IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY | an informa business
Unlimited Validation Knowledge Awaits...
Published on *IVT Network* (http://www.ivtnetwork.com)

Combination Products: Successful Product Development & Regulatory Anticipations & Complexities




By **A Golden**, **B eibowitz**, **Kurt L. Moyer**, **Roberta Goode**

Jun 1, 2021 7:00 am EDT

Combination products are everywhere. As increasingly more enter the market we are continuously questioning the unique strategies necessary for development of a product across multi-disciplinary teams. Staying up to date with changing patient needs, monitoring emerging global regulatory requirements and efficiently delivering high-quality products is only a small part of it – and now you need to do this, and more, times two! Today we have invited an expert panel of industry professionals to join us in this discussion as we highlight key concepts for drug/device combination products, best practices for adoption of 21 CFR Part 4, supply disruptions, and, of course, global regulatory variances.

Listen in to our highly esteemed panel of experts: Becky Leibowitz from Janssen, Kurt Moyer from Pine Lake Laboratories, and Alan Golden from Design Quality Consultants. Facilitating that discussion will be our moderator, Roberta Goode.

Resources for THIS Episode:

- EU Medical Device General Safety and Performance Guidance – MDR -
- ANNEX 1 Guidance
- FDA 21 CFR Part 4 – Subpart A – Current GMP for Combo Products
- FDA 21 CFR Part 4 – Subpart B Post-marketing Safety Reporting for Combo Products
- ICH Q9 QRM Guidance
- ISO 10993 – 2018
- ISO 11607 Sterile Barrier