



10 January 2019

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
via submission to regulations.gov

Re: Docket ID: FDA-2018-N-3272 for “Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions; Public Meeting; Request for Comments”

Dear Commissioner Gottlieb and members of the FDA Drug Shortage Task Force,

Thank you for the opportunity to provide input on the critical issue addressed in the above-mentioned FDA docket.

ISPE, the International Society for Pharmaceutical Engineering, is the world's largest not-for-profit association serving its Members by leading scientific, technical and regulatory advancement throughout the entire pharmaceutical lifecycle. We deliver technical and operational solutions to support our Members across the global pharmaceutical and biopharmaceutical industry in the manufacture of quality medicines for patients. ISPE aims to offer increasing and unparalleled value for Members, companies and stakeholders globally and across all constituent parts of the industry. The result will be the continued improvement and transformation of the pharmaceutical manufacturing industry to better ensure the availability of quality medicines.

In pursuit of our purpose as described above, ISPE representatives attended the FDA Drug Shortage Task Force Public Meeting, held on 27 Nov 2018, and observed a strong interest expressed by participants in identifying manufacturers with sufficient quality and reliability to minimize the potential for drug shortages. Dr. Throckmorton (FDA, Deputy Director for Regulatory Programs) also emphasized that prevention and communication are critical in reducing the number of drug shortages. Accordingly, we would like to highlight three ISPE resources and tools which are available and were specifically developed to address the underlying root causes for shortages and improve industry preparedness for reducing the occurrence, duration, and intensity of drug shortages. They can be used as a roadmap to assist both the pharmaceutical industry and regulators in identifying, managing, resolving and preventing constraints in manufacturing operations which may result in abnormal restriction in supply.

Specifically:

1. The ISPE [Drug Shortages Prevention Plan](#) is an internationally relevant plan of value to all sectors of industry and its regulating authorities. The ISPE Drug Shortages Task Team defined the following building blocks for a sustainable drug shortages prevention plan:

- Corporate Quality Culture
- Robust Quality System
- Metrics (specific to drug shortages)
- Building Capability – for example, organizational and personal competencies
- Business Continuity Planning – for example, crisis management
- Communication with Authorities

Much of the plan focuses upon better implementation of a site's (or company) quality system - and it is the GMP aspects of quality systems that are inspectable. Where supply interruptions occur or threaten, inspectors should find this plan a valuable resource not only in regard to these minimum standards, but in assisting industry towards more general quality improvement efforts.

2. ISPE has also published a [Drug Shortage Assessment and Prevention Tool](#). This Tool provides a structured approach for industry to develop strategies and practices for each of the six drug shortages dimensions described in the ISPE Drug Shortages Prevention Plan.
3. ISPE released a [Drug Shortages Introductory webinar](#) created to bring knowledge to the industry on the regulatory expectations regarding drug shortages and practical tools for use in preventing shortages.

The ISPE membership is appreciative of the ongoing effort of the FDA Drug Shortage Staff and would like to acknowledge the many accomplishments and progress they have already made in minimizing or avoiding shortages. We would also like to emphasize our shared interest in the important goals of the Drug Shortages Task Force and offer our support for the potential application of any of the available ISPE resources or tools. Additionally, we are interested in collaborating with FDA to further develop and disseminate accessible, user-friendly tools and information that may be useful in identifying and reconciling drug shortage issues; which could be presented in a traditional guidance format or shared via a drug shortages mitigation tool mobile app. ISPE is willing to provide information sessions to FDA on the tools listed above to highlight and provide any helpful context regarding this foundational work, and we would welcome participation in any potential opportunity to expand or adapt these resources or tools to maximize their value for this initiative.

Finally, due to the breadth and importance of the topics covered in the Federal Register announcement and during the Public Meeting, ISPE would like to suggest that stakeholders be provided with further opportunities to contribute to the refinement of any proposals which show the most promise for providing enduring solutions to drug shortages.

Sincerely,

John E. Bournas
CEO & President, ISPE