



CDRH: Looking Ahead

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FDLI April 2001



Performance

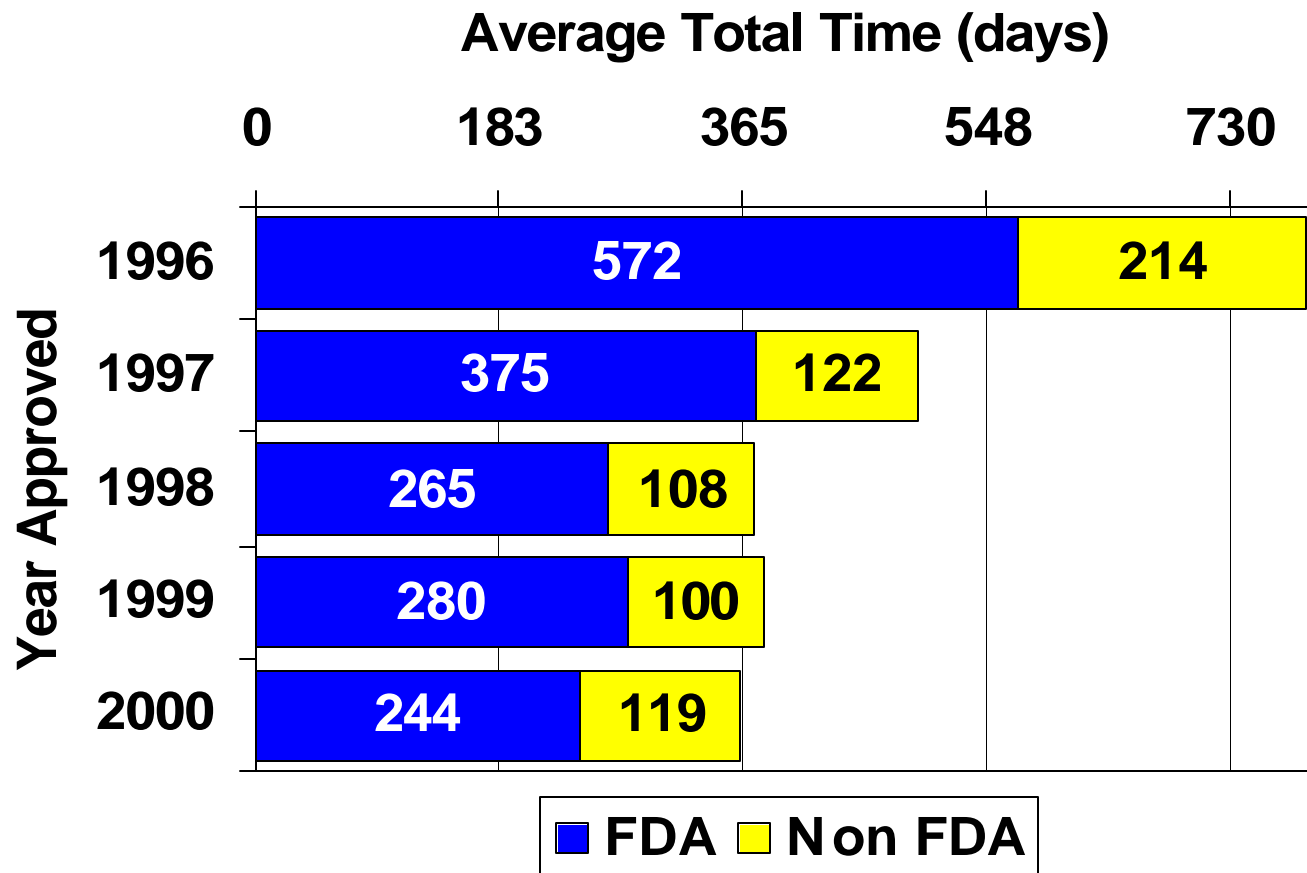
Submissions: Fiscal Year 2000

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
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Total	16919

