



**U.S. FOOD & DRUG  
ADMINISTRATION**

# 2024

## Office of the Chief Scientist Year-In-Review External Report





## A Message from the Chief Scientist

The role of U.S. Food and Drug Administration (FDA) Chief Scientist was first proposed at the [Science Board to the FDA on March 13, 1997](#). Approximately a decade later, in the FDA Amendments Act (FDAAA) of 2007, the Office of the Chief Scientist (OCS) was officially established to oversee, coordinate, and ensure quality and regulatory focus of the intramural research programs at FDA.

OCS has evolved over time, including with the recent FDA reorganization, to have laboratory programs, support cross-cutting scientific activities for extramural and intramural research, and oversee the regulation of cosmetics. The vision of OCS is "innovative science driving regulatory decisions that advance public health" and OCS has multiple responsibilities across that pathway.

OCS directly generates innovative regulatory science through forward-looking research in critical areas, such as new alternative methods (NAMs) and artificial intelligence (AI). With the recent reorganization, OCS has additional laboratory capabilities that test FDA-regulated products for surveillance and compliance actions. These laboratories are in multiple locations across the United States (U.S.) and include satellite facilities at mail hubs. Bringing these laboratory programs together in OCS facilitates the sharing and use of new analytical technologies to further protect the U.S. public from adulterated and misbranded products. A centralized agile mix of laboratory capabilities increases FDA responsiveness to new and emerging threats. This integrated OCS laboratory network requires administrative support, quality assurance, and data analytics.

FDA-regulated commodities have very specific contexts, and across FDA there are experts who address the scientific gaps for development and oversight of their product portfolios; that expertise should be leveraged for program-specific as well as centralized research. To allow for effective research, there needs to be a shared FDA infrastructure. OCS has cross-cutting roles in establishing and maintaining an infrastructure that catalyzes FDA science and enhances trust in FDA research and decision-making.

The following cross-cutting roles directly support innovative science.

- Intramural and extramural support for agency priorities including emergency preparedness; and
- Scientific training and development programs including a new FDA fellowship program with reduced overhead.

The following cross-cutting roles support trusted scientific research, regulatory decision-making, and the safety and integrity of agency operations.

- Laboratory safety as well as general safety and occupational health;
- Scientific and regulatory dispute resolution;
- Human subject protection in FDA conducted or supported research; and
- Advisory committees for input on regulatory science and decision-making.

The agency-wide reach of OCS has positioned it to oversee the growth of cosmetic regulation.

Implementation of the Modernization of Cosmetics Regulation Act (MoCRA) of 2022 leverages the science, testing, cGMP, registration and listing, compliance, and adverse event reporting experience across the agency.

In summary, OCS has evolved to have laboratory capabilities, cross-cutting agency activities, and regulatory responsibilities. OCS sub-components have had many important accomplishments in these areas over the past year, beyond those described in this report. Thank you to all OCS staff, and our FDA partners, for safe and capable laboratory programs, for enhancing trust in FDA science, and for advancing cosmetic regulation and safety.

Best wishes,

Dr. Steven Kozlowski, M.D., Acting Chief Scientist FDA

## Introduction

OCS was established under a statute of the [FDAAA](#) to “oversee, coordinate, and ensure quality and regulatory focus” of FDA’s intramural research programs. The office has evolved in the 17 years since its establishment, and, in 2024, [OCS underwent significant changes](#) as part of the FDA-wide reorganization.

In January 2023, [FDA announced](#) a proposal to create a [unified Human Foods Program](#) (HFP) and restructure its field operations. [Reorganization](#) information was published in the [Federal Register](#) in June 2024 and [implemented on October 1, 2024](#). Under the reorganization, OCS strengthened its leadership, coordination, and research expertise to support scientific excellence and innovation, aligned with FDA’s regulatory mission. OCS now comprises [nine sub-components](#) and several staffs and teams. These components work toward the following shared mission and vision:

### Vision

Innovative science driving regulatory decisions that advance public health

**ACHIEVING THE OCS VISION WILL REQUIRE TRUST**

### Mission

Promote, leverage, and lead cross-cutting, collaborative activities and initiatives that catalyze FDA science, innovation, and research

**ACHIEVING THE OCS MISSION WILL REQUIRE AGILITY**

This report highlights public health accomplishments in 2024 by all the components that make up OCS post-reorganization. Most accomplishments are within the calendar year (CY), and some metrics are based on the fiscal year (FY) or as indicated. To distinguish OCS sub-component contributions, superscripts are used throughout with a [reference table](#) provided at the end.

