



Life Sciences Regulatory Overview

Life Sciences & The Law

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Meet the Faculty

Panelists

[Howard Carolan](#) - CoapTech

[Mark Gardner](#) - Gardner Law & Chrysalis Incubator

[Jonathan Havens](#) - Saul Ewing

[Denise Esposito](#) - Covington & Burling

Moderator

[Jay Reilly](#) - Saul Ewing LLP

About This Webinar

Life Sciences Industry Basics

In this episode, we explore the complex regulatory landscape of the life sciences industry, providing attorneys with critical insights into the compliance requirements that govern pharmaceuticals, medical devices, and diagnostics. Whether you advise biotech startups, multinational pharmaceutical companies, or investors, understanding regulatory frameworks is essential for mitigating legal risks and ensuring compliance in product development and commercialization.

Attorneys will gain an overview of key regulatory bodies—including the FDA (United States), EMA (Europe), and other global authorities—and learn how evolving regulations shape product approvals, safety standards, and market access. This session will also highlight legal strategies for navigating regulatory challenges, minimizing liability, and advising clients on compliance best practices.

About This Series

LIFE SCIENCES & THE LAW 2025

This webinar is part of a series titled “Life Sciences & The Law 2025.”

"We Bring Good Things to Life" was an advertising slogan used by General Electric between 1979 and 2003, focused mainly on General Electric's appliances and lighting fixtures. We'd argue that it would be an even better slogan for the Life Sciences industry.

The Life Sciences Industry encompasses companies and organizations that are dedicated to researching, developing, manufacturing, and distributing products and technologies to improve human and animal health. Key sectors within life sciences include biotechnology, pharmaceuticals, medical devices, and diagnostics. The industry's work ranges from bench research and small-scale manufacturing to performing small and large-scale clinical trials, developing manufacturing processes on a commercial scale, working closely with regulatory agencies, to developing pricing, marketing, and distribution strategies. The life cycle of a drug or medical device often involves many parties controlling the product at various times, involving the bench of university researchers, development by small startup companies, commercialization by larger industry players, diversification by sublicensees, and distribution by resellers.

Life sciences is a highly regulated field due to its direct impact on health and safety, with strict compliance standards overseen by regulatory bodies like the FDA in the United States and EMA in Europe. The industry is characterized by high research and development (R&D) costs, long development timelines, and significant investment in innovation and technology. The life sciences industry is also increasingly interdisciplinary, intersecting with data science, artificial intelligence, and bioinformatics to drive advancements in personalized medicine, gene therapy, and diagnostics.

Episodes In This Series

1. Life Sciences Industry Basics
Premiere date: 4/29/25
2. Life Sciences Regulatory Overview
Premiere date: 6/10/25
3. Life Sciences Startups – How to Begin
Premiere date: 7/29/25
4. Funding a Life Sciences Company
Premiere date: 10/7/25
5. IP Strategies for Life Sciences Companies
Premiere date: 11/18/25

Episode #2

Life Sciences Regulatory Overview

Each Financial Poise Webinar is delivered in Plain English, understandable to investors, business owners, & executives without much background in these areas, yet is of primary value to attorneys, accountants, & other seasoned professionals. Each episode brings you into engaging, sometimes humorous, conversations designed to entertain as it teaches. Each episode in the series is designed to be viewed independently of the other episodes so that participants will enhance their knowledge of this area whether they attend one, some, or all episodes.