65
Submissions
per day

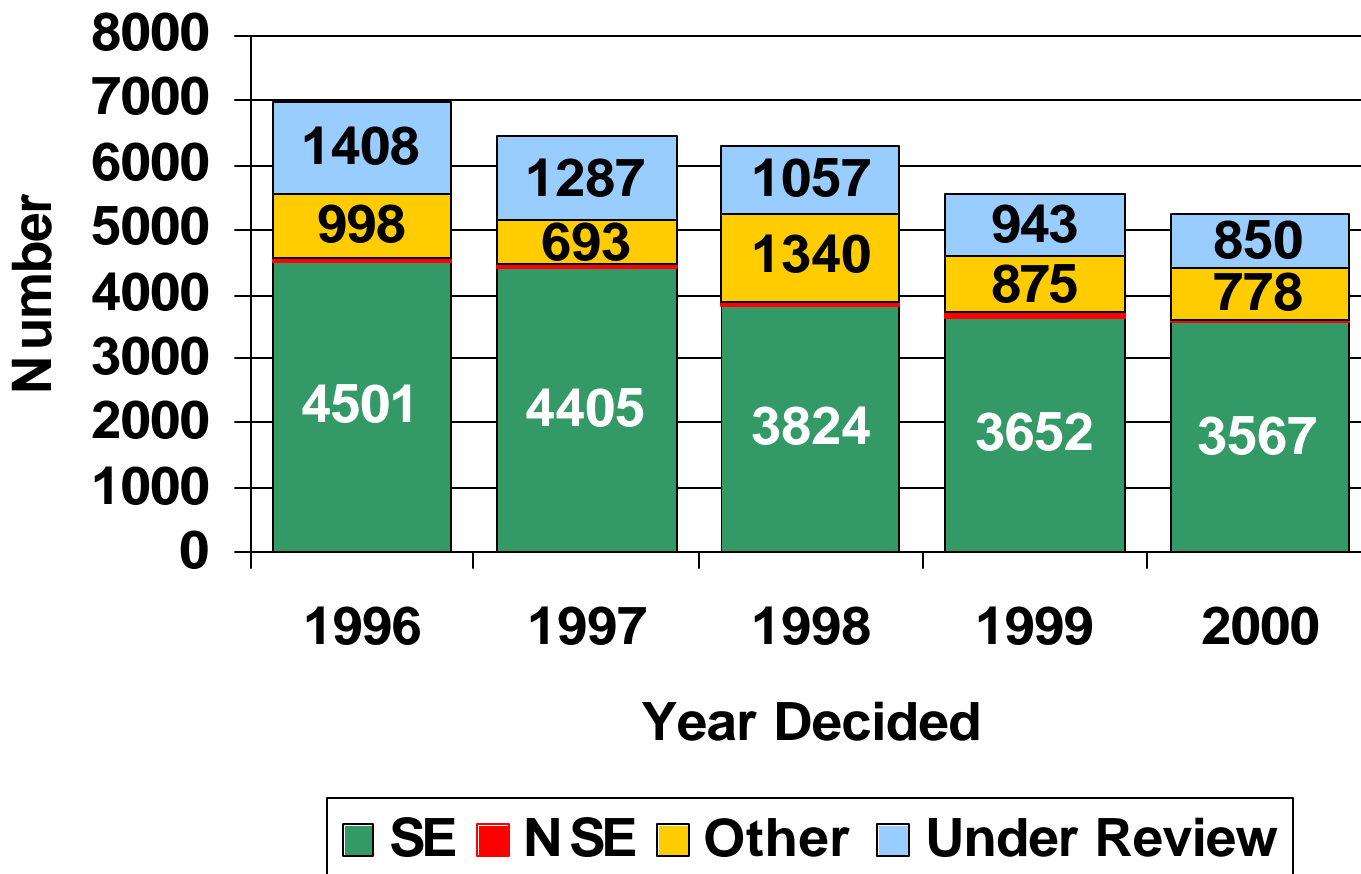
Performance

