IPQ
INTERNATIONAL PHARMACEUTICAL QUALITY
Inside the Global Regulatory Dialogue

CURRENT INSIGHTS FROM LEADING REGULATORS

FDA Europe Office 2024 Priorities for Medical Products Include Promoting Global Regulatory Convergence Around Cutting-Edge Technologies




At the DIA Europe Conference, held in Brussels in mid-March, FDA Europe Office leaders held a "Townhall" session where they spoke about the collaboration with EMA and the work of FDA's foreign offices, including the European Office. Participating in the session were FDA Liaison to the EMA Katherine Tyner, who introduced the session and discussed her role at EMA, and FDA Europe Office staff: ● Director Katie Serrano, who gave an overview of the office ● Deputy Director Shannon Thor, who spoke about the office's priorities for 2024, and ● Senior Policy Advisor Ioana Ulea, who moderated the Q&A panel discussion and gave a brief summary of the session.

Following their short "impact statements," the panelists answered questions submitted by the audience on a range of topics including: ● how areas for collaboration are decided upon ● examples of successful collaboration ● FDA and EMA work in other regions ● FDA plans for an office in Africa ● FDA-EMA parallel scientific advice ● communication on drug shortages ● interaction with MHRA and Swissmedic, and ● FDA participation in reliance programs.

UPDATES IN BRIEF: GLOBAL CMC/GMP DEVELOPMENTS

● BARDA Patch Forward Prize ● FDA Guidance on Handling and Retention of BA and BE Testing Samples ● Philippines FDA Seeking Feedback on Draft GMP Guidelines ● IPC Memorandum of Understanding with USP ● FDA OTC Monograph Drug User Fee Rates for FY 2024 ● Updated EMA Pre- and Post-Authorization Guidance ● EMA Updated Enhanced Ames Test Conditions for Nitrosamines ● USP March Announcements include Proposed Tests for *Burkholderia Cepacia*

FDA DRUG GMP WARNING LETTERS

Company	Facility Location	Product Type
Colgin	US	Finished
Higley Industries	US	Finished
Deqing Jiarou	China	Finished

FDA DRUG RECALLS

Among the four recalls posted in FDA's enforcement report during the week, one drew the most serious, Class I, rating. It involved a liquid containing tianeptine, a toxic substance not FDA-approved for any medical use in the United States.

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.

IPQ INTERNATIONAL PHARMACEUTICAL QUALITY
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FDA Europe Office 2024 Priorities for Medical Products Include Promoting Global Regulatory Convergence Around Cutting-Edge Technologies

The FDA Europe Office's 2024 priorities include promoting global regulatory convergence in areas where cutting-edge technologies call for a change in regulatory approach, further engagement in collaborative review/technology workstreams, and fostering collaborations to strengthen supply chains.

At an "FDA Townhall" session at the mid-March DIA Europe Conference, held in Brussels, FDA Liaison to the EMA Katherine Tyner, FDA Europe Office Director Katie Serrano, Deputy Director Shannon Thor, and Senior Policy Advisor Ioana Ulea shared their insights on the office's background, collaborative work, and future plans.

Office Director Serrano outlined the structure and function of the FDA Europe Office, which she joined in 2023 after six years as FDA Regional Director of Latin America. Key roles of FDA foreign offices, she explained, include: ● collaborative activities with regulatory counterparts ● "landscape analysis" in the region ● education and outreach, and ● engagement with the U.S. Embassy at the location.

Deputy Director Thor then highlighted the office's top priorities for 2024. "We really value our relationship with Europe," she stressed. "I think when we are aligned in our two regions, we really can drive the rest of the world forward."

A central focus of the Europe Office is on continuing to support engagement and collaboration through: ● the mutual recognition agreements (MRAs) with the EU, UK, and Switzerland ● the EMA/FDA Liaison Program ● the International Medical Device Regulators Forum (IMDRF), which FDA currently leads, and ● bilateral and multilateral workstreams, including a new project, the Collaboration on Gene Therapies Global (CoGenT Global) Pilot.

Thor also stressed the need to foster collaboration and strengthen supply chains by implementing and overseeing quality management systems globally and achieving "one high-quality standard for medical products, no matter where they are produced or where they are going."

After taking part in a session on combination products the day before, she also expressed her hope that FDA could work with European colleagues to "find ways to become less siloed and encourage more alignment and convergence in our approaches to combination products."

FDA Liaison to the EMA Kathryn Tyner discussed the collaborative work she is involved with daily — outlining the differences and similarities between the two regions, and noting that there may be differences in the regulatory process, but the scientific questions are the same.

