CDRH: Looking Ahead

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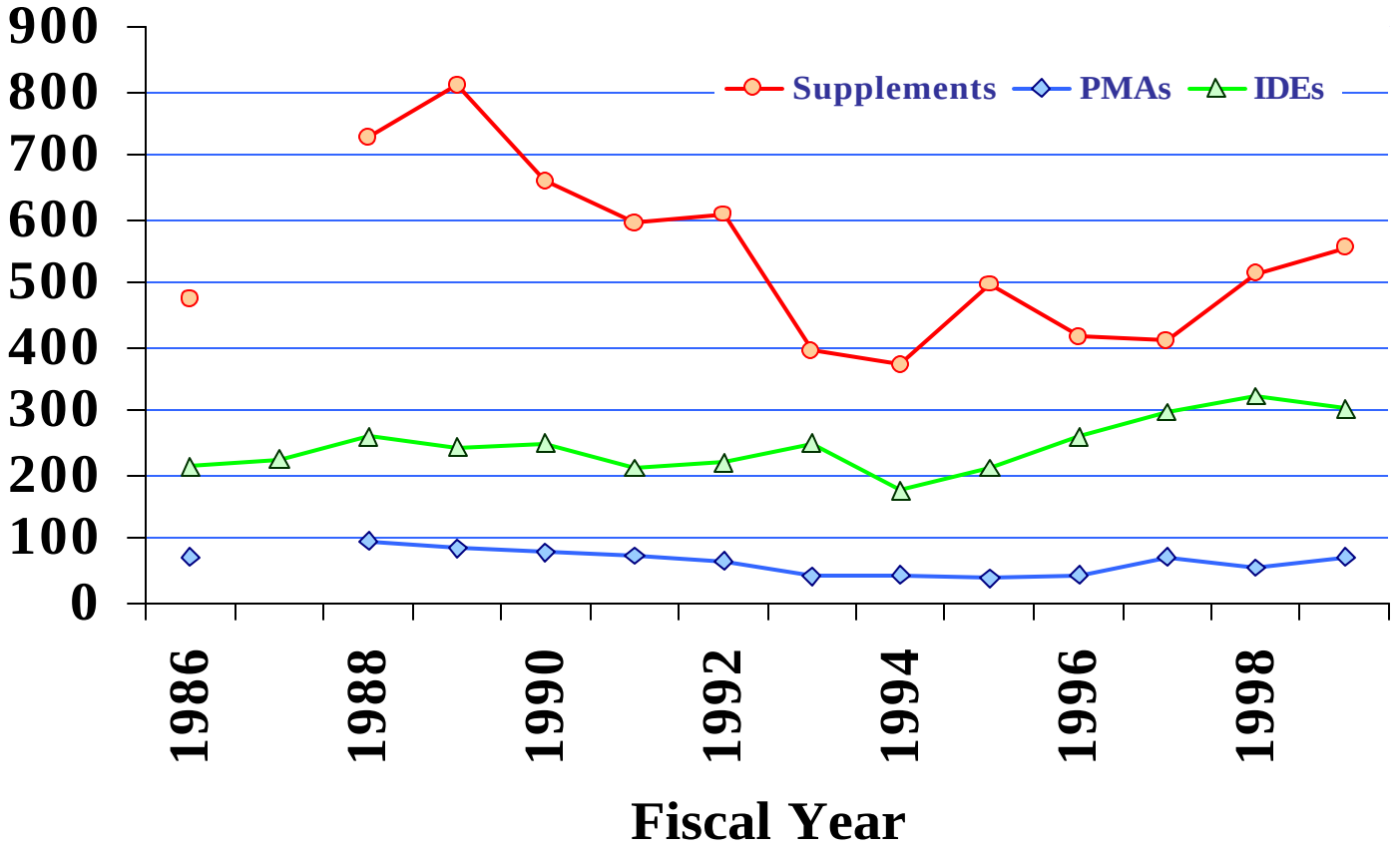
Workload

Submissions: Fiscal Year 2000

PMA Original	67
PMA Supplements	545
IDE's Original	311
IDE Amendments	240
IDE Supplements	4388
510(k)s	4202
Humanitarian DE	11
HDE Supplements	10
"Minor" Submissions	7145
Total	16919

