

# **Medical Devices Program**

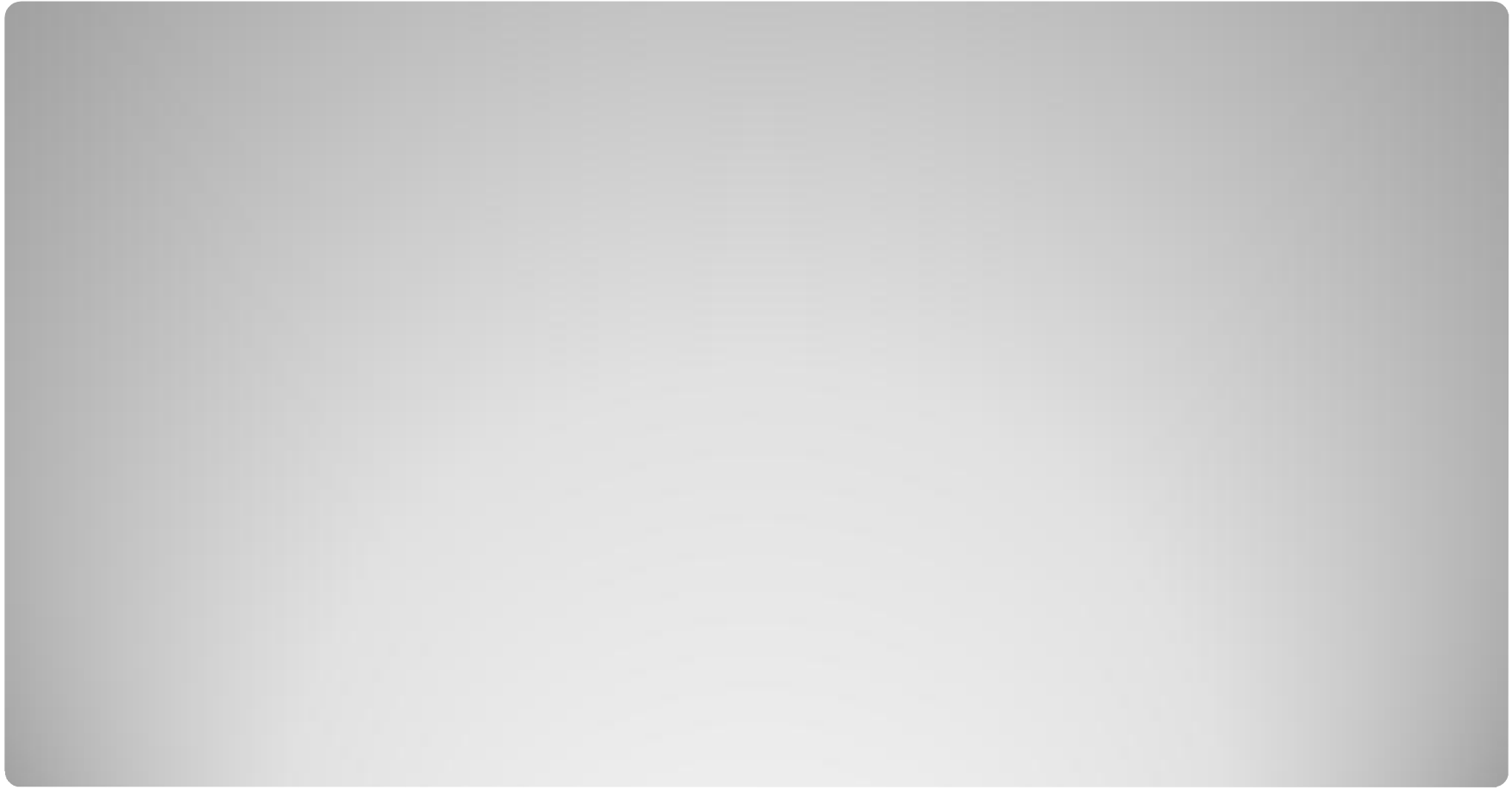
## **Vancouver, B.C.**

### **16 October 2008**

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- A little FDA history; Organization of the FDA
- Definitions
- Product Development
- Pre-market Regulatory Affairs
  - Strategies and implementation
- General update
  - On submissions and meetings with FDA
- Medical Devices Submissions
  - PMA, 510(k), HDE
- Combination Products
- Q&A on these topics