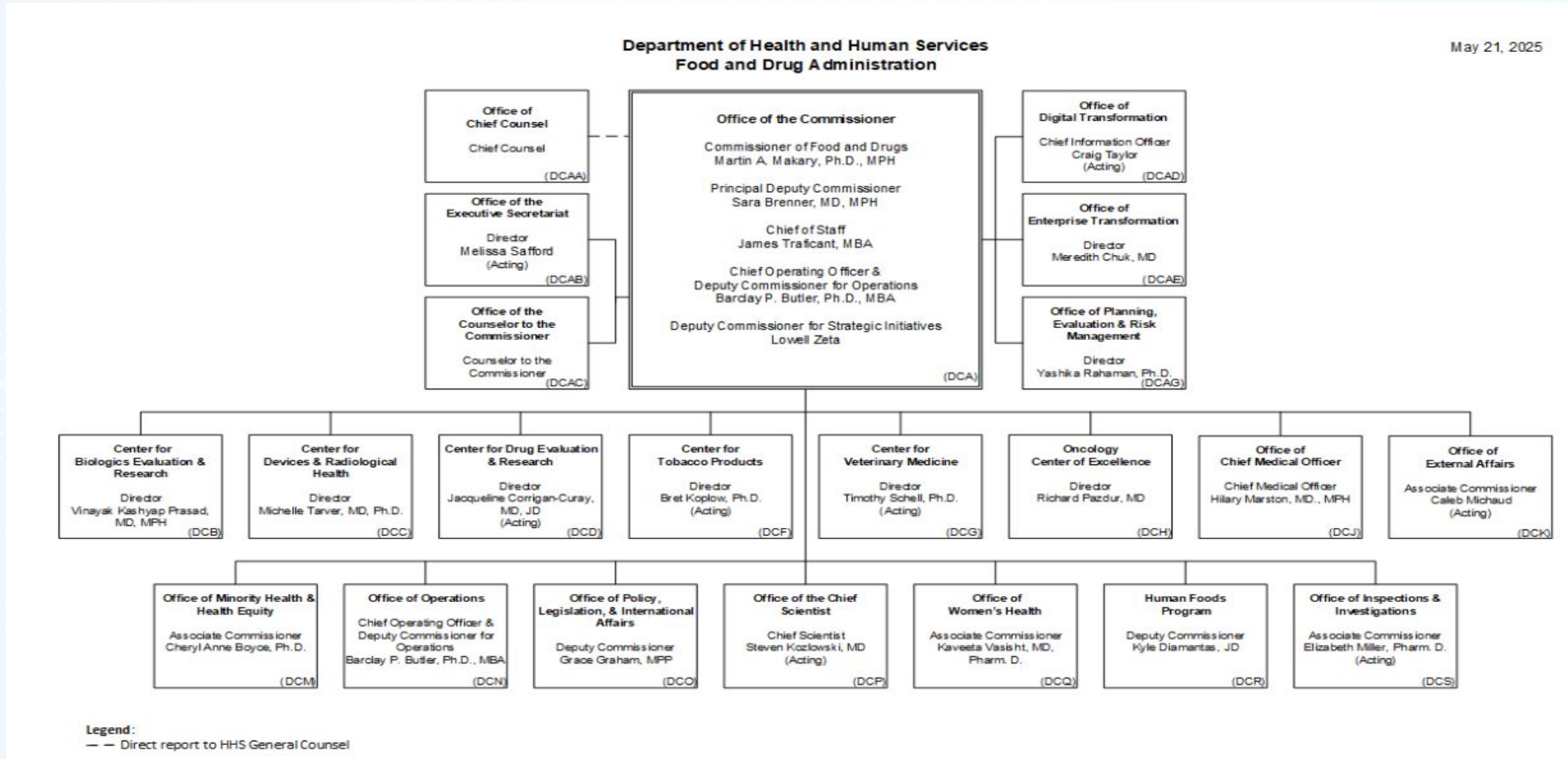
Overview

Overview

FDA Overview

- Center for Biologics Evaluation and Research
- Center for Drug Evaluation and Research
- Center for Devices and Radiological Health
- Center for Tobacco Products
- Center for Veterinary Medicine
- Human Foods Program

FDA Overview



Source: <https://www.fda.gov/about-fda/fda-organization-charts/fda-overview-organization-chart>

Overview

Threshold Question – Is your product regulated?

- Drawbacks to regulation
- Advantages to regulation
- Is my product regulated – resources
 - Medical devices
 - Animal drugs and food additives
 - Cosmetics vs. drugs
 - Dietary supplements
 - Tobacco products

Overview of Drug Approval

- Preclinical Studies and IND Requirements
 - In Vitro Studies – proof of concept, preliminary tox studies
 - In Vivo Studies
 - ✓ Pharmacokinetics
 - ✓ Pharmacodynamics
 - ✓ Toxicology
 - ✓ Safety
 - CMC – Chemistry, Manufacturing and Controls
 - Clinical Trial Design

