PDA Research

2017 PDA Aseptic Processing Survey

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PDA®
Parenteral Drug Association

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Introduction

Background

The *2017 PDA Aseptic Processing Survey* updates and extends previous PDA surveys on the topic. It was intended to help PDA identify and document current practices for aseptic processing and any improvements made by manufacturers since the last PDA survey.

This survey addresses aseptic processing practices for global secondary manufacturing (finished product filling/packaging), while taking into consideration the changes and needs of the modern, global, sterile, healthcare product manufacturing industry. The survey was not meant to be an all-inclusive perspective on sterile product manufacturing; rather, the focus was to address specific questions and positions which the task force felt required additional support in preparing for PDA Comments to the upcoming EMA/PIC-S Annex 1 Revision. Accordingly, this survey incorporated new issues, including questions from the 2003 PQRI survey, and topics arising from four PDA Aseptic Processing Workshops held in 2016.

Survey Method

The survey was open to all PDA members as well as non-members. The numbering in this report does not coincide with the numbering of the questions in the original questionnaire. Respondents could skip questions if they were not applicable (therefore results will vary in number of skipped responses). For some questions, respondents were allowed to check multiple options, therefore the sum of the response percentage may exceed 100% and the total response count may exceed the number of respondents to the survey. Rank order questions were not limited to selecting all options. All response percentages for a given question are based on the total number of those who answered that question. For questions to which there was not a significant number of responses, results were not included in this report.

The results for the *2017 PDA Aseptic Processing Survey* are based on 304 responses received between June 12 and July 31, 2017. PDA conducts its benchmarking surveys in a manner designed to protect the confidentiality of the gathered information and data. The identity of survey respondents was blinded and not revealed to the authors or other PDA members, or in any publication or presentation of the final results developed with the survey. The survey documents industry practices during the time the survey was active; readers should not infer these are necessarily current best practices.

Demographics

This survey represents practices in the global pharmaceutical industry with good geographic distribution. Of the 304 respondents, most of the responses came from Europe (35%), North America (30%), and /Australia/Asia (30%).

The surveyed respondents included a significant number of professionals who produce small volume parenterals (74%), followed by large volume parenterals (36%), biologics (42%), ophthalmic/otics (20%), inhalants (8%), ointments (4%), products for veterinary use (7%), medical devices (liquid based; 15%), medical devices (non-liquid based; 5%), cell therapies (5%), and other (5%).

Conclusions

It is not the objective of PDA to present analysis of or draw definitive conclusions from the survey results. However, we feel some general conclusions can be made from the compilation of the collective responses.

The survey data suggests that there is a need for clarified guidance to address standardization of acceptance criteria, clinical relevance, proper risk analysis and risk mitigation strategies.

There is general agreement that science- and 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 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. However, the results indicate that many respondents may not be fully utilizing this approach. Whether this is due to a lack of understanding, or varying interpretations of regulatory expectations, is unclear.

It is important that companies involved in the manufacture of sterile drug products be encouraged to identify and consider the use of modern technologies and that regulatory guidance enable this by presenting expectations that encourage the use of these technologies. When scientific approaches are similar and agreed upon, global health authority requirements and guidance should be consistent in technical language and definition. It is important that harmonized technical and regulatory language, where possible, be consistent with approaches presented in other similar guidance. This practice should promote clarity of global regulatory expectations and reduce the risk of misunderstanding and redundant efforts.