## Topics for Today



# FDA History and Organization

- Food and Drug Act of 1906
- Public Health Services Act 1908
- Modern Food, Drug & Cosmetic Act 1938
- Initial Medical Device Amendments 1976
- Safe Medical Devices Act 1990
- FDA Modernization Act 1997
- FDA Amendments Act 2007

## History

- The Constitution: 3 branches of government
  - Executive
  - Judiciary
  - Legislative
- Executive Branch: The President
  - The Cabinet
    - Department of Health and Human Services (DHHS)
      - Food and Drug Administration (FDA)
        - Office of the Commissioner

## **FDA Organization (a 30,000 foot view)**

- Office of Operations
  - Center for Devices and Radiological Health (CDRH)
  - Center for Biologics Evaluation and Research (CBER)
  - Center for Drug Evaluation and Research (CDER)
  - Center of Veterinary Medicine (CVM)
  - Center for Food Safety and Applied Nutrition (CFSAN)
  - Office of Regulatory Affairs (ORA)
  - Office of National Center for Toxicology Research
  - Office of Orphan Products Development (OOPD)
  - Office of Combination Products (OCD)

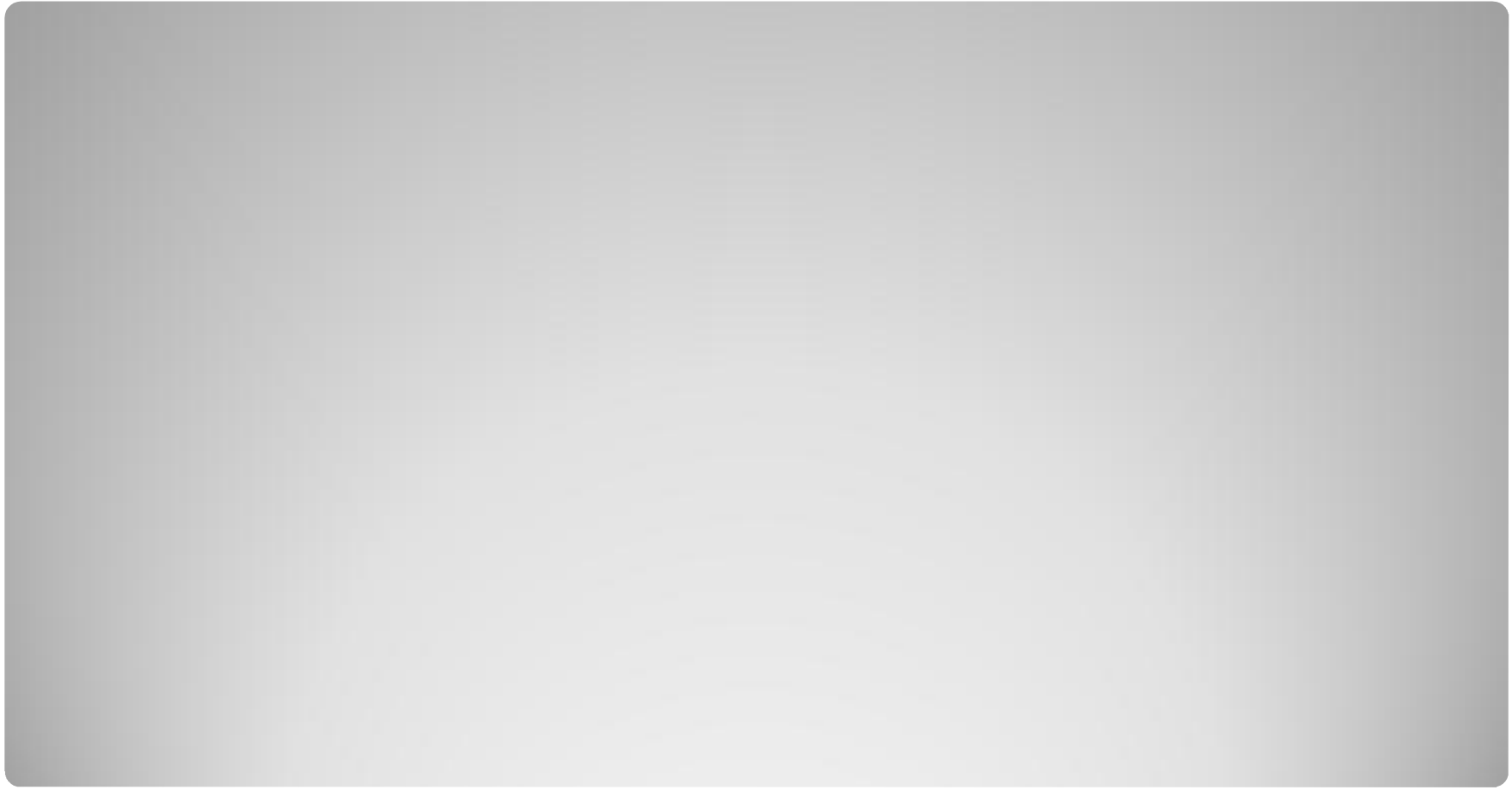
## Office of the Commissioner

- Office of the Center Director
- Office of Surveillance and Biometrics
- Office of Compliance
- Office of Systems and Management
- Office of Device Evaluation (ODE)
- Office of *In Vitro* Diagnostics (OIVD)
- Office of Industry and Industry Programs
- Office of Science and Technology

**CDRH**

- Prescription Drugs
- Over-the-Counter Drugs
- Behind-the-Counter Drugs
- Prescription Medical Devices
- Over-the-Counter Medical Devices
- *In Vitro* Diagnostic Products
- Biologic Products
- Biotechnology-derived Products
- Radiological Health Products
- Cosmetics, Cosmeceuticals
