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**NOTE FROM IPQ'S EDITOR-IN-CHIEF: The first story in our March/April issue *(pp. 4-18)* explores how the pandemic experience and the increasing expectations of regulators and industry regarding supply chain visibility and risk-management are driving the incorporation of more third-party auditing of excipient suppliers into user quality management systems. The story centers around an IPEC webinar on the developments in third-party auditing, with insights on how IPEC's guidance efforts have provided support. More recently, these efforts have included a "GMP Certification Scheme and Certification Body Qualification Guide," published in 2020, and an audit guide on excipient good distribution practices (GDP), revised in 2021.**

**Provided are insights from leading experts on the full spectrum of the third-party GMP auditing and certification process – with experience, learnings, and benefits shared by scheme owner EXCiPACT, the certified body SGS, excipient maker Dow, and excipient user Novartis.**

**The second story *(pp. 19-56)* explores the light shed at the 2022 USP peptide/oligonucleotide workshop on the effort of stakeholders to keep pace with the innovation in the peptide/oligo arena, including: • novel modifications, conjugations, and chemistries • novel formulations • the emergence of platform technologies • advanced analytical strategies and tools • supply chain advances, and • in the case of oligonucleotides, the emergence of generic and personalized therapies.**

**Part one of the three-part story provides the US and European regulator perspectives on the CMC challenges of oligonucleotides, offered at the opening session.**

**The second part focuses on the developments in compendial standards related to oligos and peptides and how the USP engagement has been expanding – discussed by two USP experts at the workshop. They highlighted: • recent updates in the peptide monographs, and • the development of standards for oligos and how USP has prioritized those for phosphoramidites, which serve as a critical starting material for oligo synthesis.**

**Part three reviews the discussions held over days two and three. These focused on analytical tools to ensure peptide/oligo quality, and manufacturing and raw material considerations, respectively. During these discussions, further light was shed on the impurity issues, which were a dominant focus at this year's USP workshop.**

**Of note in our "*Updates in Brief*" section in the March/April issue *(pp. 57-63)* is additional guidance from FDA on its data management procedures, complex generic drug classification, ophthalmics, Bio-INDS, the development of gene therapy, CAR-T, and nanomaterial products, importing unapproved products, and implementing voluntary recalls. EMA, meanwhile, addressed post-authorization issues, nitrosamines, and herbal production. Internationally, ICH released its analytical procedure guidelines Q2(R2) and Q14 for public consultation, Australia's TGA a guidance on medicinal cannabis, and India's DoP on pharmaceutical industry strengthening.**

**Pharmacopeial developments included the release of USP's findings from its medicine supply chain mapping effort and a Ph. Eur. request for input on its new general text on analytical procedure comparability.**

**There were 15 drug GMP warning letters posted by FDA during March and April *(pp. 64-74)*. Two of these went to US-based companies compounding sterile products without adequate controls. Others to US firms dealt with the production of products that did not meet OTC drug marketing requirements – including two skin bleaching products containing hydroquinone. Another ten firms producing skin bleaching products received warning letters that did not include CGMP findings *(see listing of other FDA warning letters on drug-related concerns on p. 75 and the related news brief on p. 60)*. Four of the other US-based WL recipients had hand sanitizers among their product mix. The letter going out internationally went to a Polish OTC producer based on an unsatisfactory records request response.**

**EMA posted a GMP non-compliance report issued at the beginning of April based on an inspection conducted remotely of Emergent BioSolution's manufacturing facility in Baltimore, Maryland that had been making viral vector drug substance for Janssen's COVID vaccine *(p. 76)*. The Belgian agency doing the assessment concluded that the process control was inadequate and proposed a recall and a prohibition of the J&J vaccine in EU markets with drug substance originating from the facility.**

**The leading reasons among the 67 recalls appearing on FDA's listings during March and April *(pp. 77-82)* were GMP non-compliance and not meeting potency/content uniformity specifications – with 16 recalls appearing in both categories. Labeling and packaging problems accounted for 11 recalls, two of which received a Class 1 designation. There were three Class 1s among the nine impurity-related recalls – two involving hand sanitizers, and one an injectable with silica and iron oxide particulates. All three of the recalls related to NDA/monograph compliance were rated Class 1 – involving dietary capsule products with sildenafil or tadalafil.**