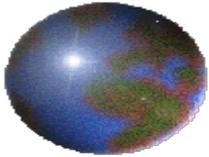
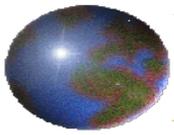


# *US FDA ORA and Field Operations*

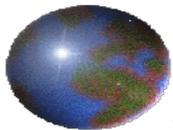


*Maida Henesian, Investigator  
Food and Drug Administration  
San Francisco District  
March 28, 2014*



# *Food and Drug Administration*

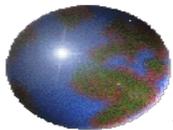




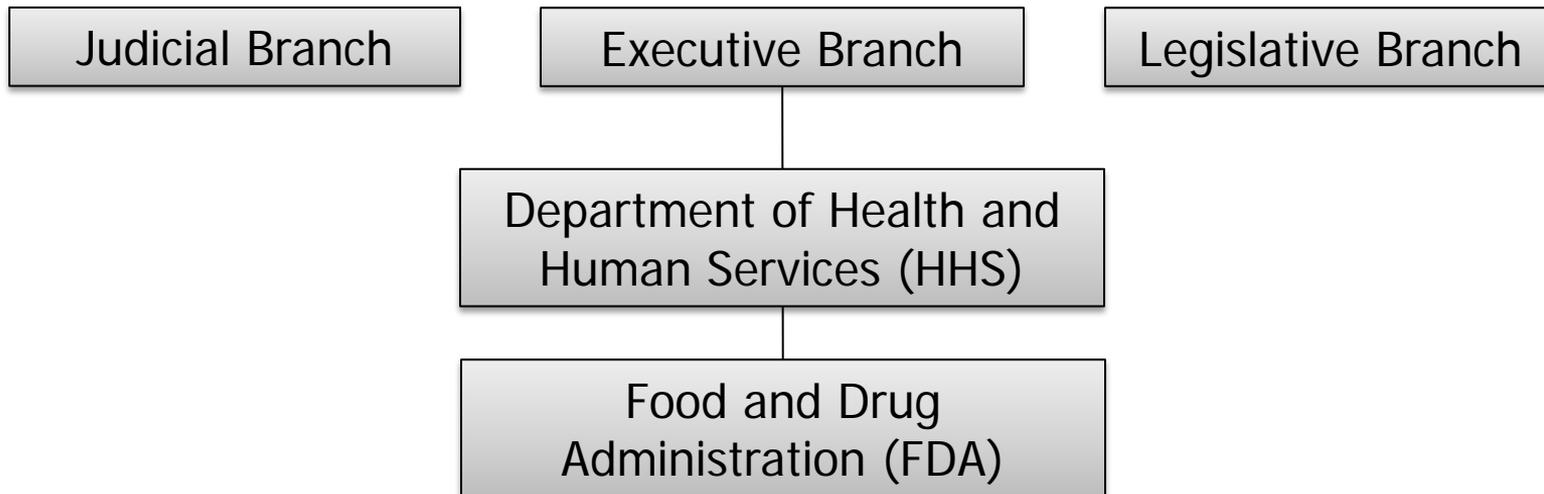
# *FDA's Mission*

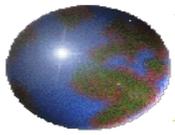
**To protect and promote the  
public health.**





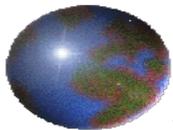
# Government Organization





# *What Does FDA Regulate?*

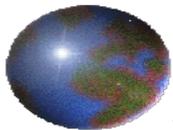
- ✦ Foods
- ✦ Drugs
- ✦ Biologics
- ✦ Medical Devices and Electronic Products
- ✦ Cosmetics
- ✦ Veterinary Products
- ✦ Tobacco Products



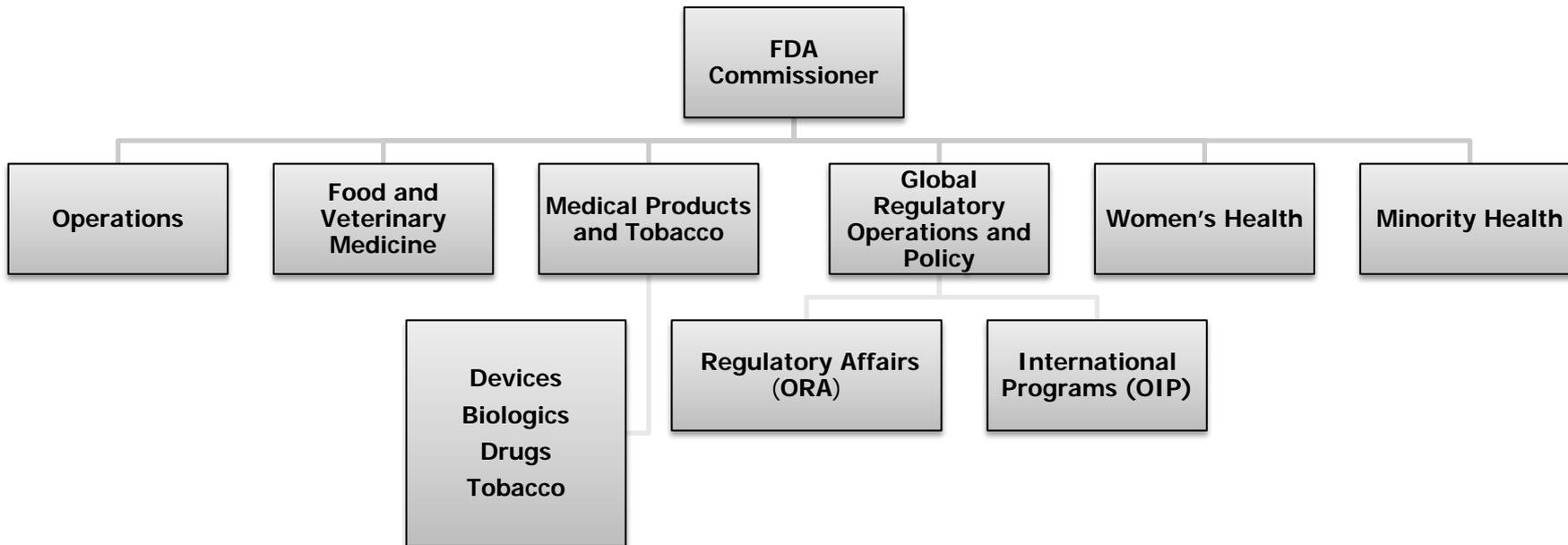
# *FDA Fun Facts*

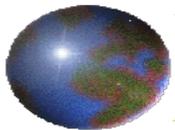
- ✦ FDA formed in 1906.
- ✦ Food, Drug and Cosmetic Act (FD&C Act) gives us authority to conduct inspections.
- ✦ Our big boss is the President.