- Nutraceuticals

**What products does FDA regulate?**



# Product Development

- Why:
  - to fulfill an unmet need
    - consumers
    - professionals
- How
  - by creating something completely new
  - by modifying something already in existence
  - by combining two things in a new way

## Product Concept

# Product Specification Development

- Definitions of drug, device, biologic, in vitro diagnostic
- What is the intended use, the indication for use
- Which Center has jurisdiction
  - drugs: CDER
  - therapeutic biotechnology-derived products: CDER
  - vaccines, blood and blood products: CBER
  - devices: CDRH; CBER
  - *in vitro* diagnostics: CDRH; CBER

## Classification of the New Product

- Examples
  - Drug-drug
  - Drug-device
  - Biotechnology-derived therapeutic – device
  - Biologic-device
- Office of Combination Products in Commissioner's Office
  - regulated in one center versus another
  - regulated by more than one center, equally, on each of the separate parts that make up the product
  - regulated by more than one center, with one center taking the lead

## Combination Products

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  - intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of 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 any of its primary intended purposes."

## Definition of a "Medical Device" [Section 201(h) of the FD&C Act]

- *In vitro* diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease, or other conditions, including a determination of the state of health, in order to cure, mitigate, treat or prevent disease or its sequelae. Such products are intended for use in the collection, preparation and examination of specimens taken from the human body.