Overview of Drug Approval

- Designing Clinical Trials
 - Who qualifies to participate (“selection criteria”)
 - How many people will be part of the study (“n”)
 - How long the study will last
 - Whether there will be a control group and other ways to limit research bias
 - How the drug will be given to patients and at what dosage
 - What assessments will be conducted, when, and what data will be collected
 - How the data will be reviewed and analyzed

Overview of Drug Approval

- FDA and the IND Process
 - Drug developers, or “sponsors”, must submit an Investigational New Drug (IND) application to FDA before beginning clinical research.
 - In the IND application, developers must include:
 - ✓ Drug developers, or “sponsors”, must submit an Investigational New Drug (IND) application to FDA before beginning clinical research.
 - ✓ In the IND application, developers must include:
 - i. Animal study data and toxicity (side effects that cause great harm) data
 - ii. Manufacturing information
 - iii. Clinical protocols (study plans) for studies to be conducted
 - iv. Data from any prior human research
 - v. Information about the investigator

Overview of Drug Approval

Clinical Trials – Phase I

- Primarily testing for safety
- Small populations of trial subjects, usually about 20-100 volunteers, depending on the type of drug and the disease being treated
- Pharmacokinetics are monitored
- Placebos are generally not used
- Dose ranging studies administer increasingly larger doses to one or more groups of subjects with differing regimens

Overview of Drug Approval

Clinical Trials - Phase II

- Primarily testing for efficacy—does the drug work, either to prevent or treat a disease, or sometimes looking to see if the progression of a disease has been slowed down
- Slightly larger populations of trial subjects, usually about 100-300 volunteers, depending on the type of drug and the disease being treated
- Phase II clinical trials often ascertain therapeutic dose level and dosing frequency
- Often placebos are used in Phase II trials to better measure effectiveness.

Overview of Drug Approval

Clinical Trials - Phase III

- Continued testing for safety and efficacy in larger populations
- Large populations of subjects, depending on the type of drug and the disease being treated

Overview of Drug Approval

Special Issues in Clinical Trials

- Vaccines
- Biologics vs. Small Molecules
- Precision Medicine
- Rare Diseases/Patient Recruitment

Overview of Drug Approval

Generics and Biosimilars

- A generic drug is typically a small, chemically synthesized molecule that is created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use
- A biosimilar is a type of biological product that is highly similar to an already approved reference biologic, with no clinically meaningful differences in terms of safety, purity, and potency
- Litigation over generics can impact the business of drug companies

Overview of Device Clearance and Approval

Overview of Device Regulations

Definition of a Device

- An “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article...which is”
- Recognized in the National Formulary or United States Pharmacopeia;
- Intended for use in “diagnosis...or in the cure, mitigation, treatment, or prevention of disease”; OR
- “[I]ntended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes”
- FDCA § 201(h); 21 USC § 321(h)

Overview of Device Regulations

Device Classifications - Overview

- FDA classifies devices into Class I, Class II, or Class III, depending upon their risk
- Classifications are essentially the global framework for device regulation
- Source of Law: 21 USC § 360c; 21 CFR Parts 862-892

Overview of Device Regulations

Device Classification - Class I

- “Low risk” devices
- General controls apply
- Generally exempt from premarket approval
- Examples: manual stethoscope, tongue depressors, arm slings



Overview of Device Regulations

Device Classification - Class II

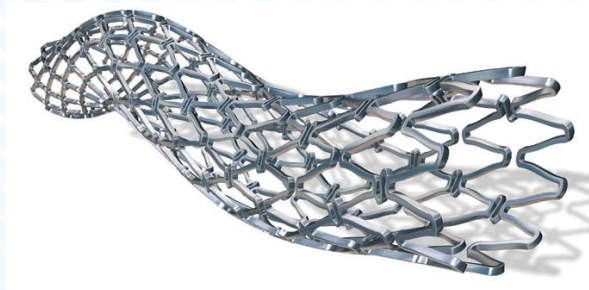
- “Moderate risk” devices
- General and special controls apply
- e.g., industry standards, guidance
- Premarket notification generally required, but sometimes exempt
- Examples: endoscopes, powered wheelchairs, infusion pumps



Overview of Device Regulations

Device Classification - Class III

- “High risk” devices
- General and special controls apply
- Premarket approval (PMA) required
- Examples: cardiac ablation catheters, coronary stents, breast implants



