Intelex Draft for SPARQ

Solving the Document Control Dilemma

Life Sciences Industry Example

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About The Presenter

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Agenda

An industry primer and quality approach for document control

- Health Authorities
- FDA, Code of Federal Regulations
- Enforcement
- Quality Systems
- Computer System Validation
- Quality Management System Overlay
- Client Example

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Our Dedicated Global Intelex Team

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Lead Intelex Consultant

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HEALTH AUTHORITIES

Agencies that regulate documents and product quality

Inside USA

- FDA: Food and Drug Administration

Outside USA

- MHRA: Medical and Healthcare Products Regulatory Agency (UK)
- HC: Health Canada (Canada)
- EMA: European Medicines Agency (European Union)
- ANVISA: Brazilian Health Regulatory Agency (Brazil)
- PMDA: Pharmaceuticals and Medical Devices Agency (Japan)

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FDA HISTORY

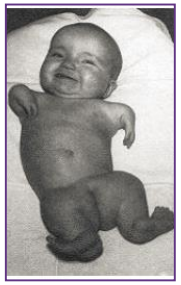
Dr. Harvey Wiley's Poison Squad

1883

Sulfanilamide Tragedy – Food, Drug & Cosmetic Act

1938

Thalidomide Tragedy – Kefauver-Harris Amend

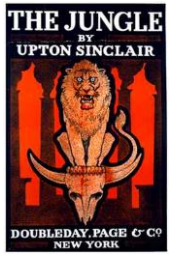


1962

Official HHS Enforcement Agency

1988

1906

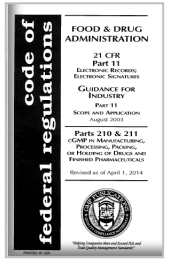


"The Jungle" – Pure Food & Drug Act

1951

Durham-Humphrey Amendment

1978



Pharmaceutical Manufacturing Regs

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Source – J&J Consumer GMP Training

FOOD AND DRUG ADMINISTRATION

The FDA governs the life sciences industry and third-party suppliers

- Human Drugs
- Vaccines
- Medical Devices
- Food Supply
- Cosmetics
- Veterinary Drugs

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CODE OF FEDERAL REGULATIONS

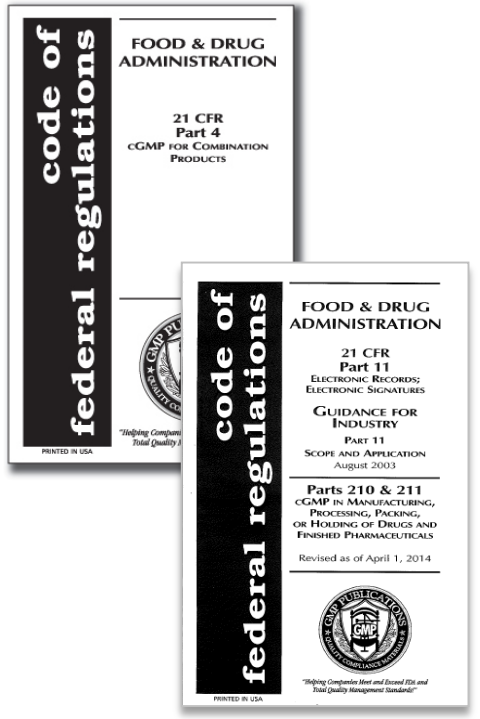
CFR Title 21 Food and Drugs governs life sciences industry – Example pharmaceutical regulations

