U.S. Food and Drug Administration sent this bulletin at 02/14/2024 12:28 PM EST

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February 2024

Global News | Briefs | Staff News | Dear Int'l Colleague | Events

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In this issue


Final Rule on QSR


OGPS meets in Kenya


LAO Director named


China Deputy named


India Office presents GCP training at ISCR


LAO to chair Nat'l Reg Authorities of Regional Ref

...and much more inside...

Global News

FDA Issues Final Quality Systems Regulation to Promote Global Harmonization

On January 31, the FDA issued a final rule, revamping its Quality Systems (QS) regulation to bring it into alignment with the international consensus standard for medical devices — ISO 13485:2016 — used by many other regulatory authorities around the world.

In adopting ISO 13485, the FDA's final Quality Management System Regulation (QMSR) incorporates risk management throughout its requirements and explicitly emphasizes risk management activities and risk-based decision making as important elements of an effective quality system.

"This final rule is the latest action taken by the FDA to promote global harmonization in device regulation to help assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices both at home and abroad," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "By harmonizing key areas of a medical device manufacturer's quality management system with the international standard, the FDA is streamlining actions device manufacturers must take to meet requirements by multiple regulatory authorities."

A manufacturer inspecting medical device quality. (Getty Images)

For more than 20 years, manufacturers of FDA-regulated devices have been required to establish and follow current good manufacturing practice requirements included in the QS regulation as defined in 21 CFR Part 820. This QS regulation provides requirements for manufacturers to follow related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use.

With the final QMSR, the FDA is incorporating by reference the quality management system requirements of ISO 13485:2016, after determining that the requirements in ISO 13485 are, when taken in totality, “substantially similar to the requirements of the QS regulation.” In short, it provides “a similar level of assurance in a manufacturer’s quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act.”

Final Rule Also is a Boon to the Medical Device Single Audit Program

While the medical device industry has been eagerly awaiting this announcement, so too have the FDA’s regulatory partners who participate with the FDA in the Medical Device Single Audit Program (MDSAP). That program was initially established as a pilot to consider whether it was possible to use a single audit of a manufacturing facility to satisfy the relevant requirements of the

participating regulatory authorities. Under this program, third-party auditors apply for and receive authorization to conduct this single audit that is based on ISO 13485.

So far, regulators in five countries are full participants in the program: the FDA, the Therapeutic Goods Administration of Australia, the Brazilian Health Regulatory Agency (Anvisa), Health Canada, and the two Japanese regulatory authorities — Japan's Ministry of Health, Labour and Welfare, and their Pharmaceuticals and Medical Devices Agency.

Over 6,900 medical device manufacturing sites worldwide are currently registered for MDSAP, and the program is now required for Class II, III, and IV medical device licenses in Canada. The European Union, the UK's Medicines and Healthcare products Regulatory Agency, and the World Health Organization are MDSAP Official Observers. As Official Observers, these countries participate in MDSAP activities and provide input into the program for consideration by the five participating regulatory authorities. Several other regulatory agencies, as Affiliate Members, are closely monitoring MDSAP's progress. They include Argentina's National Administration of Drugs, Food, and Medical Devices; the Ministry of Health of Israel; the Republic of Korea's Ministry of Food and Drug Safety; the Federal Commission for Protection from Sanitary Risks (Cofepris) of Mexico; Singapore's Health Sciences Authority; and the Taiwan Food and Drug Administration.

Device manufacturers and importers will have two years to modify their quality systems to meet the requirements of the QMSR rule by February 2, 2026. Until then, manufacturers are required to comply with the existing QS regulation.

FDA Latin America Office to Chair National Regulatory Authorities of Regional Reference

The FDA's Latin America Office (LAO) was recently selected to chair the eight-member National Regulatory Authorities of Regional Reference (NRAr) group in 2024. The announcement comes following LAO's participation in the Pan American Health Organization's NRAr meeting in December 2023, held in Brasilia, Brazil. As part of U.S. leadership of the NRAr group, LAO is hosting a meeting with the Institute of Public Health of Chile this month, in Santiago.

Group photo of the Pan American Health Organization's December 2023 NRAr meeting in Brasilia, sponsored by the Brazilian Health Regulatory Agency (Anvisa).

NRAr members are those regulatory authorities designated by the Pan American Health Organization (PAHO) as having high levels of regulatory and oversight capacity. Though the NRAr group has served as a best practice reference for other regional regulatory authorities, PAHO is now transitioning to another performance measure, the World Health Organization's Global Benchmarking Tool (GBT).

"As newly appointed chairs for the NRAr group we are committed to drive regulatory excellence, and our vision is to continue to foster collaboration and strengthening regulatory systems in the region," said Vesa Vuniqi, International Relations Specialist with LAO.

LAO staff will focus on promoting and advancing use of the GBT, training, regulatory convergence to international standards and good regulatory practice, she said. "Together, we aim to enhance the regulatory landscape and ensure production of high-quality products for public health across our diverse nations."