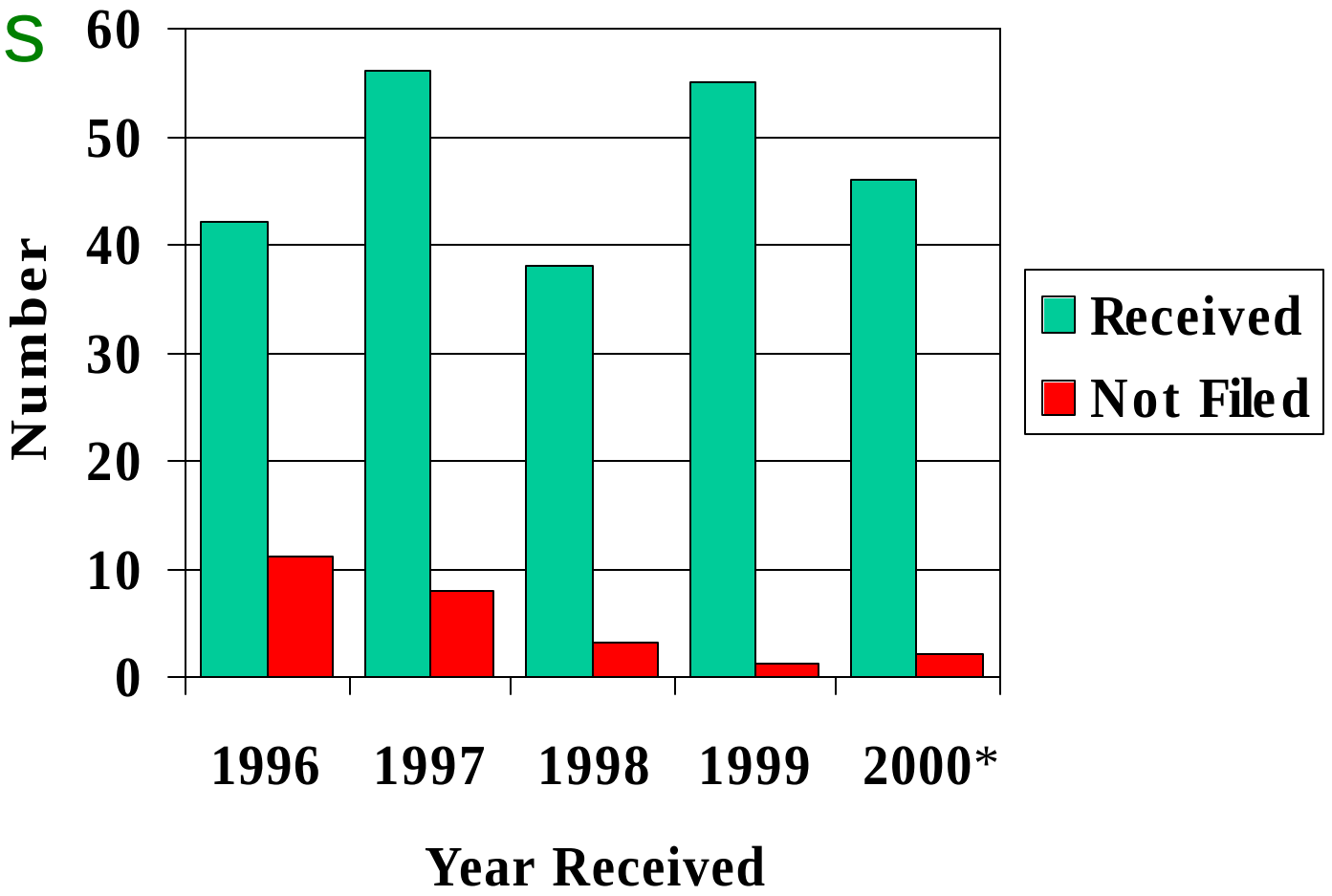
65 Submissions per day

PMAs, Supplements and IDEs



Performance

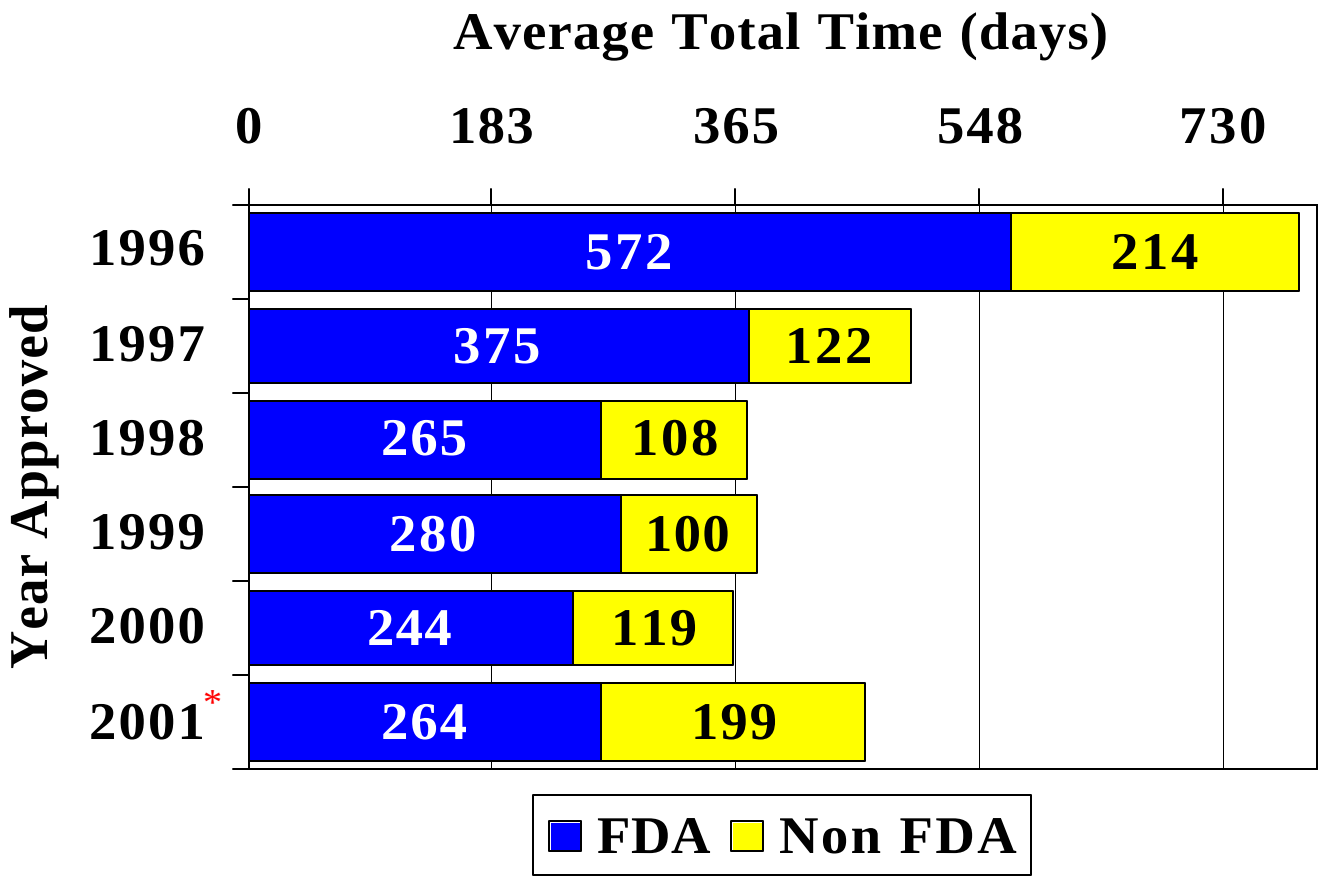
PMA's



* First 6 months 2000

Performance

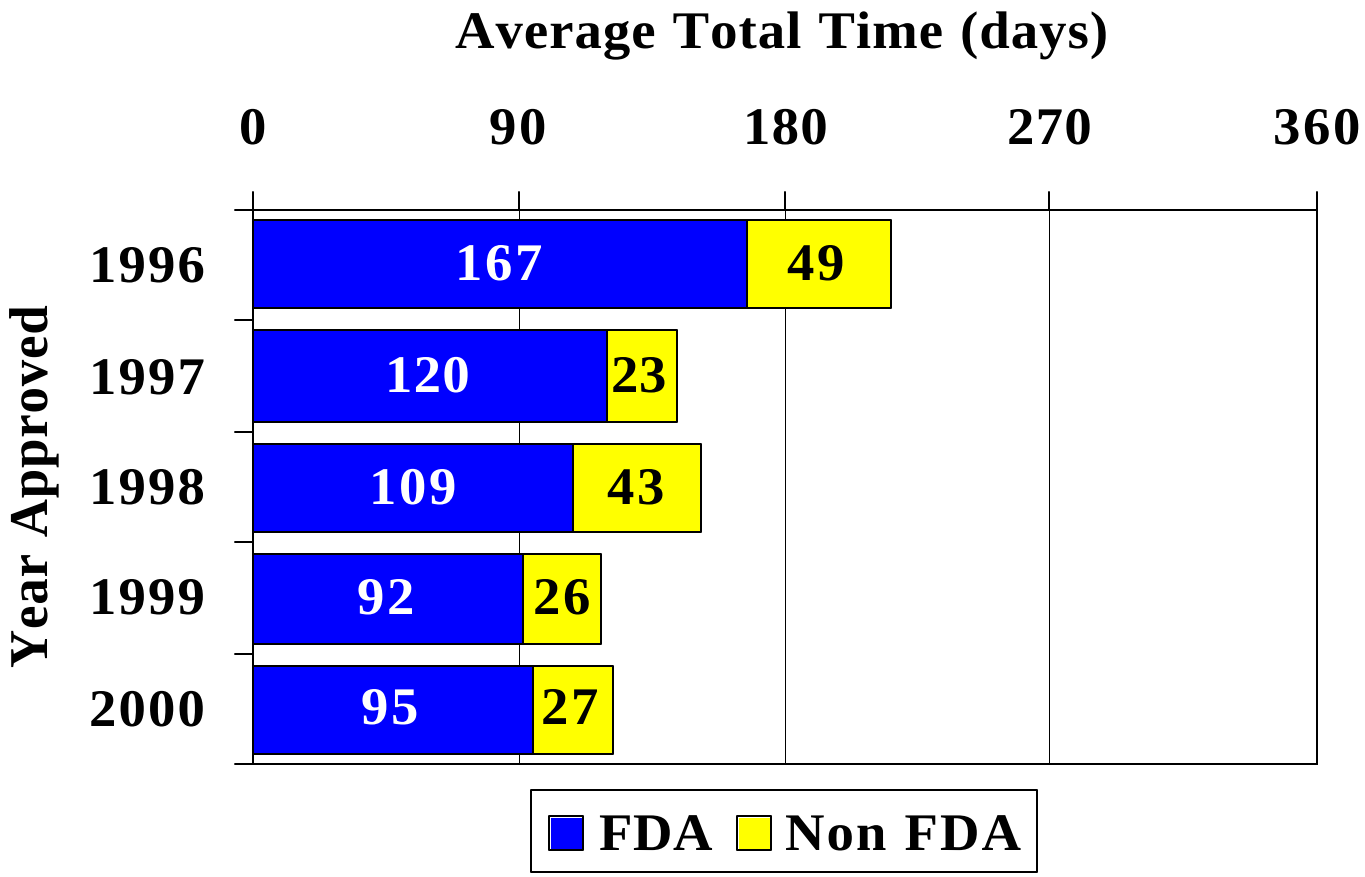