## Definition of an “*in vitro* diagnostic”

**21 CFR 809.3(a)**

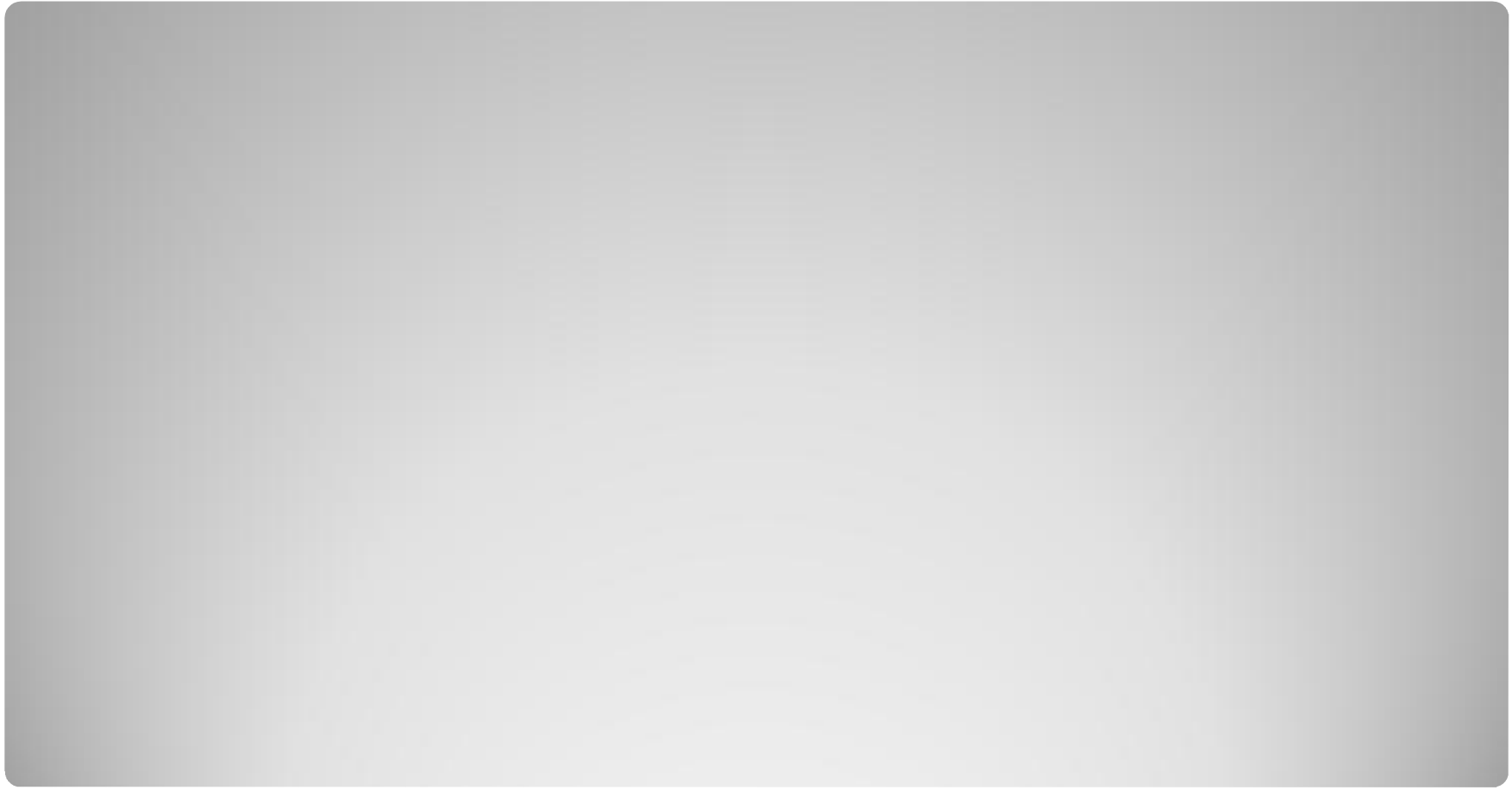
- A “biologic product” is any virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man

**Definition of a “biologic”**  
**21 CFR 600.3(h)**

- **Drug substance** means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates use in the synthesis of such ingredient

**Definition of a "drug"**

**21 CFR 314.3**



# Regulatory Strategy