CDRH Executive Briefing

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Overview

- FDAMA
- Regulations
- Reengineering
- Cross-cutting Activities
- Resources
- Alternatives in 510(k)s, MDRs
- Harmonization

FDAMA Accomplishments

Year Two

- Stakeholders meeting, live video teleconference
- Report to Congress, "Designing a Medical Device Surveillance Network" Draft guidance
- Updated lists
  - Devices for third party review
  - Recognized consensus standards

FDAMA Accomplishments

Year Two

- Draft guidance
  - Resolving scientific disputes
  - Least burdensome means to market
- Updated guidance
  - FAQ on consensus standaards
  - Amended panel procedures
  - Device tracking

Regulations Published in '99

62 regulations published in CY '99 so far

- 7 final rules
- 3 Direct to Final Rules
- 11 Proposed Rules
- 38 Notices
- 3 Advanced Notice of Public Rule Making (ANPR)

Reengineering

Examples of Reengineered Process

- New 510(k) paradigm
- Regulations development
- Recalls
- GMP inspections
- Products development protocol (PDP)
- Modular PMA review
- Standards

Reengineering

New Projects

- Postmarket process
- Registration and listing
- QSIT and HACCP
- Class I recalls
- Radiological health
- Bioresearch monitoring

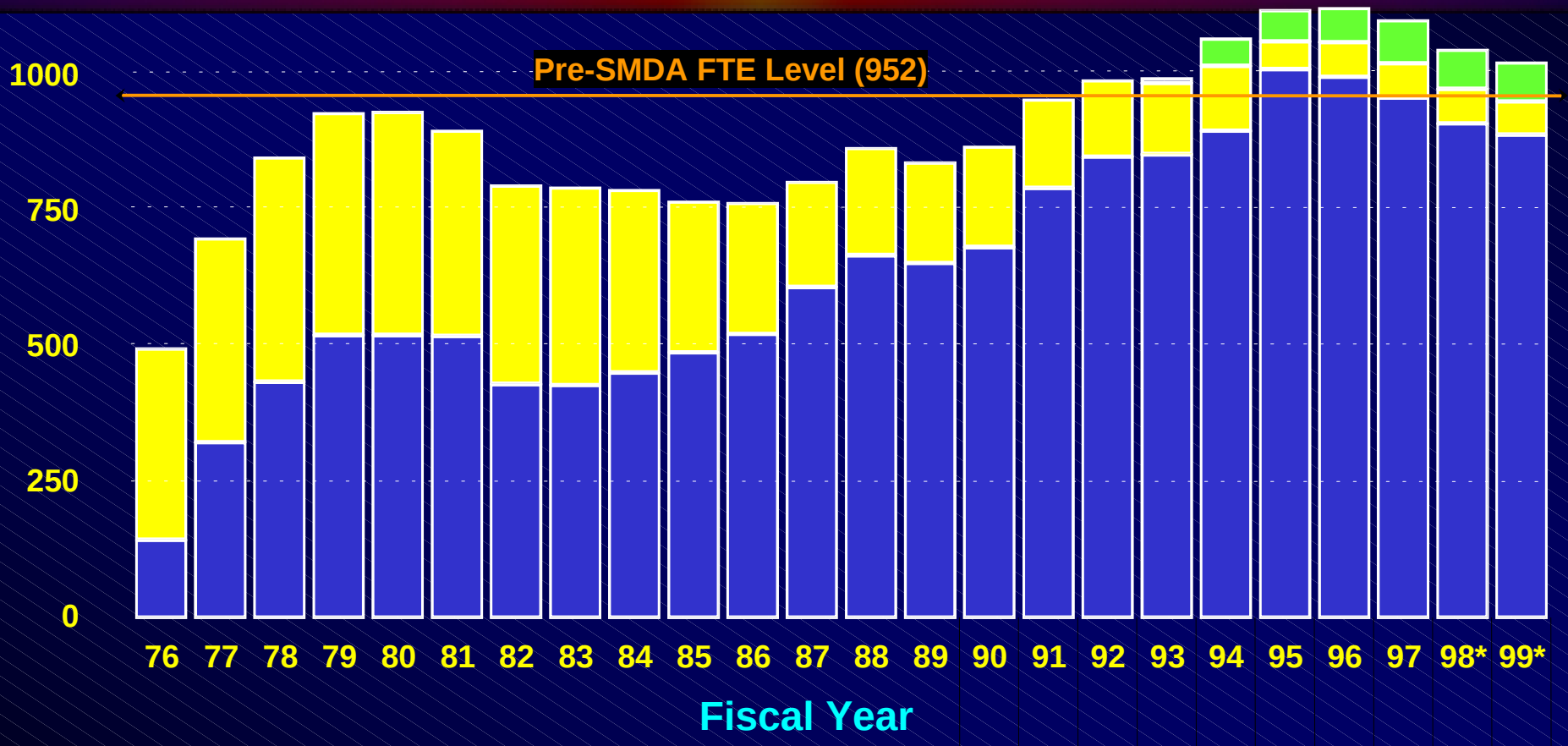
Cross-cutting Issues

Staff from many offices work together

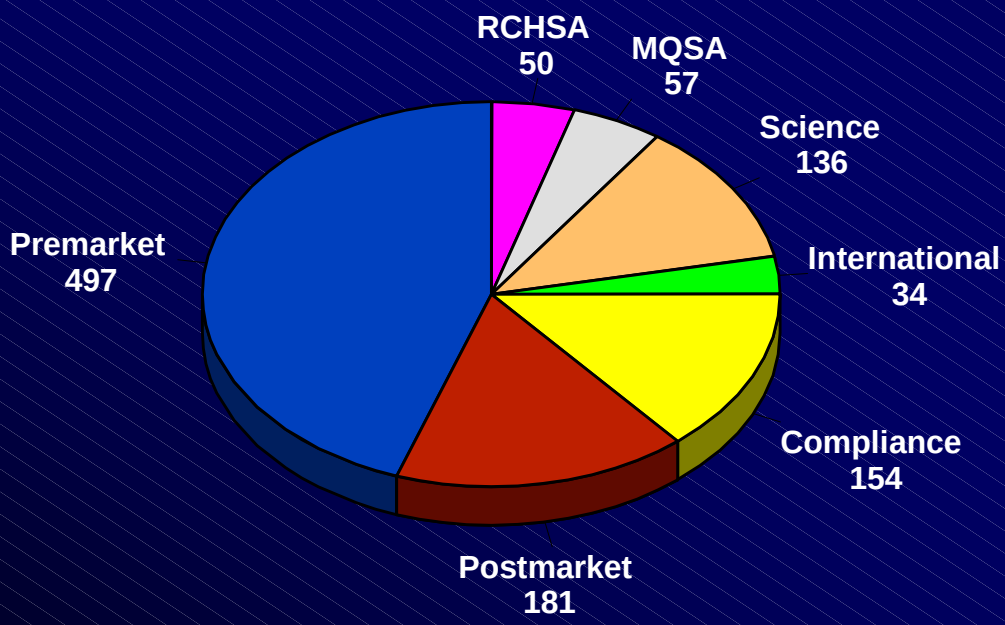
- Immediate problem - Ad hoc committee
  - Evaluates, follows issue from several perspectives
  - Safety Alert, Public Health Advisory
  - Forum for industry, medical community, consumers & gov't to work on solution together
- Standing committee on one type of device
  - Follows, coordinates activities across Center
  - Works on solutions to specific problems as above

CDRH FTE History

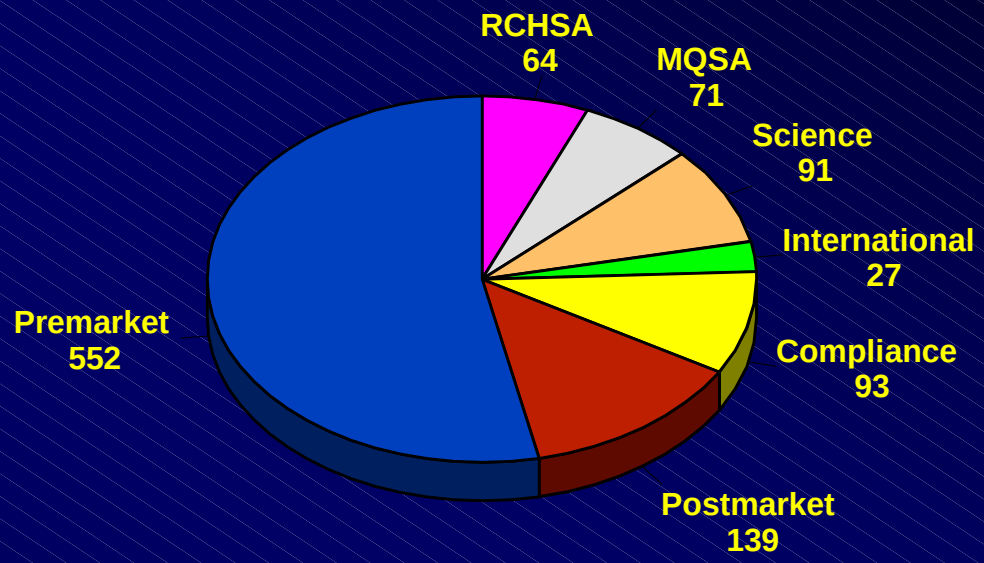
Fiscal Years 1976 - 1999*



CDRH FTE Distribution



FY95
N=1,109



FY98
N=1,037

Resources Are Shrinking

- Flat line budgets have meant actual decrease in funds available for program.
- CDRH down 113 FTEs since FY 1996; includes 45 positions cut in last fiscal year.
- FDAMA added new responsibilities without funding.
- International activities are costly.

