Compliance and Enforcement Priorities

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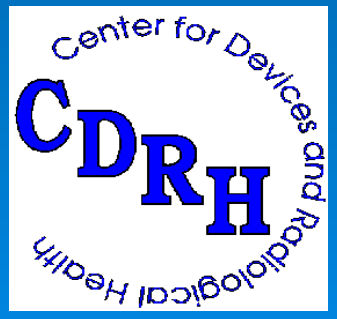
Director, Office of Compliance
CDRH/FDA



Outline

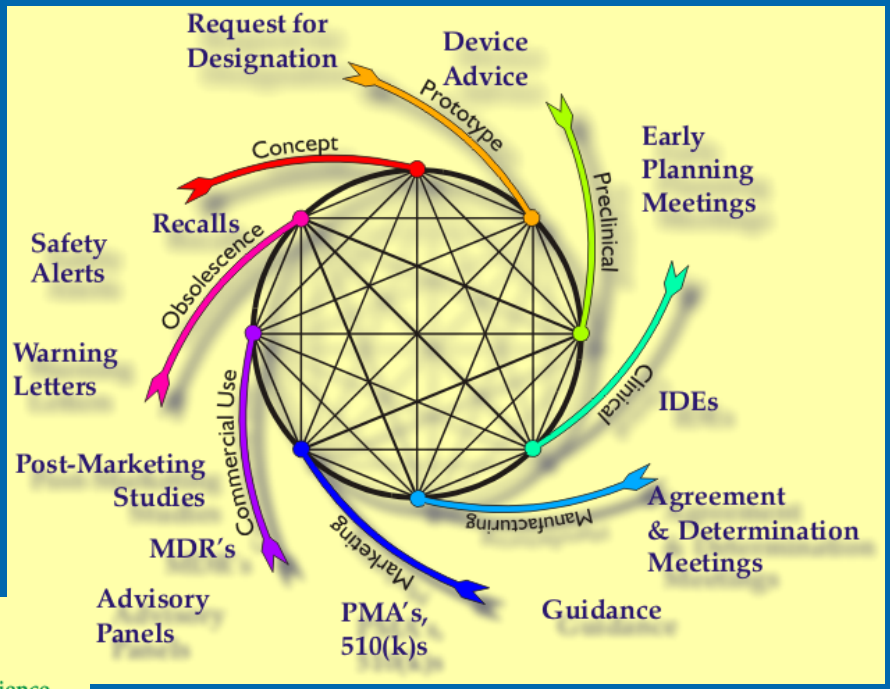
- Mission and Challenges
- CDRH Goals and Priorities
- Office of Compliance Activities
- Areas of Concern

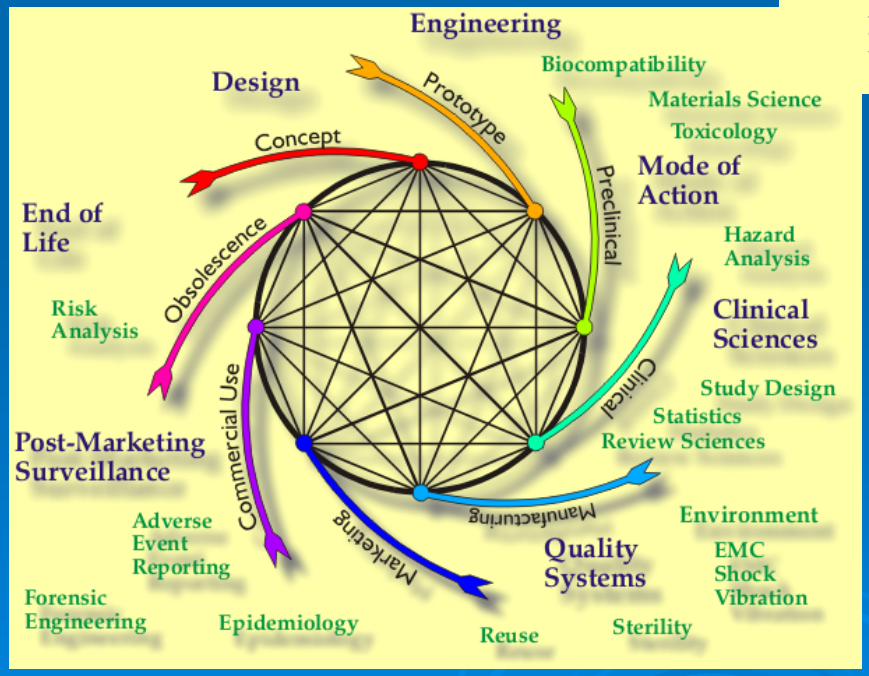
Our Mission

Promoting and protecting public health by ensuring the safety and effectiveness of medical devices and the safety of radiological products

Also

- Monitoring medical devices and radiological health products for continued safety after they are in use
- Helping the public get accurate, science-based information need to improve health

