



ISPE Drug Shortages Initiative: FAQs

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Section I: Overview / Historical Timeline

1. Historically, what events led to the creation of the Drug Shortages Task Team?

The *Drug Shortages Prevention Plan* (DSPP) is an actionable plan intended to help the pharmaceutical and biopharmaceutical industry avoid drug shortages that result from manufacturing and quality issues.

- 2012: The Food and Drug Administration Safety Innovation Act (FDASIA) was passed granting the FDA more authority regarding drug shortages. A major addition was requiring manufacturers to notify FDA of potential discontinuations of drugs used to prevent or treat serious diseases.
- 2012: EMA publishes *Reflection paper on medicinal product supply shortages caused by manufacturing/Good Manufacturing Practice Compliance problems*. "This Reflection Paper is concerned with public health crises that arise due to unforeseen disruptions within the manufacturing process, caused by manufacturing/GMP compliance problems and affecting medicinal products for human use, independent of their route of authorisation, where a need for co-ordination of the assessment and risk reducing actions at a Community level has been identified."
- 2012: ISPE Drug Shortages Team is formed and drug shortages survey developed, seeking to identify the causes of supply disruption that arise from manufacturing or quality issues.
- 2013: ISPE drug shortage survey results shared across the industry and with regulators.
- 2013: FDA issues its Strategic Plan for Preventing and Mitigating Drug Shortages. ISPE's report on its 2013 Drug Shortages Survey was cited twice in the [Strategic Plan for Preventing and Mitigating Drug Shortages](#) released by the US Food and Drug Administration (FDA). There were two goals in FDA's strategic plan. The first was to further mitigate drug shortages through the improvement and streamlining of FDA's current mitigation activities for existing or imminent shortages. The second was to develop long term prevention strategies focused on the root causes of shortages to better understand and eventually anticipate future drug shortages.
- 2013: ISPE releases the shortages survey report which focuses on manufacturing 'root causes' of supply disruption. The most common cause of supply disruption was found to be the lack of a robust 'quality system'.
- 2013: The ISPE survey presented to EMA. EMA requests ISPE contribute to a plan to address the prevention of shortages due to manufacturing and compliance issues.

- 2014: ISPE Drug Shortages Prevention Plan (DSPP) is published and focuses on a multidimensional foundation named the “Hexagon Model” in order to support a holistic approach to drug shortages prevention.
- May 2015: ISPE announces “ISPE Developing Gap Analysis Tool to Help Ensure an Uninterrupted Supply of Medicines” at the 2nd Annual European Conference in Frankfurt.

2. What led the ISPE to focus on preventing drug shortages?

Speaking broadly for the ISPE staff and group of dedicated volunteers, this represents an opportunity for the pharmaceutical industry to take ownership of this important issue and provide solutions in the space where we can leverage our technical expertise to at least mitigate those issues relating to manufacturing quality, and beyond. We realize that this is part of a broader picture in the overall health care medicines arena concerning commercial aspects. ISPE is truly driven by the need to ensure a reliable supply of quality products to patients.

ISPE has been at the forefront of this topic going back many years as the prevalence of drug shortages has been found to be increasing in recent years with a notable cause being attributed to manufacturing and facility issues. This has been reported in various documents from USFDA, EMA, and other international authorities to have played a significant role in the number of shortages of medicines, including those important to medically necessary treatments with limited or no alternatives. ISPE has stepped in as it does regarding topics key to its members and the industry it serves to understand the issue and drive solutions via the expertise of its members. We have surveyed the industry in detail to get at root causes of the issue and have updated and informed key stakeholders on the topic at all major events.

ISPE produced its Drug Shortages Prevention Plan (DSPP) for industry built on that data analysis. The DSPP is organized around a “six dimension” framework comprised of these elements: Corporate Quality Culture; Robust Quality System; Metrics; Business Continuity Planning; Communication with Authorities; and Building Capability.

<http://www.ispe.org/drug-shortages-initiative>



Now that data analysis and solutions have been provided, the next step for ISPE and its members is to focus on implementation, including wide spread communication and training and the development of tools to help industry identify gaps and implement the recommendations found in the plan.

Section II: *Drug Shortages Prevention Plan*

1. What is the *ISPE Drug Shortages Prevention Plan*?

- The *Drug Shortages Prevention Plan* is an actionable plan intended to help the pharmaceutical and biopharmaceutical industry avoid drug shortages that result from manufacturing and quality issues.

- The *Drug Shortages Prevention Plan* is ISPE's second major output on the drug shortages issue, the first being the 2013 Drug Shortages Survey of the issues and root causes of drug shortages.