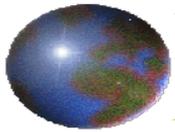
# FDA Organization





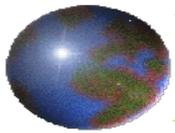
## *ORA Mission, Vision & Quality Commitment*

- ✦ **Mission** - ORA protects consumers and enhances public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products.
- ✦ **Vision** - All food is safe; all medical products are safe and effective; and the public health is advanced and protected.



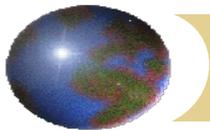
# *ORA Mission, Vision & Quality Commitment*

- ✦ **Quality Commitment** - ORA is committed to quality and continual improvement. Our actions are dedicated to effectively meeting our customers' needs.



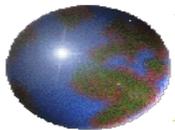
# *Office of Regulatory Affairs*

- ✦ The Office of Regulatory Affairs, which includes virtually all the field offices of FDA as well as a significant presence in headquarters, serves as the traditional eyes and ears of the agency through its network of investigators and laboratory analysts.
- ✦ ORA works closely with each of the Centers and with other components of the agency to enforce the laws that protect and advance the public health.



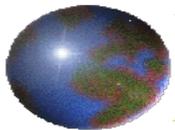
# *Types of Field Offices*

- ⊕ Regional Offices
- ⊕ District Offices
- ⊕ Resident Posts
- ⊕ Regional Laboratories

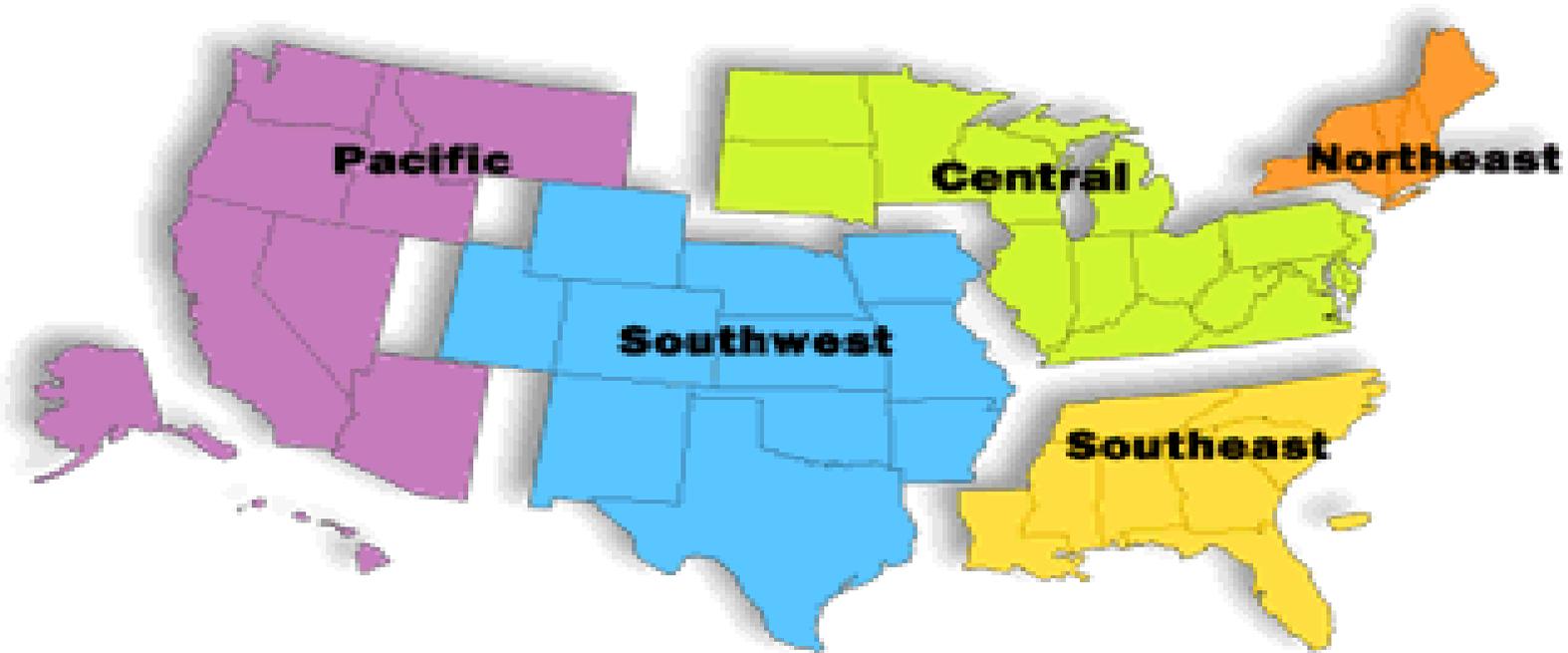


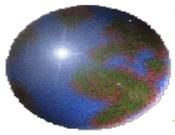
# *FDA District Offices*

- ✦ FDA/ORA has nineteen district offices throughout the US and Puerto Rico, which report in to five regional offices.
- ✦ Each district office has satellite offices called resident posts (San Francisco District has six resident posts).
- ✦ Investigators are usually assigned to a district and typically work out of either district offices or resident posts. Some specialized investigators work out of regional offices.