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## Regulation, Compliance, and Enforcement

OCS supports FDA's regulation, compliance, and enforcement efforts across several product areas, providing support for drugs, medical devices, tobacco products, and foods, with primary oversight and decision-making authority in cosmetics and colors. These efforts help ensure that safety, efficacy, and quality standards are met, regulations are enforced, and help prevent harmful products from reaching consumers. In addition, OCS supports regulatory activities to protect FDA's intellectual property from fraud and ensures that FDA's advisory committees remain in compliance with governing laws and regulations. In CY 2024, OCS posted its first annual guidance agenda and published or advanced several [guidance documents](#).<sup>1</sup>

### Oversight of Cosmetics and Color Additives

OCS<sup>1,2</sup> coordinates FDA regulation of cosmetic products and the certification of color additives for cosmetics, foods, drugs, and devices. By developing guidance and rulemaking, overseeing compliance activities, and providing expert advice, OCS helps ensure that safety standards are met, and public health is protected.

OCS significantly contributed to FDA's regulation of tattoo ink as a cosmetic product.

- With leadership from OCS,<sup>2</sup> FDA issued a [final guidance](#) to help tattoo ink manufacturers and distributors recognize situations in which a tattoo ink may become contaminated with microorganisms, and thus, be potentially injurious to health. This guidance also recommended certain steps that manufacturers and distributors can take to help prevent the occurrence of these conditions, or to identify and remediate insanitary conditions that already exist during manufacturing and distribution. [OCS research findings related to bacterial contamination of tattoo inks emphasize the importance of this guidance](#).
- In collaboration with international partners, OCS<sup>2</sup> published an article providing insights into [the medical toxicological perspective of tattooing, including regulatory strategies and improvements in the analysis of tattoo inks](#).

OCS<sup>1,2</sup> advanced implementation of the [Modernization of Cosmetics Act of 2022](#) (MoCRA) which provided FDA new authorities to help ensure the safety of cosmetic products, in collaboration with FDA partners.

- Published a [proposed rule](#) to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products;
- Developed a process for submitting electronic mandatory serious adverse event reports for cosmetics through the [FDA Adverse Event Reporting System \(FAERS\)](#), which is a highly interactive web-based tool;
- Published a [final guidance](#) to assist stakeholders with cosmetic product facility registration and product listing submissions to FDA; and
- Updated the electronic portals for submission of [cosmetic product facility registrations and cosmetic product listings](#), including [Cosmetics Direct](#).

Under MoCRA there have been:

- 9,528\* unique, active cosmetic product facilities registered
- 589,762\* unique, active cosmetic products listed

\*Data from 12/18/2023 through 01/01/2025.

In addition to cosmetics, OCS<sup>2</sup> also directs and coordinates the color additive program. Under the Federal Food, Drug, and Cosmetic (FD&C) Act, certain color additives must be certified by FDA for use in food, drugs, cosmetics, and medical devices. For those color additives that require batch certification, FDA analyzes samples from each batch of color additive received from a manufacturer and verifies that it meets composition and purity specifications. In November 2024, FDA issued a [final rule](#) that amends the color additive regulations by adjusting the fees for certification services so that FDA can continue to provide, maintain, and equip an adequate color additive certification program as required by the FD&C Act).

## Scientific Support for Regulatory Actions

OCS engages in pharmaceutical enforcement support and shelf-life extension through laboratory testing and conducts toxicology studies in support of regulatory actions. OCS accomplishments are highlighted below.