21 CFR Part 4 – CGMP for Combination Products

21 CFR Part 11 – Electronic Records; Electronic Signatures

21 CFR Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General

21 CFR Part 211 – Current Good Manufacturing Practices for Finished Pharmaceuticals



Source – J&J Consumer GMP Training

SAMPLE REGULATION CONTENTS

11 Subparts of Part 211 – cGMP for Finished Pharmaceuticals

A – General Provisions

B – Organization and Personnel

C – Buildings and Facilities

D – Equipment

E – Control of Component and Drug Product Containers and Closures

F – Production and Process Controls

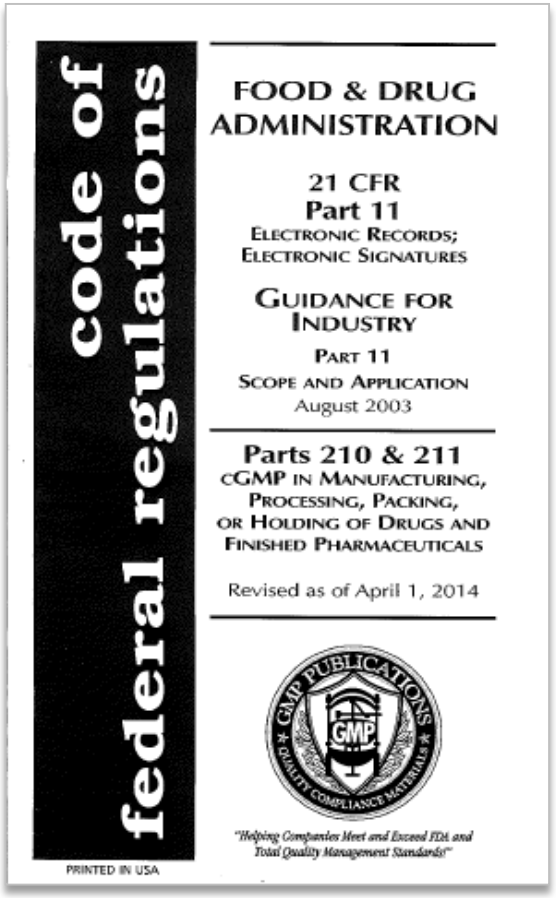
G – Packaging and Labeling Control

H – Holding and Distribution

I – Laboratory Controls

J – Records and Reports

K – Returned and Salvaged Drug Products



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FDA REGULATORY ENFORCEMENT

The FDA can exercise a range of enforcement actions to compel industry compliance

FDA 483

Non-compliance with cGMP regulations are noted

Warning Letter

First step of regulatory action and is reserved for more serious cGMP violations

Injunction

An injunction is a court order forcing a company to do what FDA tells it to do

Recall

FDA encourages companies to take such action whenever a product poses a threat

Seizure

Court order giving FDA authority to take possession of a product

Arrest

Reserved for People who knowingly manufacture and sell unsafe products

Debarment

Action taken by FDA with the support of a court to prevent an individual from working in an FDA-regulated industry

Withholding approval of new products

Pre-approval Inspection: the FDA can withhold approval to market the drug until the corrections are made

Import from foreign companies

The FDA can stop the importing of all drug products from a foreign facility

Consent Decree

Most severe enforcement action; in place for 3-5 years, removal of products from the market, large fines, penalties, disgorgement

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CORPORATE QUALITY SYSTEM

Typical quality standards and documentation based on regulations

Applies globally to

- Research & Development
- Internal Manufacturing
- Supply Chain
- ISO 9001:2015

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Source – J&J Consumer GMP Training

QUALITY MANAGEMENT SYSTEM ELEMENTS

QUALITY ORGANIZATION

EXECUTIVE MANAGEMENT

QUALITY AND COMPLIANCE

- Systems
- Validation
- Training
- Compliance
- Information Security

OPERATIONS

- Infrastructure
- Tech Ops

QUALITY FRAMEWORK

STRATEGY

Quality policy and manual

PROCEDURES – MANAGEMENT OF

Product lifecycles, incidents and changes

Security, business continuity and IT assets

CAPAs, CSVs, audits and reviews

FOUNDATION – MANAGEMENT OF

Resources, privacy, risk, and electronic documents, records and signatures

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COMPUTERIZED SYSTEMS VALIDATION

Regulations, standards and guidance

FDA 21 CFR Part 11 Electronic Records and Electronic Signatures	**FDA 21 CFR Part 210 & 211** GMP, Finished Pharmaceuticals	**FDA 21 CFR Part 820** Medical Device Good Manufacturing Practice	**EU Annex 11** GMP, Medical Products, Computerized Systems
ISO 13485 Medical Device Quality Management System	**ISO 14971** Medical Device Risk Management	**GAMP** Good Automated Manufacturing Practice	**FDA** GXP Consideration for Outsourced IT (Cloud Computing) Systems in Medical Product Manufacturing and Clinical Study Environments