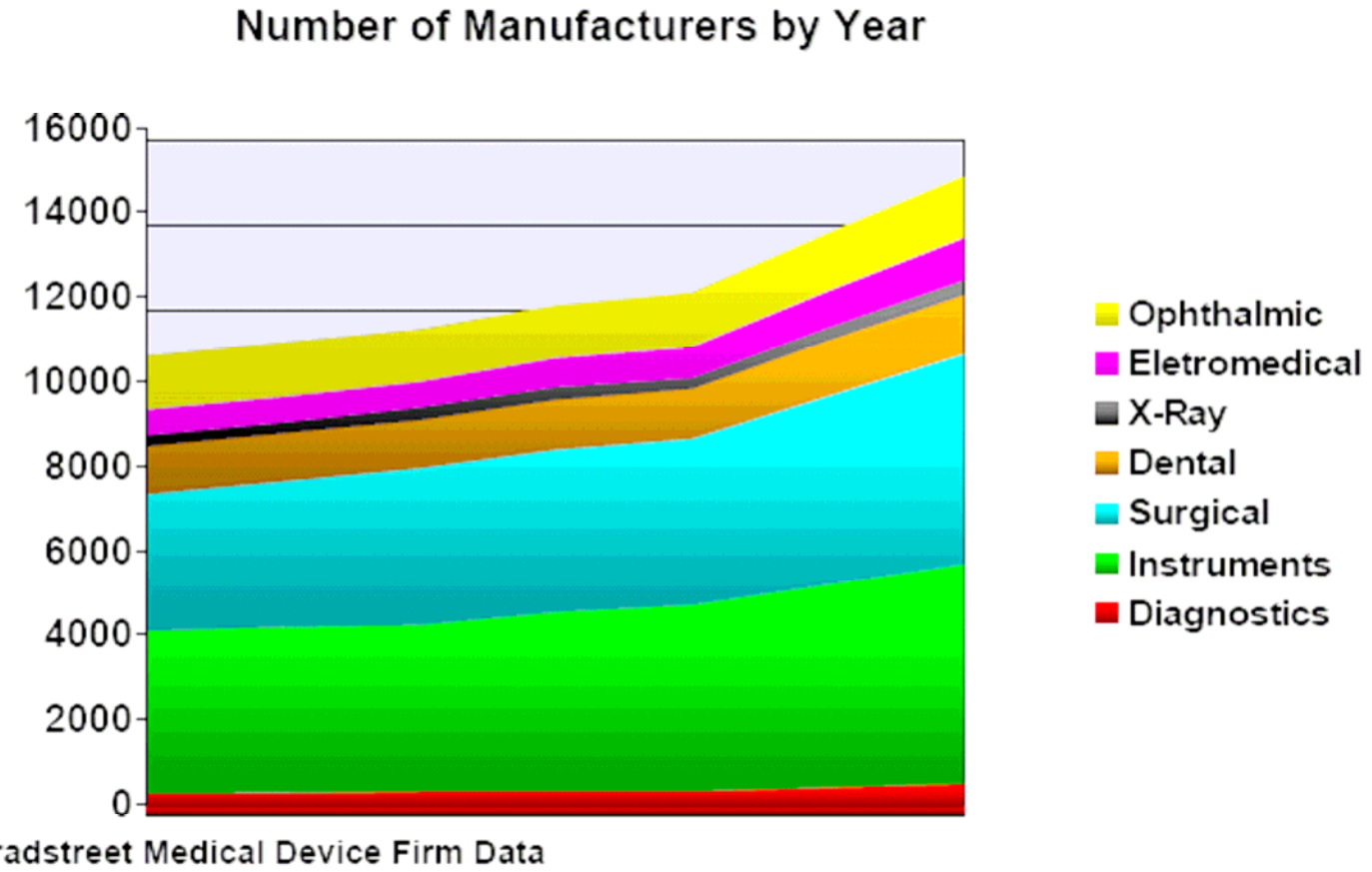




CDRH Vision

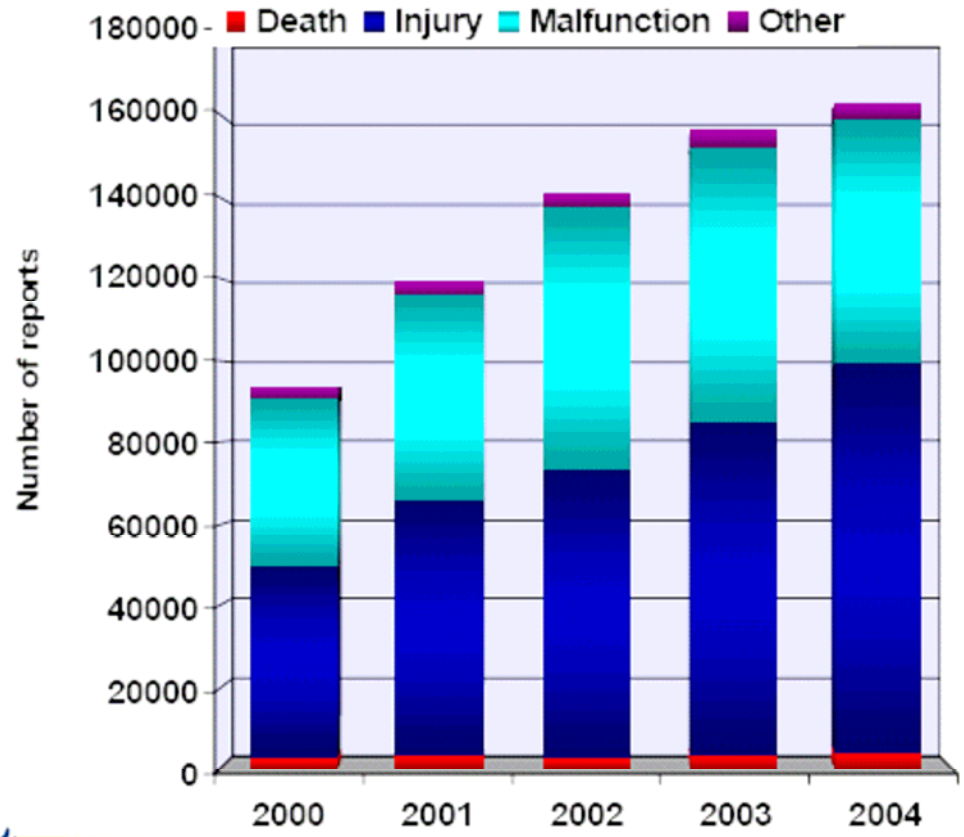
Ensuring the Health of the Public Throughout the Total Product Life Cycle – It's Everybody's Business