PAHO introduced the idea of using a benchmark to assess national regulatory authorities in the region more than 15 years ago, deeming eight regulatory authorities in the Americas to be competent and efficient in their performance of functions needed to monitor the safety, efficacy, and quality of all health technologies on the market — including drugs, vaccines, blood products, medical devices, and others. These eight nations— Argentina, Brazil, Canada, Chile, Colombia, Cuba, Mexico, and the United States —were recognized as National Regulatory Authorities of Regional Reference.

The NRAr Group comprises the National Administration of Drugs, Food and Medical Devices of Argentina, the National Health Regulatory Agency of Brazil (Anvisa), Health Canada, the Public Health Institute of Chile, the National Institute of Drug and Food Surveillance of Colombia, the Center for State Control of Medicines and Medical Devices of Cuba, the Federal Commission for Protection against Sanitary Risks (Cofepris) of Mexico, and the FDA. The group has met biannually since 2012 to discuss regulatory issues and establish annual work plans.

Importing Seafood? FDA Issues Draft Guidance on Sampling Recommendations for Seafood Subject to DWPE

On February 9, the FDA issued draft guidance for industry titled "Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination (DWPE) and Removal of a Foreign Manufacturer's Goods from DWPE."

Although the title may sound technical, this detailed guidance will be useful for industry, especially seafood importers and foreign manufacturers who are dealing with shipments that are subject to DWPE at U.S. ports.

(Getty Images)

The FDA issues import alerts to inform its field staff about products that appear to be in violation of the FDA's laws and regulations and thus may be detained without physical examination. The agency may subject future shipments of fish or fishery products to DWPE when there is information that causes future shipments of a product or products to appear violative within the meaning of section 801(a) of the FD&C Act. Such information may exist based on the violative history of a product, manufacturer, shipper, grower, importer, geographic area, or country. There are currently 47 import alerts that may relate to fish and fishery products, and 28 of those import alerts are specific to seafood. For many of these import alerts, importers often choose to submit private laboratory evidence as testimony toward overcoming detention. Collecting a good sample is the first step toward laboratory testing.

This draft guidance provides recommendations for collecting representative samples for seafood shipments detained without physical examination under an import alert because of the appearance of adulteration caused by pathogens, unlawful animal drugs, scombrotoxin (histamine), and/or decomposition. It is also intended to help foreign manufacturers and other processors of fish and fishery products subject to DWPE under an import alert to introduce evidence to the FDA to support a request to have products removed from the alert. (However, this guidance does not apply to seafood-related import alerts when sampling and testing is not relevant to securing release of individual shipments or removal from import alert.)

To address the appearance of adulteration, private laboratory test results are sometimes submitted to the agency. Industry has voiced concern about the challenges of supporting their arguments about the safety of seafood products

subject to DWPE. The intent of the draft guidance is to clarify the FDA's thinking on when the appearance of adulteration may be removed via lab testing, while giving industry the tools it needs to help support importation. The guidance addresses the following issues in depth:

- What sample size is representative and statistically robust.
- How to define a "sample unit" to help determine what and how much of a product to collect.
- References for analytical methods.
- What production-related evidence would be useful to include for FDA assessment.
- What types of evidence would be useful in requesting removal of product/manufacturer from an import alert.

The draft guidance is being distributed for comment purposes only and is not for implementation. This guidance will help foreign manufacturers and other processors of seafood products subject to DWPE submit evidence to the FDA to support a request to have an individual detained shipment released or a product removed from import alert.

Comments on the draft guidance should be submitted within 60 days after the February 12, 2024, publication in the Federal Register. Submit electronic comments to www.regulations.gov to docket number FDA-2023-D-5303.

Additional Information:

- Federal Register Notice for the Draft Guidance
- Draft Guidance for Industry: Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination (DWPE) and Removal of a Foreign Manufacturer's Goods from DWPE
- Seafood Guidance Documents & Regulatory Information
- Import Alerts for Fishery and Seafood Products
- More on Seafood from FDA

Briefs

Goa and Telangana Regulators Eligible to Observe FDA Inspections Following First Joint FDA Forums

After participating in joint regulatory forums organized by the FDA's India Office (INO), drug regulators in two of India's 29 states – Goa and Telangana – have joined the group of eligible states to observe inspections conducted by the FDA in India.

The first Annual Regulatory Forum with Goa's Directorate of Food and Drugs Administration (DFDA) was held October 18-19, 2023, while the first Annual Regulatory Forum with the Telangana Drugs Control Administration occurred on January 31, 2024.

Both inaugural forums were designed to share inspectional best practices for medical products and served as an opportunity for the FDA and state regulators to provide an overview of regulatory operations and learn about one another's current compliance practices to better inform future engagements.

FDA India Office and Telangana Drugs Control Administration participants at the forum in Telangana.

Medical product topics covered by INO staff at the meetings included the history of the FDA's drug regulations, the basic elements of a robust Pharmaceutical Quality System, and the value of a risk-based approach to Good Manufacturing Practice inspections. FDA staff then discussed the elements of the agency's Observed Inspection standard operating procedure — this process allows Indian inspectors to be invited to observe select FDA medical product inspections, one of the activities to be planned and performed under a Memorandum of Understanding that the FDA signed with India in 2020. By participating, Indian regulators can improve their capacity for regulatory oversite of medical products.

