IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

# 2023 Summary:

Global Developments in OINDP Regulations & Standards

## About IPAC-RS

The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) is an international association that seeks to advance the science, and especially the regulatory science, of orally inhaled and nasal drug products (OINDPs) by collecting and analyzing data, and conducting joint research and development projects. Representing the OINDP industry since 2000, IPAC-RS aims to build consensus and contribute to effective regulations and standards by sharing the results of its research through conferences, technical journals, webinars, and discussions with regulatory bodies.

## About This Summary of Global Developments

This document presents regulatory developments, new or revised standards, and public events relevant for orally inhaled and nasal drug products, which took place in 2023. Hyperlinks are provided for readers wishing to learn further details; all links are valid as of time of this publication.

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# I. Developments in Regulation & Standards

## Brazil

- Anvisa held a public webinar addressing and discussing main topics in the Resolution RDC No. 751 including risk classification, reporting and registration regimes, and labeling requirements and instructions for use of medical devices.
- Anvisa published three new guides providing information on complying with RDC 753 which covers registration of medicines for human use with synthetic and semi-synthetic active ingredients, classified as new, innovative, generic and similar.
- Anvisa issued new subject codes for registering new chemical drugs which are valid for the registration and presentation of safety and efficacy documents, for new and innovative synthetic and semi-synthetic drugs. The related legislation and guideline for these drugs are RDC 753/2022 and the normative instruction IN 184/2022.
- Anvisa hosted a workshop on Pharmaceutical Innovation - Construction of a regulatory strategy for radical innovation in Brazil held in support of aspects of the national agenda seeking to provide a favorable environment for local and foreign start-ups.

## China

- The Director of the CDE, Kong Fanpu, presented at the 14th China International Drug Information Conference and 2022 DIA China Annual Conference, on what the Agency is doing to improve the efficiency and quality of product review.
- China's new algorithm and AI rules are live.
- The CDE held a meeting on Comparative Research on Domestic and Foreign Pharmaceutical Technology Guiding Principles to further understand other global regions' approaches to guideline development and content.
- The CDE issued:
  - Process for Drug Evaluation to Accelerate the Review of Innovative Drug Marketing Authorization Applications (Trial)
  - Guiding Principles for Writing Pharmaceutical-Related Information on Instructions and Labels of Chemical Drugs
  - Technical Guiding Principles for Pharmaceutical Change Research of Listed Chemical Drugs, Questions and Answers on Changes of APIs (Draft for Comment)
  - A second public solicitation of opinions on "Guiding Principles for Pharmaceutical Changes and Research Techniques of Biological Products During Clinical Trials" and "Technical Guidelines for Pharmaceutical Changes and Research of Marketed Vaccines"

- The CDE held online seminars addressing:
  - Communication processes related to review and acceleration of new drug launch.
  - Basic requirements for drug registration acceptance and frequently asked questions.
  - The Agency's views and interpretations of the ICH Q13 and ICH M7(R2) guidelines.
- The NMPA issued:
  - Measures for the Administration of Drug Standards which will come into force on January 1, 2024, and are intended to support further improvements to the quality, safety and efficacy of drugs marketed in China, and will link the concepts in standards to the various regulatory measures and guidelines.
  - Guidelines for On-site Inspection of Inhalation Preparations which seeks to identify areas of quality control risk for inhalation preparations, and seeks to improve the quality of on-site inspections.
- An English version of the 2020 Chinese Pharmacopoeia was published and is available through the Pharmacopoeia to help enhance international alignment and cooperation with respect to standards, and assist in further understanding of the Chinese Pharmacopoeia.
- The Chinese Pharmacopoeia held a training course on Rubber Pharmaceutical Packaging Material Inspection Technology.
- Chinese Pharmacopoeia solicited entities to provide information on pharmaceutical plastic composite films and bags, to assist in and inform development of standards for these types of packaging and delivery system components.
- The Chinese Pharmacopoeia issued:
  - Technical Guiding Principles for Pharmaceutical Research on Generic Suspension Nasal Sprays of Chemical Drugs
  - General Principles of Metal Drug Packaging Materials
  - Guiding Principles for Generic Names of Pharmaceutical Packaging Materials.