PMA Total Approval Times



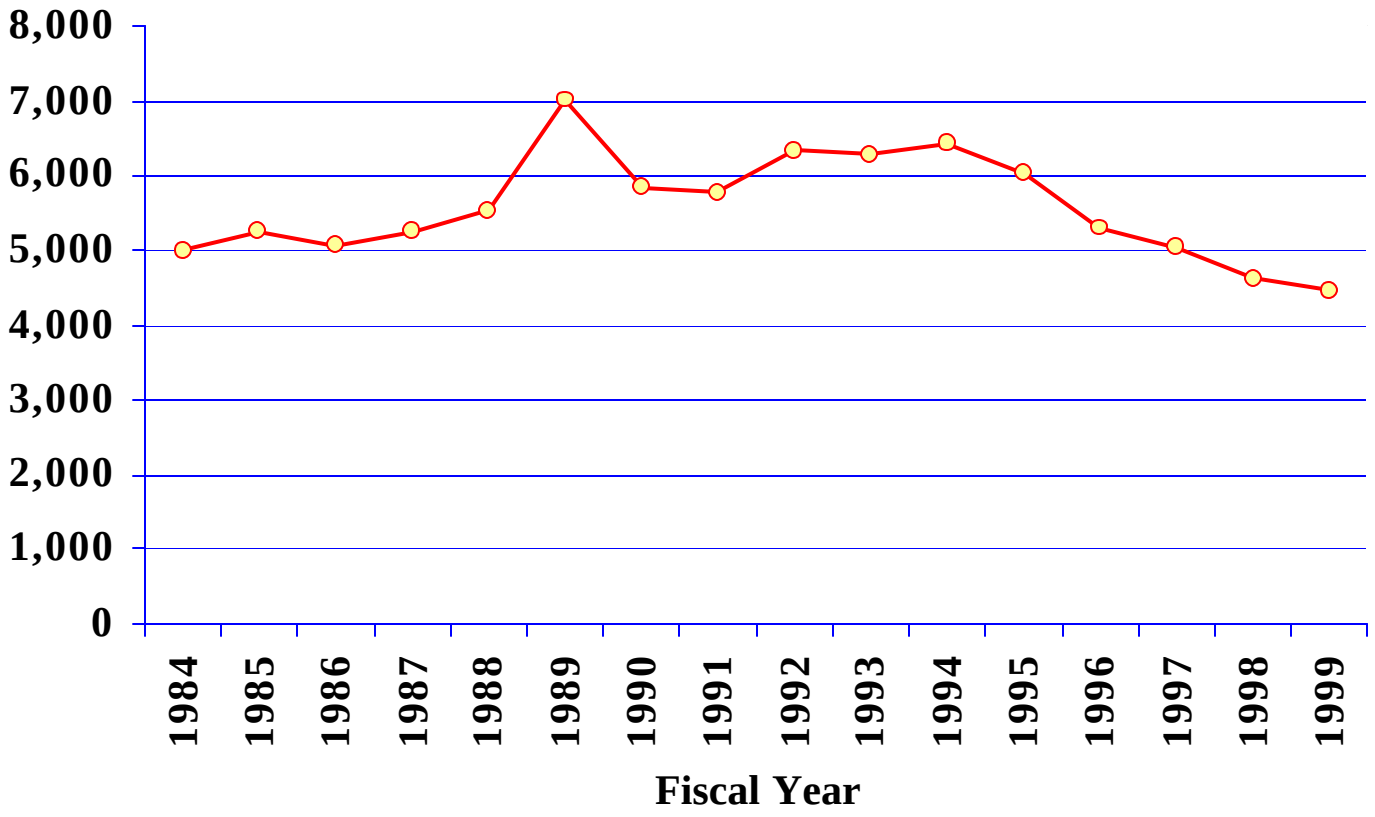
* Year to date

Performance

PMA Supplement Total Approval Times

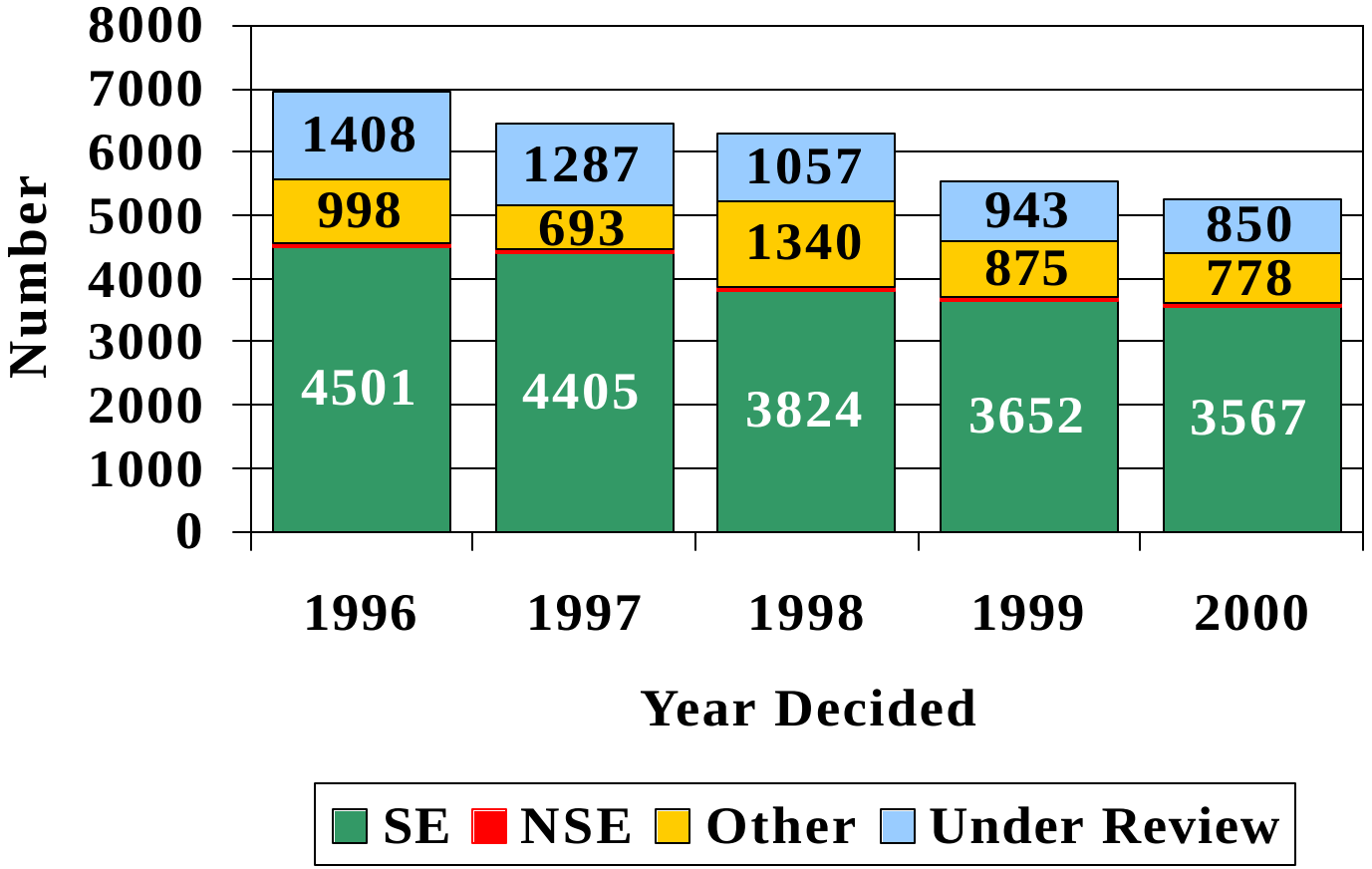


Pre-market Notifications (510k)



