

Meeting Summary
PQRI Aseptic Processing Working Group
February 6th

Working Group Members Present:

X	James P. Agalloco Agalloco & Associates	X	Carol M. Lampe Baxter Healthcare Corporation
	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		Leonard Mestrandrea Pfizer Inc.
	Don Burstyn Alkermes		Kenneth Muhvich, Ph.D. Micro-Reliance.
	Roger Dabbah USP	X	Terry Munson KMI/PAREXEL, Inc.
X	Roger Deschenes Astra Zeneca	X	Rainer F. Newman Johnson & Johnson
	Joseph Famulare FDA		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		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		Martin Van Trieste Abbott Laboratories
	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

- The minutes from the previous meeting were in revision at the time of the meeting and will be provided at the next meeting for approval.
- The group began with discussions on the recommendations #10 as summarized below:

➤ **Recommendation #10**

The discussion was lead by James Agalloco. The group actively discussed the recommendation and came to agreement points to include that are reflected in the draft. (See Attachment 1)

After the group completed the discussion on the draft the group had a very open discussion on the topic. This discussion was not to provide information for the recommendation but rather to provide an open forum to capture comments on the topic.

Listed below are points gathered from that discussion:

- Any effort in this area should be done in concert with other organizations to ensure global harmonization.
- Rulemaking should set an effective date in the future and not mandate changes to existing processes, including those in development.
- The CPMP paper was a reasonable start but needs refinement.
- Substantial discussion would be needed to develop a harmonized flowchart.
- That PNSU was preferable to time-temperature conditions for indicating process lethality.
- Imposing a post-aseptic filling adjunct treatment appears consistent with the FDA's stated goal of risk-based regulation.
- To increase SAL what about lower temperatures
- Post-aseptic fill adjunct treatments could enhance patient safety.
- An industry wide meeting might be a useful tool to explore the subject further.
- Is a flowchart the best way to address non-moist heat processes, i.e., radiation, dry heat, etc.?
- Whether any flow chart should address non-aqueous processes?
- Would destruction of a resistant bacterial spore by the post-aseptic fill treatment be required are we looking for something less?
- Different indicators (lower resistant spores) might need to be developed for adjunct processing.
- What about the use of bioburden / resistance models?
- Could alternative aseptic manufacturing technologies, i.e., isolation or BFS, be accepted as alternatives to adjunct treatments because of their higher performance capabilities?

From the discussion the group strongly recommends to PQRI that a group be formed within PQRI or another organization to further discuss the topic. As a result of this discussion 6 different flowcharts, modeled after the moist heat CPMP chart, were developed on this topic. Each (or all) of them could serve as the starting point for meaningful discussion on the subject. (See Attachment 2, separate file)

- The group reviewed the rational section of the recommendations to date. The will be further worked on and sent back out to the group.
- A review of the remaining work to be completed and the number of meeting left were discussed. The group decided that the next teleconference on February 13th will be lengthened by 30 minutes to 2 hours to provide enough time for the discussion of 2 recommendations.
- The group also decided to have a full day meeting on February 20th to complete the work of the group.
- The meeting was adjourned at approximately 1:30PM

Recommendation #10

Concept Paper Line Number Reference: 57

Question: With respect to terminal sterilization and adjunct processing what flowcharts represent the most risk-based and scientifically developed approach?

Recommendation:

- No detail should be added to the current text present in the concept paper.
- The group strongly recommends to PQRI that a group be formed within PQRI or another organization to further discuss and develop this topic.

Rational:

- This topic involves adjunct processing being used in conjunction with aseptic processing as a general concept to increase sterility assurance. As indicated by the survey this topic has value and should be explored. However, it will need to be further developed before it can be included, on a scientific basis, in a guidance document. Added scientific discussion, research, and the establishment of new standard methods will be needed to understand how it might be used and what expectations from a regulatory perspective should be considered.

Survey Data Summary: