IPQ
INTERNATIONAL PHARMACEUTICAL QUALITY
Inside the Global Regulatory Dialogue

CURRENT INSIGHTS FROM LEADING REGULATORS

MHRA's Chief Partnerships Officer Explains How the Agency Is Supporting Sustainability

At the DIA Europe Conference, held in Brussels in mid-March, MHRA Chief Partnerships Officer Glenn Wells gave an opening keynote presentation on the agency's role in supporting sustainability and Net Zero goals. He discussed: • British Pharmacopoeia sustainability initiatives • UK medical device regulation provisions • the role of MHRA and its place in the UK system for healthcare and sustainability, and • national and international collaboration.

UPDATES IN BRIEF: GLOBAL CMC/GMP DEVELOPMENTS

• FDA Guidance on Data Integrity for In Vivo Bioavailability and Bioequivalence Studies • FDA Guidance on New Dietary Ingredient Notification Master Files for Dietary Supplements • OPQ 2023 Annual Report • TGA Assessed Listed Medicines Guidelines • TGA Updated Recall Procedure • HHS White Paper on Preventing Drug Shortages • EDQM March Reference Standards and Replacement Batches • EMA Committee on Herbal Medicinal Products Activities

FDA DRUG GMP WARNING LETTERS

Company	Facility Location	Product Type
Betone	Mexico	Finished
Bodywell Natural Skin Care	Canada	Finished

FDA DRUG RECALLS

Among the five recalls posted in FDA's enforcement report during the week, one drew the most serious, Class I, rating. It involved the presence of particulate matter in treprostinil for injection.

OTHER IPQ CONTENT RELEASED DURING THE WEEK

IPQ's November/December Monthly Update contains the full five-part story on pharma's evolution from a compliance to a risk-based control strategy orientation, along with *Updates in Brief,* FDA warning letters, EMA NCRs, and FDA drug recalls that were posted at IPQ.org during the two months.

INTERNATIONAL PHARMACEUTICAL QUALITY provides in-depth coverage of emerging drug, biologic and combination product CMC and GMP issues and developments with a mission of helping advance and harmonize the quality regulatory process globally. Headquartered in Washington, D.C., IPQ is read by regulatory agencies, manufacturers, suppliers, consultants, law firms, and universities around the world.

IPQ tracks the industry/regulator dialogue at key international forums along with the developments, initiatives, regulations, guidances and standards in the quality regulatory arena to create a uniquely valuable resource for the intelligence gathering and knowledge management needs of the pharmaceutical community.

IPQ's "actionable intelligence" is particularly valuable for thought leaders and decision makers who need to have a deeper understanding of the issues and their context to help shape regulatory policy and develop implementation strategies. Subscriber support allows IPQ, in turn, to make an important contribution to the efforts of key non-profit associations and public service organizations engaged in addressing the increasingly complex manufacturing and regulatory challenges for medicines in the global context.

IPQ is published online, and the substantial archive at IPQ.org is easily searchable through its keyword search indexes. Links to documents referenced and cross-links to related previous IPQ coverage in the area are included, allowing readers to quickly dig as deeply into an issue and its context as needed.

IPQ's ***"News Alerts"*** provide links to the first few paragraphs of the stories newly posted online. Subscribers and license holders can click through to the full stories.

The ***"Monthly Updates"*** provide the stories that went online during the month in a print-friendly PDF format, and are an easy way for subscribers to keep up with the critical developments impacting the quality regulatory process worldwide. Included are ***"Updates in Brief"*** on recent CMC/GMP developments of note with links to the referenced documents and to our related in-depth analysis. Also included is an annotated listing of FDA drug GMP warning letters and recalls as well as EU GMP non-compliance statements posted during the month.

MHRA's Chief Partnerships Officer Explains How the Agency Is Supporting Sustainability

The opening plenary session of the mid-March DIA Europe Conference provided an opportunity for the UK's Medicines and Healthcare products Regulatory Agency (MHRA) Chief Partnerships Officer Glenn Wells to highlight the challenges in defining the regulator's role in promoting sustainability and to explain how MHRA is navigating those challenges in support of the "Net Zero" cause.

> **"Our job as a regulator is to look at safety, quality, and efficacy. We do not, for example, regulate Net Zero directly," Wells explained.**

However, he noted, "we can try and influence behaviors through our regulations," and "we do have influence where our activities touch other parts of any innovation ecosystem, whether in the UK or internationally."