In India, laws regulating medical products are established at the national level but enforced by both central and state governments. One of INO's important goals at these forums was providing detailed information on FDA inspectional practices so that state regulators could qualify to participate as observers of FDA inspections along with India's national regulatory counterpart, the Central Drugs Standard Control Organisation (CDSCO).

Presenters from the FDA's India Office at the forum in Telangana (left to right, top row then bottom): Dr. Sarah McMullen, Dr. Phil Nguyen, Yvins Dezan, Dr. Sudheendra Kulkarni, Guerlain Ulysse, and Karthik Siva Chaitanya.

Once a state achieves that status, the FDA notifies the CDSCO. Goa and Telangana have now become the third and fourth states, respectively, to reach this milestone, along with Gujarat and Karnataka.

Often referred as the “Bulk Drug Capital of India” and “Vaccine Capital of the World,” Telangana accounts for:

- Over 40% of the total Indian active pharmaceutical ingredients (API) production.
- More than 35% of total pharmaceutical production in India.
- Approximately 50% of API exports from India.
- One-third of global vaccine output.

Goa, located on the coast of the Arabian Sea, is India’s smallest state by area but an established base for the pharmaceutical industry and an emerging destination for the biotechnology and IT industries.

FDA India Office and Goa DFDA participants on the second day of the forum in Goa.

The first day of the multiday Goa forum was devoted to food regulation. It featured a presentation on food facility inspections from the perspective of an FDA investigator. INO consumer safety officers also reviewed the FDA's food safety regulations and facilitated a group discussion using a seafood inspection scenario. Among the other topics of discussion were INO's role in enhancing the safety of food imported into the United States, Goa DFDA and India's food regulations, and Indian programs for regulating and inspecting food products intended for export. The state is known for its seafood, spices, and jackfruit, and continues to grow its infrastructure for exporting its goods globally.

Presenters from the FDA's India Office at the forum in Goa (left to right, top row then bottom): Dipesh Shah, Dhruv Shah, Greg Smith, Kelia Hicks, Jake Lane, Kunapuli Madhusudhan, and Dr. Pankaja Panda.

INO's Good Clinical Practice Training Draws Crowd

It was standing room only at the Indian Society for Clinical Research Pre-Conference in Hyderabad on February 1 for a daylong training offered by the FDA's India Office (INO) on an important aspect of the drug business – the conduct of clinical trials.

Specific to generic drugs and particularly relevant in India, companies must submit study data to the FDA demonstrating that their drug is therapeutically equivalent to the branded drug and show that human subject studies conducted to support approval must comply with good clinical practices (GCPs) requirements as part of the application process. These requirements are intended to ensure data quality and integrity and to protect the rights and welfare of the human subjects.

To ensure GCP compliance, the FDA inspects clinical sites — what the agency calls bioresearch monitoring, or "BIMO." India is an important source of generic drugs — nine out of 10 drugs prescribed in the U.S. are generics, and 40% of those drugs come from India — so it's not surprising that many of these BIMO

inspections are conducted in India. In fact, nearly 33% of the FDA’s foreign clinical trial inspections occur in that country.

During INO’s interactive presentation, generic drug sponsors and contract research organizations listened to case studies and investigator observations and discussed GCP best practices. It was INO’s sixth and perhaps most productive engagement, with 100 participants, double the number of participants from past years.

“It was gratifying to see such active engagement at this year’s conference,” said INO Director Sarah McMullen. “It reflects, I think, an increasing desire to understand the practicalities of current GCPs globally and their implementation.”

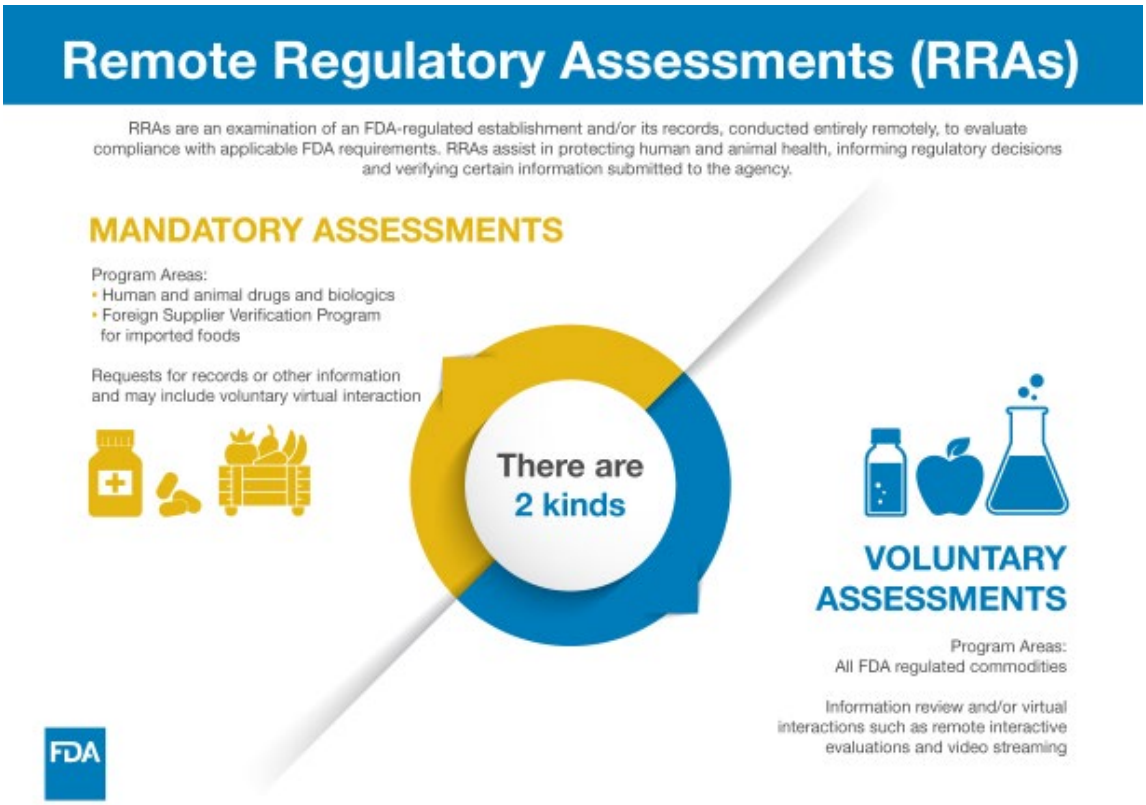
In addition to the FDA’s appearance at the pre-conference, McMullen delivered a keynote address on patient centricity in clinical trials at the main conference where the topic this year was "research transformation to better patient outcomes."