- Supported intercepting illegal products through international mail. OCS established a Satellite Laboratory Branch to support [satellite laboratories](#) (SL) at four [international mail facility](#) (IMF) locations.<sup>3</sup> The operation increased parcel screening and testing; in FY 2024 SL analyzed over 1200 samples, an increase of over 200% from the previous year. Seventy-five percent of the parcels analyzed were violative due to the identification of active pharmaceutical ingredients (APIs) in unlabeled samples, including dangerous compounds such as fentanyl, nitazenes, morphine, codeine, and sibutramine. Since the program inception, SL have identified over 400 different drug substances and prevented over 1.2 million lot units (e.g. tablets/capsules) from reaching the American public.
- Evaluated imported goods by launching an effective point of entry testing initiative with portable devices<sup>3</sup> to help FDA investigators evaluate imported goods, since samples identified in the health fraud program averaged a violative rate of ~50% over the past five years.
- Performed analytical testing in support of the [Shelf-Life Extension Program \(SLEP\)](#) in collaboration with the Center for Drug Evaluation and Research (CDER) and U.S. Department of Defense (DoD).<sup>4</sup> Stockpiling drugs, vaccines, and medical products is critical to ensure public health emergency preparedness for both the U.S. military and civilian populations. In FY 2024, SLEP testing conducted by the FDA to assess drug stability and quality led to shelf-life extensions for approximately 866 lots of MCM drug products, resulting in over \$2 billion in cost savings for the U.S. government.

Overall the OCS<sup>3,4</sup> [Medical Products Laboratories](#) and SL have supported enforcement, case work, drug shortage mitigation, shelf life extension, as well as product surveillance by analyzing over 4,000 samples. Over 1000 of these were medical device, electronic product, and food samples, including gloves, dialysis kits, balloon catheters, surgical gowns, lasers, X-rays, e-cigs, UV products, and food tested for radiation.<sup>3</sup> Many samples are collections that contain large numbers of subsamples, each requiring separate analyses for multiple analytes. Experts from these labs supported 40 domestic and 14 foreign drug inspections in FY 2024.

Under the OCS Regulatory Testing Laboratories, there have been:

- 4,397\* samples evaluated in FY 2024
- 40 domestic and 14 foreign drug inspections supported in FY 2024

\*a sample may be a collection of many subsamples

OCS<sup>3</sup> initiated the Joint Intelligence National Threat Response – El Paso Illicit Drug Laboratory ([INTREPID](#)) with the U.S. Drug Enforcement Administration (DEA) and U.S. Customs and Border Protection (CBP). This program provides attribution information to the law enforcement and intelligence communities for the millions of fentanyl containing tablets and powders crossing the U.S. border, thereby helping reduce the tens of thousands of annual opioid related deaths. In FY2024, the three organizations analyzed over 100 samples, agreed on a Memorandum of Understanding (MOU), and published a bulletin describing the sourcing of xylazine in fentanyl containing product.

OCS<sup>5</sup> conducted toxicological studies in collaboration with the Center for Food Safety and Applied Nutrition (CFSAN) (now FDA's HFP) under an Interagency Agreement with the National Institute of Environmental Health Sciences' Division of Translational Toxicology to investigate outstanding questions on the toxicological profile of brominated vegetable oil (BVO). Findings contributed to the conclusion that the intended use of BVO in food should no longer be considered safe; FDA [revoked the authorization to use BVO in food](#) in July 2024. These findings resulted in several publications, [one of which](#) was referenced in the [final rule](#).

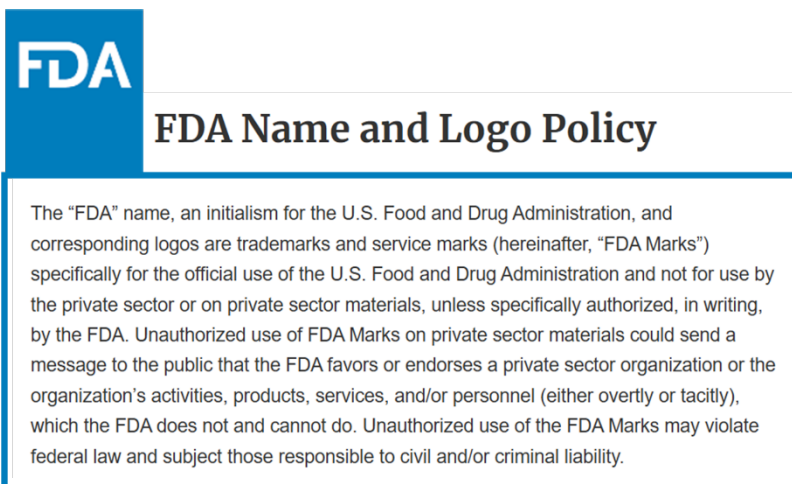
## Protecting FDA’s Scientific Credibility

OCS also coordinates the resolution of scientific and regulatory disputes. For example, OCS<sup>6</sup> coordinated and finalized [the agency decision on CDER’s proposal to withdraw accelerated approval of an oncology drug](#) under a new statutory framework for such withdrawals. Approval was withdrawn after FDA determined that the required confirmatory studies did not confirm clinical benefit and the available evidence showed the drug was neither safe nor effective under its conditions of use.