Overview of Device Regulations

Device Classification

- Determining device classification
 - Classification regulations: 21 C.F.R. Parts 862-892
 - Intended Use: Cryosurgical devices
 - ✓ Class III PMA devices for endometrial ablation
 - ✓ Class II 510(k) for ablation in a wide variety of surgical specialties, including gynecological use
- Technological Difference: Temperature Measuring Device
 - A clinical color change thermometer is a Class I device
 - A mercury thermometer is a Class II exempt device
 - A clinical electronic thermometer is a Class II non-exempt device

Overview of Device Regulations

General Controls

- Establishment Registration
- Device Listing
- Good Manufacturing Practices (GMPs)
- Labeling

Overview of Device Regulations

Special Controls (Class II)

- Referenced in classification regulations
- Promulgated via guidance documents
- May include:
 - Special labeling
 - Industry and other standards
 - Postmarket surveillance
 - Patient registries

Overview of Device Regulations

Jurisdictional Issues

- Combination Products
- Devices vs. Consumer Products

Overview of Device Regulations

Combination Products

- Consists of:
 - A drug and a device
 - A drug and a biologic
 - A device and a biologic, or
 - A drug, device, and a biologic
- Request for Designation (RFD): Seeks formal agency determination regarding primary jurisdiction (21 C.F.R. Part 3)

Overview of Device Regulations Financial Poise Webinars

Combination Products

- Office of Combination Products:
 - Develops policies and procedures for combination products
 - Assigns a Center with primary jurisdiction for the product
 - Resolves disputes regarding that assignment
 - Ensures timely and effective premarket review
 - Coordinates Center reviews
 - Ensures consistency and appropriateness of postmarket regulation of combination products
 - Resolves disputes regarding the timeliness of premarket review of combination product

Overview of Device Regulations

Combination Products

- Combination product is assigned to a Center for review based on its “primary mode of action.” (21 C.F.R. § 3.4)
- Guidance is provided at the Office of Combination Products website

Overview of Device Regulations

Devices vs. Consumer Products

- Cotton balls and swabs (“Q-tip”)
 - Consumer product: For applying make-up
 - Device: Applying medication to a body surface or absorbing body fluids
- Exercise equipment
 - Consumer product: For general health and fitness
 - Device: For rehabilitation of injuries
- Cell Phone/Mobile Apps
 - Consumer product: For communication purposes
 - Device: For use as a stethoscope

Overview of Device Regulations

- 510(k) Requirements
 - Most common route for medical device approval
 - Fastest and least costly pathway
 - New device must be "substantially equivalent" to an already marketed device, the "predicate" device
 - FDA does not "approve" medical devices, it grants clearances for medical devices

Overview of Device Regulations

- Substantial Equivalence
 - A device is “substantially equivalent” if:
 - ✓ It has the same intended use as the predicate; and
 - ✓ It has the same technological characteristics as the predicate, or has the same intended use as the predicate; and
 - ✓ It has different technological characteristics and does not raise different questions of safety and effectiveness; and
 - ✓ the information submitted to FDA demonstrates that the device is as safe and effective as the legally marketed device.

Overview of Device Regulations

- PMA Requirements
 - Requires independent evidence of safety and effectiveness
 - Results of nonclinical laboratory testing - toxicological, immunological, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests, as appropriate.
 - Results of human clinical trials - study protocols, safety and effectiveness data, adverse reactions and complications, device failures and replacements, patient information and complaints

Recent Events

- Recent Developments at FDA
 - New Secretary, Robert F. Kennedy, Jr.
 - Notoriously cutting staff from FDA, NIH, CMS, etc.
 - HHS announced terminations of 10,000 full-time employees, including 3,500 FDA workers
 - Approximately another 10,000 personnel have left HHS voluntarily
 - Federal workers about their future job status

Recent Events

- Most-Favored-Nation Prescription Drug Pricing Executive Order
 - Incent drug manufacturers to offer American consumers most-favored-nation lowest price for drugs
 - Facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers that sell their products to American patients at the most-favored-nation price
 - HHS to determine “most-favored-nation” price targets and communicate them to pharmaceutical manufacturers

Recent Events

- Research Funding Cuts
- Senate Health, Education, Labor and Pensions Committee's minority staff report—in the first three months of 2025 \$2.7 billion in cuts for NIH funding for research
- JAMA reports that 700 NIH grants equaling \$1.81 billion have been terminated
- CEO of Novo Holdings has warned that the \$160 billion fund will slow investment activity

Questions or Comments?