2. When was the *ISPE Drug Shortages Prevention Plan* Published?

- The *Drug Shortages Prevention Plan* was officially released by ISPE on 14 October 2014.

3. Who developed the *ISPE Drug Shortages Prevention Plan*, and why?

- The *ISPE Drug Shortages Prevention Plan* was developed by ISPE's Drug Shortages Task Team of expert pharmaceutical and biopharmaceutical industry members (list on page 6).
- ISPE began its drug shortages initiative in support of several global regulatory outreaches, including an FDA Workshop on Approaches to Addressing Drug Shortage in 2011, the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012, an EMA reflection paper on Medicinal Product Supply Shortages caused by Manufacturing/Good Manufacturing Practice Compliance Problems in 2012, and an EMA workshop in 2013.
- The *ISPE Drug Shortages Prevention Plan* also serves as ISPE's contribution to a multi-association collaborative plan to prevent drug shortages that was developed at the request of the EMA and presented to the Agency in December 2014.

4. What's in the Drug Shortages Prevention Plan?

- The *ISPE Drug Shortages Prevention Plan* is based in part on the 2013 Drug Shortages Survey which investigated manufacturing quality issues as a major cause of drug shortages.
- For more than a year the ISPE Drug Shortages Task Team conducted a deeper analysis of the Drug Shortages Survey data and augmented those data with discussions with leaders from more than 30 major pharmaceutical companies, regulators, and hundreds of industry professionals at ISPE conferences and workshops. The *ISPE Drug Shortages Prevention Plan* is organized into six dimensions, and contains recommendations and real-world case studies in each of the dimensions:



1. Corporate Quality Culture
2. Robust Quality Systems
3. Metrics
4. Business Continuity Planning
5. Communication with Authorities
6. Building Capability

- The *ISPE Drug Shortages Prevention Plan* is:
 1. Global: industry experts from international companies developed the plan and regulators from the EMA, FDA, and several national competent authorities in Europe reviewed and provided commentary on the Plan.
 2. Holistic: the complexity of issues that can lead to supply disruptions requires strategies that cross multiple functional areas in an organization.

5. Is the *ISPE Drug Shortages Prevention Plan* available to everyone?

- In light of the urgency of the drug shortage issue and its impact on patients and their families worldwide, ISPE is providing the *Drug Shortages Prevention Plan* as a freely downloadable PDF on its website. The URL of the document will be <http://www.ispe.org/drug-shortages-initiative>

6. Will the *ISPE Drug Shortages Prevention Plan* really eliminate all drug shortages?

- No plan can eliminate 100% of drug shortages, especially since it must be appreciated that manufacturing quality is only one of the many causes of shortages. By following the recommendations in the *ISPE Drug Shortages Prevention Plan* and utilizing the soon to be published Gap Analysis Tool, the number of shortages due to manufacturing and quality issues can be reduced and the impact on patients can be lessened.
- There are many other factors that may impact the supply of drugs, including regional economic factors, differing regulatory requirements, insurance programs, and government procurement procedures, which are outside the scope of the *ISPE Drug Shortages Prevention Plan*.

7. Is the *Drug Shortages Prevention Plan* the end of ISPE's Drug Shortages Initiative?

- In 2015, ISPE's Drug Shortages Initiative enters its third phase, which consists of delivering solutions, based on the *Drug Shortages Prevention Plan*, in ISPE conferences, training programs, and publications. A Gap Analysis Tool is being developed that will enable industry to assess the robustness of its supply chain through a series of questions based on the *Drug Shortages Prevention Plan*.
- ISPE will continue to act as global facilitators and integrators in the effort to prevent drug shortages through facilitating forums with industry leaders and regulators, and through helping industry build capability in the areas critical to building resilient supply chains.

8. How are ISPE Members and the industry being informed about the DSPP?

- Through a variety of means, including direct emails, articles in *Pharmaceutical Engineering* and other publications (e.g., *Life Science Leader*, *IPQ*, *ICHEM*), blog postings and social media, to name a few. ISPE is actively educating industry at conferences and other events around the world.

9. Who can answer questions on the DSPP?

- Direct questions to Shane Osborne, ISPE Vice President, Marketing, Communications and Membership. Mr. Osborne will direct them to the appropriate Drug Shortages Task Team member if necessary.