OCS also supports actions to prevent deceptive use of the FDA name and logo. OCS<sup>7</sup> prepared a package and memo for the FDA Commissioner to approve the registration of the FDA name and corresponding logo with the United States Patent and Trademark Office (USPTO). On September 15, 2024, the FDA Commissioner approved the registration package and memo. Once the FDA name and logo are registered as trademarks, FDA will have more tools to stop others from infringing FDA’s name and logo in a manner that is confusing or deceptive to consumers.

OCS regulatory testing laboratories meet a laboratory quality management standard ([ISO 17025:2017](#)). The labs undergo proficiency testing to ensure quality.<sup>8</sup>

OCS<sup>9</sup> helped ensure that Advisory Committee members complied with federal conflict of interest laws and regulations, including 18 U.S.C. 208 and 5 C.F.R. 2640.103. In FY 2024, only 5% of the total number of persons contacted to serve on an advisory committee did not participate because of the potential for conflicts of interest, and less than 3% of total meeting participants were granted waivers for potential conflicts of interest.

A graphic with a blue header containing the FDA logo and the title "FDA Name and Logo Policy". Below the title is a white box with a blue border containing text about the policy.

**FDA**

### FDA Name and Logo Policy

The “FDA” name, an initialism for the U.S. Food and Drug Administration, and corresponding logos are trademarks and service marks (hereinafter, “FDA Marks”) specifically for the official use of the U.S. Food and Drug Administration and not for use by the private sector or on private sector materials, unless specifically authorized, in writing, by the FDA. Unauthorized use of FDA Marks on private sector materials could send a message to the public that the FDA favors or endorses a private sector organization or the organization’s activities, products, services, and/or personnel (either overtly or tacitly), which the FDA does not and cannot do. Unauthorized use of the FDA Marks may violate federal law and subject those responsible to civil and/or criminal liability.

[FDA Name and Logo Policy](#)

## Advancing Regulatory Science

OCS invests in its laboratories, research, and scientists, and strives to provide information rooted in science and data to aid FDA in making evidence-based public health decisions. The scientific breakthroughs made in CY 2024 reflect several overarching areas of research and funding. These areas include research in toxicology, analytical testing, NAMs, and AI. OCS also encourages and advances research collaborations through both the Intramural and Extramural Regulatory Science Research programs.

### Advancing Toxicology

OCS accomplishments related to advancing toxicology are described below.

- Conducted research under the coordination of a federal working group, convened by the National Toxicology Program and the National Science and Technology Council to investigate potential human health effects of 6PPD, a chemical currently used in tires to protect the rubber from degradation. Findings suggested that 6PPD can undergo environmental oxidation to 6-PPD-Quinone, a compound known to be toxic to specific species of freshwater fish but unlikely to be directly hepatotoxic to humans at relevant environmental exposure levels. OCS<sup>5</sup> presented the findings at the 2024 Society of Toxicology (SOT) Annual Meeting and at the 2024 Microphysiological Systems World Summit.
- Presented a study on the development of biomarkers associated with a susceptibility to Non-Alcoholic Fatty Liver Disease (NAFLD) and NAFLD-related liver carcinogenesis at the 2024 SOT annual meeting, which was published in [Journal of Environmental Science and Health: Part C Toxicology and Carcinogenesis](#) and [Toxicology and Applied Pharmacology](#).<sup>5</sup>
- Collaborated with CDER to conduct safety assessments of morphine, methadone, and buprenorphine as treatment for neonatal opioid withdrawal syndrome (NOWS). As a result of the collaboration, a model of NOWS was established. OCS<sup>5</sup> and CDER presented preliminary findings at the 2024 SOT annual meeting and [FDA's Perinatal Health Center of Excellence](#) seminar.