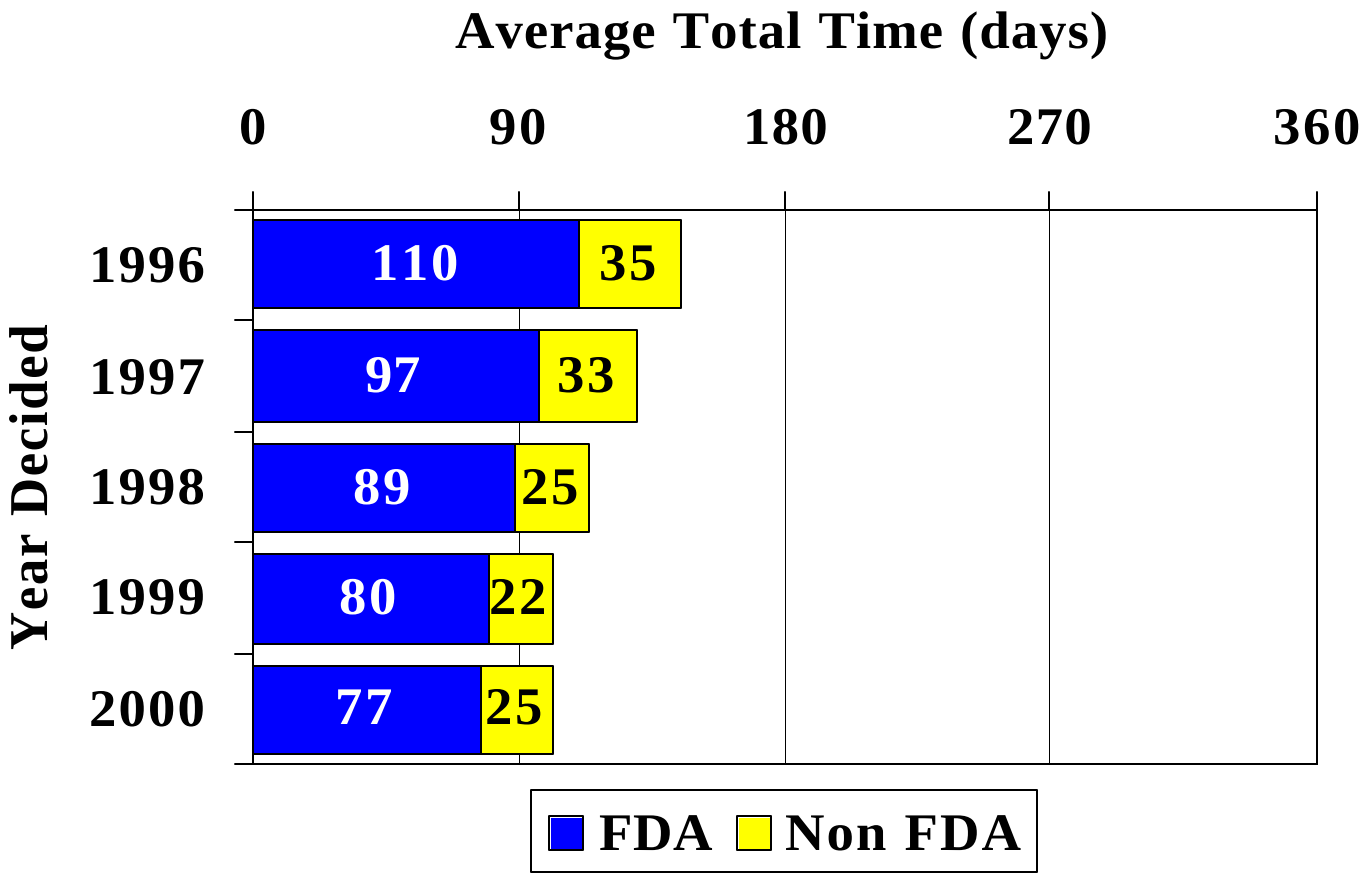
Performance

510(k) Decisions



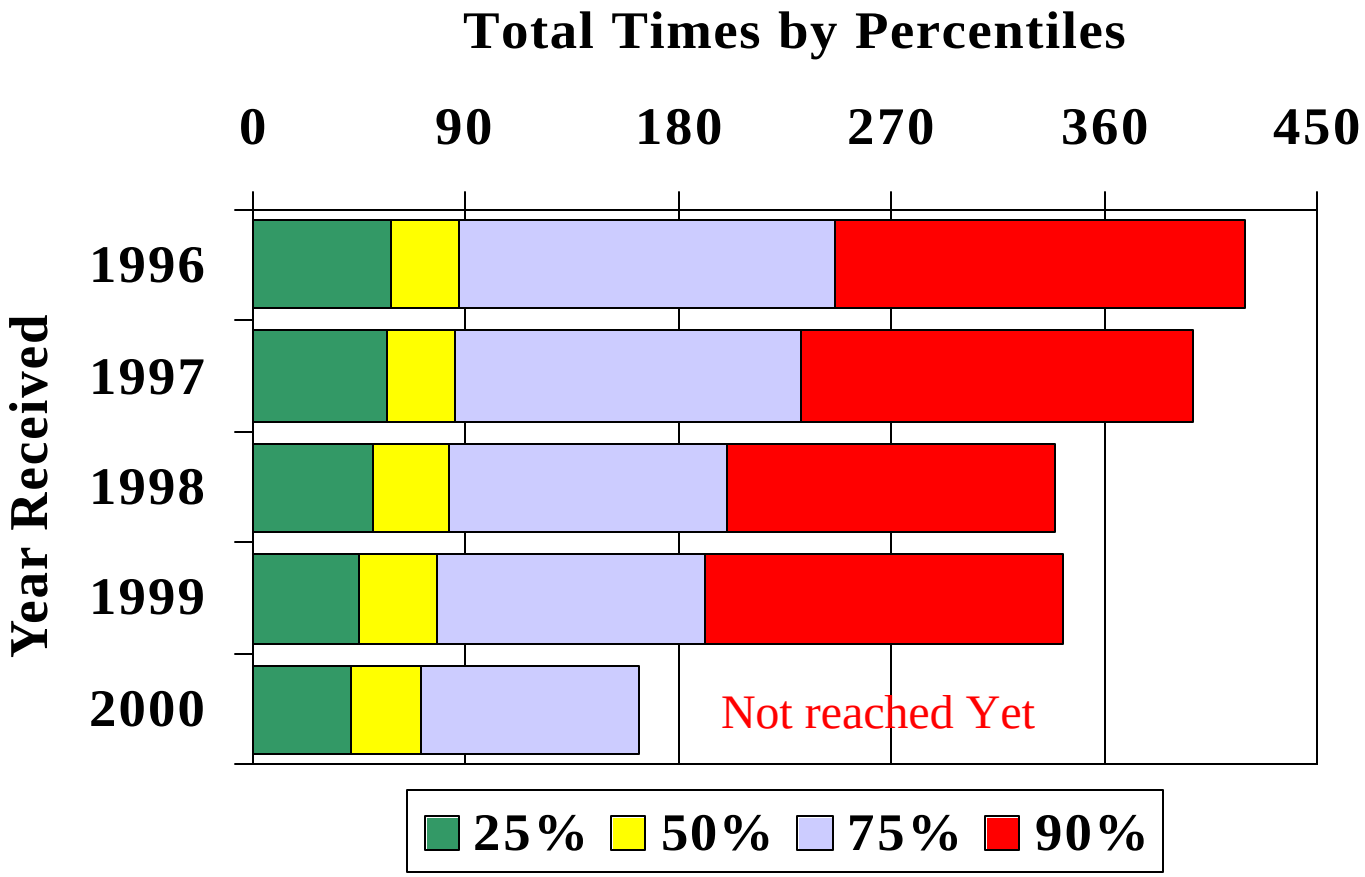
Performance

510(k) Total Decision Times



Performance

510(k) Total Decision Times



Performance

Submissions: Fiscal Year 2000

PMA Original	67	2831 Hours
PMA Supplements	545	175 Hours
IDE's Original	311	256 Hours
IDE Amendments	240	
IDE Supplements	4388	18 Hours
510(k)s	4202	62 Hours
Humanitarian DE	11	
HDE Supplements	10	
"Minor" Submissions	7145	
Total	16919	

Performance

Workload: Fiscal Year 2000

Advisory Panel Meetings	927 hours /day
Standards	1470 hours
Regulations	2520 hours
Registration & Listing	4 hours
MDR	42 Minutes
Agreement & Determination Meetings	717 hours

FDAMA Implementation

New types of 510(k) applications

Third Party 510(k) Review

Dispute Resolution:

- Ombudsman: Les Weinstein
- Dispute Resolution Panel

Least Burdensome

Using Standards in 510(k)'s

Three alternatives:

- FDA recognized standard with a declaration
  - Mfr. has data now
- FDA-recognized standard without declaration
  - Mfr. does not have supporting data at time of submission but will before marketing
- Non-recognized standard
  - Less assurance that standard will be acceptable
  - FDA may need to request additional information

ODE Performance

Performance: 510(k)s - Alternatives

Type of 510(k)	Reviews Completed FY99	Average Total Time (days)	Reviews Completed FY00	Average Total Time (days)
Abbreviated (Standards)	75	99	118	109
Special	361	29	583	32
Traditional	4155	108	3699	115

Third Party Review

A “Fee-for-Service” User Fee

- Reviewer must be acceptable to both FDA and manufacturer.
- Cost must be acceptable to manufacturer
- Review quality must be acceptable to FDA
- Use of the program frees FDA resources at the primary reviewer level while keeping the supervisory oversight.

Third Party Review

Qualifications

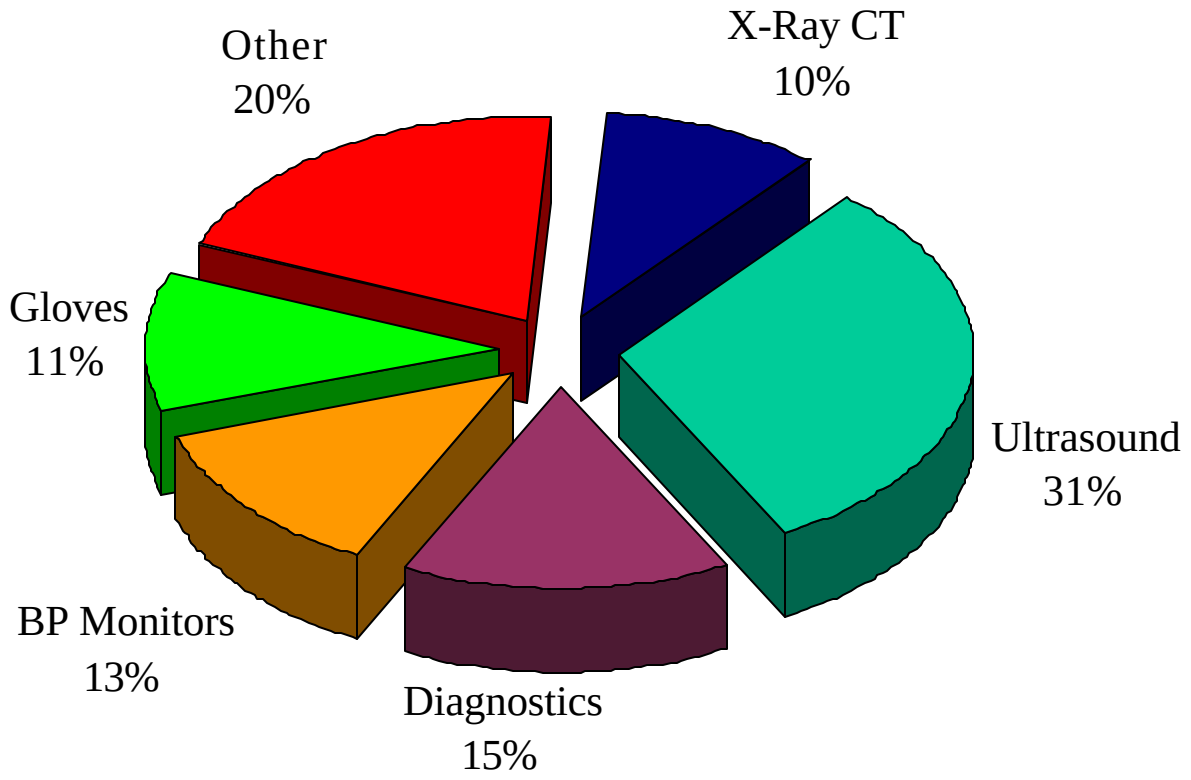
- Not a Federal Government employee
- Independent organization, not controlled by industry
- Legally constituted entity permitted to conduct 3rd party review
- Will not design, manufacture, promote or sell devices
- Operates under accepted professional & ethical business practices -- specifics agreed to in writing

Third Party Review

Who are they?	Number	% total
TUV Product Service	59	41 %
Underwriters Labs.	23	16 %
CITECH	21	15 %
TUV Rhineland of North America	15	10 %
California Dept. of Health Services	12	8 %
Intertek Testing Services	7	5 %
Entela -	4	3 %
Center for Measurement Standards ITRI	1	<1%
NV Kema	1	<1%
3 other Accredited 3rd Parties	none	

Third Party Review

Who is using it ?



Applications Received Through September 2000

Third Party Review

510(k) Eligibility

www.fda.gov/cdrh/thirdparty

- November 1998
  - 154 device classifications - 104 class II
  - 1200 eligible 510(k)s
- June 2000
  - 211 device classifications – 154 class II
  - 1600 eligible 510(k)s
- February 2001
  - 674 device classifications – 617 class II
  - 2700 eligible 510(k)s

> 70%of all 510(k)s are now eligible which trips the trigger for the 5 year sunset provision of the law in February 2006

Third Party Review

Performance

- 1999 (n=32)
  - 3rd Party Total Time 57 days
  - FDA Total Time* 105 days
- 2000 (n=47)
  - 3rd Party Total Time 68 days
  - FDA Total Time* 99 days
- 2001 (projected n = 92)

* Matched by 510(k) product code

Ombudsman

First Year Experience

- Complaints: 24
- Disputes: 11

Complaint about or Dispute with:

(Some Complaints/Disputes were about more than one Office)

- ODE: 23 (61%)
- OC: 6 (18%)
- Other: 9 (24%)

About:

- 510(K): 18 (51%)
- PMA: 2 (6%)
- Registration & Listing: 2 (6%)
- Other: 13 (37%)

Ombudsman

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Complaint about or Dispute with:

(Some Complaints/Disputes were about more than one Office)

- ODE: 23 (61%)
- OC: 6 (18%)
- Other: 9 (24%)

If ODE:

DRARD: 1 (4%)
DCLD: 2 (9%)
DGRND: 9 (39%)
DDIGD: 5 (22%)
DCRD: 6 (26%)
DOED: 0 (0%)

About:

- 510(K): 18 (51%)
- PMA: 2 (6%)
- Registration & Listing: 2 (6%)
- Other: 13 (37%)

Ombudsman

Issues: (Some complaints/disputes had more than issue.)