FDA Publishes Revised Draft Guidance on Remote Regulatory Assessments

The Food and Drug Administration recently published a revised draft guidance for industry titled Conducting Remote Regulatory Assessments Questions and Answers. A Remote Regulatory Assessment (RRA) is an examination of an FDA-regulated establishment and/or its records, conducted entirely remotely, to evaluate compliance with applicable FDA requirements.

Some of the tools used in RRAs include remote records requests, remote livestreaming video of operations, teleconferences, and screen-sharing. These approaches have enabled the agency to provide oversight to as many facilities as possible when travel was restricted while continuing to deploy resources where possible to protect consumers and patients and promote public health.

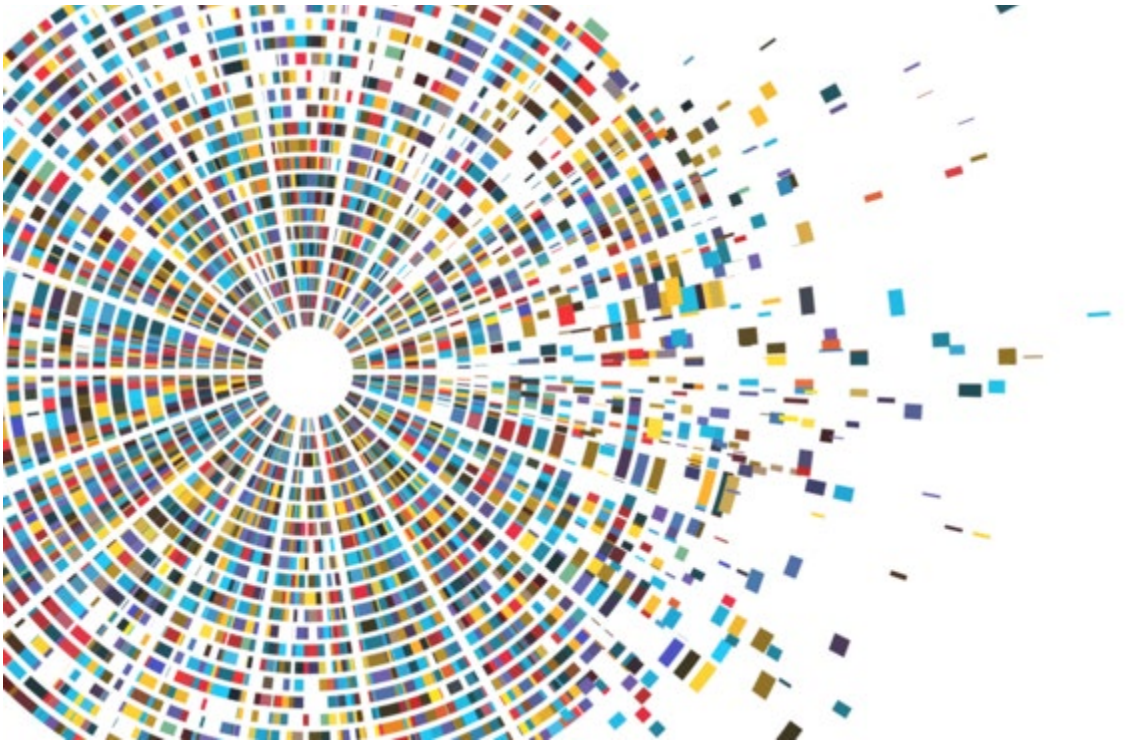
Throughout the pandemic, for example, the FDA used RRAs both domestically and abroad for certain FDA-regulated products to help the agency conduct oversight, mitigate risk, and meet critical public health needs when inspections could not be conducted. For example, RRAs assisted the FDA in verifying corrective actions taken in response to inspections of previously compliant manufacturers. They have provided information about deficient practices, leading the agency to take regulatory actions and/or conduct inspections, while informing future inspection planning. RRAs also were used to help support review and promote timely approval or authorization of marketing submissions for FDA-regulated products. In the FDA's food program, RRAs have helped to determine compliance with veterinary feed directive regulations, assess foreign manufacturing process records, add foreign establishments to import alerts, and issue warning letters.



