GLOBALIZATION:
CHALLENGES AND SOLUTIONS

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THIS PRESENTATION WILL ADDRESS THE FOLLOWING TOPICS:

• Overview of Globalization

• How to implement Efficient Compliant Quality Systems Using Risk Management Tools and Techniques

• How to implement Global Medical Products Quality and Supply Chain Integrity

• How to establish a Quality-by-Design (QbD) approach to Medical Product Audits
OVERVIEW OF GLOBALIZATION

- Increase in foreign production of FDA-regulated medical products and materials
- Origin from various countries (manufacturers, importers, wholesalers) of FDA-regulated products
- Increase in FDA-regulated products shipments entering US ports
- Challenges in regard to FDA-regulated Supply Chains
GLOBAL SUPPLY CHAINS

• Geographic increase of number of individuals, producers and companies
• Growing availability of distribution channels for products (e.g., advertisements, internet)
• Growing compromised integrity
CHALLENGES OF GLOBALIZATION AND GLOBAL SUPPLY CHAINS

• Challenges for the FDA’s domestic and international affairs

• Transformation of domestic safety issues into global environments

• Need for preventive quality controls throughout the supply chains in rapidly changing global environments

• Need for partnership liaisons with others to achieve the acceptable levels of safety and security

• Development of a mechanism to combat counterfeit and substandard products

• Coordination with World Health Organization (WHO) global surveillance and monitoring system
CRITICAL PATHWAYS TO GLOBAL PRODUCT SAFETY AND QUALITY

• Uniform access to global product inspection data base and network systems

• Enhance partnerships with global coalitions of regulators to ensure global product safety and quality

• Initiate critical paths on combined efforts of various governments, industries, public and private third-parties

• Global collaboration of standards harmonization to address product safety and quality
QUALITY RISK-BASED MONITORING AND INSPECTIONS

- ISO 31000 Risk Management document is designed to help global organizations
- ISO 31000 and ISO Guide 73 can be useful for any global enterprise group or individual organization
- These documents can be useful for implementing risk analysis within any global organization responsible for implementing risk management
- These documents can be useful for developers of global standards, guides, procedures and codes of practice
ISO 31000 IS DESIGNED TO ASSIST ORGANIZATIONS

- For establishing a reliable basis for planning and decision making
- Application of quality controls
- Effectively assign and use resource management for risk treatment
- Improve global operational efficiency and effectiveness
- Enhance health and safety performance parameters, as well as, environmental protection
- Minimize losses, improve loss prevention and incident management
This document provides Application of Risk Management principles, including preliminary Hazard Analysis techniques. It addresses:

- Materials used or produced and their respective reactivity
- Equipment used in process controls
- Operating environment
- Design and facility layout
- Interface among system components
ISO 14971 – GLOBAL HAZARD AND OPERABILITY STUDIES

- Addresses accidents caused by process deviations from the design of studies
- Emphasizes team approach
- Addresses Fault Tree Analysis, top down / bottom up approaches to risk management
ISO 14971 – SEVERITY DETECTION CRITERIA

Provides guidance for establishing worksheets, severity criteria and detection limits for acceptability, medical intervention, life-threatening injuries and catastrophic events
HOW TO IMPLEMENT GLOBAL MEDICAL PRODUCTS QUALITY AND SUPPLY CHAIN INTEGRITY

• Quality Systems Approaches to Auditing for Compliance

• Preparing for the global Audit Tools and Templates

• Auditing and Data Capture process control (This involves use of a standardized approach to global statistical sampling guidance for overall audit quality)

• This effort will involve developing and implementing plans and procedures for geographical global corrective action and verification

• Guidance need to be developed and implemented for monitoring purposes in collaboration with respective countries
ESTABLISHING A QbD APPROACH TO MEDICAL PRODUCTS IN THE GLOBAL ENVIRONMENT

• QbD approaches may involve training in regard to regulatory perspectives of each geographic location

• May involve harmonized compliance and inspectional strategies

• May integrate Bio-research Monitoring (BIMO) and Enforcement activities into a global network

• Specialized training may be needed on Six Sigma Quality Design and process improvements

• Guidance and standards may be needed for Manufacturing Methods and Processes for Pre-Approval Inspections
CONCLUSION

• FDA-regulated products are beginning to play a pivotal role in and around the borders and in global environments

• Globalization presents global safety concerns in today’s complex challenges with supply chains and channels

• Globalization requires multifaceted strategic solutions