

MONTHLY UPDATE - MARCH / APRIL 2022 IN REVIEW

Pandemic Experience and Supply-Chain Risk Management Expectations Increase Attention on Excipient GMP Third-Party Auditing... [p. 4](#)

Progress in Addressing Impurity Challenges in Focus at USP's 2022 Peptide/Oligo Workshop... [p. 19](#)

- US and European Regulator Perspective on the CMC Challenges of Oligonucleotides..... [p.20](#)
- USP Standards Development Efforts for Peptides and Oligos..... [p. 43](#)
- Peptide and Oligo Analytical, Manufacturing and Raw Material Considerations..... [p. 55](#)

UPDATES IN BRIEF..... [p. 57](#)

US: • PQ/CMC Project • CDER Data Management MAPP • Data/Technology Modernization • OPQ Quality Management Maturity • Quality Metrics Program • ICH M7(R2) • GDUFA Science and Research • Generic Drug Science and Research • OGD Complex Generics MAPP • Ophthalmics Guidance • Bio-INDs MAPP • Biosimilar/Interchangeable Products • Gene Therapy Guidance • CAR-T Guidance • Nanomaterials • pH Adjuster Waiver Requests • Inactive Ingredient MDE • CDER Hand Sanitizer Testing • Outsourcing Facility Inspections • DSCSA Verification • Importation Requests • Voluntary Recalls • CBD Warning Letters • Skin Lightening Warning Letters • NAC Guidance • USP Supply Chain Map • USP Analytics for Metals, Viral Vector Vaccines, and Botanical Micro • Accelerated Approval Integrity Act

EUROPE: • EU Legislation on EMA Processes • EMA on ICH Q9 (R1) Comments • EMA Post-Authorization Guidance • EMA GMDP Inspectors Working Group • EMA Nitrosamine Q&A • EMA on Herbals • Swissmedic GMP Certificate Extensions • MHRA Inspection Action Group Pilot • MHRA Health Technology Assessments • EDQM Certifications • Ph. Eur. CEP Submissions • Ph. Eur. On Analytical Comparability

INTERNATIONAL: • ICH Q2(R2) and Q14 • WHO on Egypt and Nigeria • IPEC Nitrosamine Guide • TGA Medicinal Cannabis • India Pharma Strengthening

FDA WARNING LETTERS AND RECALLS, EMA NON-COMPLIANCE REPORTS POSTED IN MARCH AND APRIL..... [p. 64](#)