One of those touchpoints is the relationship between the MHRA's role as a regulator and the British Pharmacopeia (BP), which the MHRA is responsible for.

Wells discussed: ● British Pharmacopoeia (BP) sustainability initiatives ● UK medical device regulation provisions ● the role of MHRA and its place in the UK system for healthcare and sustainability, and ● national and international collaboration. ***[Wells' full remarks are appended below.]***

> **The BP, he noted, serves a "global community" and "has recently embarked on a series of initiatives to review and reduce our carbon footprint."**

Pointing to some of the internal efforts to reduce the use of hazardous solvents in monographs, repackage reference standards into cardboard cartons, and recycle mobile phases in analytical techniques, Wells also highlighted the external stakeholder work on the BP "Sustainability Information Pack," which was published in March.

"We have to understand from events such as these and engagement with the community what we need to do — and what we perhaps don't need to do — to get out of the way and let innovation flourish."

He challenged the audience with questions about the regulator's role in supporting the efforts of others involved in sustainability initiatives at a national and international level. "It is going to be a team effort, like innovation. We are innovating in this space. We have to work with everybody else."

Opening Plenary Underscores Importance of Partnerships for Sustainability

Keynote speakers and panelists in the DIA Europe opening plenary session underscored the critical role of partnerships between stakeholders across the healthcare ecosystem for progress toward sustainability goals — including industry, regulatory agencies, value experts, investors, and patients.

> **Offering an industry perspective, UCB Global Head of Sustainability Corporate Affairs and Risks Véronique Toully gave a call to action for an integrated approach to sustainability issues that "harmonizes both the social and environmental agendas."**

She commended the European Green Deal for the approach toward a "fair, prosperous, and environmentally responsible society," aiming for: ● no net emissions of greenhouse gases by 2050 ● economic growth decoupled from resource use, and ● "no person and no place left behind."

After outlining the efforts at UCB in valuing both patients and the planet through scientific innovation, access to medicines, and controlling CO_2 emissions — including those of suppliers – Toully asserted that further progress will require integration of "different, and sometimes contradictory perspectives."

To address the challenges of bringing diverse stakeholders together, the final keynote was given by Partnership Brokers Association Partnerships and Sustainable Development Specialist Leda Stott, who explained that sustainable partnerships are "multidimensional relationships that promote transformation by addressing complex challenges holistically and creatively."

In remarks that were referred to throughout the rest of the conference, Stott highlighted the key principles required to build sustainable partnerships: ● respect ● diversity ● equity ● transparency ● mutual benefit ● balance ● courage, and ● learning. ***[Editor's Note: Stott's full comments on partnerships will be included in an upcoming IPQ story.]***

The opening plenary session concluded with a panel discussion moderated by Sustainable Healthcare Coalition Chair Fiona Adshead. The panel shared insights and perspectives from health technology assessment bodies, patients, and investors on encouraging sustainability initiatives. Adshead also chaired a plenary session on the final day of the conference, in which industry and regulatory agency representatives discussed the urgent need for broad action to reduce the environmental impact of healthcare.

DIA Session Considers Sustainability and CMC

Among other DIA sessions focusing on sustainability was a CMC session co-chaired by European Federation of Pharmaceutical Industries and Associations (EFPIA) Director for Science Policy Kirsty Reid and GSK CMC Excellence Senior Director Matt Popkin. Popkin serves as vice chair of the EFPIA Manufacturing and Quality Expert Group.

The session was a follow-up to the DIA Europe 2023 session on CMC sustainability, which highlighted issues around the potential ban of titanium dioxide in medicinal products and restriction on the use of per- and polyfluoralkyl substances (PFAS) in pharma manufacturing.

Speakers from the European Commission, industry, EMA and the European Directorate for the Quality of Medicines & HealthCare (EDQM) discussed the impact of the European Green Deal on the continuity of pharma R&D and manufacturing in Europe.

In the presentations and ensuing panel discussion, participants shared their insights into how manufacturers and regulators can collaborate to deliver on the EU Green Deal "revolution" without risks to the supply of medicines. ***[Editor's Note: See IPQ June 11, 2023, and July 21, 2023, for an in-depth analysis of the impact of proposed changes to EU legislation on the pharma industry. An upcoming story will review the DIA Europe 2024 CMC sustainability session.]***

BP Publishes Sustainability Information Pack

The BP Environmental Sustainability Information pack released in March is openly available on the BP website and is intended to be a "living document." It is focused on reducing the environmental impacts associated with quality control testing, and, as such, "predominantly applies to a laboratory setting."

