

Second ISPE-FDA Event Attracts Top Names, Features Release of Drug Shortage Survey Results

ISPE will hold its second annual Redefining the “C” in CGMP conference 11 – 13 June 2013 in Baltimore, Maryland, USA. Themed “Ensuring a Reliable Supply of Quality Medicines,” the event will feature strategic education on issues of interest to industry leaders and global regulatory officials focused on quality systems, processes, and technology utilization that drive quality enhancements that support a reliable drug supply.

“This event is where industry and regulators must come together to share their views on contemporary regulatory issues and solutions,” said ISPE President and CEO Nancy

Berg. “The sessions, case studies and workshops will be focused on how great companies are establishing and sustaining a culture of quality through contemporary quality management strategies, new methods and technologies, metrics and more effective approaches to integrating suppliers into quality systems.”

The event will feature top speakers from the pharmaceutical industry and regulatory agencies, including:

- Howard Sklamberg, Director, Office of Compliance, US FDA
- Andy Skibo, Regional Vice President, Biologics-Supply, MedImmune/AstraZeneca
- Gerald Heddell, Director of Inspection, Enforcement and Standards, MHRA, UK
- John Pinion, Senior Vice President, Quality/Compliance, Genentech, Inc.
- Zena Kaufman, Senior Vice President, Global Quality, Hospira
- Cindy Salamon, Vice President, Global Quality Services, Bristol-Myers Squibb
- Carol Bye, Vice President, Pharmaceutical Sciences Quality Operations, Pfizer, Inc.

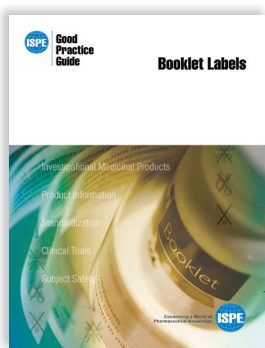
ISPE Releases New Guidance for Standardizing Use of Booklet Labels in Global Clinical Trials

The use of booklet labels in clinical trials is still growing; however, considerations of how to use booklet labels have become increasingly important in maintaining site and subject compliance.

The *ISPE Good Practice Guide: Booklet Labels*, published in March, aims to provide information and recommendations for the pharmaceutical industry on how to design and structure a booklet label, and how to standardize the use and application of booklet labels. This Guide is intended to support harmonization of labeling requirements and provides recommendations for the effective use of booklet labels to support investigational products across countries, trial programs, and/or protocols.


This Guide discusses the relevant GMP and GCP concerns related to the use of booklet labels for global clinical

Concludes on page 2.



Education content will focus on providing attendees with new insights and executable action plans to help resolve challenges related to quality leadership, quality metrics, CMO quality management, flexible manufacturing and other hot topics related to product quality and patient safety.

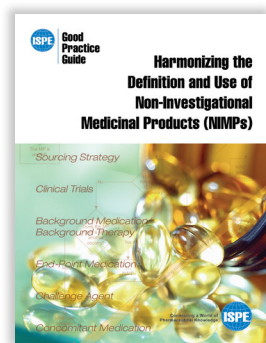
The event will also feature the first public release of key data resulting from the ISPE Drug Shortage Survey, with an expert industry team providing commentary on the ISPE research, the impact of drug shortages, and potential solutions. A Meet the Press session will feature a joint regulatory and industry panel answering questions from recognized pharma media experts on strategies for industry and regulatory collaboration, as well as compliance and product quality issues.

Other Special Events include an Industry-Led Hot Topic Discussion Forum where participants will have an opportunity to interact directly with industry executives and have questions and concerns addressed, and a Breakfast with the Inspectors, where participants can meet and talk with pharmaceutical inspectors about their recent inspection observations and industry trends. 

ISPE Releases New Guidance for Definition and Use of NIMPs in Clinical Trials

Currently, there are no complete regulations or practical guidelines for Non-Investigational Medicinal Products (NIMPs). As a result, pharmaceutical organizations may overcomplicate their clinical trials by submitting products as Investigational Medicinal Products (IMPs) when they could have

been managed as NIMPs. Alternatively, organizations may file clinical trial products as NIMPs only to be denied approval by a health authority later in the process. The *ISPE Good Practice Guide: Harmonizing the Definition and Use of Non-Investigational Medicinal Products (NIMPs)* is intended to help alleviate regulatory and operational ambiguity.



The Guide summarizes current consensus on what the pharmaceutical industry and regulations/guidelines define as NIMPs. It aims to address regulatory, manufacturing, and clinical site aspects related to NIMPs. Development of the Guide followed an on-line survey with the goal of understanding how the pharmaceutical industry manages NIMPs. The Guide elaborates upon three key findings from that survey:

1. Which NIMP category is most often utilized?
2. Which NIMP category is most commonly challenged by the local competent authorities?
3. Which functional area of the clinical trial sponsor organization determines if a medicinal product should be categorized as IMP or as a NIMP?

The Guide provides an overview of regulatory requirements and incorporates practical operational guidance, based on industry experience, for the use of NIMPs. It is intended to provide support to personnel in clinical supplies, quality, or clinical operations who may have a need to include NIMPs within their clinical protocols.

Current approaches to supply chain management of NIMPs are considered in order to create guidance and schematics around:

- Sourcing strategies
- Approaches to packaging and labeling
- Recommendations for storage and distribution
- Approaches to clinical site re-imburement
- Approaches to management of drug accountability, traceability, complaints, and recalls with reference to the original sourcing strategy

In addition, an appendix is provided that categorizes regions or countries according to regulations and practices related to NIMPs.

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trials and responds to the practical needs of users.

This Guide aims to help to ensure greater safety and compliance for subjects participating in clinical trials. Guidance is provided on the type of information that should be included within booklet labels.

This *ISPE Good Practice Guide: Booklet Labels* proposes a standard booklet label layout and using booklet labels in a standardized manner; helping to reduce or eliminate risks and concerns expressed by investigational sites and competent authorities.

Standardization of booklet labels can benefit the pharmaceutical industry by eliminating variability and reducing confusion amongst users. Similarly, standardization can help to reduce dispensing errors by sites and allow subjects and site personnel to become familiar with the label design, so they know where to look for pertinent information. Guidance is provided on the design of booklet labels for product pooling by recommending positioning of the trial identification in a manner that will make just-in-time labeling/identification of trial identification more feasible.

This Guide also includes recommendations to support eliminating use-by dates on labels when controlled using an Interactive Response Technology system. Special consideration is given to clinical trial materials labeled for multiple protocols, known as pooled products. The Guide also includes recommendations for booklet labels applied to IMP for use in hospitals (in-subject) and at-home treatments (out-subject).

This Guide is a result of a joint effort of representatives from the pharmaceutical industry and review by several pharmaceutical discussion groups. General support and professional insights have also been provided by representatives from the MHRA (UK).