# Office of Regulatory Affairs (ORA)

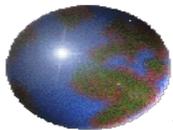




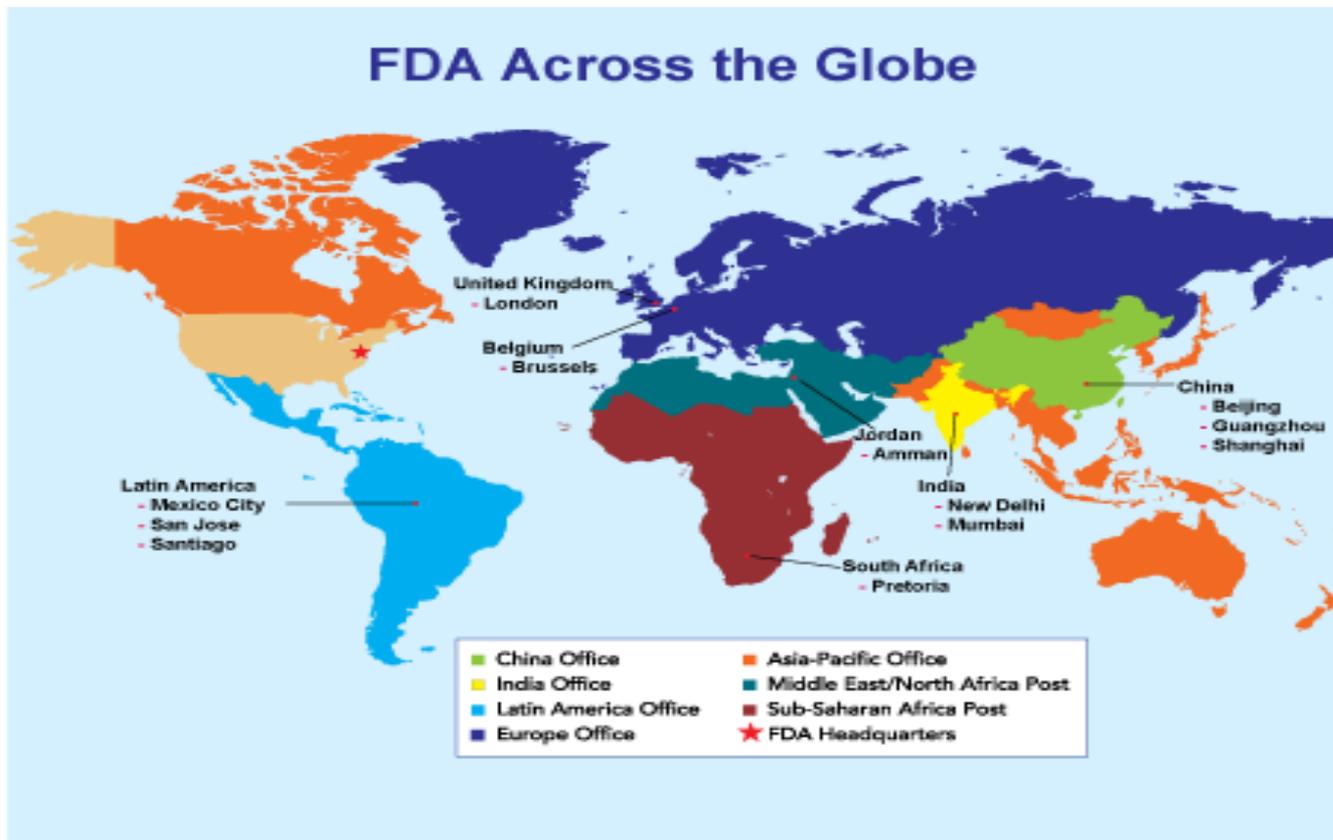
# *San Francisco District Office*

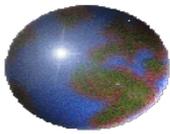


*ITA-FDA Medical Devices Regulatory Capacity Building Training Program for International Medical Devices Regulators  
March 27 - 28, 2014; San Francisco, California*



# Office of International Programs (OIP)

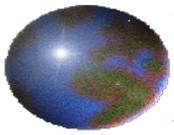




# ORA Web-site

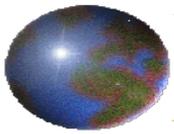
The screenshot shows a Windows Internet Explorer browser window displaying the FDA website. The address bar shows the URL: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/default.htm>. The page header includes the U.S. Department of Health & Human Services logo and the FDA logo with the tagline "U.S. Food and Drug Administration Protecting and Promoting Your Health". A search bar is visible with a "SEARCH" button. The main navigation menu includes links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main content area is titled "About FDA" and "About the Office of Regulatory Affairs". On the left, there is a sidebar menu for "FDA Organization" with links to "Office of Global Regulatory Operations and Policy", "About the Office of Regulatory Affairs", "ORA Mission & Quality Commitment", "ORA Quality Manual", "Industry Assistance", "Contact ORA", and "ORA FOIA Electronic Reading Room". The main content features a video thumbnail of a man in a blue shirt with the text "BE SMART BE AWARE BE CAREFUL". To the right, there is a "Spotlight" section with a list of links: "Enforcement Policy Statement (PDF - 19KB)", "FDA Public Affairs Specialists", "Import Program", "Bioresearch Monitoring", and "Criminal Investigations". Below the spotlight is a "Recalls & Alerts" section. The browser's taskbar at the bottom shows various application icons and the system tray with the date and time: 10:58 AM 3/4/2014.

*ITA-FDA Medical Devices Regulatory Capacity Building Training Program for International Medical Devices Regulators  
March 27 - 28, 2014; San Francisco, California*



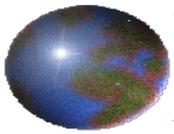
# *ORA Web-Site*

- ✦ <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/default.htm>
- ✦ OR you can go to this site by following the links in the order shown below;
  - www.fda.gov
  - Click on “FDA Organization” link
  - Click on “Office of Global Regulatory Operations & Policy
  - Click on “About the Office of Regulatory Affairs”



## *Resources; Compliance Programs and Guides*

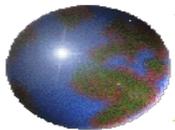
- ❖ FDA's Compliance Programs provide instructions to FDA personnel for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act and other laws administered by FDA.
- ❖ Compliance Programs are made available to the public under the Freedom of Information Act.



## *Resources; Compliance Programs and Guidances*

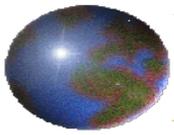
- ❖ Compliance Programs and Guidances do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used as long as the approach satisfies the requirements of the applicable statutes and regulations.
- ❖ Compliance Programs for all FDA program areas may be accessed at