The 36-page document outlines efforts being led by BP and industry to work towards greener, more environmentally friendly practices. Chapter 1 covers "laboratory, facilities and management." The second chapter is on testing methods and solvents. Chapter 3 focuses on monitoring and measuring "greenness."

Eleven case studies are provided in the initial version with the expectation that more will be added. The information pack cautions that sustainability initiatives that work in one laboratory under one set of conditions may not be transferable and that relevant regulatory requirements must still be met.

BP SUSTAINABILITY INFORMATION PACK PURPOSE AND LIST OF CASE STUDIES

Below is the description in the BP Environmental Sustainability Information Pack of its purpose and a list of the initial case studies provided in it. Minor edits and formatting changes have been made by IPQ. A link to the BP website for the full information pack is provided below.

Purpose of the Information Pack

In 2019, the UK Government committed to net zero greenhouse gas emissions by 2050 and healthcare contributes approximately 5% of the UK's emissions. Recent reports, such as from the Office of Health Economics, highlight the joint action that needs to be undertaken by the UK government, the NHS and industry, in order to tackle healthcare's carbon footprint.

In the 2022 Annual Report, the Medicines and Healthcare products Regulatory Agency (MHRA) committed to reducing its carbon emissions and adopted several Net Zero ambitions to meet targets set in the 2021 Greening Government Commitments. These ambitions span from achieving a net zero building estate to reducing water consumption and minimising waste by embracing a 'circular economy'.

Whilst these ambitions are internally focused, following initial consultation with interested stakeholders, the British Pharmacopoeia (BP) Secretariat has developed this environmental sustainability information pack as a starting point, for BP users and other relevant professionals, to encourage and support the adoption of more sustainable practices where appropriate.

As detailed in section 2.1, collaboration, culture, and advocacy are important actions to drive forward sustainability alongside more practical measures. This information pack is the BP's initial step in outwardly advocating for sustainable changes where possible. This information pack aims to support industry's efforts in reducing environmental impacts through:

- **Uniting the sector's action and ambition behind sustainability.**
- **Identifying key challenges and priority areas to focus efforts.**
- **Convening sustainability information and case studies of sustainability changes.**
- **Facilitating compliance with the BP to be maintained through any sustainability changes.**

Environmental impacts occur throughout the lifecycle of biotechnological and pharmaceutical products. However, given the remit of the BP, this information pack is focused on reducing the environmental impacts associated with quality control testing and so predominantly applies to a laboratory setting. Various types of laboratory settings exist, such as from research and development to diagnostic laboratories. Whilst this information pack has general principles applicable to all laboratories, there is a particular focus on greening analytical laboratories.

Case Studies

Case studies have been collated from an open call for contributions that went up on the BP website. Case studies on internal practices have also been included. We would welcome receiving further case studies to incorporate into future iterations of this document. Please see our page on how to provide case studies.

Case study 1 – MHRA replaces old freezers

Case study 2 – BP Chemical Reference Substances Packaging Change

Case study 3 – Solvent recycling and repurposing

Case study 4 – Digital tools in analytical method development

Case study 5 – Harmonising analytical methods

Case study 6 – Scaling column dimensions

Case study 7 – Recirculating solvents to reduce waste

Case study 8 – Alternative solvents for liquid-liquid extraction

Case study 9 – Modernisation and use of alternative solvents for chromatographic methods

Case study 10 – Reducing the use of chloroform in BP monographs

Case study 11 – Measuring greenness to optimise methods

LINK:

- BP Environmental Sustainability Information Pack

[Subscribers CLICK HERE for Wells' complete remarks at the DIA Europe Conference.]

IPQ'S IN-DEPTH COVERAGE RELEASED SINCE 2020

The following are the headlines of the in-depth stories that IPQ has released since 2020. The topic headings for parts of a larger multipart story are included. The stories are listed in reverse chronological order. Readers of the Weekly Supplement can then click though to those that are of particular relevance to the regulator presentation, news briefs, and compliance information featured in the issue. Those of particularly high relevance to the Weekly regulator story are indicated with a red star.

