

Quality in Biopharmaceuticals

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FDA Regulations

- Federal Food, Drug, and Cosmetic Act (FD& C Act):
 - Chapter V for Drugs & Devices
- Public Health Service Act (for Biologics)
- CFRs (a codification of the rules published in the Federal Register)
- Guidance Documents

- Food ▶
- Drugs ▶
- Medical Devices ▶
- Vaccines, Blood & Biologics ▶
- Animal & Veterinary ▶
- Cosmetics ▶
- Radiation-Emitting Products ▶
- Tobacco Products ▶



Get Updates

- E-mail Updates
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Spotlight

- Combination Products
- Product Safety and Tracking Program (Sentinel)
- Acetaminophen Information
- Drug Safety Information for Patients & Providers
- Licensed Vaccines
- MQSA (Mammography) National Statistics

Science & Research

- Combination Products
- Critical Path Initiative
- Clinical Trials
- Pediatrics
- Rare Diseases
- Toxicological Research

[More Science & Research](#)

Regulatory Information

- How to Comment on Proposed Regulations
- Code of Federal Regulations
- Dockets Management
- FDA Federal Registers (FR)
- Laws FDA Enforces

[More Regulatory Information](#)

About FDA

- [FDA Organization](#)
- [Advisory Committees](#)

Public Health Focus

- 2009 H1N1 Flu Virus (Swine Flu)
- FDA Transparency Task Force -- Participate in Blog
- Plainview Milk Cooperative Ingredient Recall
- Electronic Cigarettes
- Warning on Body Building Products Marketed as Containing Steroids or Steroid-Like Substances
- Dental Amalgam

[More Public Health Focus](#)

News & Events

- ▶ August 03, 2009 - FDA Approves New Cholesterol-Lowering Drug
- ▶ August 03, 2009 - FDA Gives Update on Botulinum Toxin Safety Warnings; Established Names of Drugs Changed
- ▶ August 03, 2009 - FDA, European Medicines Agency Launch Good Clinical Practices Initiative
- ▶ August 01, 2009 - U.S. Marshals Seize Skin Sanitizer, Protectant Products Made by Clarcon Biological Chemical Laboratory Inc.
- ▶ July 31, 2009 - FDA Takes Action Against Teva Animal Health Inc.

Report a Problem

- Drugs, Medical Devices... (MedWatch)
- To Report an Emergency
- To Report a Non-Emergency
- Report Suspected Criminal Activity

Recalls & Alerts

- [Recalls & Safety Alerts](#)
- [Warning Letters](#)

[More Safety Information](#)

Approvals & Clearances

- [Product Approvals](#)