Because of the effectiveness of these tools, the agency will continue to use RRAs when appropriate in overseeing industry and ensuring the safety and effectiveness of all types of regulated products, supplementing critical oversight tools such as inspections.

The draft guidance, once finalized, will describe how the FDA will use RRAs for FDA-regulated products. The revised draft guidance reflects the agency's consideration of comments to draft guidance from July 2022, as well as revisions to align with recent changes in law concerning mandatory records requests. The FDA welcomes public comments on the draft guidance during the 60-day comment period via the Federal Register website.

FDA Co-Hosts Workshop in Peru on Whole Genome Sequencing



The FDA's Office of Regulatory Science in the Center for Food Safety and Applied Nutrition (CFSAN) and the United Nation's Food and Agriculture Organization hosted a joint workshop in Lima, Peru, in late January on how whole genome sequencing (WGS) can be used to prevent and respond to water- and foodborne outbreaks. In addition to experts in Peru, the workshop drew members of the Latin American Surface Water Surveillance Program, which CFSAN supports through a cooperative agreement with the Maryland-based Joint Institute for Food Safety and Applied Nutrition. In that program, participants isolate and sequence *Salmonella enterica* from South American surface waters associated with crop irrigation, including rivers, reservoirs, irrigation channels, ponds, lakes, streams, creeks, and irrigation canals.

The workshop focused on summarizing the state of the current technology, various sequencing networks, and how data can be shared within and between interoperable networks. Peru participates in the GenomeTrakr network, a network of public health and university laboratories that collect and share genomic and geographic data regarding foodborne pathogens. The data (over 1.2 million samples) is housed in public databases at the National Center for Biotechnology Information and can be accessed by researchers and public health officials for real-time comparison and analysis that can speed foodborne illness outbreak investigations and reduce foodborne illnesses and deaths. To date, Peru has uploaded over 5,000 sequences into this international database.

At the workshop, experts also exchanged ideas on the proposed solutions — and related challenges — for transitioning to a more robust whole genome sequencing food safety program in Peru, which would require greater resources and sectoral coordination.

FDA subject matter experts Dr. Marc Allard and Dr. Narjol Gonzalez-Escalona were speakers and the Latin America Office's point of contact for WGS, Bruce Ross, also joined for liaison and in-person interactions with seminar participants.

CVM Develops Draft Guidance on GMPs for Veterinary Active Pharmaceutical Ingredients

On January 24, the FDA's Center for Veterinary Medicine announced the availability of a draft guidance for industry (GFI) #286 (VICH GL60) entitled, "Good Manufacturing Practice for Active Pharmaceutical Ingredients used in Veterinary Medicinal Products." This draft guidance has been developed by the

International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

VICH is a trilateral program officially launched in April 1996. The program aims to harmonize technical requirements for the approval of veterinary medicinal products in the European Union (EU), Japan, and the United States, and includes input from both regulatory and industry representatives. In support of wider international harmonization of regulatory requirements, VICH guidelines are also available for use by other countries.

This draft guideline has been developed based on a similar guideline (ICH Q7: Good Manufacturing Practice for Active Pharmaceutical Ingredients) intended to cover human drugs from the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). The objective of this draft guidance is to provide recommendations regarding good manufacturing practices (GMPs) for the manufacturing of active pharmaceutical ingredients (APIs) for use in veterinary medicinal products. It facilitates harmonization of a single set of international standards for GMP inspections of facilities that manufacture APIs and starting materials for use in such products. It also allows manufacturers and regulators a framework to ensure that APIs meet the quality and purity characteristics that they are intended to possess.

The FDA's work with VICH aims to ensure regulatory certainty for veterinary products, including predictable and uniform requirements across the EU, Japan, and the United States. The collective work also helps to reduce animal testing, facilitate trade, and ensure veterinary product safety and consumer confidence in the regulated products.

To submit comments electronically, visit Regulations.gov and type the following docket number into the search box: FDA-2023-D-4761. The agency requests submissions be made by March 25, 2024, to ensure that the FDA considers your comment(s) before it begins work on the final version of the guidance document.

FDA to Host International Medical Device Regulators Forum

The U.S. Food and Drug Administration (FDA), as the Chair and Secretariat of the International Medical Device Regulators Forum (IMDRF), will host the 25th Session of the IMDRF in Washington, D.C., on March 11-15, 2024.

The first two days of the meeting are free and open to the public and will be offered either virtually or in person. Day One is a joint IMDRF-Industry workshop on the topic of medical device regulatory reliance, exploring such topics as what reliance is and why it is important, reliance in a premarket setting, and reliance in a postmarket setting. Day Two will feature regulatory updates from the IMDRF Management Committee and IMDRF's Official Observers. The last three days, March 13-15, are for IMDRF invitees only.