### Advancing Alternative Methods

OCS supports the [New Alternative Methods \(NAMs\) Program](#) through central coordination and management of specific programmatic objectives across FDA. The NAMs Program intends to spur the adoption of Alternative Methods for regulatory use that can replace, reduce, and refine animal testing (the 3Rs), prevent products with increased toxicological risk from reaching the market, and improve predictivity of nonclinical testing to streamline development of FDA-regulated products. NAMs-related research at OCS<sup>5</sup> included studies on [human in vitro air-liquid-interface airway tissue models](#), [human liver cells](#), [human lymphoblastoid cell lines](#), and [microphysiological human placental barrier models](#) as options for animal model replacement.



## Artificial Intelligence

To enhance the analysis of complex scientific data and support regulatory decision-making, in CY 2024, OCS<sup>5</sup> used AI-driven approaches that helped identify potential risks more efficiently and accelerate toxicological research. OCS<sup>5</sup> used advanced AI technologies to both compile unique FDA datasets and design software applications specific to each FDA product center's needs. Office highlights include:

- Published multiple manuscripts that explored the use of large language models (LLM) within the regulatory environment.<sup>5</sup> These [manuscripts](#) described a strategy to harness public LLMs for FDA-sensitive data in a secure environment, and [explored the utility of ChatGPT](#) and [other generative AI models](#) to automate scientific literature screening and help enhance the review of FDA-regulated drug products.
- Published two publicly available datasets based on FDA-approved drug labeling documents.<sup>5</sup> The [Drug-Induced Cardiotoxicity Rank dataset](#) contains the largest number of drugs ranked by the risk of drug-induced cardiotoxicity of any known database using FDA labeling documents, while the [Drug-Induced Renal Injury List dataset](#) is a large database of single-molecule, oral-administered drugs for human use annotated for drug-induced renal toxicity and nephrotoxicity.



## Analytical Testing Research & Development

Office accomplishments supporting analytical testing research and development include:

- Investigated the [presence of anaerobic and aerobic bacteria in commercial tattoo and permanent makeup \(PMU\) ink](#).<sup>2,5</sup> This research demonstrated that nearly half of the PMU ink samples and close to one-quarter of the tattoo ink samples tested contained bacterial contamination, even if the products were labeled as “sterile.” The findings reinforced the importance of monitoring these products for bacteria to reduce the risk of ink-related infections. OCS also [issued guidance including recommendations to help reduce microbial contamination in tattoo inks](#).
- Established testing strategies supporting the analysis of fraudulent pandemic diagnostic kits, medicines, treatments, filtered face respirators, and hand sanitizers related to regulatory and criminal investigations. OCS<sup>3</sup> published five manuscripts to advance regulatory science, pharmaceutical enforcement, and prevent [adulterated products](#), and [unsafe products containing opioids](#), from entering the U.S.
- Supported CDER's Office of Compounding Quality and Compliance (OCQC) in drug compounding research.<sup>5</sup> Notably, this project support resulted in enhanced reproducibility and methodology for identification of compounds in complex mixtures of pharmaceutical ingredients (spectra) and more accurate chemical analysis.
- Developed [methods to rapidly screen for novel synthetic 2-benzylbenzimidazole opioids](#), also known as nitazenes, which allows screening of suspect tablets and identification of nitazene-type drugs in suspect counterfeit tablets at remote sampling sites.<sup>3</sup>
- Contributed to standardization of methods for sporicidal efficacy assessment and an accurate efficacy database for sporicidal products, as presented at the American Society for Microbiology conference in June 2024.<sup>5</sup>
- Led strategic planning and implementation for FDA's state partnerships initiative over the past four years.<sup>10</sup> OCS facilitated development of the [Laboratory Flexible Funding Model](#), which greatly increased collaboration and partnerships with 55 state laboratory organizations. This leverages the agency's analytical testing capabilities. This effort resulted in defined analytical tracks for state laboratories.



## Enabling Intramural Regulatory Science Research

OCS<sup>11</sup> provides funding to support high-priority regulatory science research for internal FDA scientists under the [Cross-Agency Regulatory Science \(CARS\) Program](#) as well as advancing public health emergency preparedness regulatory science research through the [Intramural MCM Regulatory Science Program](#)..