## European Union and United Kingdom

- The EU Court of Justice partially overturned the 2019 restrictions on TiO2 (titanium dioxide).
- European Parliament voted to extend MDR transition period.
- Team-NB issued a best practices guidance for submission of technical documentation under MDR Annexes II and III.
- UK scientists can once again apply for EU Horizon 2020 funding.
- Fluorinated gases and ozone-depleting substances: Council and Parliament reach agreement.
- European Chemicals Agency (ECHA) issued a proposal which restricts polyfluoroalkyl substances (PFASs) - both HFC134a and 227ea would be banned 18 months after 2025. Submitted restrictions under consideration. ECHA published Q&As from a webinar on the PFAS restrictions held in 2023.

- The European Environmental Bureau published an "explainer" of the universal PFAS restriction.
- Carbon reduction plan requirements for the procurement of NHS goods, services and works came into effect in April 2023.
- UK's MHRA indicated that large language models such as ChatGPT and Brad, when used in medical treatment, will be regulated as medical devices: Large Language Models and software as a medical device
- MHRA updated its Software and AI as a Medical Device Change Programme – Roadmap.
- EMA piloted scientific advice for certain high-risk medical devices.
- European Commission proposed reforming the EU pharmaceutical legislation.
- European Commission published its first Proposal for a Regulation laying down harmonised rules on artificial intelligence.
- European Commission held a webinar to discuss its digital health program. Agenda and presentation are available at Online webinar on the DIGITAL Europe Work Programme 2023 - Digital Health topics | Shaping Europe's digital future (europa.eu)
- The European Commission considered new directives for pharmaceutical products:
  - Proposal for a Regulation EUR-Lex - 52023PC0193 - EN - EUR-Lex
  - Proposal for a Directive EUR-Lex - 52023PC0192 - EN - EUR-Lex
- EDQM explained in Gene Therapy Products that two updated chapters have been published for comment in Pharmeuropa 34.3: *"Gene therapy medicinal products for human use (3186)" and "Additional information on gene therapy medicinal products for human use (5.34)."*
- The 2022 EMA Annual Report was published.
- EMA published a report on its response to the COVID-19 pandemic.
- EMA's issued the following for comment: Reflection paper on the use of artificial intelligence in the lifecycle of medicines
- EMA published Questions and answers on data requirements when transitioning to low global warming potential (LGWP) propellants in oral pressurised metered dose inhalers
- MHRA published in collaboration with FDA and Health Canada: Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles.
- for PRIME and certain marketing authorization applications targeting an unmet medical need.
- European Environment Agency published an updated report on air quality which identified air pollution as the most serious single health risk.
- EMA published a new iteration of its Q&A document, Nitrosamines EMEA-H-A53)-1490 - QA Art. 5(3) Implementation for July CHMP CMDh - (QA3).
- The European Fluorocarbons Technical Committee (EFCTC) issued a survey on F-gases.
- EMA published an article summarizing the use of real-world evidence to support efficacy/effectiveness.
- The EU Court of Justice partially overturned the 2019 restrictions on TiO2 (titanium dioxide).
- The European Council gave their support for the European Commission's proposal to delay the transitional deadlines for medical devices under MDR. The proposal was made to extend deadline for higher risk class III and class IIb devices to 2027, and deadline for lower risk class I and class IIa devices to 2028.

## International

- US FDA and Health Canada launched a pilot program entitled "eSTAR" to facilitate submission of applications to both agencies for 510(k) and De Novo devices.
- US FDA added Switzerland to the list of countries with which the agency has signed a Mutual Recognition Procedure related to cGMPs.
- 2023 TEAP progress report (which discusses propellants as well as PFAS, among other subjects) was published.
- AAMI and BSI Join Forces to Publish Guidance on Artificial Intelligence.
- ICH finalized a number of guidelines, including the following:
  - M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk and ICH M7 Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk
  - Q13 Continuous Manufacturing of Drug Substances and Drug Products.
- Performance Characteristics of Mass Spectrometry-Based Analytical Procedures for Quantitation of Nitrosamines in Pharmaceuticals: Insights from an Inter-laboratory Study was co-authored by representatives of the US FDA, European Directorate for the Quality of Medicines & HealthCare (EDQM), Health Canada and TGA/Australia.