The medical device industry is growing



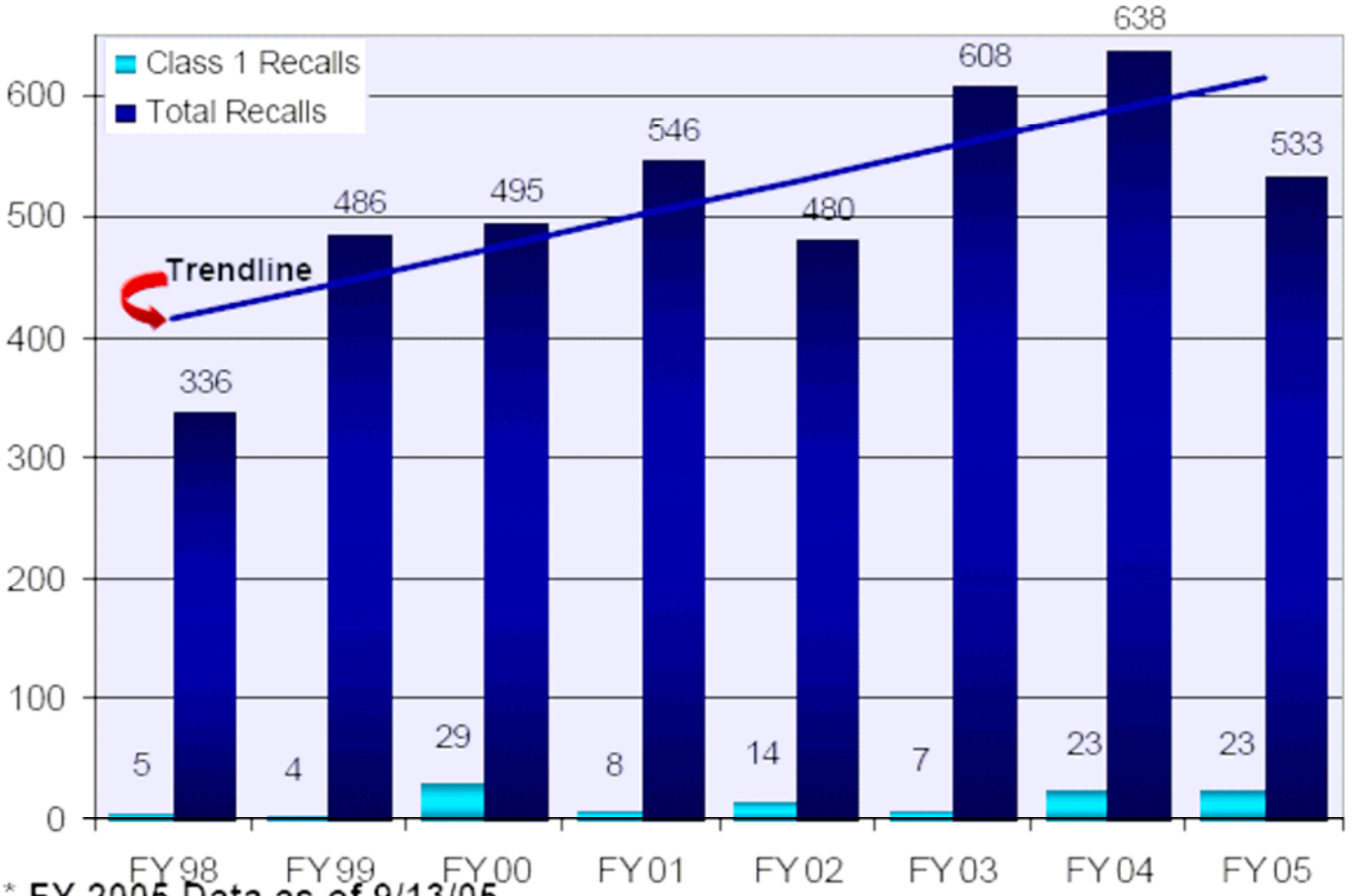
Dun & Bradstreet Medical Device Firm Data

Medical device reports are increasing



CDRH receives about 180,000 reports annually. >1,125,000 total

Medical device recalls are increasing



* FY 2005 Data as of 9/13/05

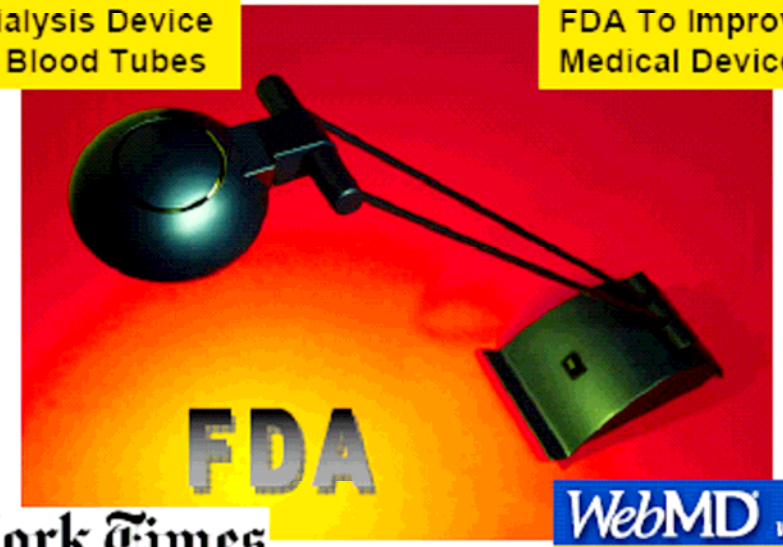
FDA is under scrutiny

WSJ.com THE WALL STREET JOURNAL. ONLINE

Recall of Hemodialysis Device Points to Kink in Blood Tubes

KAISER FAMILY FOUNDATION kaisernetwork.org

FDA To Improve Guidelines for Medical Devices



The New York Times ON THE WEB

F.D.A. Puts Restrictions On Guidant

WebMD with AOL Health

FDA Issues Alert for Abbott Glucose Meters

Check the Meters' Setting, Says FDA and Abbott Diabetes Care

We have established clear goals:

- Access accurate and timely data about adverse events
- Analyze and assess this information quickly
- Alert device users to potential risk

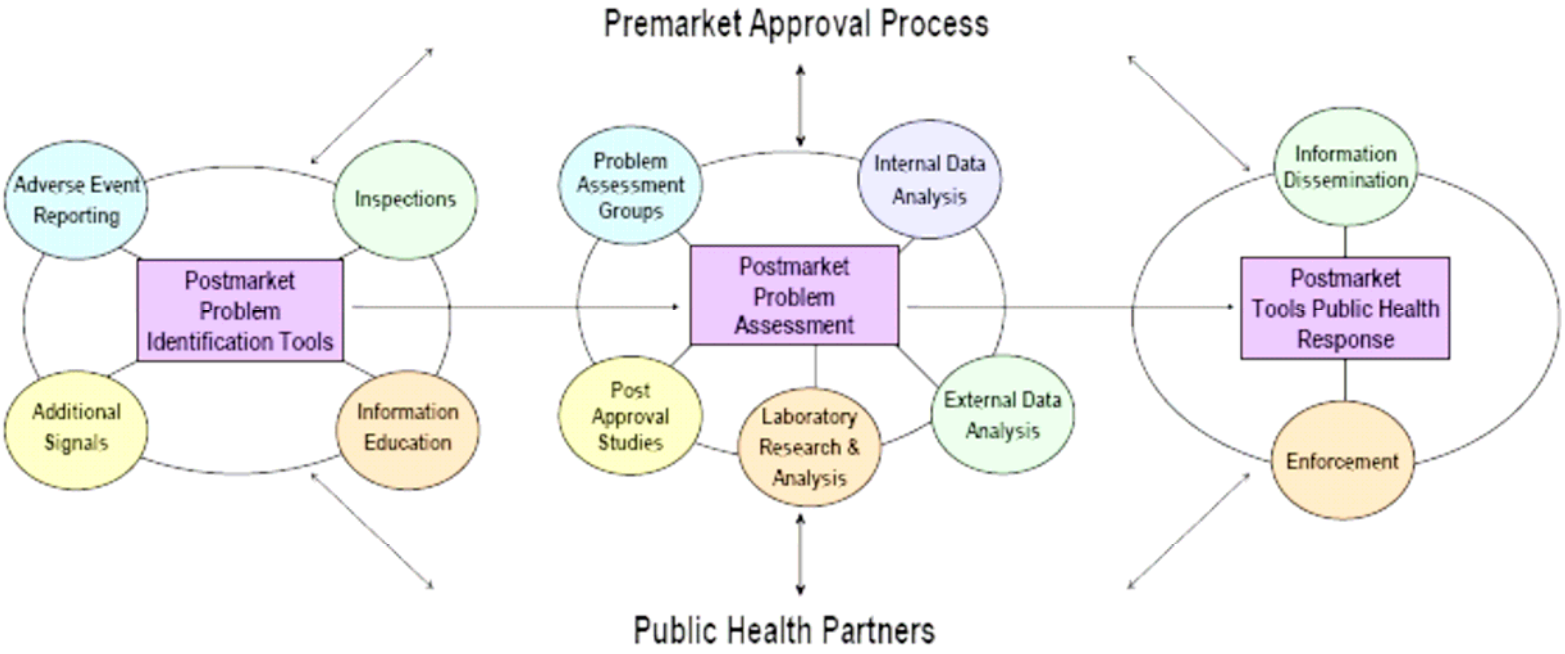
We have aligned our FY 06 Priorities with those goals…