<http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/default.htm>

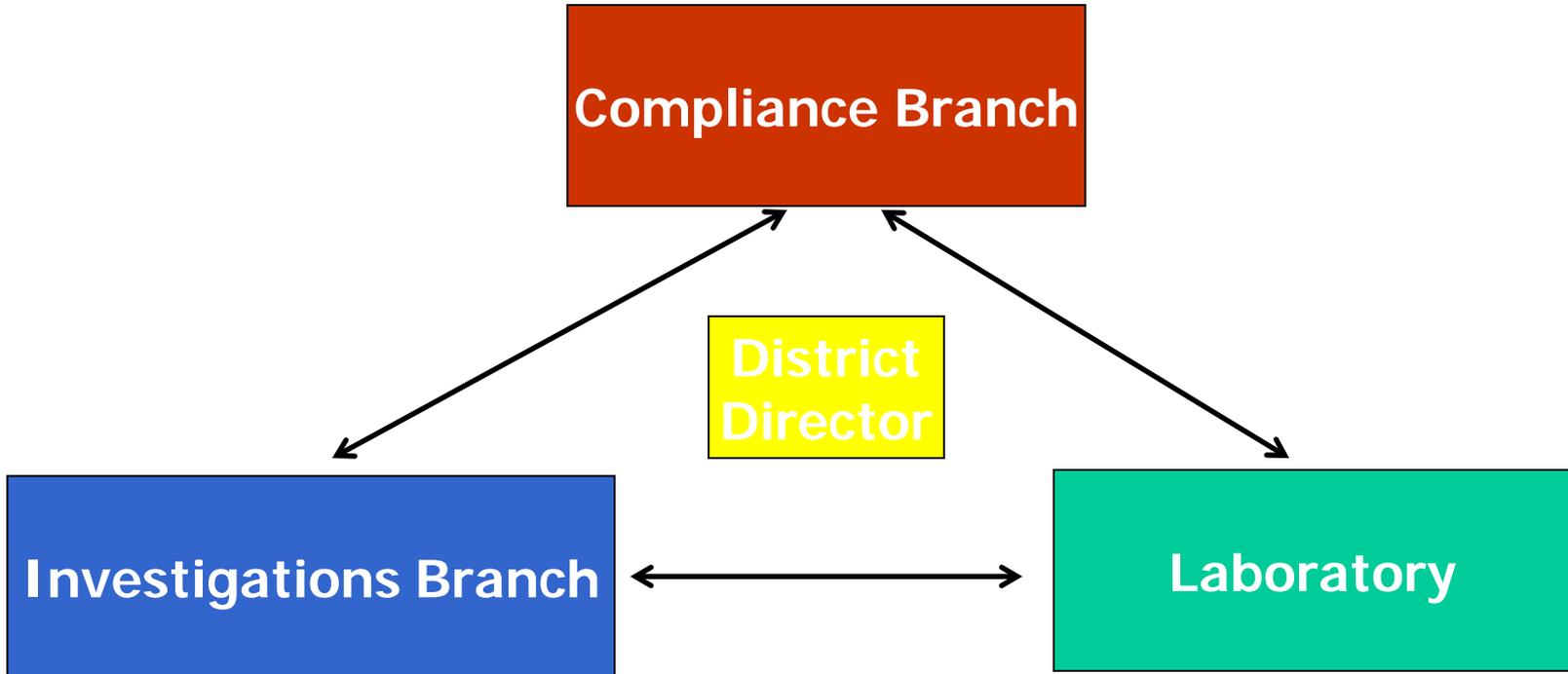


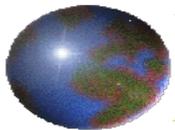
# *Resources; Compliance Programs*

- ❖ Examples of CP for Medical Devices
  - ❖ 7382.845; Inspection of Medical Device Manufacturers
  - ❖ 7383.001; Medical Device Premarket Approval and Postmarket Inspections
  - ❖ 7385.014; Inspection and Field Testing of Radiation-Emitting Electronic Products



# Typical FDA Field Office – Basic Regulatory Structure





# *Typical Branch Responsibilities*

- ✦ Investigations Branch (Domestic)

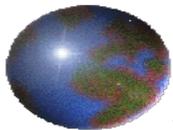
Inspects, investigates, collects samples, interviews, construct reports and memos regarding findings, makes initial district recommendations

- ✦ Compliance Branch (Domestic)

Reviews, advises, drafts advisory and regulatory actions, makes final district recommendations

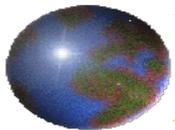
- ✦ Laboratory

Analyzes samples, provides guidance and advice

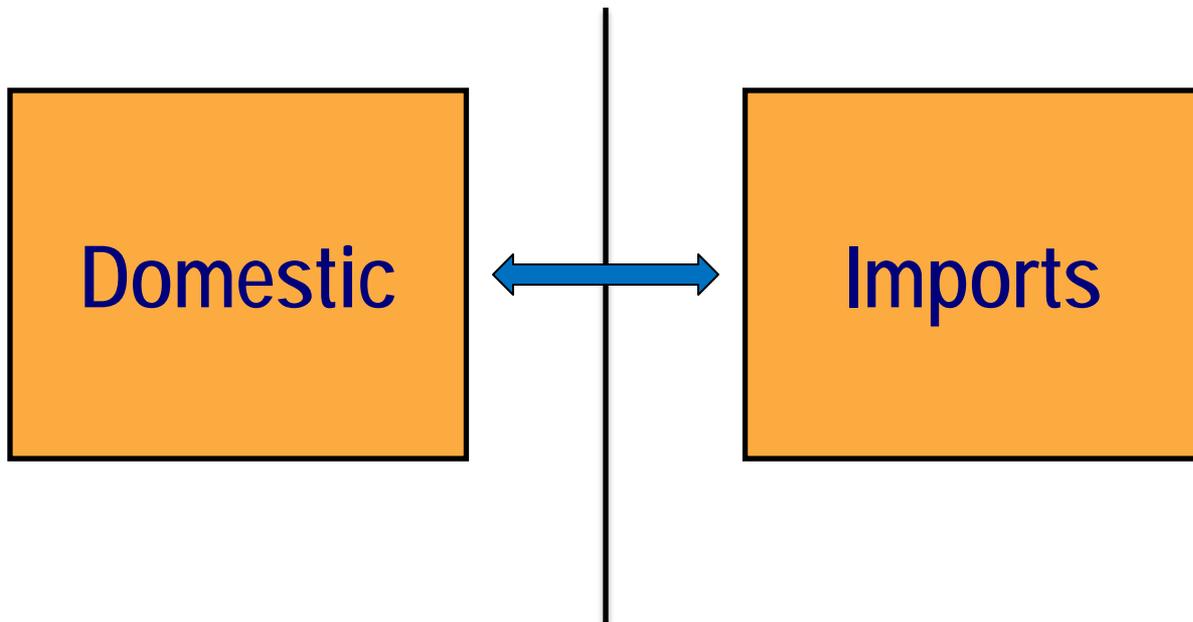


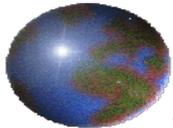
# *Who Staffs a District Office?*

- ✦ District Director
- ✦ Branch Directors
- ✦ Supervisors
- ✦ Investigators (CSOs)
- ✦ Compliance Officers (CSOs)
- ✦ Recall Coordinator
- ✦ Complaint Coordinator
- ✦ Public Affairs Specialists
- ✦ Analysts
- ✦ Physical Science Technicians
- ✦ Inspectors (CSIs)
- ✦ Technicians (CSTs)
- ✦ Legal Instruments Examiners



# *Breakdown of Work*





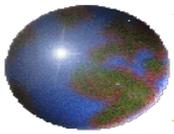
# *Work Planning and Special Assignments*

## ✦ Work Plan

- ✦ Based on legal obligations, congressional mandates, and public health concerns, the FDA district develops a yearly workplan consisting of inspections of firms within its jurisdiction.

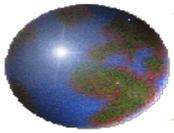
## ✦ Special Assignments

- ✦ Work that will impact planning throughout the year – includes emergencies, pre-approval assignments, complaint follow-ups, recall audit checks, and special investigations. District management alters workplan to accommodate.