## Japan

- The Japan MHLW and PMDA and the Japan Federation of Medical Devices Associations (JFMDA), representing the Japanese industry, were endorsed as members of the Global Harmonization Working Party at the February GHWP meeting in Riyadh, Saudi Arabia. The PMDA will seek to move toward harmonization of medical device regulations through its participation in this international group.
- The PMDA's 4th Special Subcommittee on Programmed Medical Devices Using AI met and discussed topics such as data re-use, requirements for data evaluation, and examination of adaptive AI where performance is intended to change after marketing.
- The PMDA and the National Hospital Organization (NHO) formally agreed on a collaboration that seeks to substantially expand the amount of data in the PMDA's medical information database, MID-NET® through coordination with the NHO's National Hospital Organization Clinical Data Archives (NCDA) database.
- The PMDA posted the proceedings of the 6th Special Subcommittee on Programmed Medical Devices Using AI from June 2023 which covered topics including analysis of relevant domestic and international trends; discussions of bias in machine learning; status of research for reusing evaluation data in post-market learning and problem solving; new method of data augmentation; status and issues of learning data construction by physical model simulation, and perspectives on databases. The PMDA's Scientific Committee issued a report on Programmed Medical Devices Utilizing AI.
- The PMDA's 46th Scientific Committee published minutes from its meeting in July. Topics covered include programmed medical devices using AI and the evaluation of vectors for in vivo gene therapy products with target specificity. PMDA's scientific committees provide recommendations on policies and guidelines to the PMDA.

# United States

## U.S. Food and Drug Administration (FDA)

- FDA announced OPQ reorganization to alleviate 'long-standing pain points'
- The US FDA and several other US federal agencies issued a Request for Information; Identifying Ambiguities, Gaps, Inefficiencies, and Uncertainties in the Coordinated Framework for the Regulation of Biotechnology for comment.
- FDA's research on orally inhaled and nasal drug products was described in several sections of the recently released FY 2022 GDUFA Science and Research Report.
- Device-led combination products were included in the scope of the proposed Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers.
- FDA started a dedicated webpage with resources on Augmented Reality and Virtual Reality in Medical Devices.
- FDA updated its list of Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices with 171 new AI/ML devices approved in the last year.
- List of FDA Guidance Documents that CBER planned to Publish During Calendar Year 2023.
- Beginning February 13, 2023, CDER and CBER restarted in-person, face-to-face industry meetings (with a hybrid component).
- FDA Recognized First AI-Focused Document, AAMI CR34971:2022, in List of Consensus Standards.
- FDA published a new batch of product-specific guidances (PSGs) which provide recommendations for developing generic drugs and generating evidence to support abbreviated new drug application (ANDA) approvals, helping to streamline generic product development and ANDA assessment.
- FDA published the 2022 Office of Generic Drugs (OGD) Annual Report.
- FDA's ramped up for transition to Quality Management System Regulation (QMSR) for devices.
- FDA posted updates for Artificial Intelligence/Machine Learning Assisted Image Analysis for Characterizing Biotherapeutics.
- FDA Released Two Discussion Papers to Spur Conversation about Artificial Intelligence and Machine Learning in Drug Development and Manufacturing
- FDA posted research updates for Pharmacodynamic Biomarkers: Their Role in Biosimilar Product Development.
- FDA updated its Manual of Policies and Procedures (MAPP), Assessment of Bioequivalence Studies with Clinical Endpoints in ANDAs.
- FDA provided guidance for Verification Test Problems for Cardiac Electrophysiology Modeling Software
- FDA released information on Upcoming Product-Specific Guidances for Generic Drug Product Development.
- FDA CDER established the CDER Quality Standards Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality.