Resources Are Shrinking

- Workload complexity is increasing.
- Review timeframes are still too long (e.g., PMAs – 12.4 months total elapsed time).
- Administration's FY 2000 budget does not request additional premarket resources.
- Congressional budget includes targeted increases and an unfunded pay-raise

Shrinking Resources: Re-engineering

Mechanisms:

- 510(k) Changes
- Modular PMA
- 3rd party review
- MDR Summary reporting

510(k)s - Alternatives

	Applications Received (4-98 to 9-99)	Review Complete	Average Review Time
Abbreviated	105	82	91
Special	458	411	28
Traditional	6147	6453	110

510(k)s - Third party review

- 154 device types eligible
  - mostly class II
- same device types = 1200 510(k)s / yr
- only 32 510(k)s submitted to 3rd parties so far this fiscal year
- Average total review time for comparable 510(k)s -- same product code & fiscal year:

  3rd party - 57 days

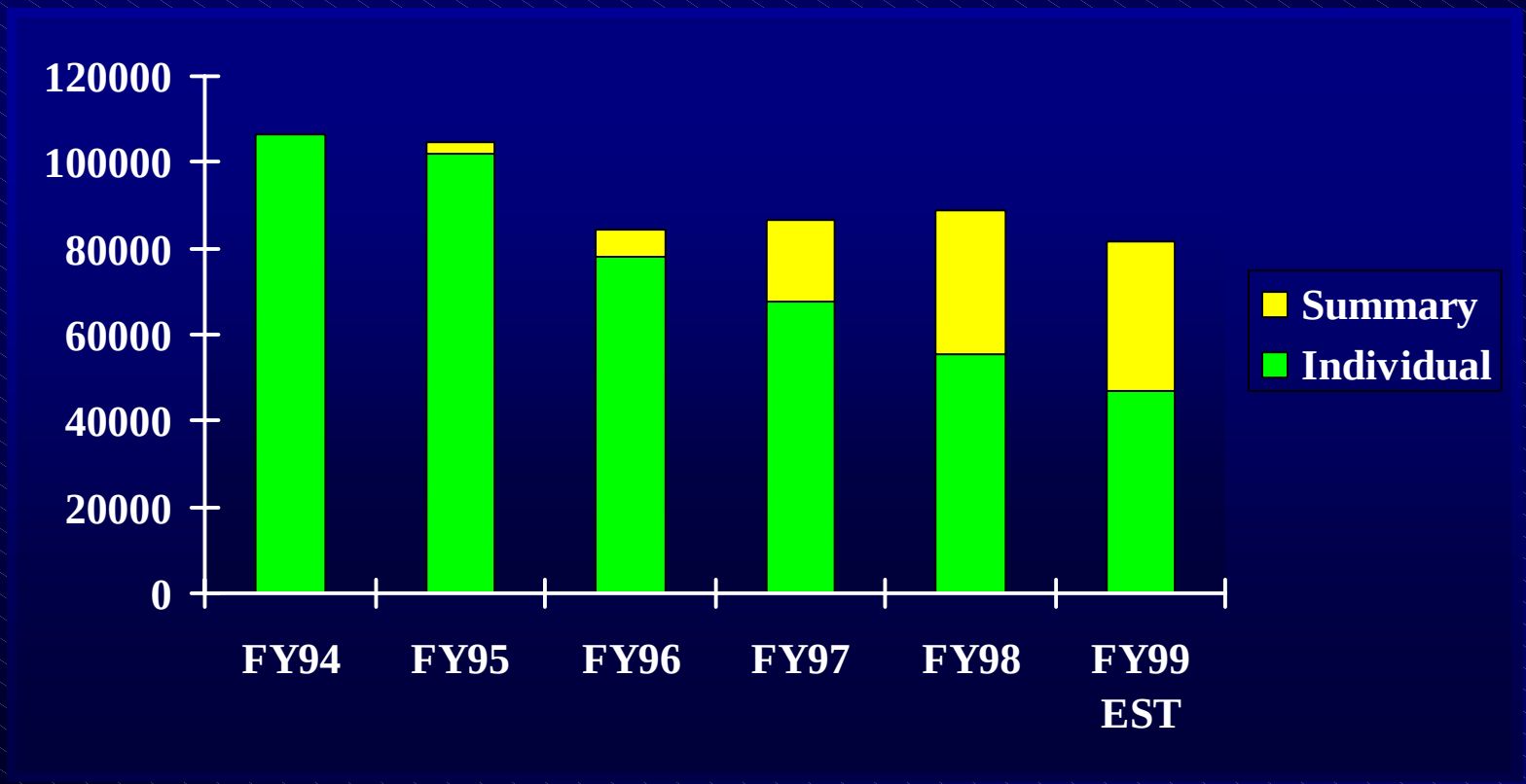
  All FDA review - 105 days

Summary Reporting of MDRs

Goal: Reduce "noise" in the MDR system, improve the signal to noise ratio

- Allow periodic submission of well-known, repetitive reports in line item format
- Expect 38,000 summary reports in FY '99
- 45 manufacturers participating
- 52 exemptions
- New system in place for January 2000

Manufacturer Reports
(Includes Summary Reporting)



Global Harmonization

7th meeting on June 27-July 1, 1999
Hosted by the U.S.

Http://www.fda.gov/cdrh/harmmain.html

CDRH: The Future

- Transparent
- Adequately Resourced
- Re-engineered
- FDAMA-ed
- Science Based
- Partners
- Credibility
  - "Yours and Ours"

Our Website:

www.fda.gov/cdrh