2024

The Challenges of Evolving Pharma from a Compliance to a Risk-Based Control Strategy Mindset Are Drawing Conference Spotlight

- Critical Thinking in Risk Management and Data Governance
- Quality Culture/Oversight in Aseptic Operations
- Takeda's Annex 1-Based Global CCS Program
- QRM Tools in Root Cause Analysis
- Annex 1 Revisions and the CCS Implications

2023

CMC Innovation Support Programs Advance at EMA and FDA, with Distributed and Continuous Manufacturing on Front Burner

- European Regulatory Network Support for Manufacturing Innovation
- FDA's Expanding Engagement with Advanced Technologies
- Barriers to CM Adoption Explored at USP/RAPS Workshop
- Distributed/POC Manufacturing and the CMC/Quality Regulatory Paradigm

Implementing ICH Q9(R1) Will Entail a Heightened Focus on Integrating Knowledge into Risk-Based Decision-Making

- Insights from Expert Working Group Members on ICH Q9 Revisions
- Panel Discussion Among PRST Meeting KM/QRM Experts
- Risk-Based Decision-Making
- Risk Management in Drug Shortage Prevention

★ **Industry is Urging EMA to Increase its Focus on Medicine Impact of EU Food, Chemical, and Environmental Legislation**

- The Need for Pharma Stakeholder Engagement
- EU PFAS Action and Pharma Mitigation Needs
- Industry and EMA on F-gases and Hydrofluorocarbons in Inhalation Products
- DIA Europe Legislative Session Panel Discussion
- Intensified Industry Dialogue on TiO2 and Nanoparticles Ahead of More EMA Review

★ **IPEC is Helping Marshal Expertise Across Stakeholders to Forestall a Potential TiO_2 Ban in Pharmaceuticals**

USP Continues to Refine Its Strategies for Keeping Pace with and Supporting the Rapidly Advancing Biotechnology in the MAb, Vaccine and CGT Arenas

- USP Bio Stakeholder Forum Opening Remarks and Mass Spec Standards for Proteins
- USP's CGT Initiatives
- FDA and Industry Experience with CAR T Potency Testing
- Update on USP Strategies and Initiatives in the MAb, Vaccine, and CGT Arena

Government/Industry/Academia Collaborative Efforts to De-Risk and Accelerate Manufacturing Innovation Draw Strength from Pandemic Learnings

- NIIMBL and its "Going First Together" Mantra
- US Manufacturing Innovation Leaders Weigh In
- The Importance of Process and Facility Innovation in Global Health
- Charting the Advanced Therapy CMC Pathways and Other NIIMBL Projects
- CBER's Marks on Taking CGTs to the Next Level

ICH Q3D Implementation Continues with Workshops, Research, and Guideline and Pharmacopeial Revisions

- Role of PQRI/FDA Workshop in Q3D Implementation Dialogue
- Regulatory Experience and Perspectives in Implementing Q3D
- Pharmacopeial Harmonization with ICH Q3D
- Outcomes of PQRI Study on Variability in Elemental Impurity Analysis

2022

Strengthened European Regulator Support for Advanced Technologies Includes New EMA Quality Innovation Group

- Europe's Focus on CMC Innovation and Agile Regulation
- Innovation Issues Explored at CASSS CMC Forum in Europe
- MHRA's "New Era in Regulation"

EMA Toolbox on CMC Flexibilities has been Evolving to Incorporate Industry Input and Learnings from the Pandemic

- EMA Perspective on its Toolbox Guidance and OPEN Initiative
- Industry View on Efficiency Tools and CMC Flexibility Learnings from COVID
- Panel Discussion on Effective Tools for the Future

CBER's Advanced Technologies Program Growing Stronger with Increased Funding, Expertise, and Collaboration

mRNA-LNP Vaccines Spur Global Dialogue on Nanomaterial Standards and Regulatory Approaches

- Pfizer/BioNTech Lipid Challenges with mRNA-LNP COVID Vaccine
- FDA's Novel Excipient Review Pilot Program and Nanomaterials Guidance
- USP's Draft Guideline and Other Efforts on mRNA Vaccine Quality
- The EDQM Nanomedicines Dialogue and WHO on Regulating mRNA Vaccine Quality
- Potency Assays for mRNA-LNP Vaccines

NASEM-Led Study for FDA is Helping Drive Industry/Regulator Agenda on Innovation Needs