- CDRH is modernizing its 510(k) program and published for comment related draft guidances:
  - Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions
  - Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission
- CDRH issued Digital Health Frequently Asked Questions (FAQs).
- FDA template made available for use: New Bioequivalence Data Summary Table: Morphologically Directed Raman Spectroscopy.
- FDA presentations at the Pharmaceutical Quality Symposium 2023: Quality, Supply Chain & Advanced Manufacturing addressed topics such as ICH Q12 and Q13 (continuous manufacturing), nitrosamines, and AI in manufacturing.
- FDA invited public input on Scientific Challenges and Opportunities to Advance the Development of Individualized Cellular and Gene Therapies
- FDA co-authored Regulatory Experience with Continuous Manufacturing and Real Time Release Testing for Dissolution in New Drug Applications - Journal of Pharmaceutical Sciences
- Final FDA policy for immediate implementation: testing any alcohol containing product for the presence of methanol, including in inhalation products.
  - Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol: "...the policy outlined in this guidance applies to pharmaceutical alcohol used as an active or inactive ingredient in a drug product regardless of whether the drug product is a hand sanitizer product."
- Draft FDA Guidances published for comment including:
  - Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act (Revision 1)
  - Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder
  - Content of Human Factors Information in Medical Device Marketing Submissions
  - Demonstrating Substantial Evidence of Effectiveness Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence
  - Discussion Paper: Artificial Intelligence in Drug Manufacturing.
  - Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls Data Elements and Terminologies.
  - FDA Data and Technology Modernization Strategy.
  - Increasing Patient Access to At-Home Use Medical Technologies
  - Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products.
  - Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions.
  - Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting Viral Pathogens
  - Pulmonary Tuberculosis: Developing Drugs for Treatment
  - Quality Considerations for Topical Ophthalmic Drug Products
  - Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers

- FDA published a number of final guidances, including:
  - Antimicrobial Susceptibility Test (AST) System Devices – Updating Breakpoints in Device Labeling
  - Application of Human Factors Engineering Principles for Combination Products: Questions and Answers
  - Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions
  - Benefit-Risk Assessment for New Drug and Biological Products
  - Chronic Rhinosinusitis with Nasal Polyps: Developing Drugs for Treatment.
  - Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products
  - Content of Premarket Submissions for Device Software Functions.
  - COVID-19: Developing Drugs and Biological Products for Treatment or Prevention
  - CVM GFI #279 Demonstrating Bioequivalence for Type A Medicated Articles Containing Active Pharmaceutical Ingredient(s) Considered to be Poorly Soluble in Aqueous Media, That Exhibit Little to No Systemic Bioavailability, and Are Locally Acting.
  - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
  - Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act.
  - DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry
  - Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act
  - Federal Register: TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances
  - Format and Content of a REMS Document Guidance for Industry.
  - Framework for the Use of Digital Health Technologies in Drug and Biological Product Development.
  - General Considerations for Animal Studies Intended to Evaluate Medical Devices.
  - Nontuberculous Mycobacterial Pulmonary Disease Caused by Mycobacterium avium Complex: Developing Drugs for Treatment
  - Off-The-Shelf Software Use in Medical Devices
  - Q9(R1) Quality Risk Management
  - Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities
  - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

## U.S. Pharmacopeia (USP)

- USP and ATCC Launched First Set of Standards for Biological Therapeutics.
  - USP's Pharm.Forum 49(1) published the following chapters for comment:
  - (661) Plastic Packaging Systems and Their Materials of Construction.
  - (1151) Pharmaceutical Dosage Forms, with an updated section for suspensions to "include lipid nanoparticles (LNP), and viral vectored vaccines and gene therapies (e.g., adenovirus and adeno-associated virus, respectively)."
  - (467) Residual Solvents.
  - (1467) Residual Solvents—Verification of Compendial Procedures and Validation of Alternative Procedures.
  - (1236) Solubility Measurements.
- USP PharmForum 49(2) published the following chapters for comment:
  - (87) Biological Reactivity Tests, In Vitro
  - (88) Biological Reactivity Tests, In Vivo
  - (660) Containers - Glass
  - (661.2) Plastic Packaging Systems for Pharmaceutical Use
  - (791) pH
  - (1031) The Biocompatability of Pharmaceutical Packaging Systems and Their Materials of Construction
  - (1184) Sensitization Testing
- USP PF 49(6) (76) published for comment by January 31, 2024:
  - (1040) Quality Considerations of Plasmid DNA as a Starting Material for Cell and Gene Therapies.
- USP Pharm.Forum 49(3) published the following chapters for comment:
  - (129) Analytical Procedures for Recombinant Therapeutic Monoclonal Antibodies
  - (198) Nuclear Magnetic Resonance Spectroscopy Identity Testing of Bacterial Polysaccharides Used in Vaccine Manufacture
  - (711) Dissolution
  - (1132.1) Residual Host Cell Protein Measurement in Biopharmaceuticals by Mass Spectrometry
  - Selecting an Appropriate Volume for the Subvisible Particles Per Container Calculation
- USP Pharm.Forum 49(4) published for comment, "Proposals for the Development, Composition, and Routine Use of System Suitability Standard Mixtures in Support of Chromatographic Screening for Organic Extractables and Leachables" (stimuli article)
- USP PharmForum 49(5) published the following chapters for comment:
  - USP-NF Proposals for the Development, Composition, and Routine Use of System Suitability Standard Mixtures in Support of Chromatographic Screening for Organic Extractables and Leachables
  - USP-NF Testing the in Vitro Product Performance of Mucosal Drug Products: View of The USP Expert Panel
  - (429) Light Diffraction Measurement of Particle Size (revised general chapter)

