WEEKLY SUPPLEMENT: WEEK ENDING APRIL 26, 2024

IPQ

INTERNATIONAL PHARMACEUTICAL QUALITY

Inside the Global Regulatory Dialogue

CURRENT INSIGHTS FROM LEADING REGULATORS

FDA's Lawrence Perez Reviews Key CMC Challenges for Synthetic Oligonucleotides at USP Peptide/Oligo Workshop

At the opening session of the 2024 USP peptide/oligo workshop, held at USP's Rockville, Maryland headquarters in April, FDA Office of Pharmaceutical Quality (OPQ) Senior Pharmaceutical Quality Assessor Lawrence Perez discussed the CMC challenges the agency has been seeing in reviewing synthetic oligonucleotide therapeutics. His presentation covered: • defining synthetic oligos, and the different classes that have been approved • the specification of the API's identity, purity, and assay, and • manufacturing issues, including starting materials, API sameness for generics, and platform technologies.

UPDATES IN BRIEF: GLOBAL CMC/GMP DEVELOPMENTS

• TGA Update on Nitrosamine Impurities Acceptable Intakes • DRAP Post-Registration Variation Guidelines for Pharmaceutical and Biological Products • FDA FY 2022 Annual Report on the Status of PMRs and PMCs • EMA Recommendations to Strengthen Supply Chains of Critical Medicines • FDA Udated Biosimilars Action Plan, and BsUFA Milestone • FDA Guidance on Composition Statements and Corresponding Labeling in NDAs and ANDAs • USP April Announcements, including New Chapters on Iron Colloidal and Microsphere Products • APIC Best Practices Guide for Managing Suppliers of API Manufacturers, and 2023 Annual Report • Philippine Guidelines on Import/Export Notifications for Drug Products and Raw Materials

FDA DRUG GMP WARNING LETTERS AND EMA NCRs

There were no FDA drug GMP warning letters nor EMA non-compliance reports posted during the week.

FDA DRUG RECALLS

Among the six recalls posted in FDA's enforcement report during the week, two drew the most serious, Class I, rating. One of these involved one lot of non-sterile product, atovaquone powder, for potential *Bacillus cereus* contamination. The second recall involved four lots of superpotent vancomycin liquid due to the overfilling of drug powder.