- Communication: 17 (23%)
- Evidence Requirements (data, testing): 11 (15%)
- Timeliness: 10 (13%)
- Conflict of Interest, Bias, Retaliation: 5 (7%)
- Rudeness/Difficulty Working With: 5 (7%)
- Procedures: 5 (7%)
- Disclosure: 4 (5%)
- Level Playing Field: 3 (4%)
- Competence: 2 (3%)
- Drug/Device: 2 (3%)
- Other: 11 (15%)

Ombudsman

Outcome:

- Resolved and/or Satisfied: 18 (51%).
  - in industry's favor 15 (83%)
  - in FDA's favor 3 (17%)
- Pending: 13 (37%)
- Referred or Unknown: 4 (11%)

Ombudsman

Dispute Resolution Panel

- First Meeting October 31, 2000
  - Orientation and Organizational Agenda
- Second Meeting June 4, 2001
  - First manufacturers request for an appeal
    - PMA application heard before an FDA panel with recommendation not to approve
    - New analyses to address concerns did not reverse FDA decision to concur with initial recommendation
  - Dispute Resolution Panel's recommendation will decide the issue unless there are compelling public health issues to disagree.

Working with CDRH

- Agreement Meetings
- Determination Meetings
- Pre-IDE Meetings
- Real Time Review

Meetings

	1998	1999	2000	Total	
Agreement Meetings	7	16	2	25	(24 reached agreement)
Determination Meetings	3	8	4	15	(14 reached agreement)
100 Day Meetings	5	15	7	27	
Total	10	24	6	67	

Pre IDE	300	299	315

Meetings

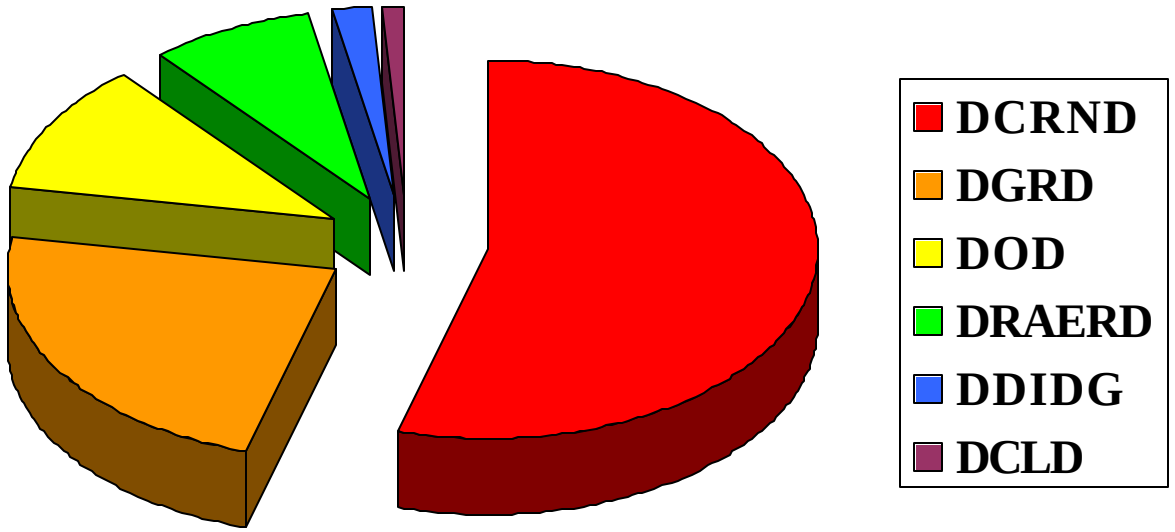
	1998	1999	2000	Total	
Agreement Meetings	7	16	2	25	(24 reached agreement)
Determination Meetings	3	8	4	15	(14 reached agreement)
100 Day Meetings	5	15	7	27	
Total	10	24	6	67	

1996	1997			
9	106	300	299	315

Meetings

Real Time PMA Supplements

- 146 requests for Real-Time PMA Supplements
  - Representing 27% of all PMA supplements
  - 134 were approved
  - Most by telephone conference



Least Burdensome

Ombudsman Survey

- 1. In the meeting, were the least burdensome principles applied in determining the need for prospective data in the following:
  - Was pre-clinical testing considered in lieu of clinical data?
    Yes: 2 No: 9
  - Was the use of previously collected non-US data, literature, and/or registry data considered?
    Yes: 5 No: 6

Least Burdensome

Ombudsman Survey

- 2. In the meeting, were the least burdensome principles applied in designing the clinical trial in the following:
  - Were alternatives to an actively controlled trial considered? Yes: 5 No: 4 n/a: 1
- If yes, check the following:

Literature control	Yes: 1 No: 3
Historical control	Yes: 2 No: 3
Non-active control	Yes: 1 No: 3
Patients as their own control	Yes: 1 No: 3
Objective Performance Criteria	Yes: 1 No: 3
Other	Yes: 1 No: 3

Least Burdensome

Ombudsman Survey

- Was the use of surrogate endpoints considered?
  Yes: 1 No: 8 n/a: 1
- Was a least burdensome approach considered in determining how the primary and secondary endpoints will be measured? Yes: 4 No: 3 n/a: 1
- Was early submission of the application considered? That is, could the application be submitted after a mutually agreed to percentage of the patients had been followed for a pre-defined period of time?
  Yes: 3 No: 6 n/a: 1
- Was the role of post marketing information considered as a mechanism for reducing the premarket requirements? Yes: 2 No: 8
- Were the least burdensome principles applied in other areas of the trial design not mentioned above?
  Yes: 2 No: 6 n/a: 1

Global markets – Global Standards

Global Quality System Standards

Global Regulation

Global Scientific Leadership

Evidence Based Medicine

Harmonization

Global Harmonization Task Force

Next Meets: October 11-16, 2001 Barcelona, Spain

Four study groups:

- Regulatory Requirements / Premarket Review
- Device Vigilance / Post-Market Surveillance
- Quality System Requirements and Guidance
- Auditing

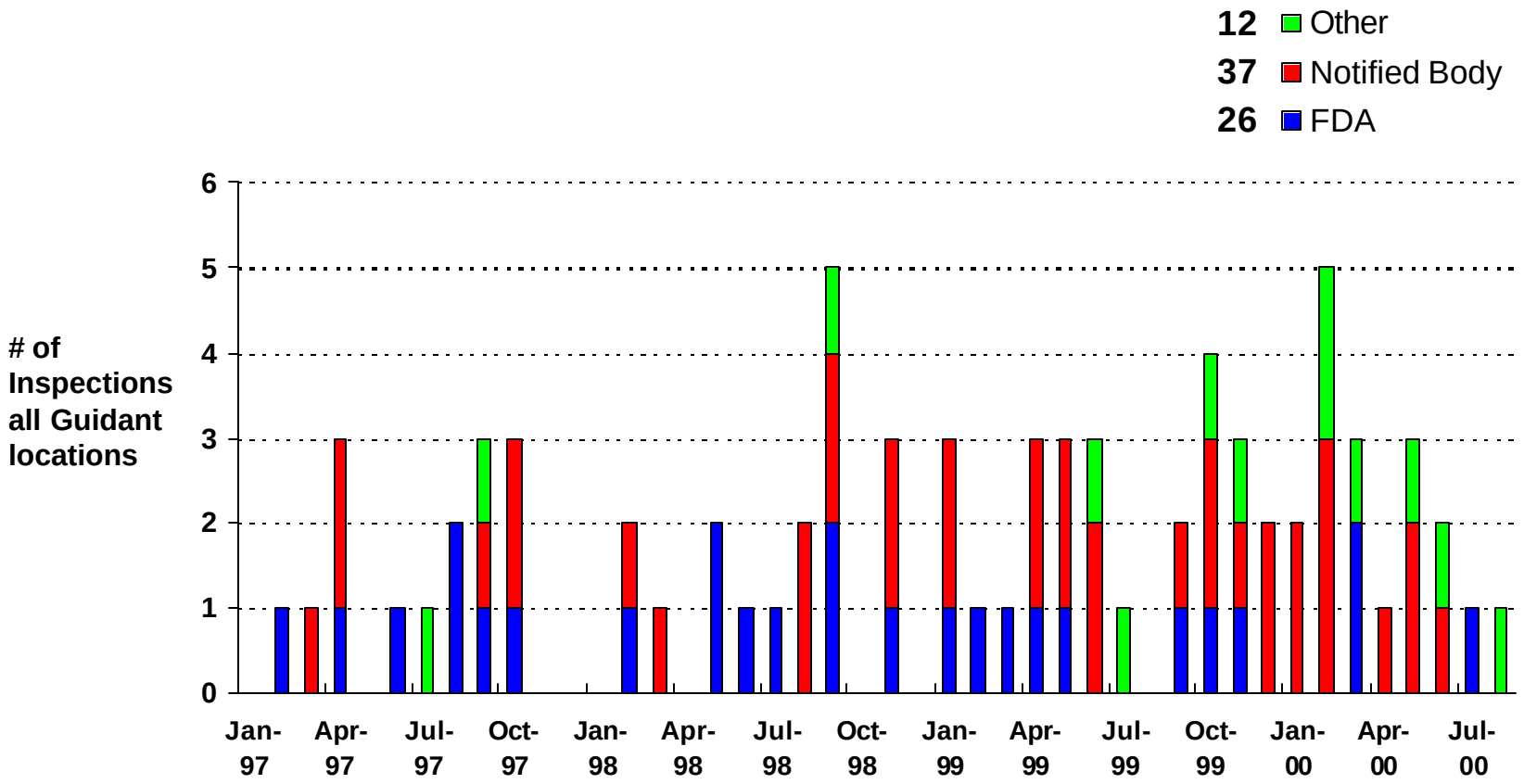
www.ghtf.org

International Standards Organizations

	ANSI	BSI	DIN	Centralized European			CDRH
				CEN	CENLAC	ETSI	
Budget (Millions $)	15	293	100	10	4	21	140
Staff	79	4000	1000	115	36	107	1200 Including field
Committees	262	2888	4600	1844	387	64	
Standards	14202	19129	24000	5131	2863	709	500 Recognized