- (1060) Mass Spectrometry-Based Multi-Attribute Method for Therapeutic Proteins (new general chapter)
- (1243) Wetting Properties of Pharmaceutical Systems (new general chapter)
- Proposed Definitions of Excipient Components— Revisions to 2018 Definitions (stimuli article)
- USP Responses to Comments on Stimuli Article "Revisions to the USP–NF Lactose Monographs—Focusing on Inhalation and Injection Grades" (stimuli article)
- Anhydrous Lactose (monograph)
- Lactose Monohydrate (monograph)

## U.S. Environmental Protection Agency (EPA)

- The EPA Administrator signed the proposed rule Phasedown of Hydrofluorocarbons: Restrictions on Certain Uses of Hydrofluorocarbons Under Subsection (i) of the American Innovation and Manufacturing Act.
- EPA published finalized/updated rules (available from Protecting Our Climate by Reducing Use of HFCs) on:
  - Phasedown of Hydrofluorocarbons: Allowance Allocation Methodology for 2024 and Later Years
  - Phasedown of Hydrofluorocarbons: Adjustment to the Hydrofluorocarbon Production Baseline.
- US EPA signed final rule on HFC restrictions:
  - EPA technology-transitions-final-rule-fact-sheet-2023.pdf
  - Federal Register: Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances
  - Federal Register: TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances

## Congress & Other U.S. Agencies

- NIST and ASTM published a report on Fostering a Circular Economy of Manufacturing Materials.
- New Postmarket Cybersecurity Responsibilities Poised to Have Major Impact on Device Manufacturers.
- NIST released the AI Risk Management Framework (AI FRM 1.0) which aims to help incorporate trustworthiness into AI products.
- US FTC warned against unwarranted promotion of AI capabilities in products in Keep your AI claims in check.
- US Copyright Office clarified that human authorship is required for copyright, per the Copyright Registration Guidance: Works Containing Material Generated by Artificial Intelligence.
- US Patent and Trademark Office accepted public input on its Request for Comments Regarding Artificial Intelligence and Inventorship.
- President Biden issued an Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence. Full text of the Executive Order can be found here.
- The US government launched a new website AI.gov: Making AI Work for the American People.
- A bill introduced in the US House of Representatives includes considerations for AI/ML-enabled drug prescribing. For details, see Text - H.R.206 - 118th Congress (2023-2024): Healthy Technology Act of 2023

# II. Events, Webinars, & Meetings

- CRCG/FDA workshops:
  - Identifying, Developing, and Evaluating Generic Drug Device Combination Products (DDCP) (March 16, 2023)
  - Bioequivalence considerations for OINDPs (April 20-21, 2023)
  - Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics (June 15, 2023).
  - Comparative User Interface Assessment for Drug-Device Combination Products: Updates and Challenges in Demonstrating Generic Substitutability (November 2-3, 2023).
  - Characterization of Complex Excipients/Formulations (December 7-8, 2023).
- FDA/CRCG Training Course: Drug-Device Combination Products 101: Identifying, Developing, and Evaluating Drug-Device Combination Products (May 10, 2023).
- FDA's FY 2023 Generic Drug Science and Research Initiatives Workshop (May 11-12, 2023).
- PQRI Workshops:
  - TiO2 Use in Pharmaceuticals – Global Regulatory and Technical Challenges (June 13-14, 2023).
  - FDA/PQRI Workshop on the Regulatory Framework for the Utilization of Artificial Intelligence in Pharmaceutical Manufacturing. (September 26-27, 2023).
- Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) AI workshop – Smart regulation on a rapidly evolving world (November 20-21, 2023).

# Questions?

IPAC-RS
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For questions about IPAC-RS' priorities, initiatives, or membership, please email info@ipacrs.org or contact:


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