- *Increase our ability to identify, analyze and act on post-market information*
- *Increase communication of risk/benefit information to all of our stakeholders*
- Continue to implement and assess MDUFMA 1 and prepare for MDUFMA 2
- Advance the "critical path" for medical and radiological products
- Invest resources strategically to support the priorities of HHS, FDA, and CDRH

We are working on specific postmarket issues:

- Strengthening Condition of Approval studies
- Improving targeted surveillance systems: MedSun
- Focusing on risk-based inspections
- Implementing third party inspections
- Better communicating risk/benefit information
- Improving our automated information systems

We need to connect the dots…

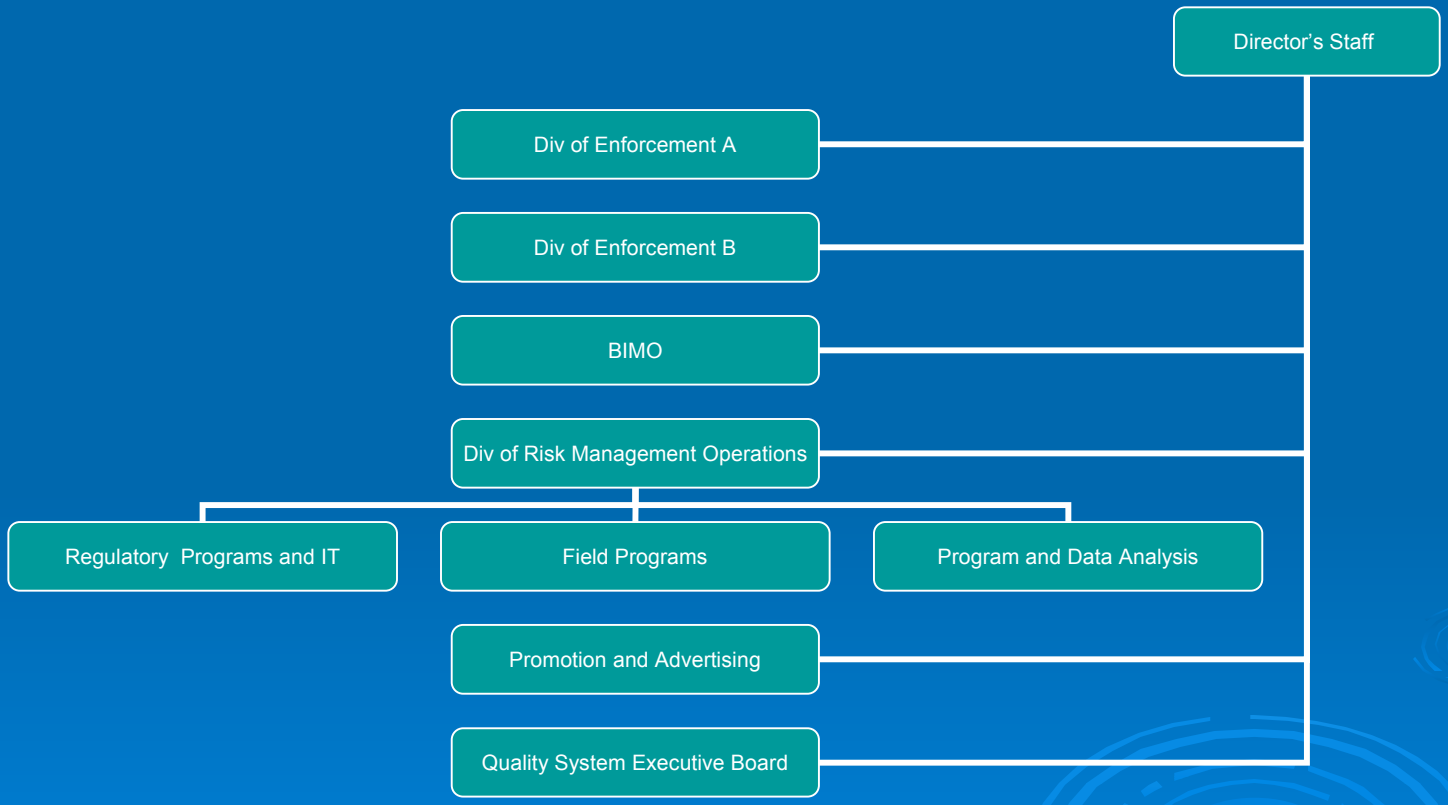


Postmarket Problem Identification | **Postmarket Problem Assessment** | **Postmarket Public Health Response**

Office of Compliance Activities

- Premarket submission activities
- The inspection workplan
- Recall classification and associated tasks
- Risk assessment
- Quality System, Bioresearch Monitoring, Reporting enforcement decisions and actions
- Promotion and advertising activities
- Counterterrorism activities
- Import/export activities
- Registration and listing
- Training
- Support of multiple agency initiatives
- International activities

Organization



Premarket Activities

- Review of manufacturing sections of premarket approval applications
- Premarket quality system and BIMO inspections
- 30 day notices
- PMA annual report reviews
- Presubmission and other meetings

QS Inspection Workplan

- For Cause
- MDUFMA – PMA/GMP inspections and other pre-market inspections including BIMO
- Follow-Up to Violative Inspections
- High/Significant Risk Class III and II Manufacturers
- Special Emphasis