If you have any questions about this webinar that you did not get to ask during the live premiere, or if you are watching this webinar [On Demand](#), please do not hesitate to email us at info@financialpoise.com with any questions or comments you may have. Please include the name of the webinar in your email & we will do our best to provide a timely response.

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Meet The Faculty

Howard Carolan - howard@coaptech.com



Mr. Carolan is the CEO and Co-Founder of CoapTech, Inc. He has led CoapTech which has now brought two 510(k)-cleared medical devices to market, raised over \$25M in private and NIH-grant funding, and used its solution in over 1500 adult and pediatric patients. Prior to leading CoapTech, Mr. Carolan worked in clinical innovation and patient safety at the Johns Hopkins Armstrong Institute for Patient Safety and at the Johns Hopkins Center for Innovation in Quality Patient Care. In his 10 years with Johns Hopkins, Mr. Carolan was involved with a number of strategic and operational projects spanning the healthcare continuum, with a focus on patient safety, quality improvement, revenue enhancement, and information technology.

Howard's interest in these areas was forged at the Johns Hopkins Bloomberg School of Public Health, where he earned his MPH, received an NIH grant for Public Health training, and served as President of the Anna Baetjer Society for Public Health. [Read More](#)

Denise Esposito - desposito@cov.com



Denise Esposito co-chairs Covington & Burling's global Food, Drug, and Device Practice Group. Denise has more than 30 years of experience in the life sciences industry, including in senior leadership roles within the U.S. Food and Drug Administration (FDA), as the General Counsel of a publicly traded biopharmaceutical company, and as a Partner in private practice. She provides strategic, policy, and regulatory advice to biopharmaceutical, medical device, and other FDA-regulated clients, with a focus on matters that involve navigation of FDA and the complex political and policy challenges faced by regulated industry. Denise's practice includes advising clients on product development, marketing authorization strategies, incentive programs, expedited approval programs, life cycle management, and the advertising and promotion of medical products. She works with clients on FDA engagement strategies, formal and informal FDA dispute resolution, FDA administrative hearings and public meetings, and crisis management around FDA actions.

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Mark Gardner - mgardner@chrysalisincubator.com



Mark Gardner, MBA, Esq., is an attorney, professor, and entrepreneur with over 25 years of experience in the healthcare industry. He founded Gardner Law, an FDA law firm specializing in regulatory, compliance, privacy, litigation, and commercial transactions matters. He founded Chrysalis Incubator, where he guides inventors and medical device companies through the complexities of bringing innovative products to market. Mark is an adjunct professor at Mitchell Hamline School of Law, the Carlson School of Management, and the University of Minnesota Law School. His experience includes commercial roles at medical device and biotech companies. Mark often speaks and writes on topics such as AI in healthcare and medical device regulations.

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Jonathan Havens is the co-chair of both the Cannabis Law Practice and the Food, Beverage & Agribusiness Practice at Saul Ewing LLP. He also serves as Managing Partner of the Firm's Baltimore office. He counsels state cannabis and psychedelics license applicants and awardees, ancillary service and product providers, investors, management companies, and various other entities that are affected by federal and state cannabis and psychedelics laws. In addition, Jonathan maintains an active food and beverage practice, particularly with regard to cannabidiol (CBD) products, in which he counsels manufacturers, importers, distributors, and retailers of conventional foods, dietary supplements, and beverages on product development, claim substantiation, labeling, promotion, registration, reporting, and recall issues to ensure compliance with U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), and state and local requirements. [Read More](#)

Jay Reilly - Jay.Reilly@saul.com



Jay represents biotech, medical device, diagnostic and software companies, as well as universities and nonprofits, in strategic transactions in the life sciences industry, particularly complex collaborative arrangements and technology acquisitions and dispositions. Jay has extensive experience negotiating and closing joint ventures, licensing arrangements, mergers and acquisitions, and venture capital financings. He also handles day-to-day agreements such as manufacturing, clinical trial, consulting and sponsored research agreements.

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