In September, the FDA's Center for Devices and Radiological Health issued a draft International Harmonization Strategic Plan to encourage harmonization, convergence, and reliance among medical device regulatory authorities. That plan defined reliance as an act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible, and accountable regarding the decisions made, even when it relies on the decisions and information of others.

The IMDRF forum will be held at the Ronald Reagan Building and International Trade Center located at 1300 Pennsylvania Avenue NW in Washington, D.C. Space is limited for in-person attendance and early registration is encouraged.

The public can also attend the meeting via livestream. Registration for in-person attendance closes on February 16, 2024.

The IMDRF was established in October 2011 and is a voluntary forum for medical device regulators from different jurisdictions who have agreed to work together to advance international regulatory harmonization and convergence in the field of medical devices.

The forum develops internationally agreed-upon documents related to a wide variety of topics affecting medical devices. When finalized, IMDRF members adopt these documents where appropriate, and in some cases adapt them to meet the regulatory requirements of their jurisdictions.

The IMDRF Management Committee includes representatives from Australia, Brazil, Canada, China, the European Union, Japan, Russia, Singapore, South Korea, the United Kingdom, and the United States. Argentina, Switzerland, and the World Health Organization are official observers to the IMDRF. Affiliate Members are Chile, Cuba, Egypt, Israel, Montenegro, South Africa, and the Taiwan Food and Drug Administration.

FDA and EMA Host Discussion Panel on Significant Advances in Cancer Treatments and Therapies

The FDA's Oncology Center of Excellence (OCE) recently collaborated with the European Medicines Agency (EMA) in hosting "Conversations on Cancer: Transforming Patient Lives by Therapeutic and Regulatory Innovations," on February 1.

The panel discussion, which took place ahead of World Cancer Day on February 4, focused on three forms of cancer – multiple myeloma, chronic myelogenous leukemia (CML), and melanoma – all of which have experienced significant advances over a 25-year period. The panelists were asked why progress was made in these diseases and what was the role of regulatory agencies, scientists, and clinicians in achieving this progress.

"When I take a look at these diseases, I'm amazed at the progress that's been made," said OCE Oncology Director Richard Pazdur, M.D. "I've covered a wide variety of patients throughout my clinical career within these three diseases. You still see the faces and ask yourself, what would be their stories be now. It's a tragic irony that treatments used today were not available then."

Both the FDA and EMA have programs in place to expedite the development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions.

The FDA's accelerated approval program, initially developed for HIV/AIDs drugs in the 1990s, is a popular path to market for oncology drugs. Under this program, products are approved based on a surrogate endpoint that is thought to predict clinical benefit but is not itself a measure of clinical benefit. The use of a surrogate endpoint can considerably shorten the time required prior to receiving FDA approval. In oncology the surrogate endpoint may be tumor

shrinkage or a composite endpoint where an event is defined as either growth of tumor beyond an arbitrary threshold (progression) or detectable recurrence of disease, or death. Drug companies are still required to conduct studies to confirm the anticipated clinical benefit. If the confirmatory trial shows that the drug actually provides a clinical benefit, then the FDA grants traditional approval for the drug.

Currently over 75% of the products approved for marketing under the accelerated approval program are for treatment of malignancies, said Pazdur. Over time, the accelerated approval program has evolved to single-arm trials for oncology products where all patients with the targeted medical condition are given the experimental therapy and then followed over time to observe their response. This is in contrast to a randomized trial where patients are randomly selected to receive one of two or more therapies and then compared.

The EMA has its own accelerated approval program, a priority medicines scheme that it calls PRIME. This voluntary scheme targets unmet medical needs and is based on enhanced interaction and early dialogue with developers of promising medicines, to optimize development plans and speed up evaluation so these medicines can reach patients earlier.

In addition, the EMA has another program that supports the development of medicines that address unmet medical needs – conditional marketing authorization. Applicants may be granted a conditional marketing authorization for such medicines on less comprehensive clinical data than normally required, where the benefit of immediate availability of the medicine outweighs the risk inherent in the fact that additional data are still required. Conditional marketing authorizations are valid for one year and can be renewed annually. Once a conditional marketing authorization has been granted, the marketing authorization holder must fulfill specific obligations within defined timelines. These obligations could include completing ongoing or new studies or collecting additional data to confirm the medicine's benefit-risk balance remains positive. An estimated 80-85% of approvals under conditional approvals are oncology drugs, including several drugs used to treat multiple myeloma.

Patient advocates — Jan Geissler from Germany, Fredrik Ostman from Sweden, and Yelak Biru from the United States, were three of the nine panelists. Geissler, a CML patient since 2001, benefited from imatinib — a drug that has revolutionized CML treatment today – when it was an experimental treatment. Ostman was diagnosed with melanoma in 2014 — and currently has no evidence of the disease. Yelak Biru’s was diagnosed with myeloma in 1995 and has been in remission for decades.

“Since 2003, there are almost 20 approved drugs to treat multiple myeloma. Life expectancy has changed from two to three years to 10 or more for standard risk

patients, but challenges in getting treatments to patients early on, remains a challenge," Biru said.