    Focus on Risk-Based Center Initiated Assignments

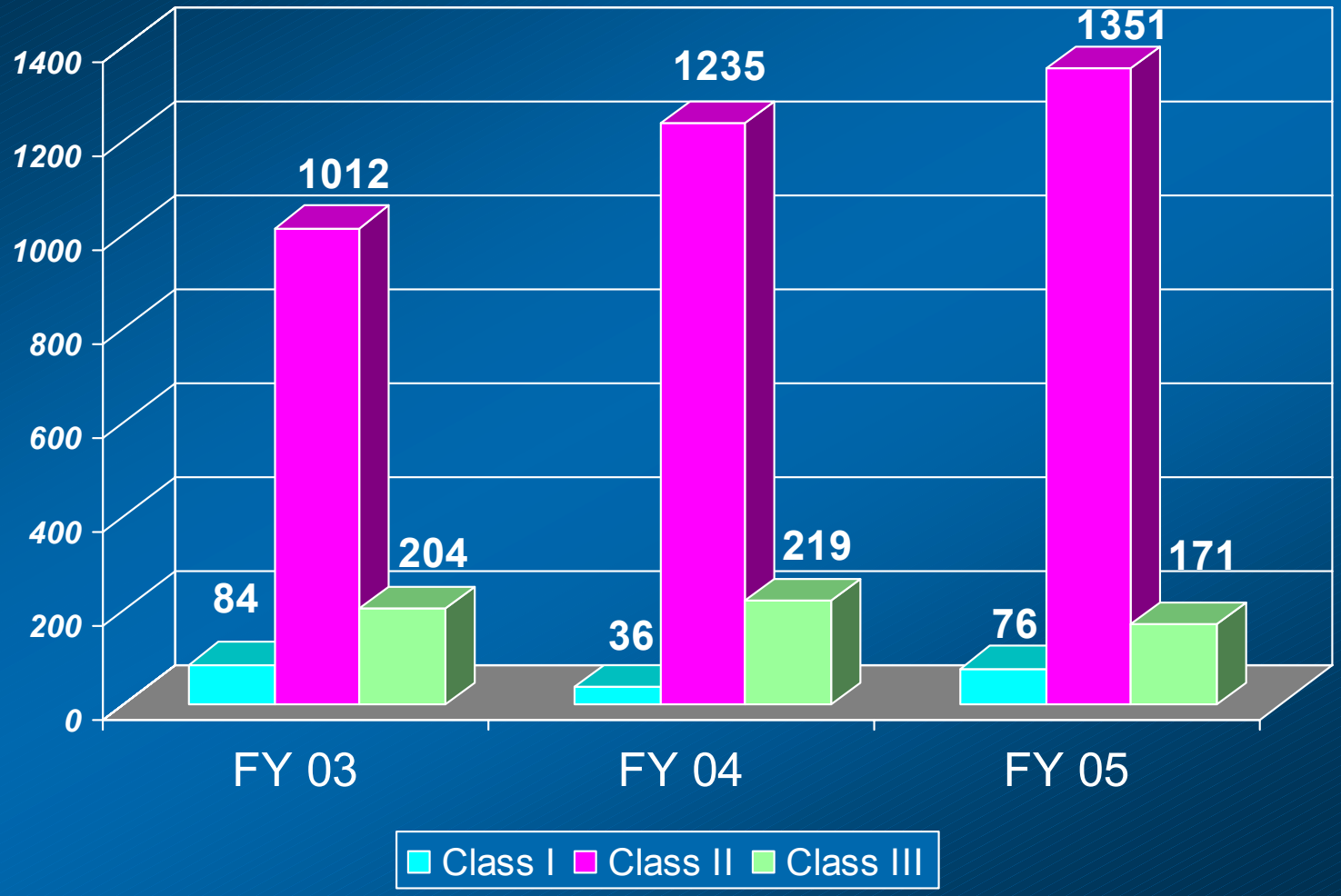
BIMO Workplan

- Research Misconduct (For Cause)
- PMA (Directed)
  - Expedited Review
  - Standard Review
- 510(k) (Directed)
- Follow-Up to Violative Inspections (Routine)
- High Risk/Breakthrough Devices (Routine)
- Vulnerable Population (Routine)
- Probability Sampling (Routine)
- Surveillance (Routine)

Risk-Based Planning

- Qualitative
  - Assessment of current and emerging issues
  - Determination of QS and inspection component to potential solution
- Quantitative
  - Factor analysis (manufacturer, product, process)
  - Scoring and prioritization

Recall Z-numbers



Top 10 Recalled Medical Devices

Rank	2005	2004	2003	2002**
1	Infusion Pump (25)	Diagnostic Biliary Cath (9)	Data Processing Calculator Module (36)	Chemistry Analyzer (16)
2	Intravascular Administration Set (11)	Electrosurgical Cutting/Coag (9)	Chemistry Analyzer (15)	Data Processing Module (14)
3	Nuclear MRI System (9)	Chemistry Analyzer (8)	Intravascular Admin Set (10)	AC Powered Hospital Bed (8)
4	Heart Valve Allograft (9)	Nuclear MRI System (8)	Differential Cell Counter (9)	Glucose Oxidase (8)
5	Implantable Defibrillator (9)	Automatic External Defibrillator (8)	Fluoroscopic X-Ray (8)	Dialysate Concentrate for Hemodialysis (3)
6	Automatic External Defibrillator (8)	Angiographic X-Ray System (7)	Coronary Stent (8)	Intravascular Therapeutic Catheter Short-Term (3)
7	Continuous Ventilator (7)	Ventilator (6)	Automatic External Defibrillator (8)	Infusion Pump (2)
8	Automated differential cell counter (7)	Rhodamine Antigen Antiserum Control Transferrin (6)	Diagnostic Biliary Catheter (6)	Intravascular Administration Set (2)
9	Introducer Catheter (6)	AC Powered Adjustable Bed (6)	Infusion Pump (6)	Single Lumen Hypodermic Needle (2)
10	Intravascular Cath (Therapeutic Long-term use, greater than 30 days) (6)	Intravascular Therapeutic Catheter (6)	Electrosurgical Cutting/Coag (6)	Anesthetic Conduction Kit (2)

Recall Issues

- Classification - Why Class 1
- Communication – timely, accurate, comprehensive
- Quality System-related deficiencies – mandatory reports under Section 806, handling of complaints, trending, risk assessment, corrective and preventive actions
- Implementing recall strategy