Research focus areas included:

- Leveraging AI tools to predict antigenic evolution of respiratory viruses with pandemic potential;
- Validating and implementing versatile radiochemical separation procedures to enhance the FDA's radioanalytical capability and enable the rapid detection of radiological threats;
- Assessing fresh produce for the uptake and bioaccumulation of emerging chemicals of concern (e.g., poly and perfluoroalkyl substances (PFAS) and toxic elements/heavy metals) and developing methods to assess the subsequent impact on human health; and
- Developing a high-throughput community level antimicrobial resistance (AMR) toolkit for detecting and reporting of AMR from surface waters, and waters representative of input to human and animal food processing.

## Enabling Extramural Regulatory Science Research

To encourage development and innovation in regulatory science, FDA funds extramural research using various contract mechanisms and grants to address high-priority needs. OCS<sup>11</sup> manages FDA-wide programs that provide funding to promote extramural regulatory science research through managing the [FDA Broad Agency Announcement \(BAA\) for Advanced Research and Development of Regulatory Science](#) and the academic [Centers of Excellence in Regulatory Science and Innovation \(CERSIs\)](#). Key accomplishments included:

- Coordinated review of 278 submissions and issuance of 24 extramural research awards under the BAA across 15 topic areas including advanced manufacturing, biomarkers, clinical outcome assessment, AMR, and substance use and misuse; and
- Provided core funding to sustain 5 CERSIs, facilitating the establishment of 23 new collaborative research projects, and supporting 14 ongoing research projects and six workshops with 5,599 attendees on topics including women's health, clinical outcome assessment, clinical trial design, alternative methods, AI, oncology, and substance use disorders.

In addition, OCS<sup>11</sup> advanced public health emergency preparedness research by supporting extramural regulatory science under the [Extramural MCM Regulatory Science Program](#). Research focus areas included:

- Developing lung and lymph node organs-on-chips models to support vaccine development; and
- Advancing the development and functionality of a [microbial genetic sequence database](#) that can support the development of countermeasures.



## Leveraging Science and Technology

Enabling innovation in regulatory science and technology requires a safe environment for cutting-edge regulatory research. It also requires effective partnerships. Fully leveraging regulatory science requires enabling product development and licensing. Transparency and engagement on science and technology facilitates the best public health outcomes.

### Enabling Innovation

OCS supports the FDA mission by providing safety policy and oversight for laboratory science operations. OCS<sup>12</sup> published an article about [the safety and security measures needed for biosafety and biosecurity practices in biological research working with pathogens and toxins](#) to ensure safety and health of laboratories and surrounding communities while supporting scientific innovation. OCS oversight of laboratory safety enables FDA to leverage science and technology safely and effectively.

OCS facilitated collaboration with the [Reagan-Udall Foundation](#) for activities in FY 2024 including coordinating new funding for 20 new and continuing projects that support critical aims of a cooperative agreement. The aims of the FDA-wide cooperative agreement are:

- 1) Supporting the use of real-world evidence in regulatory science;
- 2) Facilitating public understanding of FDA's role in regulatory approval; and
- 3) Providing education and outreach related to nutrition and human foods.

Projects under these aims included communications studies to support the HFP, studies to assess the response to Highly Pathogenic Avian Influenza (HPAI), continued support of FDA's controlled substances initiative and substance abuse disorder program, workshops to support real-world evidence generation and human health risk communication, the gathering of public/stakeholder input to respond to rare diseases, support for the Expanded Access Navigator, and support of the Biosimilar User Fee Agreement (BsUFA) III Regulatory Science Pilot Program.

### Product Development and Licensing

Under the new [Innovative Technologies and Advanced Manufacturing Hub](#) (I-TEAM Hub), OCS<sup>11</sup> helped address regulatory science and training needs related to emerging technologies in the early stages of development. In collaboration with the FDA Center for Devices and Radiological Health (CDRH), a [Smart Design and Manufacturing Pilot](#) was launched to facilitate industry adoption of smart design and manufacturing processes. This collaboration will generate data to enable FDA reviewers, investigators, and policy makers to advance regulatory science and product development.