She highlighted the "foundational" basis of collaboration through a confidentiality commitment established 20 years ago and elaborated on other key areas of: ● ad hoc communication ● fostering innovation, and ● supporting global regulatory development. ***[The full remarks of the speakers and the Q&A that followed are appended below.]***

Collaboration and Communication Further Exlored in Q&A

Following their short "impact statements," the FDA panelists answered questions submitted by the audience on a range of topics including: ● how areas for collaboration are decided upon ● examples of successful collaboration ● FDA and EMA work in other regions ● FDA plans for an office in Africa ● FDA/EMA parallel scientific advice ● communication on drug shortages ● interaction with MHRA and Swissmedic, and ● FDA participation in reliance programs.

A strong theme emerging from the Q&A session was the value of conversations and "real-life intelligence gathering," which could then lead to more formal dialogue and, in some cases, development into global initiatives.

In terms of successful collaborations, Tyner shared her experience and interaction with the EMA Quality Innovation Group, which led to the in-person participation of the FDA's Emerging Technology Team at the second QIG "Listen and Learn Focus Group" on digital novel technologies for manufacturing and QC testing. With both agencies in the room, perspectives could be more readily discussed with a view to aligning future policies and guidance.

Serrano had the opportunity to discuss the evolving functions of the FDA foreign offices, based on her time leading at the Latin America Office, and the "real effort" now within the agency to "build more bridges" between the offices.

During the discussion on parallel scientific advice (PSA), Tyner encouraged companies to submit requests for advice on CMC-related issues and complex generic development. Thor recommended listening to a recording of a webinar for tips on using the PSA route, in which she appears alongside Tyner's counterpart, EMA Liaison to the FDA, Anabela Marcal. ***[Links are provided below to the PSA webinar and FDA's complex generics webpage.]***

Regarding communication on drug shortages, Tyner pointed out that there is a multinational regulator "cluster" focused on drug shortages, as well as quarterly bilateral discussions between FDA and EMA and ad hoc communication. On April 2, the U.S. Department of Health and Human Services (HHS) released a white paper proposing steps for policymakers to consider in preventing and mitigating drug shortages. ***[A link to the white paper is provided below.]***

When asked about the connections with the UK's Medicines and Healthcare Products Regulatory Agency and Swissmedic, Thor commented that there are many interactions, "especially lately with MHRA."

Serrano also pointed to an interview with MHRA CEO Dame June Raine about the "vital importance of working in partnership with other regulators,"which is available on the FDA website. ***[A link is provided below.]***

In response to a question about whether the Europe Office could help coordinate GMP inspections across the regions, Serrano explained that staff can offer a "listening ear" about issues being encountered and provide feedback to FDA centers such as the Office of Regulatory Affairs (ORA). She encouraged delegates to share pain points and suggestions for resolution with the office.

Reliance Activities Draw Most Questions and Comments

At the start of the session, an audience poll showed that the main topic of interest was reliance, which was reflected in many other DIA Europe sessions. The final question to the panel was also on reliance, asking about plans "for FDA to more collaboratively participate in global reliance programs."

All four of the FDA panelists contributed their perspectives, with Serrano explaining that an act of Congress would be needed for FDA to be able to rely on another country's regulatory decision, but that the agency looks for ways to streamline "as much as we can through the relationships that we have built over the years." Thor discussed collaborative assessments, such as Project Orbis, clusters, and guidance, and Tyner affirmed that there of ways of working collaboratively "with the tools we have."

Ulea drew attention to the International Medical Devices Forum meeting taking place the same week in Washington, D.C. – highlighting that FDA is chairing the forum this year and that the first day of the meeting focused on pre-market and post-market reliance.

She encouraged delegates to review the slides available on the IMDRF website, which include: ● jurisdictional updates ● working group updates, and ● scene setting and case studies from a joint IMDRF/industry workshop on reliance. ***[A link to the "outcome statement" and slides from the Washington meeting is provided below.]***

In her summary comments, Ulea thanked the audience for their engagement and for "sharing your questions and ideas on the areas where you think we could collaborate more with our European counterparts." While there may be differences between the European and US systems, she said, "there are actually more similarities that allow for such fruitful collaboration."

Commissioner's Visit Highlights Strategic Importance of Europe Office

The FDA Europe Office, based in Brussels, is a component of the FDA Office of Global Policy and Strategy (OGPS), which is, in turn, part of the Office of the Commissioner. The office is one of seven that the agency has established around the world and works closely with the EMA through an FDA Liaison based in Amsterdam.

Underscoring the strategic importance of the European Office and collaborative partnerships in the region, a delegation of OGPS staff joined FDA Commissioner Robert Califf on a visit to Europe in February to meet with leaders at the European Commission (EC) Directorate for Health and Food Safety (DG Sante), EMA, and European Food Safety Authority (EFSA). The visit to Europe also included a meeting with the UK MHRA.