10. Where can I find out more about ISPE's DS Initiative and drug shortages in general?

- <http://www.ispe.org/drug-shortages-initiative>
- Introductory Summary of the [ISPE Drug Shortages Prevention Plan](#)
- Current Drug Shortages:

- [Reported to EMA:](#)
- [Reported to FDA:](#)

Section III: *Gap Analysis Tool*

1. What is the Gap Analysis Tool and Why is it Needed?

The gap analysis tool represents an important element of the implementation stage, providing a succinct way to look at the DSPP and analyse risks in each of the dimensions cited e.g. Business Continuity and mitigate those risks. We envision that companies will use the Tool and the DSPP as part of their overall Drug Shortages Prevention Program. It is a guide for industry to assess the robustness and resilience of the supply chain via a series of questions based on the *Drug Shortages Prevention Plan*.

They can first use the DSPP as a reflection paper, to help them look holistically across their entire supply chain. The Gap Analysis Tool then assists industry to evaluate their current processes, systems and practices and assess the risks in the 6 different dimensions compared with a 'desired state' as described in the DSPP.

2. What is the biggest challenge in developing the tool?

The tool is currently still under development. ISPE has tackled some of the larger challenges of doing a deep dive into the root causes of manufacturing related causes and has provided a comprehensive prevention plan. The tool should flow from that solid foundation.

The challenge is to meet rapidly industry's need for an easy-to-use enabler that can support a change management process which comprises a systems based assessment of an organisation's current state against the DSPP's 'desired state'.

3. How will the tool help prevent drug shortages?

The tool itself will provide a succinct way to measure an organisation's gaps from the best practices recommended in the prevention plan (DSPP) and assess potential risks in the supply chain (under the six headings) and take proactive measures where possible to prevent shortages.

4. How will the tool be made available?

In the first instance, the tool will be included in a new ISPE Good Practice Guide on Drug Shortages Prevention Preparedness Planning.

5. What other tools can we expect to see coming out of the Drug Shortages Initiative?

Stay tuned. ISPE is committed to the long term in the resolution and management of drug shortages. This gap analysis tool, once completed, will be part of our education and training programs to support implementation and effectiveness across the industry.

6. When will a finished tool be launched?

Our goal is the second half of 2015.

7. Will regulators interact with the tool and if so, how?

The tool is intended purely for industry. However, prior to release, regulators will be asked for their views on the tool. Use of the tool is also expected to help industry prepare for any questions a regulator may ask concerning their ability to avoid a potential or manage an actual shortage.

Section IV: Drug Shortages Task Team Members

Drug Shortages Task Team Members

Steering Committee

- François Sallans (Chairman), Vice President and Chief Quality Officer, Johnson & Johnson
- Thomas Hartman, Vice President, GPM Operations, GlaxoSmithKline
- John Bournas, President and CEO, ISPE
- Joseph C. Famulare, Vice President Global Compliance and External Collaboration, Pharmaceutical Technical Quality, Genentech Inc.
- Frances Zipp, President, Lachman Consulting Services, Inc.
- Peter Bigelow, President, XCell Strategic Consulting, LLC
- Shane Osborne, Vice President, Marketing, Communications, and Membership, ISPE

Core Team

- Andreas Brutsche, Head of Global Quality Assurance, Sandoz International GmbH
- Paul D'Eramo, Vice President Pharma Regulatory Compliance, Johnson & Johnson
- Mairead Goetz, Head of Compliance, Group Compliance & Audit Group Quality Assurance, Novartis Pharmaceutical Corporation
- Donna Gulbinski, Senior Vice President, Global Quality and EHS, Bristol-Meyers Squibb Co.
- Karen Hirshfield, Senior Compliance Specialist, Genentech, Inc. (Member of the Roche Group)
- Paige Kane, Director Knowledge Management, Pfizer Global Supply
- Larry Kranking, Vice President, International Consulting, Commissioning Agents, Inc.
- Stephen Mahoney, Senior Director, Global Quality and Compliance, Genentech, Inc. (Member of the Roche Group)
- Robert Landertinger-Forero, Marketing Manager, Sartorius Stedim Biotech GmbH
- David Mierau, Director of Reliability Solutions, Life Cycle Engineering
- Christopher Reid, CEO, Integrity Solutions
- Shannah Schodle, Director of Business Development, CRB
- Sumanth Venugopal, Director, PricewaterhouseCoopers LLP

ISPE Staff/Resources

- John C. Berridge, PhD, ISPE Advisor
- Anna Maria Di Giorgio, Senior Director, Publications, ISPE
- Alicia Montes, Director of Training, ISPE
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- Carol Winfield, Director of Regulatory Operations, ISPE
- Bryan Wright, ISPE Regulatory Advisor
- Thomas Zimmer, Vice President of European Operations, ISPE