Major differences

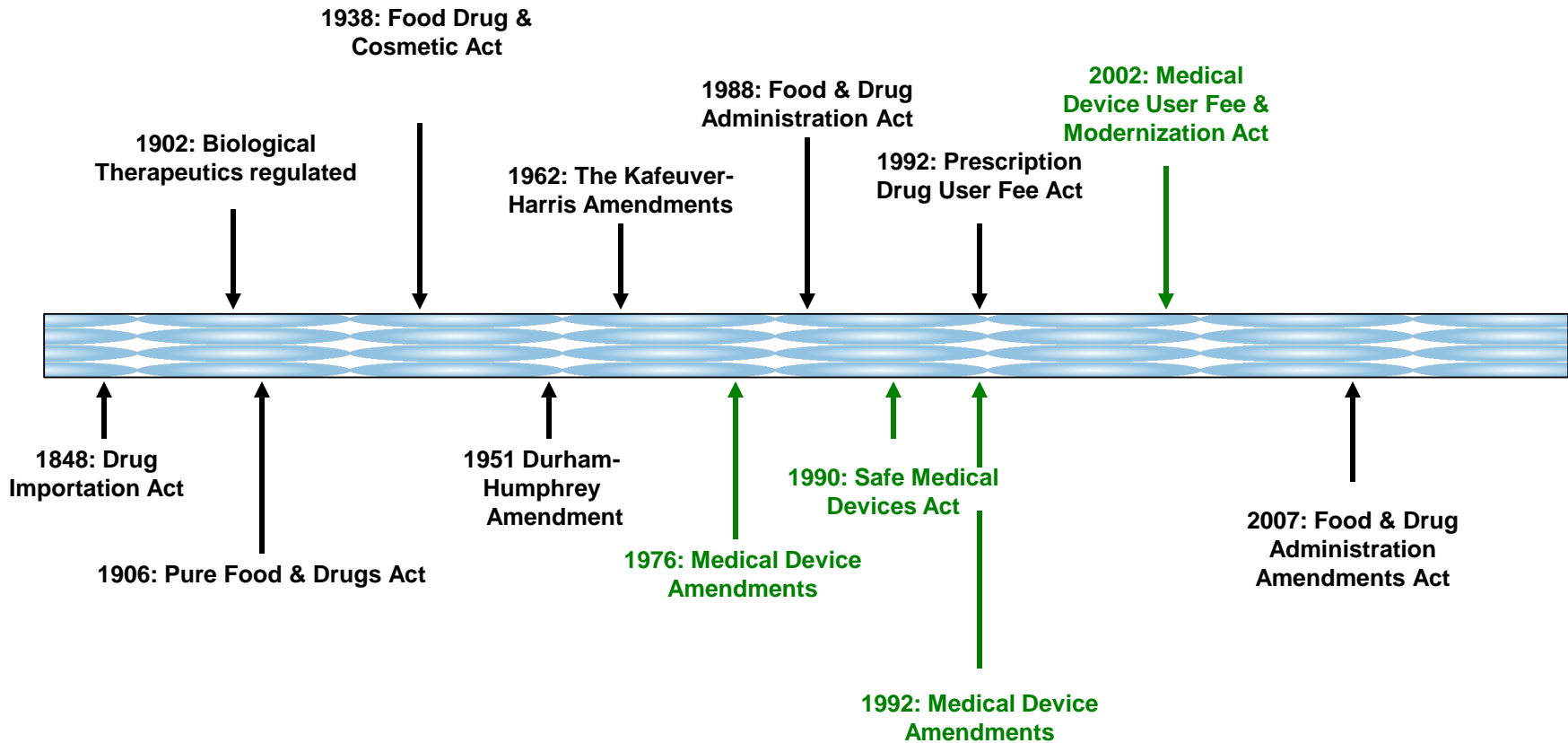
ISO 9001

- Optional – inspections paid by client
- Passing the audit results in certification
- Non-conformance results in audit findings to be resolved
- Market driven
- Inspections always scheduled with firm
- Regulations are purchased
- Procedure not required; can all be covered through training
- Focus on compliance

FDA

- Legally required to follow acts & CFRs
- Non-conformance results in audit findings to be resolved
- Major non-compliance results in seizure & injunction
- Approval required prior to marketing in USA (no certification)
- Can demand a recall
- Inspections may be without notice (generally no charge)
- Regulations are public information
- Procedures are required
- Focus on compliance, safety & efficacy

History of the FDA



Responsibilities of the Quality Unit

- 21CFR211.22 for drugs
 - Responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated
 - Responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product

Responsibilities of the Quality Unit

- ICH Q7 (FDA Guidance – GMP for API)
 - The quality unit(s) should be involved in all quality-related matters.
 - The quality unit(s) should review and approve all appropriate quality-related documents.
 - The main responsibilities of the independent quality unit(s) should not be delegated. These responsibilities should be described in writing and should include, but not necessarily be limited to:

Responsibilities of the Quality Unit

1. Releasing or rejecting all APIs. Releasing or rejecting intermediates for use outside the control of the manufacturing company
2. Establishing a system to release or reject raw materials, intermediates, packaging, and labeling materials
3. Reviewing completed batch production and laboratory control records of critical process steps before release of the API for distribution
4. Making sure that critical deviations are investigated and resolved
5. Approving all specifications and master production instructions
6. Approving all procedures affecting the quality of intermediates or APIs
7. Making sure that internal audits (self-inspections) are performed
8. Approving intermediate and API contract manufacturers
9. Approving changes that potentially affect intermediate or API quality
10. Reviewing and approving validation protocols and reports
11. Making sure that quality-related complaints are investigated and resolved
12. Making sure that effective systems are used for maintaining and calibrating critical equipment
13. Making sure that materials are appropriately tested and the results are reported
14. Making sure that there is stability data to support retest or expiry dates and storage conditions on APIs and/or intermediates, where appropriate
15. Performing product quality reviews (as defined in Section 2.5)

Backup Slides

Drug & Biologic Regulations

- 21 CFR part 11 Electronic Records & Signature
- 21 CFR part 210 cGMP
- 21 CFR part 211 cGMP
- 21 CFR part 312 Investigational New Drug Application
- 21 CFR part 320 Bioequivalence and Bioavailability
- 21 CFR part 314 Applications for FDA Approval to Market a New Drug
- 21 CFR part 600 Biological Products
- 21 CFR part 601 Biological Product Licensing
- 21 CFR part 606 cGMP for Blood and Blood Components
- 21 CFR part 607 Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Components
- 21 CFR part 610 General Biological Products Standards
- 21 CFR parts 640 to 680 Blood