Points to Consider No. 1: Aseptic Processing (Revised 2023)

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Introduction

Points to Consider No. 1: Aseptic Processing (Revised 2023) offers PDA's thoughts and does not represent a standard or regulatory guidance.

PDA first issued *Points to Consider for Aseptic Processing* in 2003. To address the impact of the knowledge gained in the intervening years, PDA assembled a task force of subject-matter experts from industry to revise this report. Published in 2015 and 2016, *Points to Consider for Aseptic Processing* parts 1 and 2 provided positions on current topics, best practices, and areas of clarification important to the manufacture of quality sterile products.

NOTE: The topics discussed in the 2015 and 2016 Points to Consider documents are superseded by this revision.

With technology and regulatory advancements, specifically the issuance of the revised *European GMP Annex 1: Manufacture of Sterile Medicinal Products* (EU Annex 1)[1] in August 2022, another update of this document was undertaken. This revision reflects current industry best practices and scientific positions as well as regulatory expectations. Where there may be a divergence between recommendations in this Points to Consider document and a regulatory position, that divergence is noted.

Many of the topics included in the 2015 Points to Consider resulted from discussion and input from PDA members at conferences and meetings. These topics were reviewed considering the advancements made in the past decade and, where applicable, this report has been revised based on similar inputs.

While the current revision maintains the original organization of topics into categories, topics that had been discussed separately in Parts 1 and 2 have been combined into a single document. Each topic discussion begins with a problem statement in the form of a question about issues or points needing clarification on that specific topic. Recommendations from the PDA task force are then presented as an answer to the question. The rationale and references for each recommendation follow.

This document provides points to consider on topics related to the physical environment in which aseptic processing is conducted, monitoring of that environment, cleanroom personnel, material transfer, aseptic-process simulation and validation, "modern" blow-fill-seal technology, cleaning, disinfection and sterilization, and critical utilities. It also includes points to consider on aspects of filter-integrity testing and water-for-injection (WFI) preparation. For additional information on specific topics, other PDA points to consider, technical reports, or similar documents are referenced. The recommendations presented in this Points to Consider document are based on five guiding and linked principles for improvement in sterile health care products:

1. Scientifically sound, risk-based approaches should be used to obtain information needed to make decisions related to the evaluation, design, qualification, operation, and monitoring of sterile-product manufacturing processes. Risk- and science-based approaches should be used as well to develop and implement control strategies and acceptance criteria designed to ensure the establishment and maintenance of manufacturing conditions that affect the sterility of products. Sterile drug-product manufacturing processes and testing requirements should have a basis in and relevance to risks to product quality and patient safety. Similar principles and considerations may also apply to non-sterile drug products. Risk management and assessment methods should be developed not only to identify risks, but also to allow the improvement of processes and control strategies.

2. Where feasible, the use of newer technologies should be considered to mitigate or reduce risks to product quality identified in manufacturing processes and operations. Companies involved in the manufacture of sterile drug products should be encouraged to identify and consider the use of

[1] The PIC/S GMP Annex 1 is identical to the EU Annex 1 and, hereafter, EU Annex 1 means EU-PIC/S Annex 1.

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