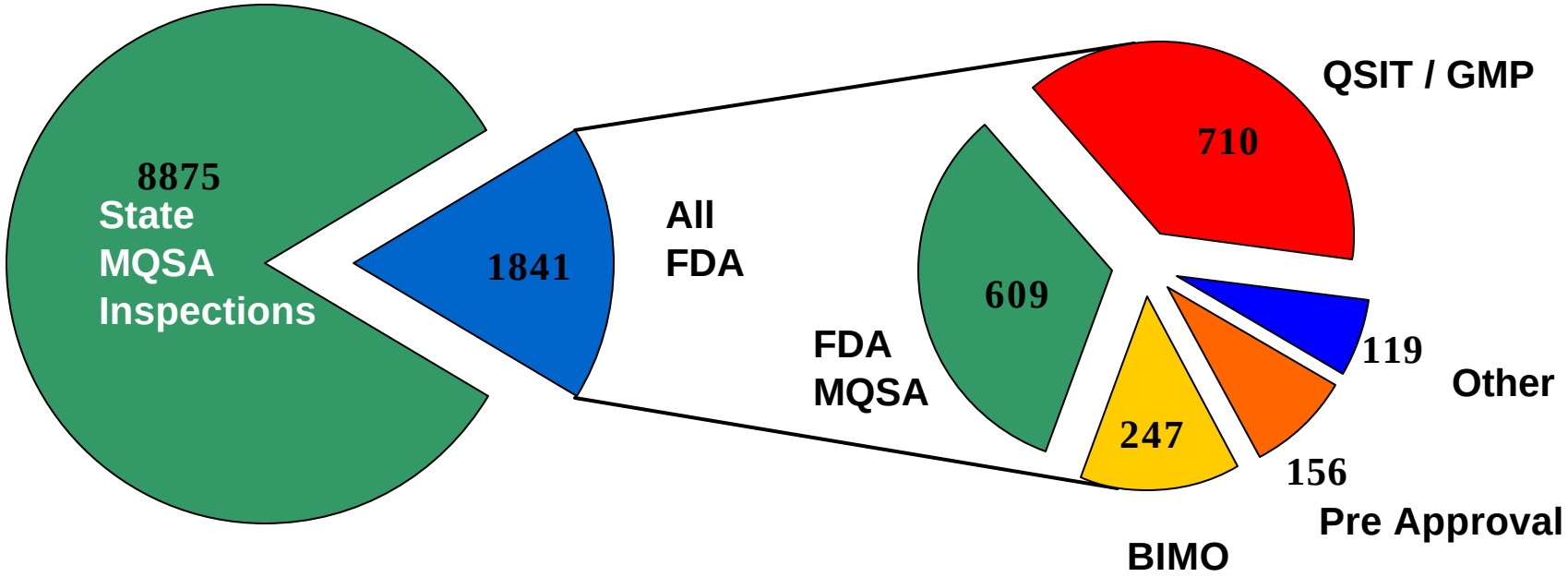
Guidant Global Compliance

Inspections 1997-August 2000



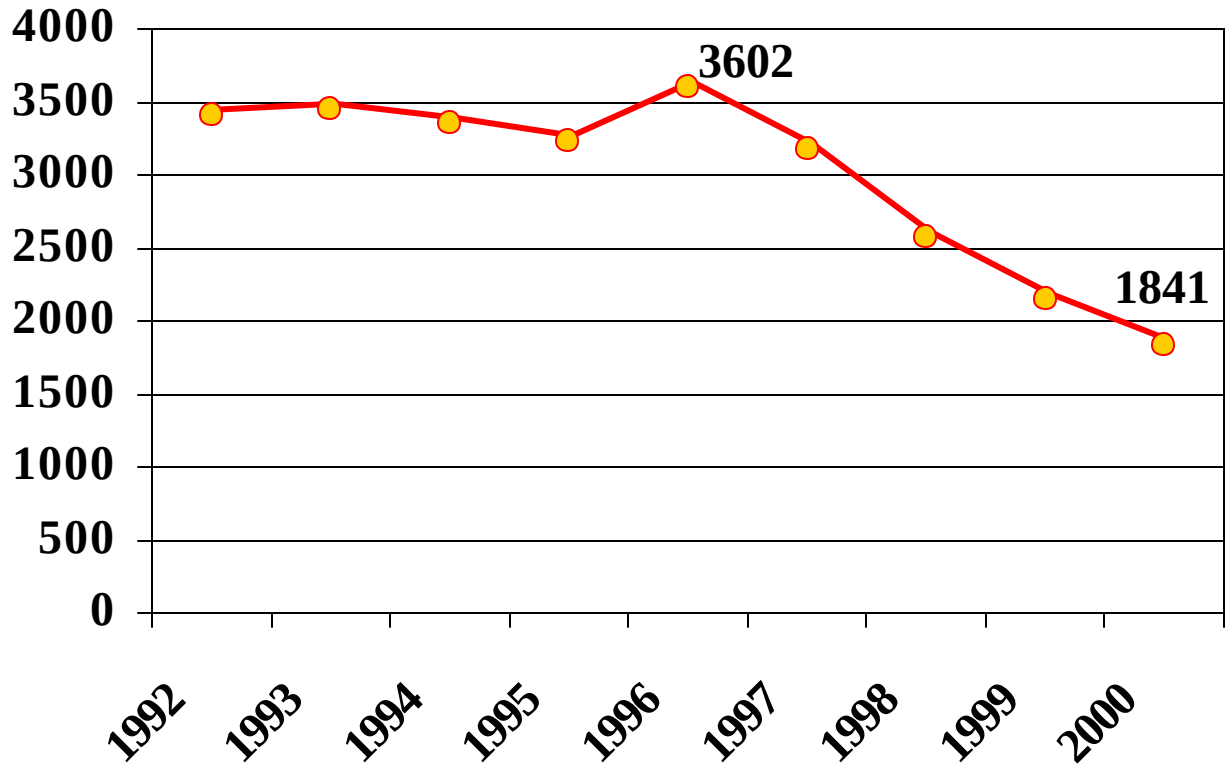
Courtesy Michael Gropp, Guidant

Resources



2000 Device Inspections

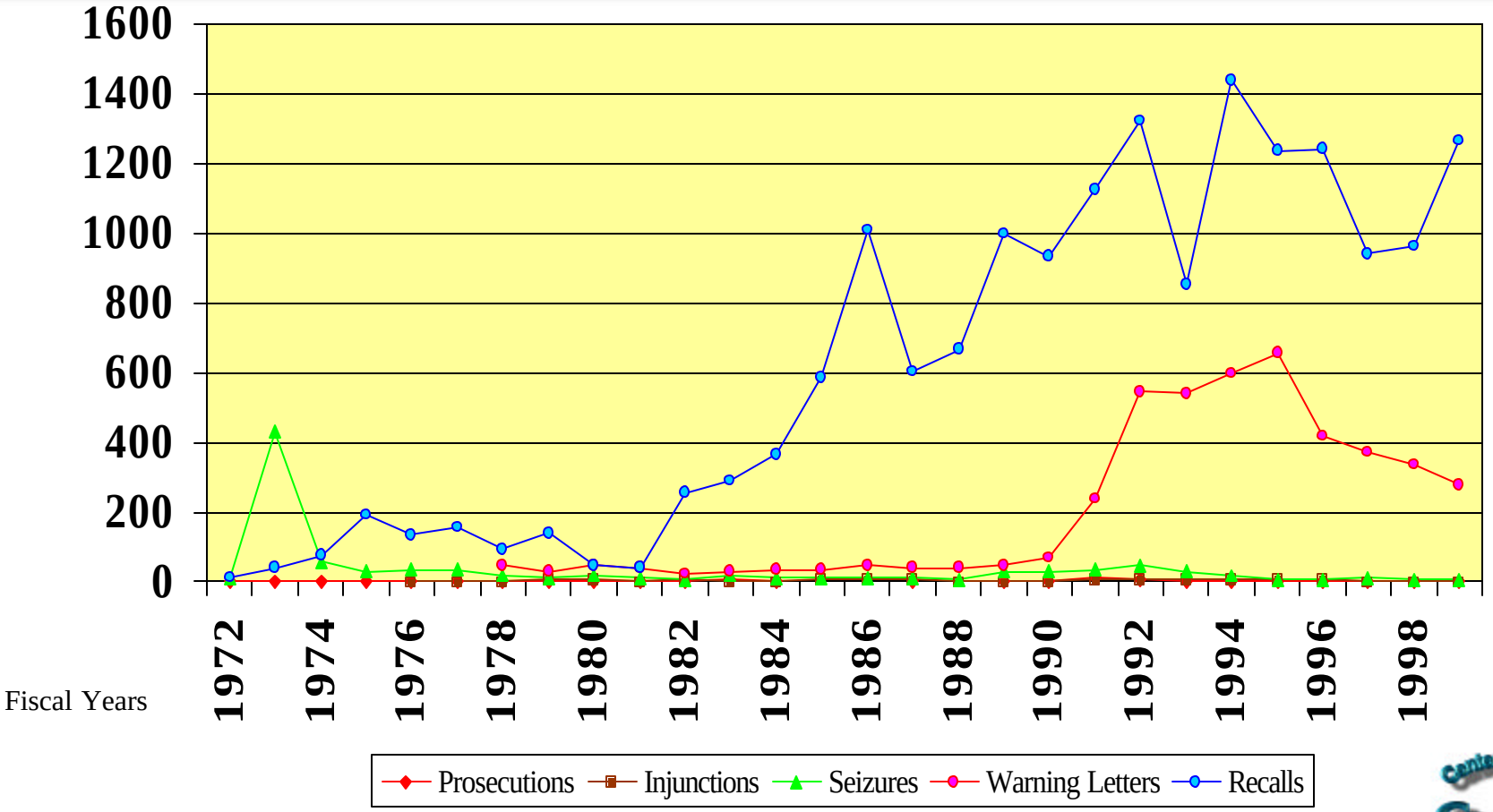
Resources



Device Establishment Inspections

Enforcement Action

Medical Devices and Radiological Health



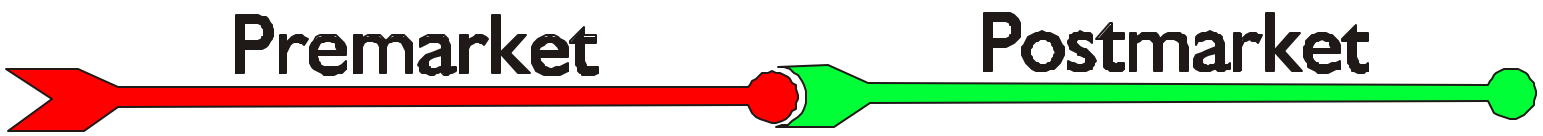
* Prior to 1976 Injunctions and Prosecutions were combined

