Webinar on

Understanding The Drug Supply Chain Security Act: Latest Regulatory Developments and Best Practices

Learning Objectives

- *Discuss the DSCSA and the requirements going into effect next year and beyond*
- *Examine potential methods of compliance for the DSCSA*
- *Explore the FDA's guidance, and how the agency is working with the industry to determine compliance standards*

In this course, you will be updated on the implementation processes in order to gain a clear understanding of the guidelines and tactics to avoid non-compliance.

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Areas Covered

Topic 1:Key Regulatory Requirements under DSCSA

- Reporting licensure
- Knowing how to handle suspect and illegitimate products
- Confirming authorized trading partners
- How to comply with important guidance documents; including FDA's guidance on how to exchange product tracing information (DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information)

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Areas Covered

Topic 2: Review Critical Elements of Implementing DSCSA

-Who exactly is regulated under DSCSA, such as repackagers, wholesale distributors, dispensers and third-party logistics providers
- What the most complicated and nuanced requirements are under DSCSA, such as product serialization and exchange of transaction information, transaction history, and transaction statement
- Which areas will be regulated soon under DSCSA, such as requirements for dispensers and distributors
-How FDA is enforcing DSCSA, recent actions including warning letters

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The Drug Supply Chain Security Act (DSCSA) outlines requirements for pharmaceutical manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers.

PRESENTED BY:

Ms. Thomas has over two decades of cGMP hands-on industry experience in both pharmaceutical and medical device manufacturing operations. Her experience covers all Quality Systems; as well as, all areas of validation; including, process/product validation, facilities validation, CSV and 21 CFR Part 11, test method validation, equipment/automated processes and cleaning validation.

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Duration : 90 Minutes

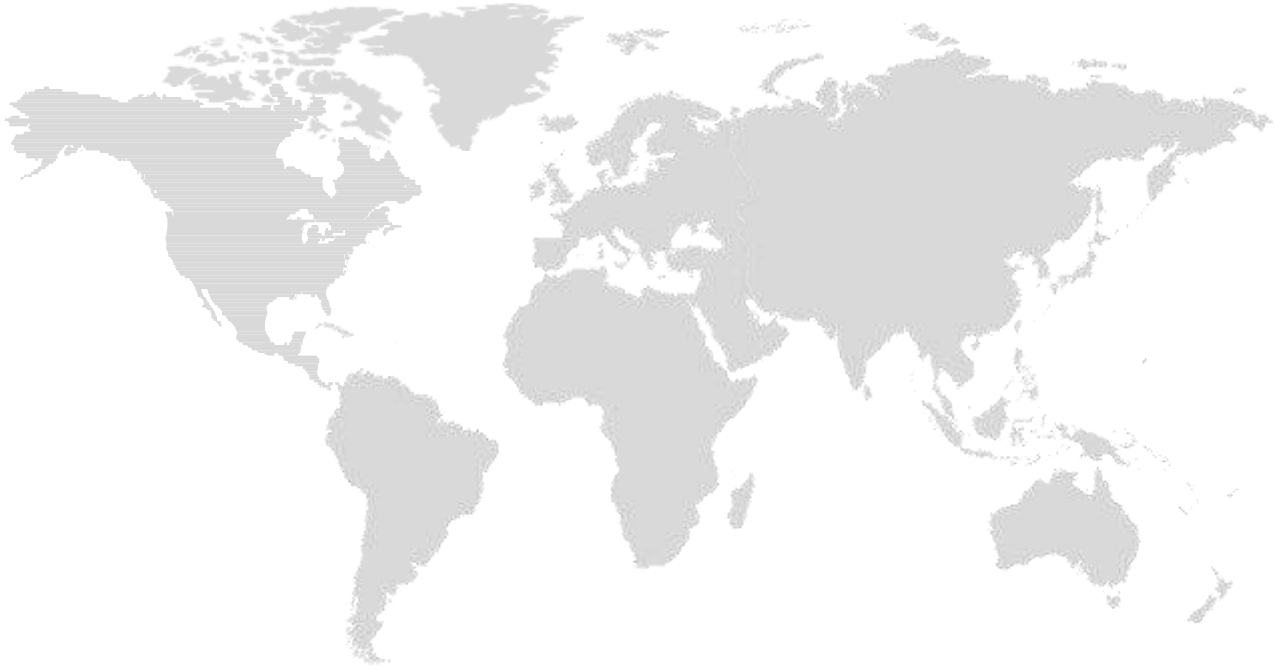
Price: $200

Webinar Description

The Drug Supply Chain Security Act (DSCSA) outlines requirements for pharmaceutical manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers. Some requirements began in November 2014 and several key requirements began at various stages in 2015. The requirements, development of standards, and the system for product tracing will continue to be phased in until 2023. However, it has become clear that many organizations are currently not in compliance with the Act, and are not prepared to be compliant with the requirements that are soon-to-come.

FDA will continue working with the industry to effectively implement the requirements. As the Drug Supply Chain Security Act's (DSCSA) key requirements continue to take effect, the FDA has begun enforcement.

Who Should Attend ?



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