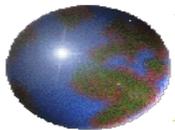
# *International Inspections*

- ✦ International Inspections by FDA are typically performed by experienced district investigators. Districts have a number of international inspections built into the work plan every year. The trips are managed out of Medical Products and Tobacco Inspections Coordination Branch/DMPTI.
- ✦ Reports are reviewed by district supervisors.



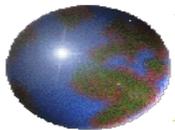
# *Are You Up For Inspection?*

- ✦ Increased Chance of Inspection:
  - ❖ No recent inspection – FD&C Act requires FDA to inspect medical device manufactures every two years
  - ❖ Recent violative history – FDA plans to follow-up with problem firms more quickly than others
  - ❖ Recalls (Corrections & Removals) and MDRs – may indicate significant Quality System deviations
  - ❖ Product of interest – can be subject of special directed assignment. Can range from one manufacturer to nationwide and international coverage



# *FDA Investigator Job Description and Requirements*





# *FDA Investigator*

Basic requirements to apply:

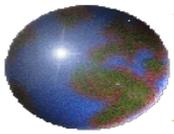
- ✦ US Citizen

- ✦ Education:

30 units at an accredited college or university leading to a bachelor's or higher degree

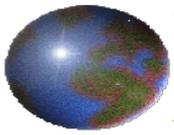
OR

30 semester hours of course work as described above plus appropriate experience or additional education



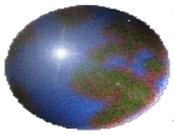
# *What Do Investigators Do?*

- ⊕ Inspections
- ⊕ Investigations
- ⊕ Consumer Complaint Follow-ups
- ⊕ Recall Audit Checks
- ⊕ Conduct Informant Interviews
- ⊕ Sample Collections and Examinations



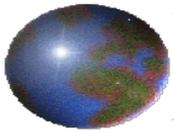
# Preparation

- ✦ When preparing an investigator often will:
  - ✦ Review any Special Assignment Instructions
  - ✦ Review the “Factory File”
    - Includes previous inspection reports (EIRs), memos of investigation & correspondence, complaints received by FDA, previous legal actions.
  - ✦ Review FDA databases, including
    - MDRs, Corrections & Removals, Complaints
    - Pending and completed approvals, clearances, IDEs
  - ✦ Contact HQ staff if appropriate (reviewers, specialists) and investigator who conducted previous establishment inspection (EI)



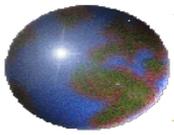
# *During the Inspection*

- ✦ During an Inspection an Investigator may return to the office to:
  - ✦ Review any assignments, clarify requirements
  - ✦ Discuss the inspection with other investigators, the supervisor, and compliance officers
  - ✦ Research unfamiliar topics
    - Legal requirements
    - Products or processes
  - ✦ Compose an FDA-483 and otherwise prepare for a close-out meeting

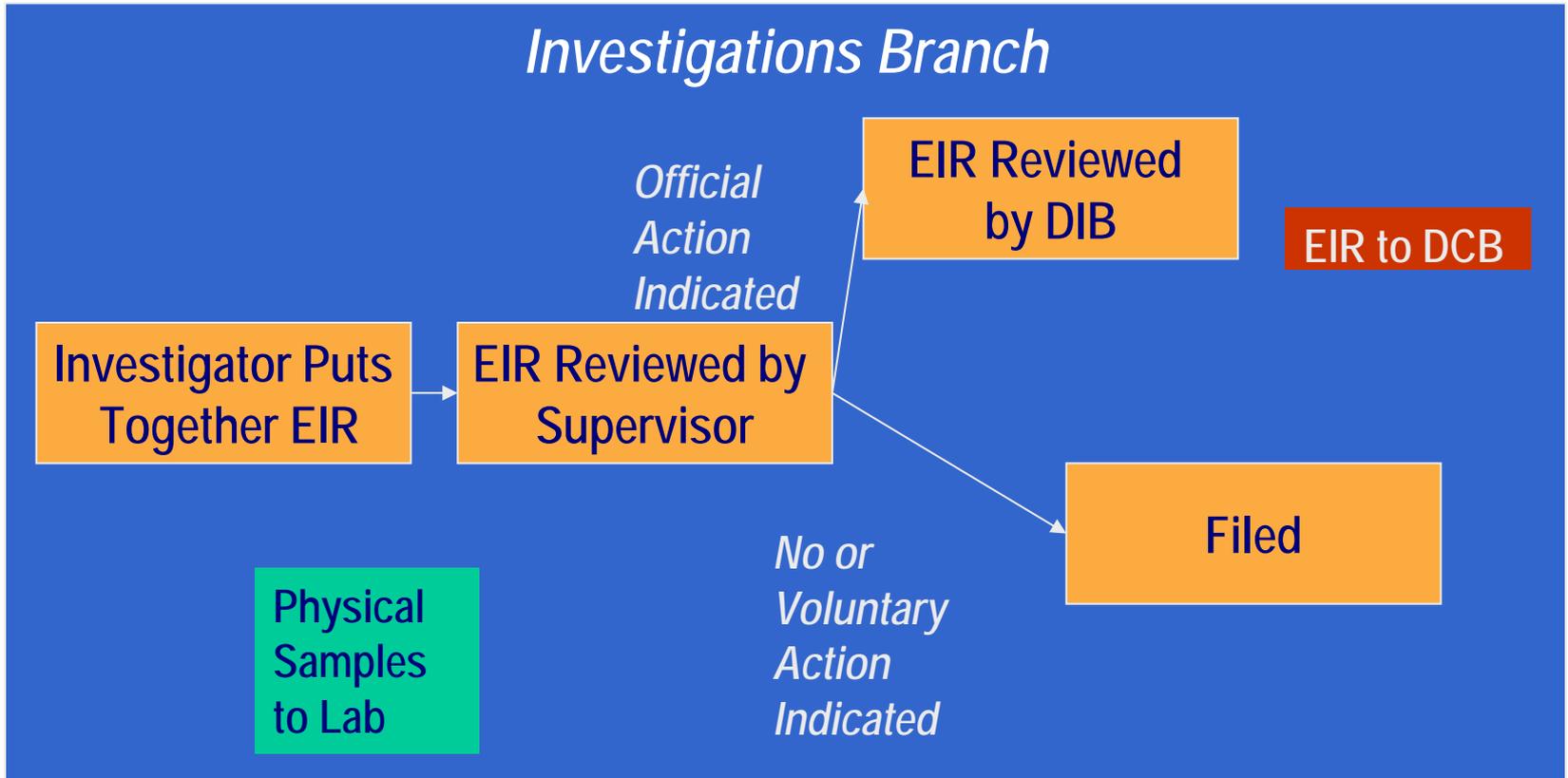


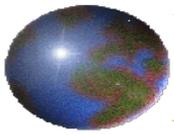
# *After the Inspection*

When closing out, the investigator generally has a good idea about whether the agency needs to take official action based on his or her findings. However, the investigator does not determine official agency action. The investigator will recommend an action to the supervisor once the investigator puts the observations and evidence together in a case report.