- The NASEM Study and FDA Reflections
- Existing Mechanisms to Enable Innovation
- Challenges and Opportunities
- The Path Forward

Pandemic Experience Showcases the Potential for Faster Innovation, More Collaboration, and Workplace and Operations Modernization

- The Evolving Landscape of Pharmaceutical Operations
- Government-Industry Collaboration in This and Future Pandemics
- Reducing the Cost of Vaccine Manufacturing for Broader LMIC Access

Progress in Addressing Impurity Challenges in Focus at USP's 2022 Peptide/Oligo Workshop

- US and European Regulator Perspective on the CMC Challenges of Oligonucleotides
- USP Standards Development Efforts for Peptides and Oligos
- Peptide and Oligo Analytical, Manufacturing and Raw Material Considerations

Pandemic Experience and Supply-Chain Risk Management Expectations Increase Attention on Excipient GMP Third-Party Auditing

Janet Woodcock and Jeff Baker will Continue to Play Key Manufacturing Innovation Roles in New FDA and NIIMBL Positions

FDA's KASA and Related PQ/CMC Initiatives on Improving CMC Data Structuring and Sharing Will Help Support ICH M4Q Revision

- The Advancing Knowledge-aided Assessment Component of KASA
- Bringing Biologics into the KASA System
- The Progress of FDA's PQ/CMC Initiative
- The Goals of Accumulus Synergy in CMC Data IT and Regulatory Communication
- The Drivers for Revising ICH M4Q and Evolving the CMC Regulatory Process

Key GMP Focal Points in Europe Include Guidance Revisions, New Vet Regulations, and Adaptive Assessment/ Inspection Approaches

- Update on EMA GMP-related Activities
- MHRA Innovation Pathway and Proposal for Point-of-Care Regulatory Framework
- Insights from Europe and ICMRA Regarding Onsite Inspection Alternatives

2021

USP and Ph. Eur. Initiatives in the Biologics Arena Continue to Bear Fruit; FDA Joins the Pharmacopeias in Upgrading Particulate Guidance

- Update on USP's Evolving Role and Current Initiatives In the Biologics Arena
- European Pharmacopoeia and FDA Join USP in Focusing on Particulate Control

COVID Vaccine Industry Project Leaders Are Sharing Insights on How the Daunting CMC Challenges Were Addressed

- Implementing the Pfizer/BioNTech mRNA Vaccine Development Plan
- New Digitalized Facility as Springboard for Moderna's mRNA Vaccine
- Oxford University/AZ Partnership for Global Adenovirus Vaccine Access
- J&J's Experience in Handling the Supply Chain Challenges
- Novavax's Approach to Assuring Comparability for its Protein-based Vaccine
- Inter-Company Panels at DIA and ISPE Meetings on Vaccine Experience

Biomanufacturer Raw Material Control on Regulatory Front Burner as Analytical Power and Formulation Challenges Intensify

- Biotech Regulator Vantage Point on Raw Material Control
- The Added Challenges of Materials Management for CGTs
- Biomanufacturer Use and Control of Polysorbates

Manufacturing, Impurities, and Characterization Methods Are Key Regulatory Focal Points for Peptides and Oligonucleotides

- Recent CMC/Regulatory Challenges of Oligonucleotide Drugs
- Comparability Challenges in Crossing Over to Generics
- Comparing Peptide and Oligonucleotide CMC Issues
- Starting Material Specifications for Oligonucleotides

A Confluence of Forces Is Now Spurring Combination Product Regulatory Reform in Europe

- EU Pharma Strategy Roadmap, Comments from Industry, and Related Agency Strategies
- Culture/Structure/Process Change and Global Alignment
- HPRA CEO Lorraine Nolan on HPRA and EMA Strategy
- EMA's Zaïde Frias and NB/Industry Perspectives on EU Regulatory Transformation

Pandemic Urgencies Highlight Constraints in Manufacturing Change Regulatory Paradigm and Where Adjustments Are Needed

- Industry Quality Leaders on the Global PAC Regulatory Problem and Solutions
- Evolving the Quality Regulatory Paradigm at the Global Level

Regulators Are Exploring with Industry How to Strengthen Quality Risk Management Practices, with Revision of ICH Q9 a Key Focal Point