This event was the second collaboration between the FDA and EMA. Previously, the two agencies hosted a discussion with breast cancer patients diagnosed with advanced-stage or metastatic disease in October.

The Oncology Center of Excellence's Conversations on Cancer series started years ago as an internal program to educate FDA staff outside of OCE on oncology advancements and treatments. OCE leadership expanded the series – with the help of technology – to an external, worldwide audience.

The event was hosted on YouTube and recorded with subtitles. Attendees were able to post comments and questions to OCE's X account (formerly known as Twitter).

FDA Partners with ROK for AI Regulatory and International Symposium in Seoul

The FDA and the Republic of Korea's Ministry of Food and Drug Safety (MFDS) are co-hosting a joint symposium from February 26-29 in Seoul on the use of artificial intelligence (AI) in the medical products industries.

The Artificial Intelligence Regulatory and International Symposium (AIRIS) 2024 is the realization of a Memorandum of Cooperation (MOC) between the FDA and the MFDS to facilitate a joint workshop on the topic. FDA Commissioner Robert Califf, M.D., and MFDS Minister Yu-Kyoung Oh signed the MOC April 27, 2023, in Washington, D.C. Moreover, "exchanging information about the safe production of medical products with AI" was one of the further cooperative

activities cited in a White House Fact Sheet following a state visit by Republic of Korea President Yoon Suk Yeol to Washington that same week.

This month's symposium will feature speakers from global government agencies, industry, and academia, and focus on the use of AI in a wide range of medical products including biologics, pharmaceuticals, and medical devices. Seven sessions are planned and will cover such topics as transparency, explainability, and bias; technology trends (including machine learning for clinical decision support systems and using AI for safety surveillance); and what direction regulators should go in cooperating on the regulatory aspects of AI to ensure that medical products that use this technology remain safe and effective.

OGPS Senior International Policy Advisor Sema Hashemi will represent the FDA at the symposium along with Hussein Ezzeldin, Digital Health Technology Review Team Lead, Center for Biologics Evaluation and Research. The FDA delegation will also include the Center for Drug Evaluation and Research's Tala Fakhouri, Associate Director for Policy Analysis; Mira Jacobs, Acting Assistant Director for the Digital Health Policy Team; Anindita Saha, Assistant Director for Partnerships and Regulatory Science; and Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health.

For more information, visit AIRIS 2024.

Bonus: OGPS Photo Album - Around the Globe

Nairobi, Kenya | Medical products, GRPs

Building on the technical exchanges held in November 2023, OGPS' Office of Trade and Global Partnerships (OTGP) led a meeting with Kenya's Pharmacy and Poisons Board (PPB) that was held in person on January 26. During the meeting, OTGP and PPB discussed ways to strengthen the regulator-to-regulator relationship.

The group photo above is from the trade talks with colleagues from the United States Trade Representative and the Kenya Bureau of Standards, as well as the Kenya Law Reform Commission; Ministry of Trade, Investments and Industry; Pharmacy and Poisons Board; and Ethics and Anticorruption Commission. The two-person photo is OTGP Director Joseph Rieras (on the right) with a colleague from PPB.

Also, trade representatives from the United States and Kenya met recently in Nairobi for ongoing negotiations related to the U.S.-Kenya Strategic Trade and Investment Partnership. OTGP's Jade Pham (below, seated second from the left) represented the FDA as part of an interagency team. Agriculture and Good Regulatory Practices were among the topics discussed at the talks.

Panama City, Panama | Tobacco

Last week, FDA Center for Tobacco Products Director Brian King was in Panama for the 10th session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control. Participants were able to discuss tobacco regulation with their public health colleagues.

King commented that he "appreciated the opportunity to engage with many of his fellow regulators who are working to prevent disease and death from tobacco products worldwide."

Kochi, India | Seafood

FDA India Office Director Sarah McMullen goes back to her roots of seafood decomposition work — presenting at the first FDA seafood decomposition training in India! The February event was hosted by the Indian Council of Agricultural Research's Institute of Fisheries Technology (ICAR-CIFT) and experts from the FDA and the Joint Institute for Food Safety and Applied Nutrition shared their expertise on ensuring the quality of shrimp. McMullen also connected with officials from India's Marine Products Export Development Authority and Export Inspection Council.

Staff News

We have new leadership at our foreign offices in China and Latin America.

Rodriguez Takes Reins of the FDA's Latin America Office

On January 10, 2024, the FDA's Office of Global Policy and Strategy (OGPS) welcomed **Captain Michelle Rodriguez, Ph.D.,** as the new Director of the FDA's Latin America Office (LAO), headquartered in San Jose, Costa Rica. She has an extensive, broad background and brings a wealth of insight and experience to the position.

In her previous role as LAO's Deputy Director, stationed in Mexico City, Rodriguez led strategic initiatives to transform the FDA-Mexico relationship and increase regulatory cooperation, including spearheading the U.S.-Mexico Food Safety Partnership to improve food safety cooperation. She also led regional engagements on whole genome sequencing, supply chain challenges, and regulatory convergence in the oversight of medical products, including work with multilateral institutions, governments, and forums. Rodriguez was also at the forefront in implementing a federal mandate to establish regulatory arrangements with the largest U.S. shrimp importers, which would strengthen the enforcement of food safety measures.

