Combination Products: Successful Product Development & Regulatory Anticipations & Complexities - PODCAST




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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