As part of technology transfer activities in support of development of FDA research, OCS<sup>7</sup> evaluated 17 new inventions for commercial viability and the potential product's impact on improving public health. Inventions evaluated ranged from cancer therapies based on novel chimeric immunotoxins to salmonella subtyping panels.

OCS<sup>7</sup> established one new technology license agreement and amended two existing license agreements in FY 2024 to meet mandates under the Federal Technology Transfer Act of 1986. This allowed for FDA inventions to be developed, incorporated, or otherwise made into widely available products through the commercial sector.

## Public Engagement on FDA Regulatory Science

Across OCS, sub-components engaged with the public through various initiatives that fostered transparency, collaboration, and scientific exchange. OCS<sup>11</sup> hosted annual training courses on [Achieving Data Quality and Integrity in Maximum Containment Laboratories](#) and [Clinical Trials Involving High-Consequence Pathogens](#) with 335 attendees from over 33 countries.

OCS<sup>13</sup> supported fellowship programs including launching the new [FDA Research and Science Traineeship](#) in 2024. Over 100 scientific students were recognized at the annual [Student Scientific Research Day](#), which highlighted the importance of their research projects on advancing FDA regulatory science. In addition, OCS<sup>13</sup> coordinated the [Learning Portal for Students, Industry and Academia](#), which provides access to FDA education and resources.

To educate the public on key regulatory topics and showcase research advancements and their impact on public health, OCS facilitated lectures and meetings throughout 2024, including:

- Coordinated [FDA Grand Rounds](#), a monthly lecture that showcased the impact of FDA's research on public health to 2,301 attendees;<sup>13</sup>
- Hosted the [14<sup>th</sup> Global Summit on Regulatory Science](#), focusing on Digital Transformation in Regulatory Science, where topics of discussion included artificial intelligence and machine learning (AI/ML), public health, and novel applications and regular use of digital technologies in regulated products.<sup>5</sup> Approximately 200 participants attended the conference in Little Rock Arkansas, including more than 50 international participants from 15 countries, in addition to local participation and robust FDA representation.

OCS also co-authored an article in [Nature Medicine](#) that addressed the role of advisory committees, how they work, and why they are important to improve public understanding of [FDA advisory committees](#).<sup>9</sup>

## OCS Sub-Component Superscript Reference Table

Number	Sub Component
1	Regulatory Policy and Compliance Team (RPCT)
2	<a href="#">Office of Cosmetics and Colors</a> (OCAC)
3	<a href="#">Office of Specialty Laboratories and Enforcement Support</a> (OSLES)
4	<a href="#">Office of Analytical and Regulatory Laboratories</a> (OARL)
5	<a href="#">National Center for Toxicological Research</a> (NCTR)
6	<a href="#">Office of Scientific Integrity</a> (OSI)
7	<a href="#">FDA Technology Transfer Program</a> (FTTP)
8	<a href="#">Office of Science and Laboratory Advancement</a> (OSLA)
9	<a href="#">Advisory Committee Oversight Management Staff</a> (ACOMS)
10	<a href="#">Informatics and Business Operations Staff</a> (IBOS)
11	<a href="#">Office of Regulatory and Emerging Science</a> (ORES)
12	<a href="#">Office of Occupational Safety and Health</a> (OOSH)
13	<a href="#">Office of Scientific Professional Development</a> (OSPD)

## Glossary

Abbreviation	Definition
AMR	Antimicrobial resistance
AI/ML	Artificial intelligence/machine learning
BVO	Brominated vegetable oil
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CERSI	Centers of Excellence in Regulatory Science and Innovation
CBP	U.S. Customs and Border Protection
DoD	U.S. Department of Defense
DEA	U.S. Drug Enforcement Administration
FDA	U.S. Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act
HFP	Human Foods Program
IMF	International Mail Facility
LLM	Large language models
MCM	Medical Countermeasures
MOU	Memorandum of Understanding
MoCRA	Modernization of Cosmetics Regulation Act
NAFLD	Non-Alcoholic Fatty Liver Disease
NAM	New Alternative Methods
NOWS	Neonatal opioid withdrawal syndrome
OCS	Office of the Chief Scientist
PMU	Permanent Makeup
SL	Satellite Laboratory/Laboratories
SLEP	Shelf-Life Extension Program



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