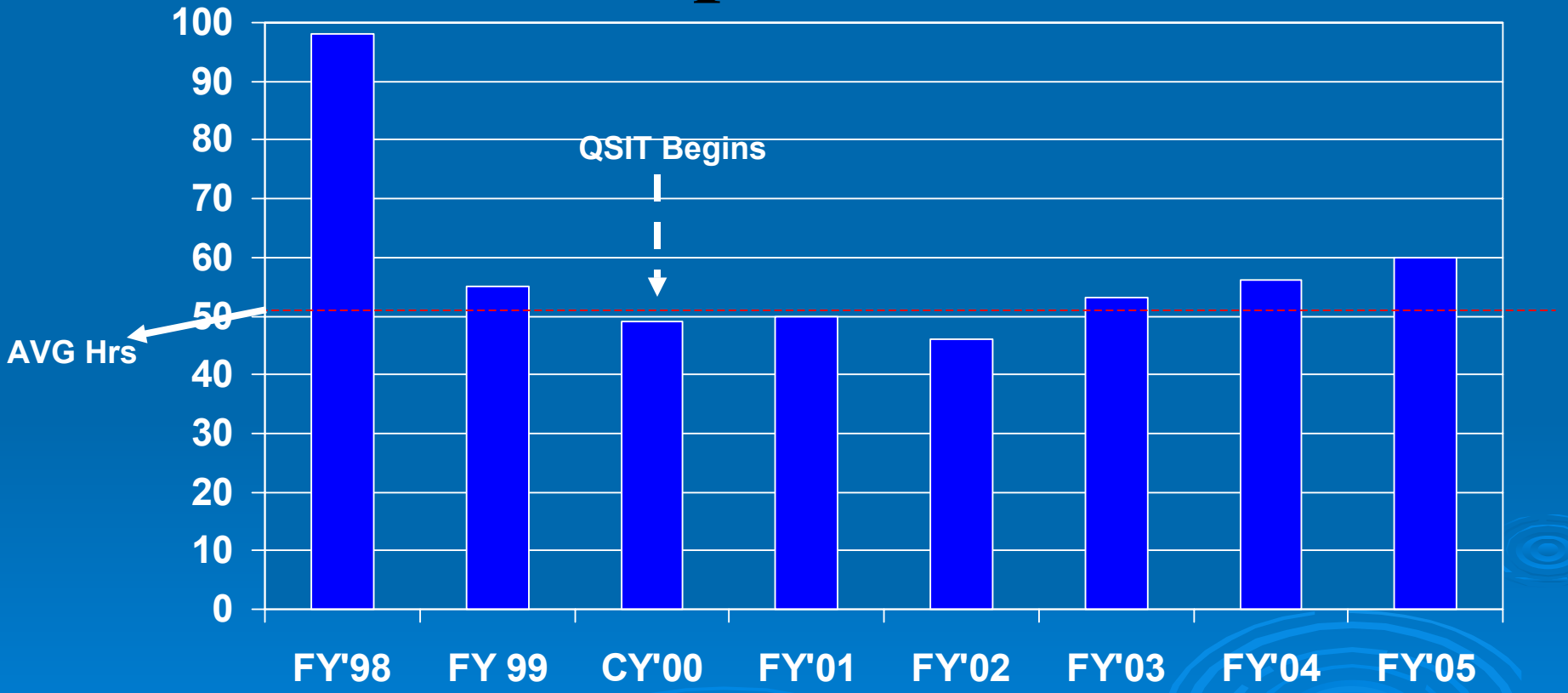
Legal/Admin Actions - CDRH

	FY 03	FY 04	FY 05
WL	205	219	182
Injunctions	3	1	4
Seizures	1	6	5
Civil Money	3	1	0
Civil Contempt	0	1	1

