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Sterilization and Sterility Assurance in Medical Device Packaging

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Patient safety is the primary concern in medical packaging. When we think about packaging, we may immediately be concerned with straightforward patient communication and transparency. However, patient safety in packaging starts way before the words are ever printed on the package or label. Today we are going to discuss the nuts & bolts around “Selecting medical device packaging materials and sterilization methods to achieve appropriate sterility assurance levels and sterile barrier integrity throughout the labeled shelf life.” We have invited Roberta Goode to help us understand the intricacies of this process.

Resources from this episode:

- Planes, Trains, and Automobiles: Simulated Distribution of FDA-Regulated Products for Packaging Validation - Journal of Validation Technology - http://www.ivtnetwork.com/sites/default/files/Planes, Trains, and Automobiles - Simulated Distribution of FDA-Regulated Products for Packaging Validation.pdf
- ISO 14971:2019 Medical devices – Application of risk management to medical devices - https://www.iso.org/standard/72704.html
- ISO 24971:2020 Medical devices – Guidance on the application of ISO 14971 - https://www.iso.org/standard/74437.html
- ISO 11607:2019 Packaging for terminally sterilized medical devices - https://www.iso.org/standard/70799.html
- ISO 13485:2016 Quality Management System for medical devices - https://www.iso.org/standard/59752.html
- 21 CFR 820 Quality System Regulation - https://www.govinfo.gov/app/details/CFR-2011-title21-vol8/CFR-2011-title21-vol8-part820
- ASTM D4169 -16: Standard Practice for Performance Testing of Shipping Containers and System - https://www.astm.org/DATABASE.CART/HISTORICAL/D4169-09.htm
- ISTA 2a: Partial Simulation Performance Tests - https://ista.org/test_procedures.php