarding a disinfectants efficacy against spore forming microorganisms?

Note: The text to be modified was narrowed from that present in the working plan with the first sentence in the paragraph being removed. I was determined that this first sentence was out of scope.

***Clarified Text***

Routinely used disinfectants should be effective against the normal microbial vegetative flora recovered from the facility. Many common sanitizers are ineffective against spores, for example, 70%isopropyl alcohol is not effective against *Bacillus* spp spores. Therefore a sound disinfectant program should also include a sporicidal agent, used according to a written schedule, and if environmental data suggests the presence of bacterial spores.

- The meeting was opened up for general discussion.

The group commented that the clarification leaders did an excellent job preparing the information for the meeting and leading the discussion.

It was decided that at the next teleconference we would be covering the next three clarifications (#4, #5, and #6).

- The meeting was adjourned at approximately 1:15 PM with the next meeting being scheduled for January 23<sup>th</sup>.