Before joining OGPS, Rodriguez held various leadership and supervisory roles at the FDA in the areas of regulatory compliance, import and export operations, and emergency response activities. She served as Branch Chief within the FDA Center for Tobacco Product's Office of Compliance and Enforcement and was also a compliance reviewer and later a postmarket team leader in the Center for Devices and Radiological Health's Office of In Vitro Diagnostics and Radiological Health.

Earlier, Rodriguez was at the Center for Disease Control and Prevention's (CDC) National Center for Emerging and Zoonotic Infectious Diseases, managing the national and international deployment and use of medical countermeasures in the U.S. Strategic National Stockpile as well as regulatory

applications required for stockpiling. She also supported the CDC's emergency preparedness, response, and outbreak activities in Latin America.

Since her commissioning in the U.S. Public Health Service in 2011, Rodriguez has deployed and collaborated with various government agencies in support of public health responses impacting the Latin American community, such as unaccompanied minors, Zika virus, and Hurricane Maria.

Rodriguez holds a microbiology degree from the University of Puerto Rico. She completed her doctoral studies in immunology at the University of Florida and later completed a postdoctoral ORISE fellowship in virology at the CDC.

Brandi McGrady Joins FDA China Office as Deputy Director

Brandi McGrady has joined the FDA's Office of Global Policy and Strategy's (OGPS) China Office as Deputy Director. She comes to OGPS from the FDA's Office of Regulatory Affairs' Domestic Human and Animal Food Operations, where she was Branch Chief for the Produce Safety Network.

McGrady has spent nearly 15 years with the FDA conducting high profile inspections both domestically and abroad, responding to foodborne emergencies, and managing highly skilled teams of investigators. For the past seven years, she has worked exclusively on the successful development of the Produce Safety Network and the implementation and enforcement of the Produce Safety Rule. She is known as a confident leader who uses enthusiasm, technical expertise, and a passion for relationship building to effectively accomplish agency goals.

McGrady obtained master's degrees in business administration from Anderson University and also in public health with a concentration in emergency management from American Public University. She has a bachelor's degree in biomedical science with an emphasis in chemistry from Grand Valley State University.

Vanessa Shaw-Dore Departs FDA China Office, Heads to Africa

FDA China Office Director Vanessa Shaw-Dore wrapped up her nearly four-year tour in Beijing and has left the agency to accept a management position with the Peace Corps as their Country Director in Rwanda, based in Kigali. For the time being, Supervisory Consumer Safety Officer Roy Stephens is the Acting China Office Director.

Rwanda has received increasing attention on the global health stage, as the African Union is planning to establish the African Medicines Agency in the country's capital.

"Africa is becoming a region of greater interest for the FDA, where attention to public health regulations and prioritization for Africa's regulatory capacity has increased because of the pandemic. The FDA, through OGPS, is considering how best to help in standing up the African Medicines Agency — or AMA — dedicated to improving access to quality, safe, and effective medical products in Africa," said Mark Abdoo, FDA Associate Commissioner of Global Policy and Strategy, during a speech at the International Bar Association World Life Sciences Conference in June 2023. And on January 26, 2024, the European Medicines Agency announced it had received a grant of 10 million euros from the European Commission to support regulatory systems at a national and regional level in Africa, and in particular for setting up the African Medicines Agency, in collaboration with African, European, and international actors.

FDA delegation meets with NMPA at its office in Beijing. Shaw-Dore is third from the left.

Shaw-Dore's position as CNO Director was her first role at the FDA. She joined in April 2020 near the beginning of the COVID-19 pandemic and had to navigate the difficulties posed by the pandemic shutdown. That eliminated the possibility of face-to-face meetings with the FDA's regulatory counterparts in the People's Republic of China — the National Medical Products Administration and the China National Center for Food Safety Risk Assessment — until last year. Nevertheless, CNO staff continued to perform mission-critical work and virtual outreach, and investigators continued to perform inspections in 2020, 2021, and 2022, she said last year at the DIA China conference in Suzhou.

Dear International Colleague

Recent communications from OGPS to our international stakeholders (list does not include weekly FDA Roundup summaries), November 27, 2023, through January 31, 2024.

- FDA Announces Withdrawal From Global Harmonization Working Party
- FDA, USDA, & EPA Propose National Strategy to Reduce U.S. Food Loss and Waste
- FDA Advances Reorganization Proposal for Unified Human Foods Program, Field Operations and Additional Modernization Efforts
- FDA Authorizes Florida's Drug Importation Program
- Registration is Open for the International Medical Device Regulators Forum
- An Invitation to Attend AIRIS 2024 in Seoul
- FDA issues Draft Guidance on GMPs for Vet Drug APIs
- FDA Publishes Revised Draft Guidance on Remote Regulatory Assessments
- FDA Issues Quality Management System Regulation: Final Rule Amending the Quality System Regulation

Events

February 26-29	AIRIS 2024 in Seoul, Korea.
February 29	Rare Disease Day
March 11-15	IMDRF 25th Session in Washington, D.C.

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