

Meeting Summary
 PQRI Aseptic Processing Working Group
 January 23rd, 2003

Working Group Members Present:

X	James P. Agalloco Agalloco & Associates	X	Carol M. Lampe Baxter Healthcare Corporation
X	James E. Akers, Ph.D. Akers Kennedy & Associates	X	John Lindsay Aseptic Solutions Inc.
	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	X	Kenneth Muhvich, Ph.D. Micro-Reliance.
X	Roger Dabbah USP		Terry Munson KMI/PAREXEL, Inc.
X	Roger Deschenes Astra Zeneca		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		Jeff Yuen Jeff Yuen and Associates
X	Joe Lasich Alcon Laboratories, Inc.		

Summary:

- The meeting began with a review of the previous meeting summary. An error in the revised test for Clarification 1 was noted. The word “each” was removed from the first sentence. The revised meeting summary (with the word “each” included) was approved.
- The group began discussions on Clarifications #4, #5, and #6 as summarized below:

➤ Clarification #4

The discussion was lead by John Grazal. 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: 1055

Original Text

“After the initial assessment of sanitization procedures, ongoing sanitization efficacy should be frequently monitored through specific provisions in the environmental monitoring program, with a defined course of action in the event samples are found to exceed limits.”

Clarification: What type of clarification should be made in regards to expectations surrounding sanitization efficacy being monitored by the environmental program?

Clarified Text

Once sanitization procedures are established, adequacy is evaluated through the routine environmental monitoring program.

➤ Clarification #5

The discussion was lead by Richard Johnson. 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: 1070

Original Text

“Manufacturers should be aware of a device's air monitoring capabilities, and should determine suitability of any new or current devices with respect to sensitivity and limit of quantification”

Clarification: What type of clarification should be made in regards to determining the suitability of new or current devices and the comment around sensitivity and limit of quantification?

Clarified Text

Manufacturers should be aware of a device's air monitoring capabilities, and the air sampler should be evaluated for its suitability for use in an aseptic environment based on cleanability, ability to be sterilized, and disruption of unidirectional airflow. Manufacturers should assure that it is calibrated and used according to instructions. Because these attributes vary from device to device, the user should assess the suitability of all monitoring devices before they are placed into service.

➤ Clarification #6

The discussion was lead by Don Burstyn. 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: 1419

Original Text

“Multiple material transfers are generally made during the processing of a batch. Frequently, transfers are performed via direct interface with a decontaminating transfer isolator or dry heat depyrogenation tunnel with balanced airflow. Such provisions, if well designed, help ensure that microbiological ingress does not result from the introduction of supplies. Properly operated RTPs (rapid transfer ports) are also generally considered to be an effective transfer mechanism. The number of transfers should be kept to a minimum because the risk of ingress of contaminants increases with each successive material transfer.”

Clarification: What clarification should be suggested regarding the number of RTP transfers and the risk of contamination?

Clarified Text

Multiple material transfers are generally made during the processing of a batch. Frequently, transfers are performed via direct interface between manufacturing equipment and isolator. Properly maintained and operated (rapid transfer ports (RTPs) are an effective mechanism for aseptic transfer of materials into and out of isolators.

Note: As the group discussed the clarification a suggestion was made to place part of the clarification text into Line 275 of the concept paper. The group discussed this suggestion and agreed that that section was the best location fit for the information.

Added Clarification text (concept paper reference Line 275).

...surrounding environment. The number of transfers into an isolator or the critical zone of a clean room should be minimized.

- 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.

A general review of the draft meeting agenda for the January 30th and 31st meeting was discussed.

- The meeting was adjourned at approximately 1:30 PM with the next meeting being scheduled for January 30th and 31st.