Among the team traveling to Europe was Associate Commissioner for Global Policy and Strategy Mark Abdoo and John "Barr" Weiner, who took up a new role earlier this year as Director of OGPS' Office of Global Operations after serving over 15 years as Associate Director for Policy in the FDA Office of Combination Products (OCP).

Weiner now oversees the FDA's foreign offices and the international policy advisors, regional experts, and global operations and program support staff located at FDA headquarters.

Speaking in his previous OCP role at the late November 2023 AFDO/RAPS "Combination Products Summit," Weiner highlighted the increasing focus on convergence across global jurisdictions, with the goal of achieving a more consistent, efficient, risk-based regulatory approach to the combined use of drug, device, and/or biologic products.

This message was reiterated at the DIA/RAPS "Combination Products in the EU Summit" in January as well as in other sessions at the March 2024 DIA Europe conference – demonstrating an increasing recognition of the urgency of addressing the regulatory interface challenges.

[Editor's Note: See IPQ's Weekly Supplements for the weeks ending January 26, 2024, and March 22, 2024, for a review of the FDA OCP and European initiatives on combined products, respectively. An upcoming IPQ story will delve further into global initiatives for combination products.]

Former FDA Leader Woodcock to Speak at Quality Business Leadership Summit

Former FDA Principal Deputy Commissioner Janet Woodcock, who retired in February after serving in leadership roles at the agency for over 40 years — including as Director of the Center for Drug Evaluation and Research (CDER) — will speak at a summit on "quality business leadership" (QBL) on May 1 in Dublin, Ireland.

Organized by the Pharmaceutical Research Science Team (PRST) based at the Technological University of Dublin, the QBL summit will address: ● how quality can be owned by all employees in the organization ● ways to actively engage employees in quality improvements ● learning how to speak compliance in financial terms ● how the quality system can be turned into an engine of value creation, and ● how confidence in quality management can be improved.

> **Woodcock will give a keynote presentation on "GMPs for the 21st Century: Then, Now and a Vision for the Future," alongside Ireland Healthcare Products and Regulatory Authority (HPRA) CEO Lorraine Nolan, who will speak about international collaboration between regulatory agencies and industry quality leaders towards harmonized regulatory requirements.** ***[See IPQ February 28, 2022 for a in-page review Woodcock's contribution to advancing quality regulation and manuacturing innovation, and IPQ July 2, 2021 for insights from Nolan on evolving and harmonizing quality regulation, particulary in the combination product space.]***

FDA and HPRA co-lead the International Coalition of Medicines Regulatory Authorities (ICMRA) Pharmaceutical Quality Knowledge Management System (PQKMS) initiative.

Other speakers at the summit include leaders from HPRA, FDA, industry and an expert in change leadership. The meeting is a follow-up to the 2023 PRST summit "ICH Q9(R1): The Next Frontier."

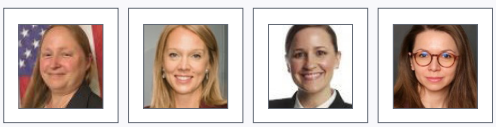
The organizers for this year's summit — who also played key roles in the previous one — are Quality Business Administration CEO and co-lead for the "One Voice of Quality" industry initiative Anders Vinther, TU Dublin Professor and PRST Director Anne Greene, and consultants/PRST members Valerie Mulholland and Marty Lipa.

[Editor's Note: See IPQ September 25, 2023 for an extensive review of the 2023 Q9(R1) meeting. A link to PRST's proceedings, which IPQ helped author, is also provided below. IPQ will attend and cover the 2024 summit.

An upcoming IPQ story will explore how 2023 was a "watershed" year for global quality initiatives, culminating in a joint work plan for harmonization and convergence involving ICMRA, ICH, the Pharmaceutical Inspection Coordination Scheme (PIC/S), and the International Pharmaceutical Regulators Programme (IPRP), released in December (see IPQ Updates in Brief December 29, 2023).]

LINKS:

- FDA Office of Global Policy and Strategy
- FDA/EMA Parallel Scientific Advice Webinar
- Parallel Scientific Advice for Complex Generics
- HHA White Paper on Drug Shortage Prevention
- Interview with MHRA CEO June Raine
- FDA and Swissmedic MRA
- IMDRF 25th Meeting Outcome Statement and Slides
- PRST Quality Business Leadership Summit
- PRST ICH Q9(R1): The Next Frontier



[Subscribers CLICK HERE for the FDA panelists' comments 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 Titanium Dioxide 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**