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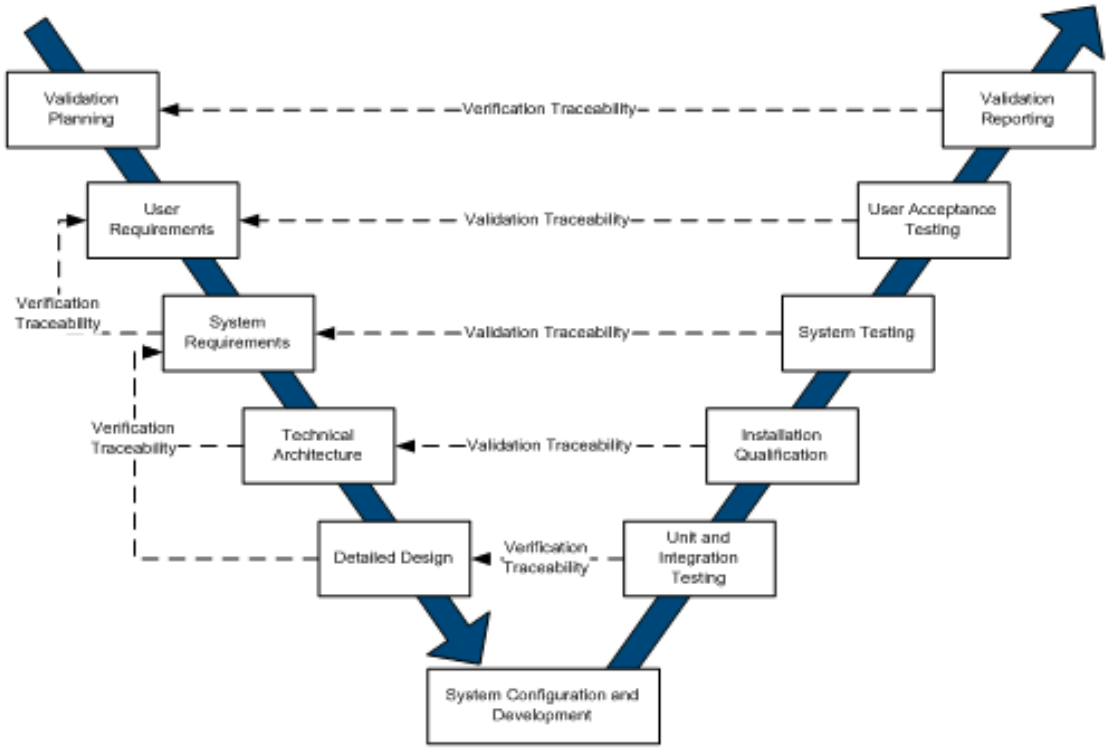
COMPUTERIZED SYSTEM VALIDATION

FDA 21 CFR Part 820 requires that "when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established use."

Computerized system validation takes into account both hardware and software.

TRADITIONAL ON-PREMISE VALIDATION

Validation Model



Validation Documentation or Artifacts

- Validation Plan
- Validation Strategy – Risk Based Approach
- User Requirements
- Functional Requirements
- Traceability Matrix
- Installation Qualification
- System Testing / Operational Qualification
  - Test Protocol, Test Scripts and Test Report
- User Acceptance Testing (Performance Qualification)
  - Test Protocol, Test Scripts, Test Report
- Validation Summary Report

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GLOBAL DOCUMENT CHALLENGES

OPPORTUNITIES THAT EXIST AT MANY COMPANIES, FOR EXAMPLE

- Legacy organizations brought together through mergers and acquisitions
- Regional, country or line of business funding for document management
- Digital transformation requires a single-source of truth that is reliable and current
- Quality, Compliance and Regulatory standards evolve over time
- People and processes move from work group knowledge to enterprise risk management

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GLOBAL FEATURES FOR DOCUMENT CONTROL

A LABELING EXAMPLE, BEST PRACTICES

Centralized Repository

Authoring in Word

Content Reuse

Renditions

Pre-configured Labels

Label Tracking

Translation Management

User-Friendly Workflow

eSignatures

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QUALITY MANAGEMENT SYSTEM ACTIVITIES

ISO 13485 Medical Device QMS

Source – Intelex

Thank You

Questions?

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