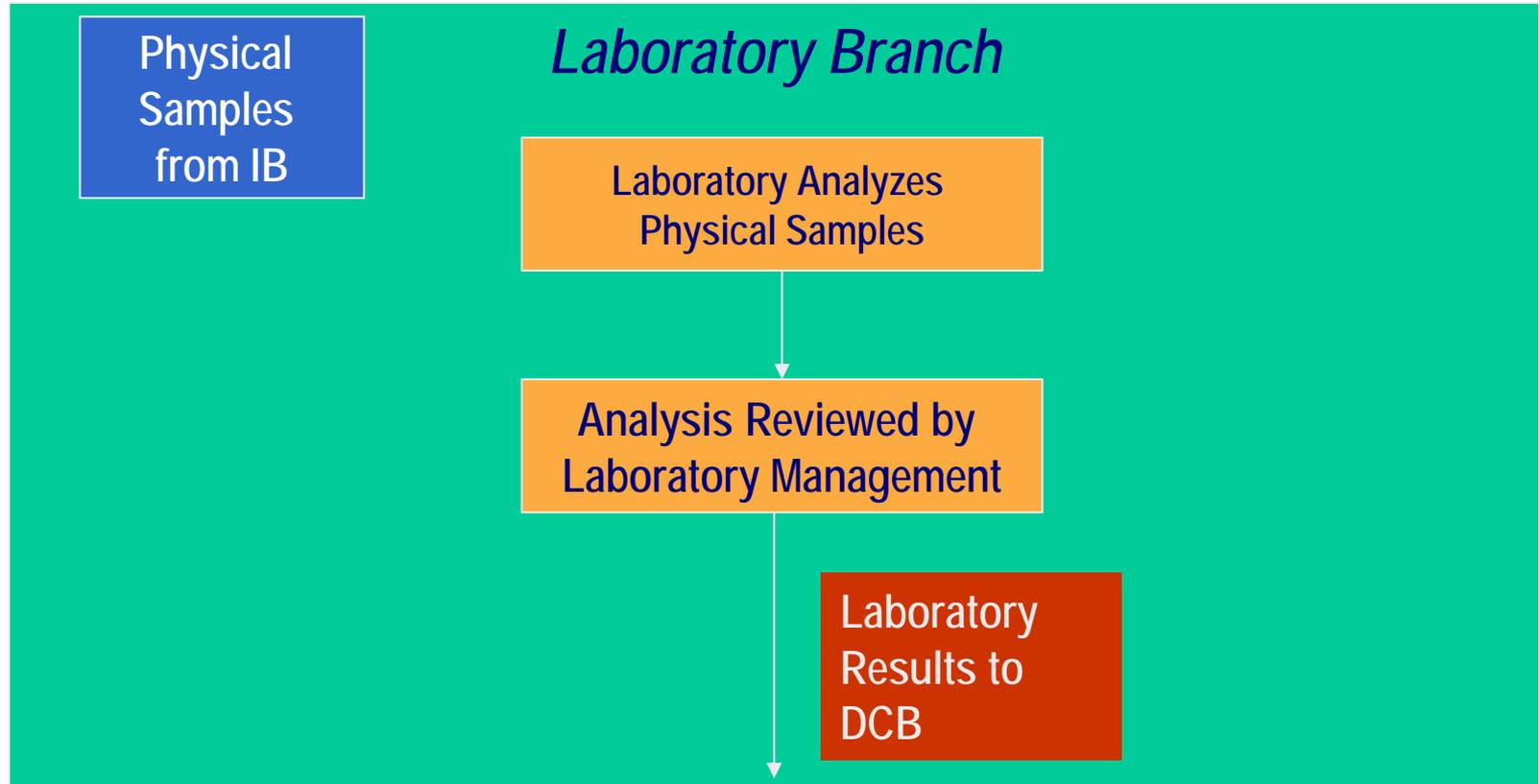


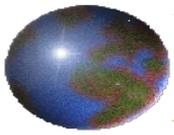
# After the Inspection – Investigations Branch