CDRH's Strategic Plan

Mission:

CDRH promotes and protects the health of the public by ensuring the safety and effectiveness of medical devices and the safety of radiological products.

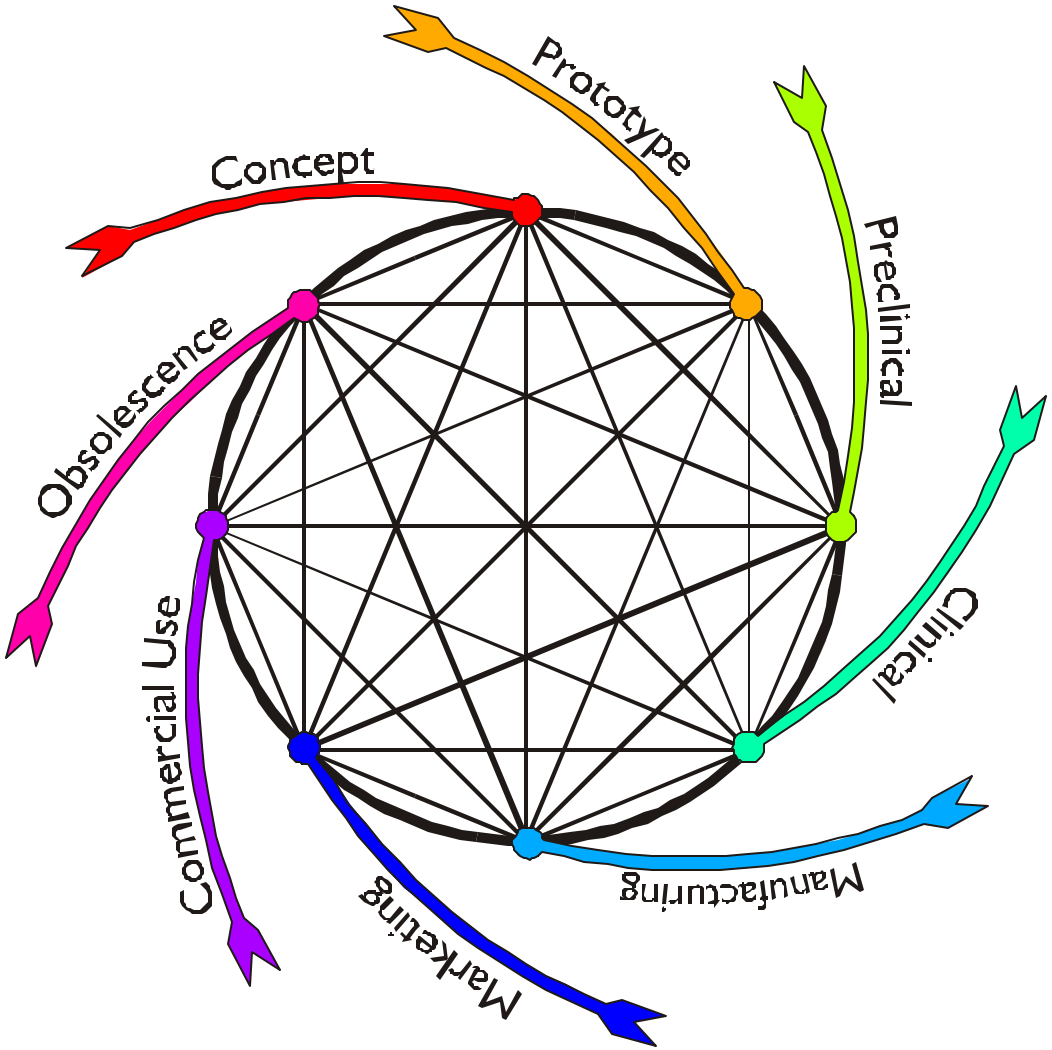
Consumer Protection



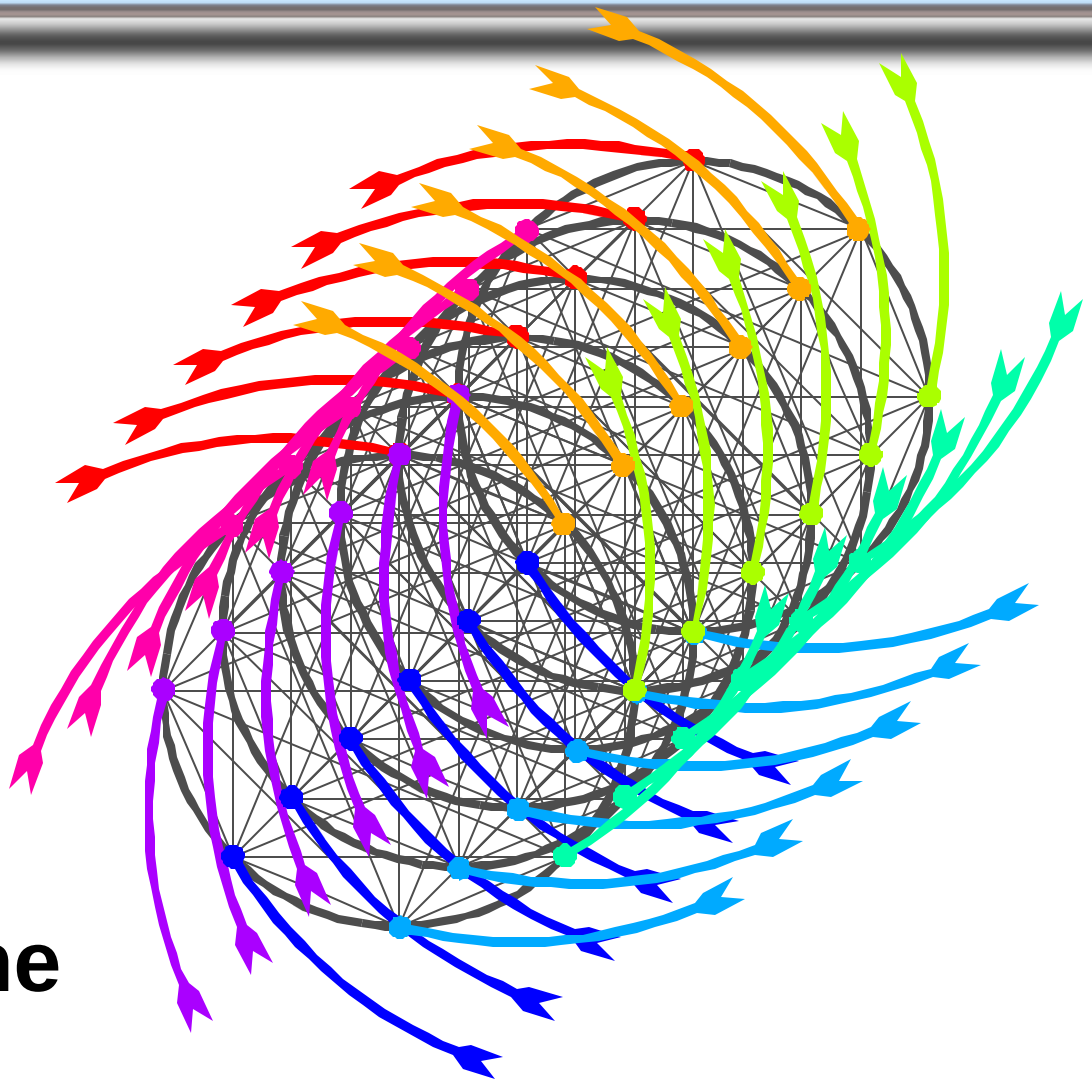
Safe experimentation
Premarket safety
Premarket effectiveness
Research Inspection

Truthful promotion
Adverse Event Reporting
Postmarket studies
Manufacturing Inspection