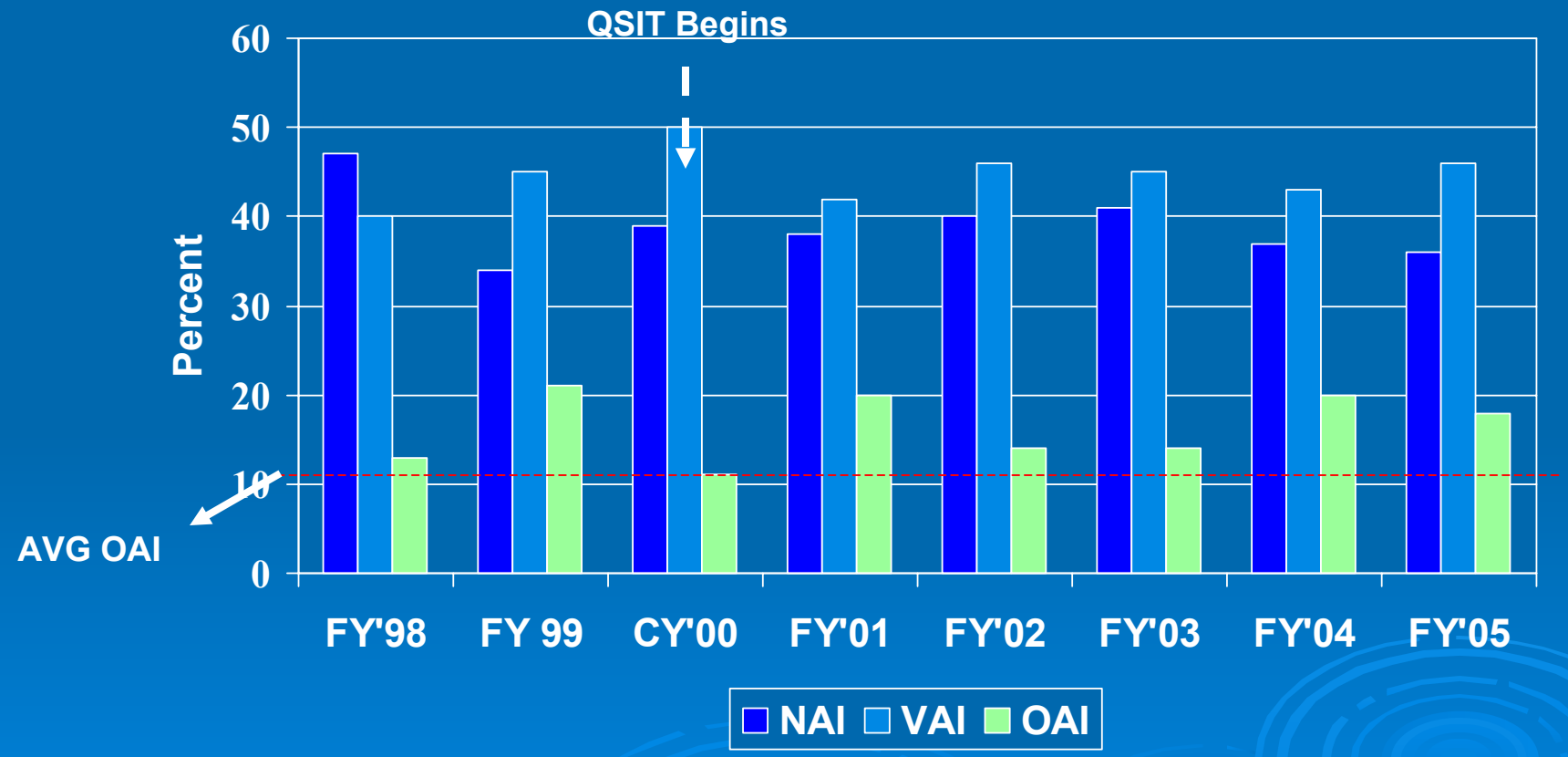
Enforcement Decisions and Actions

- Goal is compliance, cooperatively
- The 483
- Communication with Districts and CDRH Compliance (and/or OIVD)
- The warning
- Verifying conformance
- Action or resolution

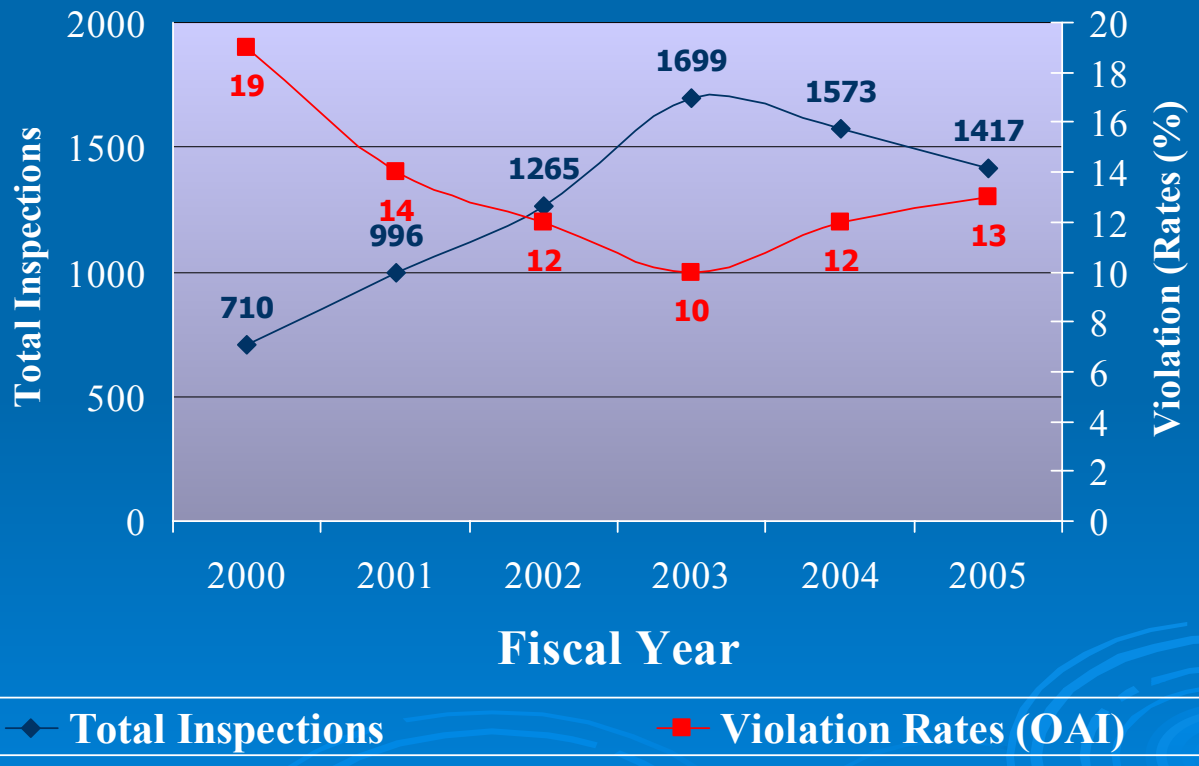
Average number of hours per comprehensive inspection



Final EIR Classification for Comprehensive



Summary of Domestic QS/GMP Inspections
FY 2000 through 2005
Domestic GMP Inspections