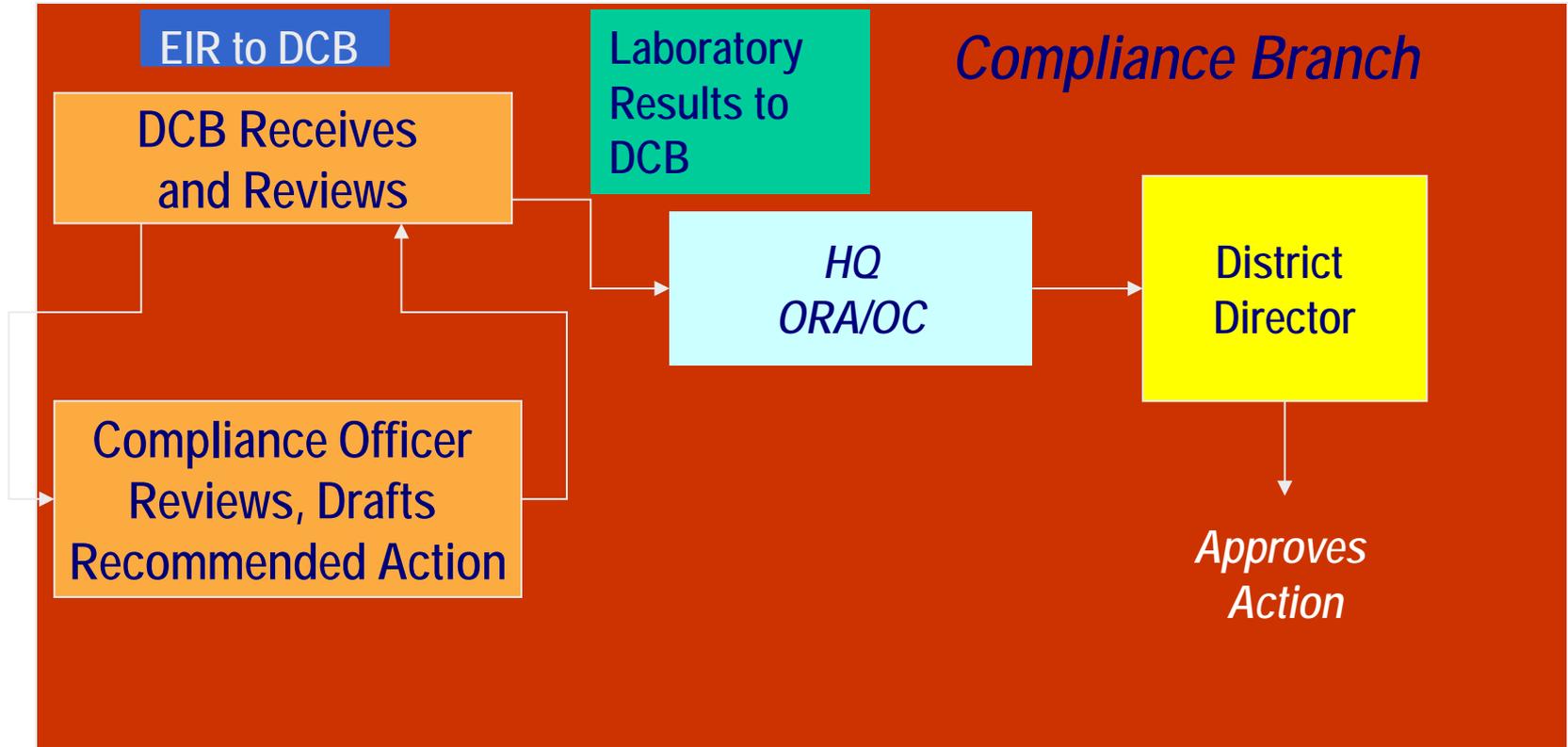


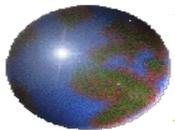
# *After the Inspection – Laboratory*





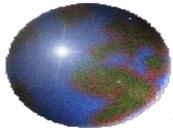
# After the Inspection - Compliance





# ***MEDICAL DEVICE INVESTIGATOR***

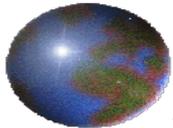




# *Training Given to Medical Device Investigators*

Basic training for all Investigators:

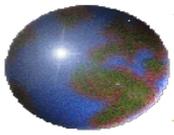
- ✦ FDA Law
- ✦ Evidence Development
- ✦ Personal Safety and Interviewing Skills
- ✦ On-the-Job Training



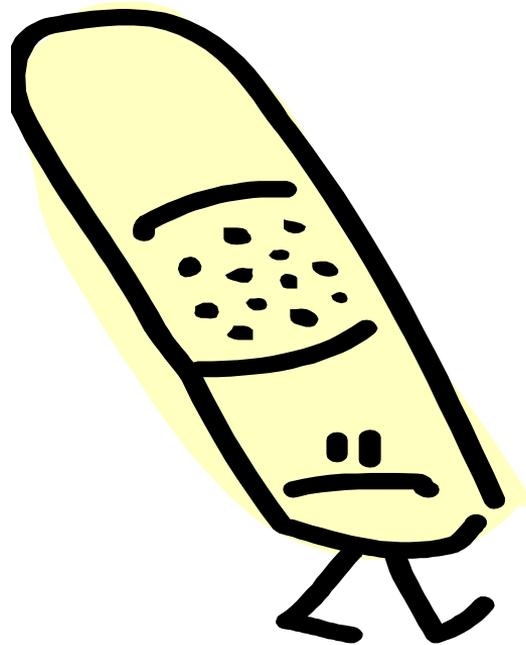
# *Training Given to Medical Device Investigators*

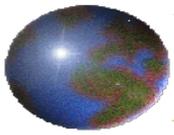
Specific training for Medical Device Investigators:

- ✦ Basic Medical Device School
- ✦ Computer Aided Inspections
- ✦ Process Validation
- ✦ Sterilization



# *What is a MEDICAL DEVICE?*



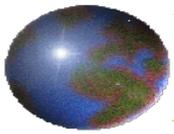


# *What is a Medical Device?*

FD&C Act, Section 201(h):

An instrument, apparatus, implement, machine, contrivance, implant, or in vitro reagent, which is

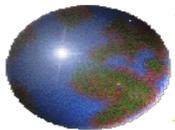
- ✚ recognized in the National Formulary (NF) or the United States Pharmacopoeia (USP)
- ✚ Used in the diagnosis, cure, mitigation, treatment, or prevention of a disease



# *What is a Medical Device?*

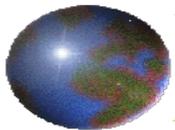
FD&C Act, Section 201(h):

- ✦ intended to affect the structure or any function of the body and that does not achieve its primary intended purposes through chemical action and is not dependent upon being metabolized for the achievement of any of its primary intended purposes.



# *Examples of Various Medical Devices*

- ✦ Surgical forceps/scissors
- ✦ Catheters
- ✦ Glucose Meters
- ✦ Implantable Devices (*e.g.* heart implants)
- ✦ X-Ray Machines
- ✦ Robotic Surgical Systems
- ✦ Mobile Apps



# *Medical devices fall into three classes*

## Class I (Low Risk)

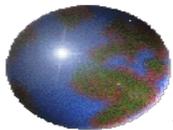
- Elastic Bandages
- Examination Gloves
- Mechanical Wheelchairs

## Class II (Medium Risk)

- Infusion Pumps
- Catheters
- Glucose Meters
- Powered Wheelchairs

## Class III (High Risk)

- Pacemakers
- Heart Valves
- Artificial Hearts
- HIV diagnostic tests



# Requirements for each class of Medical Devices

## Class I (Low Risk)

- No FDA approval process required

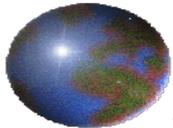
## Class II (Medium Risk)

- FDA clearance required (i.e. 510(k)/  
Premarket Notification (PMN))

## Class III (High Risk)

- FDA approval required (i.e.  
Premarket Approval (PMA))

**This shows a general approval process. There are exceptions to each class of devices.**



## *Three Things a Device Investigator Should Cover During an Inspection*

- ✦ Quality System Regulation (QS Reg)

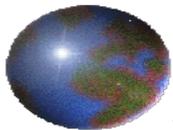
21 CFR 820

- ✦ Medical Device Reporting (MDR)

21 CFR 803

- ✦ Corrections and Removals (C/R)