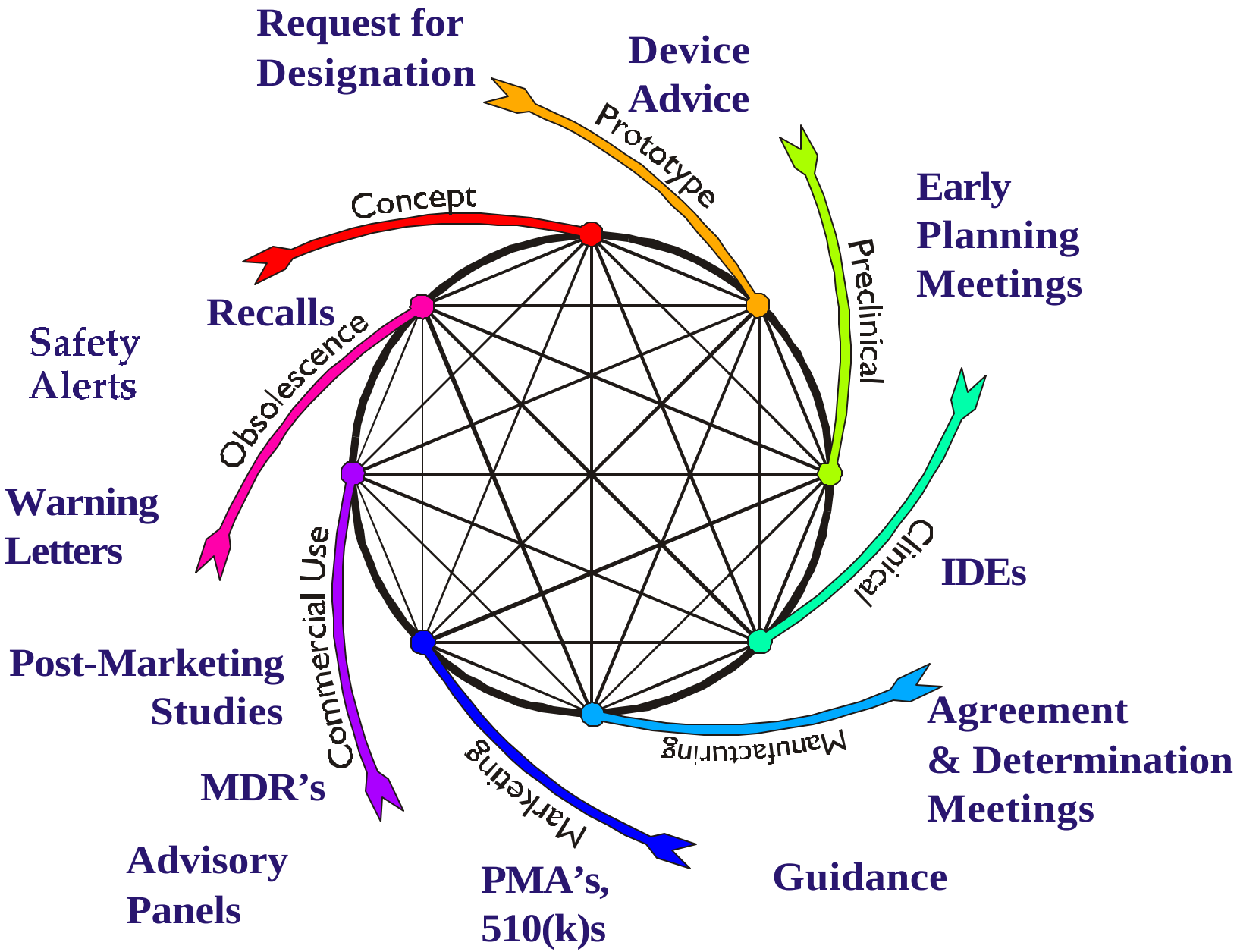
CDRH Vision - Total Product Life Cycle

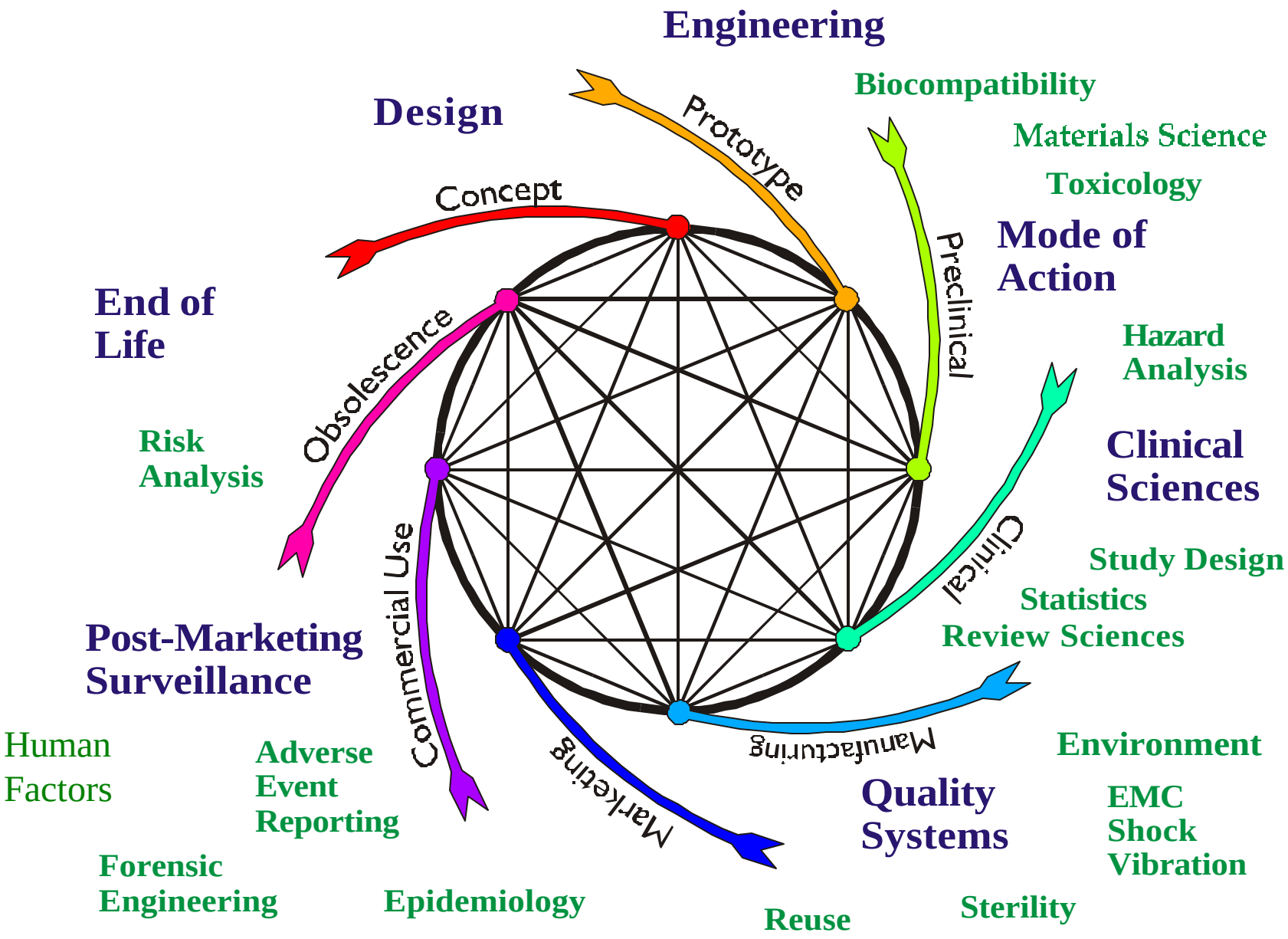


CDRH Vision - Total Product Life Cycle



The Pipeline


Request for Designation
Device Advice
Early Planning Meetings
IDEs
Agreement & Determination Meetings
Guidance
PMA's, 510(k)s
MDR's
Advisory Panels
Post-Marketing Studies
Warning Letters
Safety Alerts
Recalls
Concept
Prototype
Preclinical
Clinical
Manufacturing
Marketing
Commercial Use
Obsolescence


Engineering
Design
Concept
Prototype
Biocompatibility
Materials Science
Toxicology
Mode of Action
Preclinical
End of Life
Obsolescence
Hazard Analysis
Risk Analysis
Clinical Sciences
Clinical
Study Design
Statistics
Review Sciences
Post-Marketing Surveillance
Commercial Use
Manufacturing
Human Factors
Adverse Event Reporting
Marketing
Environment
Quality Systems
EMC
Shock
Vibration
Forensic Engineering
Epidemiology
Reuse
Sterility

Strategic Goals

- Total Product Life Cycle
- Magnet for Excellence
- Knowledge Management
- Meaningful Metrics

Information Empowered Consumers

Consumers increasingly independent

Direct to Consumer Sales

- Directed Advertising
- Internet

FDA Internet Site

- Increase from 30 million to 45 million hits per month in the last 6 months
- Some consumer brochures are downloaded a million times per year

Home Care

Self Care

Center for Devices and Radiological Health

Question:

What will we lose if the scientific and regulatory leadership and credibility of FDA is lost ?

- *will the needs of Evidence Based medicine be met by "substantially equivalent to a pre-1976 device"?*
- *risk based inspection with decreasing assurance of conformance to quality standards?*
- *expansion the EU CE-mark clout as the de facto quality standard?*
- *world-wide impact by regional concerns and experiences?*
- *will "precaution" replace "risk-benefit"*

Vision:

Ensuring the health of the public throughout the

Total Product Life Cycle

— it's everybody's business