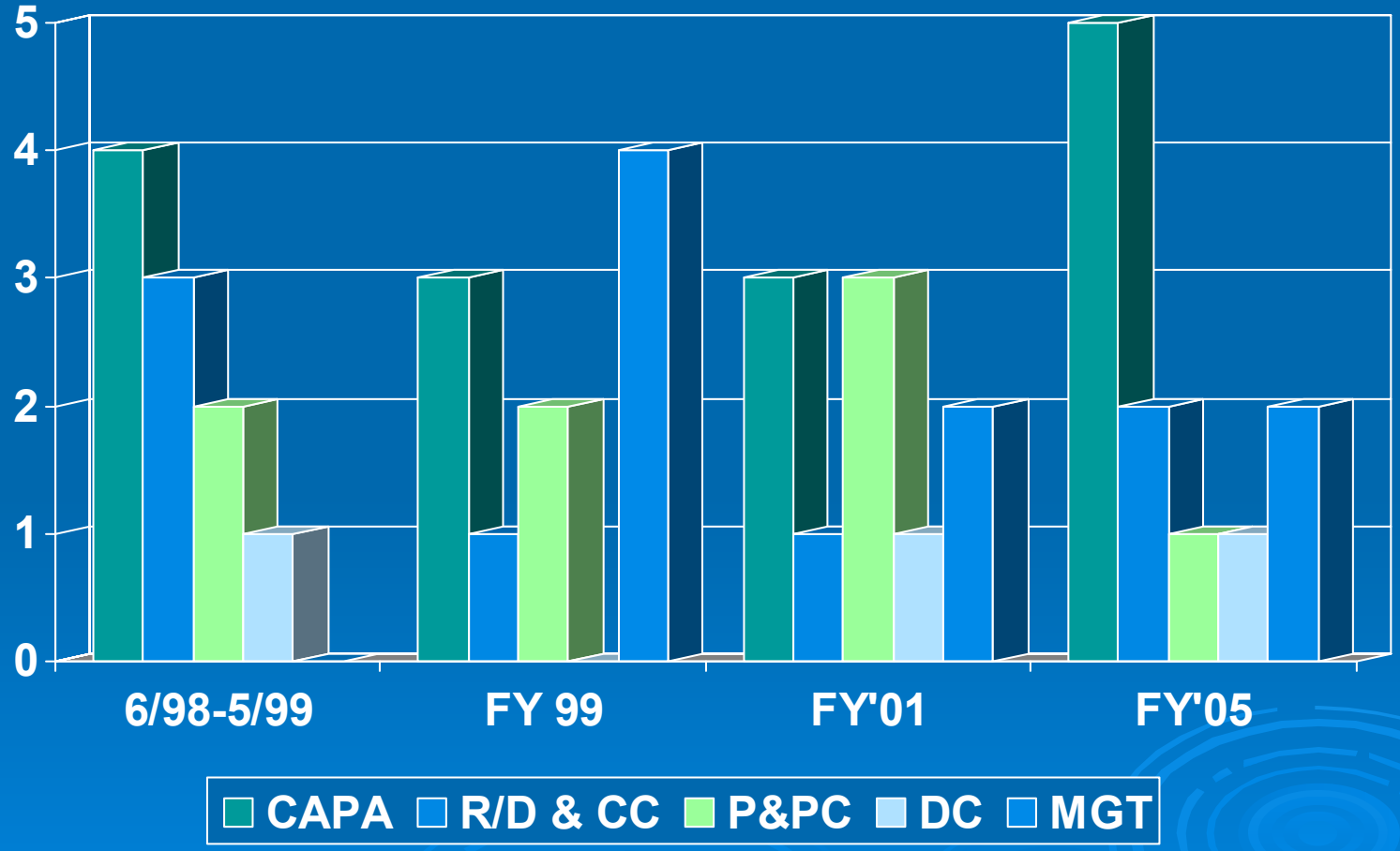


Source: ORA/FACTS

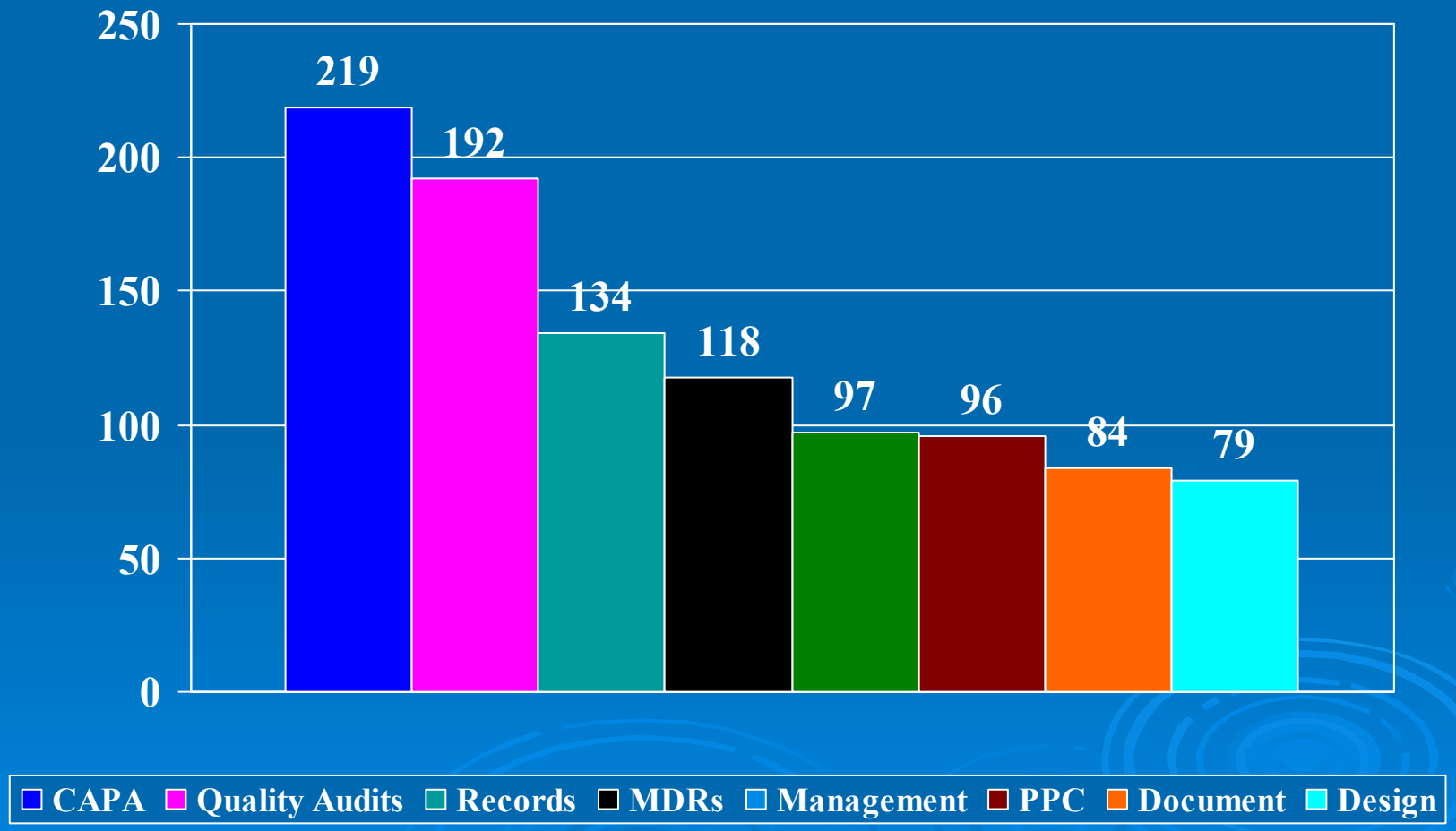
Summary of Foreign QS/GMP Inspections
FY 2000 through 2005
Foreign GMP Inspections

Source: ORA/FACTS

Top Five 483 Cites by Subsystem



Top Eight Observations Noted During Inspections (from TURBO/483) – FY 05



N = 1016

Corporate Actions

- Violative condition identified that is broad enough and serious enough to merit cross-cutting action
- Impact on exports, imports, premarket submissions, pending inspections
- When corrections are in place then FDA verifies
- Note: Always assess relevance of violations across the corporation

Promotion and Advertising Concerns

- Direct to Consumer ads
- Help Seeking ads
- Comparative claims
- Off-label claims
- Fair balance
- The current public health threats and illegal claims

To Round Out Some Activities

- Mutual Recognition Agreement
- Third Party Inspection Program
- Global Harmonization
- E-registration and listing
- Import process improvements
- Assessment of recall and warning letter processes

Center for Devices and Radiological Health

Food and Drug Administration
Centennial Celebration
1906 – 2006

Protecting and Promoting Public Health

www.fda.gov/centennial