- ICH Q9 Revision Lead O'Donnell on the Evolution of QRM
- FDA's Rick Friedman on Advancing Aseptic Processing through QRM
- Industry/Academia Thought Leaders on the Evolving QRM/KM Relationship

★ **Regulators Share Pandemic's CMC Impact at CASSS Japan Forum; Guidance Output Continues Apace in Q1 2021**

- EMA Perspective
- FDA CBER Perspective
- FDA CDER Perspective
- Panel Discussion Among US, Europe, and Japan Regulators

Academia/Industry Collaboration Intensifies on Addressing the Pressing Needs in Biopharma Workforce Development

- NIIMBL's Engagement with Academia on Workforce Development Needs
- ISPE Workforce of the Future Traction at UMBC and UC Davis
- Keck Institute's Behrens on Biopharma Talent Needs and KGI/Industry Partnering
- Xavier's Phillips on Sharable Quality and Regulatory Science Curriculum
- CASSS Panel on Opening Up Biopharma Career Pathways
- European and Global Workforce Development Collaborations

Latest Improvements in FDA's Inactive Ingredient Database Include Change Log and Use of Maximum Daily Exposure

Recent Technology and Partnership Advances Made Possible Precision and Speed of Vaccine Response to Pandemic, NIAID's Graham Stresses at CASSS WCBP Conference

Pandemic Intensifies USP's Focus on Supply Chain Vulnerabilities and Vaccine Development

2020

Pandemic Spurs Deepening of Pharmacopoeia/Regulator/Industry Communication Channels

- EDQM Pandemic Actions Continue Apace in Fall 2020
- Pharmacopeia, Regulator and Industry Expert Panel Explores Pandemic and Nitrosamine Communications
- Second Panel Focuses on Pandemic Organizational Impacts and Key Learnings
- EDQM and Ph. Eur. Evolution Addressed by Leaders Keitel and Vielle

COVID Vaccine Global Distribution Challenges Explored by Bio Supply Management Alliance (BSMA) Panel of European Experts

Pandemic Stresses Increase FDA Attention on Risk Management Plans for Drug Shortage Prevention and Mitigation

USP's Global Efforts to Strengthen Standards and Accelerate Innovation for Biologics Include ICH Engagement

CBER Director Marks Traverses the Complex COVID-19 Vaccine/Therapy Regulatory Landscape at FDLI's Annual Conference

Stronger Unapproved Stem-Cell Enforcement Accompanies FDA Center for Biologics' Cell and Gene Therapy Advancement Efforts

Design-Based Development Paradigm for Cell/Gene Therapies Will Significantly Reduce Costs, Timelines and Regulatory Concerns, AGT CEO Galvin Maintains

Synthesis and Analysis Advancements Are Unleashing the Potential of Peptides and Oligos, Spurring CMC Regulatory Dialogue

USP Convention Meets Virtually in May 2020 to Review Upcoming Priorities, with Both 200-Year Legacy and Current Pandemic in Focus

COVID-19 Vaccine Urgency Throws Spotlight on Next-Gen Sequencing as Key Facilitator

- Adventitious Agent Testing in Focus at CASSS CMC Forum Europe
- Sanofi Pasteur and Ghent University Experience with NGS
- A Decade of Regulator/Industry Collaboration on NGS
- Stakeholder Engagement Begins on ICH Q5A Revision
- Effort to Reduce Animal Testing for Vaccines Includes Global Health Fund Support for NGS

NIIMBL Progress Includes Partnership with Biophorum on Buffer Mixing and Global Health Fund with Gates Foundation

Top FDA Drug Compliance Concerns during 2019 Included OTCs, Supply Chain Information Flow, Compounding, and Genotoxic Impurities

Existing Accelerated CMC, Advanced Manufacturing, and Inspection Initiatives are Supporting Regulators in Pandemic Response, FDA's Cruse Explains in Recent Field Office Updates

Attention Heightens on Creating an Independent Regulatory Pathway for Introducing Novel Excipients

- FDA'S Novel Excipient Program Proposal and Stakeholder Comments
- IPEC/IQ Thought Leaders on the Novel Excipient Drivers
- Subcutaneous Biotherapeutics, Pediatrics, and Delayed Release
- USP Initiatives Supporting Novel Excipient Development
- Assessing and Managing Excipient Risks

US/EU MRA Implementation, US Congressional Hearings, and Industry Surveys Shed Light on Global GMP Inspection Challenges and Collaboration Opportunities