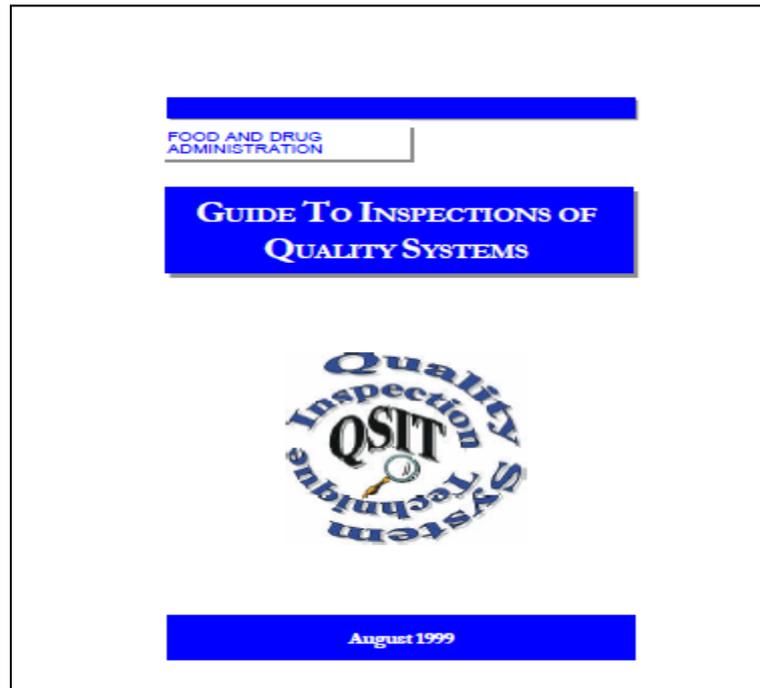
21 CFR 806

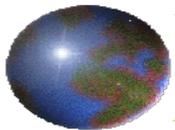


# Quality System Inspection Technique (QSIT)

## What is QSIT?

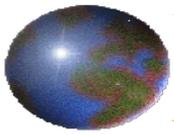
QSIT is a method on how to conduct a medical device inspection.





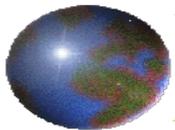
# *Why Learn About QS Reg and QSIT?*

- ✦ It is relevant to passing FDA Inspections.
- ✦ Gives you the ability to market your medical device that requires a pre-market approval inspection.



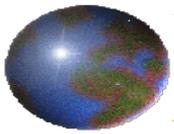
# *Basic Quality System*

- ✦ Management Controls
- ✦ Design Controls
- ✦ Production and Process Controls
- ✦ CAPA (Corrective Action and Preventive Action) /  
Complaint Handling / MDR (Medical Device  
Reporting)
- ✦ Management Controls



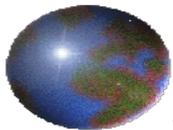
## *What is QS Reg (Quality System Regulation)?*

- ❖ QS Reg contains requirements intended to ensure that finished devices are safe, effective, and in compliance with the Act.
- ❖ Manufacturers must establish and follow quality systems to ensure that their products consistently meet applicable requirements and specifications.
- ❖ This will ensure that finished devices are safe and effective.



## *What is Quality System Regulation (QS Reg)?*

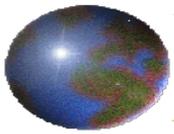
- ✦ The quality system regulation for medical devices are known as current good manufacturing practices (CGMP's).
- ✦ QS Reg requirements for devices are in part 820 (Title 21 CFR part 820).



# *QS Reg – 21 CFR 820*

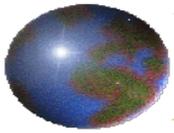
## *Basic Quality System Regulations:*

- ✦ Management Controls
- ✦ Design Controls (Verification, Validation, Design Transfer)
- ✦ Production and Process Controls (P&PC)
- ✦ Corrective Actions and Preventive Actions (CAPA) / Complaint Handling / Medical Device Reporting (MDRs)



# *Management Controls; 21CFR820.20(c)*

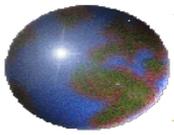
- ✦ Quality policy
- ✦ Resource
- ✦ Management representative
- ✦ Management review
- ✦ Quality audits.



# *Design Control; 21 CFR 820.30*

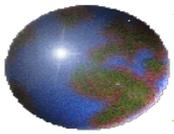
Each manufacturer shall establish and maintain Design Control Procedures.

- ✦ Design and development plan
- ✦ Design input
- ✦ Design output
- ✦ Design review
- ✦ Design verification
- ✦ Design validation
- ✦ Design changes
- ✦ Design transfer
- ✦ Design history file



## *Definition of Establish; 21CFR820.3(k)*

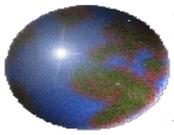
- ✦ *Establish* means define, document (in writing or electronically), and implement.



# *Production & Process Control; 21CFR820.70*

Each manufacturer shall establish and maintain procedures for:

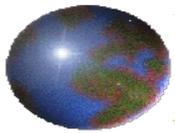
- ✦ Production and Process Changes
- ✦ Environmental Control
- ✦ Personnel
- ✦ Contamination Control
- ✦ Building
- ✦ Equipment
- ✦ Maintenance Schedule
- ✦ Inspection
- ✦ Adjustment
- ✦ Manufacturing Material
- ✦ Automated Process



## *Corrective & Preventive Action; 21CFR820.100*

Each manufacturer shall establish and maintain procedures for:

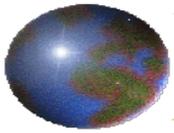
- ✦ Analyzing quality problem
- ✦ Investigating the cause of problem
- ✦ Verifying or validating the CAPA is effective
- ✦ Implementing
- ✦ Disseminating to those responsible
- ✦ Submitting to management review



# *Records Maintained*

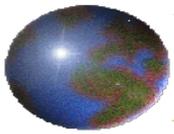
Each manufacturer shall maintain

- ✦ Device master records (DMR's); 21CFR820.181
- ✦ Device history records (DHR's); 21CFR820.184
- ✦ Complaint file; 21CFR820.198



## *Medical Device Reporting (MDR); 21CFR803*

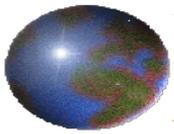
If you are a manufacturer, you must submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.



## *Reports of corrections and removals; 21CFR806*

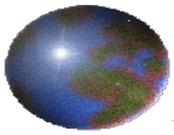
Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:

- ✦ To reduce a risk to health posed by the device; or
- ✦ To remedy a violation of the act caused by the device which may present a risk to health



## *Reports of corrections and removals; 21CFR806*

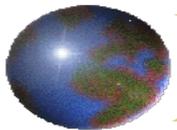
- ✦ The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal.



# *FDA – Office of Regulatory Affairs: Field Offices*

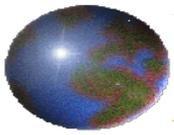


*ITA-FDA Medical Devices Regulatory Capacity Building Training Program for International Medical Devices Regulators  
March 27 - 28, 2014; San Francisco, California*



# *More Information About FDA*

[www.fda.gov](http://www.fda.gov)



*Thank You*

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