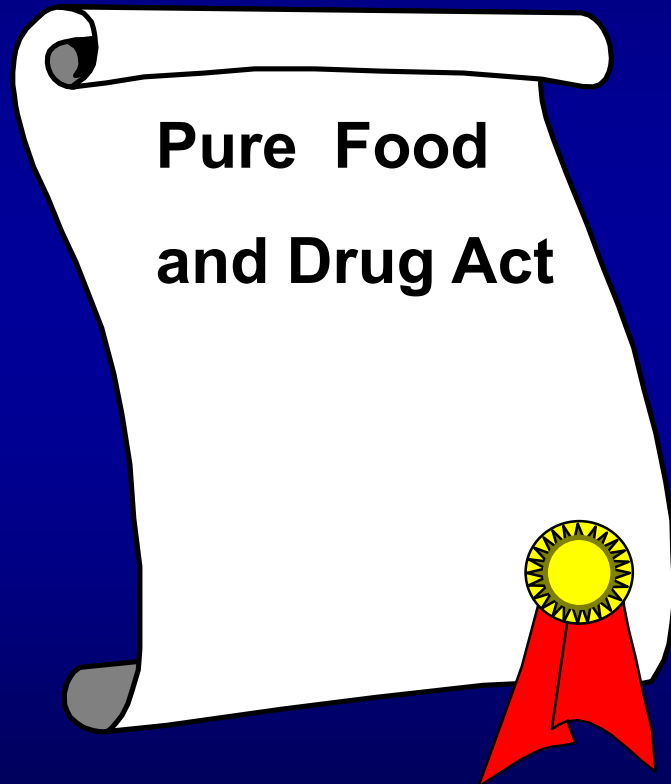


Medical Device Regulations

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The Food, Drug and Cosmetic Act: Brief History



- **First passed 1906**
- **Drug safety 1938**
- **Drug efficacy 1962**
- **Medical devices 1976**
- **Device GMPs 1978**
- **Safe Medical Devices Act 1990**

The Food, Drug and Cosmetic Act: General Concepts

- **Products regulated**
- **Adulteration**
- **Misbranding**
- **Approval to market**
- **Inspection provisions**
- **Protect the public health**

Medical Device Regulations

- **USA:**
 - <http://www.fda.gov/cdrh/devadvice/default.htm>.
- **Canada:**
 - <http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php>
- **EU:**
 - <http://www.mhra.gov.uk/Howweregulate/Devices/MedicalDevicesDirective/index.htm>

Framework

- Regulatory Submissions
 - The communication with the Regulatory Body to prove Risk versus Benefit.
 - Jurisdictions
- Quality Systems
 - The rules and standards that guide the design and development of the product.

Regulatory Concepts

- Classification – Risk Based Approach
 - Follow Schedule 1 of the Canadian Medical Device Regulation
 - Keyword index for Medical Devices
 - FDA Searchable Database

Regulatory Concepts

- Substantial Equivalence
 - Predicate Devices

Regulatory Concepts

- 510(k)
 - Class 1 and Class 3, and most Class 2 medical devices, are required to file a 510(k) with the FDA.

Regulatory Concepts

510(k) Summary 21CFR807.92

- Sponsor
- Device Name
- Predicate Device
- Device Description
- Intended Use
- Technological Characteristics and Substantial Equivalence
- Performance Data

Regulatory Concepts

- *in vitro* Diagnostics definition:
 - Reagents instruments and systems intended for use in 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 sequale... use in the collection, preparation, and examination of specimens taken from the human body.

Regulatory Concepts

- IVDs are subject to premarket and postmarket controls

Regulatory Concepts

- General Controls:
 - Adulteration; misbranding; device registration and listing; premarket notification; banned devices; notification, including repair, replacement or refund; records and reports; restricted devices; and good manufacturing practices.

Regulatory Concepts

- Pre-IDE
 - Pre-submission process.
 - The new product involves cutting edge technology and it will be helpful to familiarize FDA with the technology in advance of the submission.

Regulatory Concepts

- IVD 510(k) – Substantial equivalence
 - Analytical studies using clinical samples.

Regulatory Concepts

- IVD PMA
 - Class III.
 - The safety of the device relates to the impact of the device's performance, and in particular on the impact of false negative and false positive results, on patient health.

Quality Systems

- 21CFR820 and ISO 13485
 - ISO standard as the basis of regulatory requirement
 - ISO based on ISO 9001 with Medical Device specifics added.
 - Continuous Improvement stressed in 9001

Quality Systems

21CFR820 Current Good Manufacturing Practices

- Quality System Requirements
- Design Controls
- Document Controls
- Purchasing Controls
- Identification and Traceability
- Production and Process Controls
- Acceptance Activities
- Nonconforming Product
- Corrective and Preventive Action
- Labeling and Packaging Control
- Handling, Storage, Distribution and Installation,
- Records
- Servicing
- Statistical Techniques

Current Good Manufacturing Practice

- Failing to adhere to cGMP/QSR constitutes an *adulteration* under the law
- Product need not be demonstrably defective
- cGMP/QSR = Basic Quality Assurance
- cGMP/QSR = Minimum acceptable quality level
- “Umbrella” approach due to diverse nature of the industry

Questions?