PMA Total Approval Times



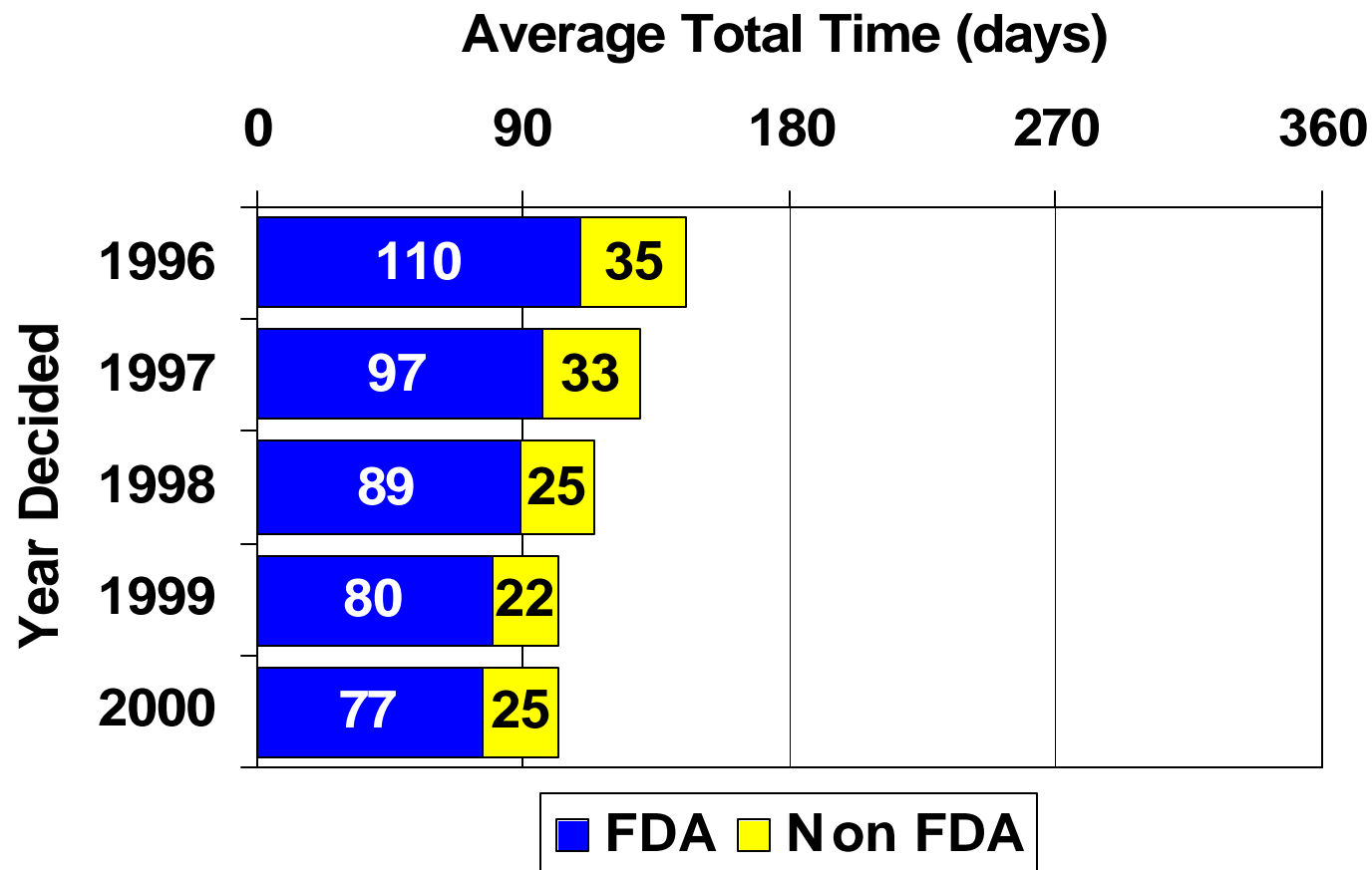
Performance

510(k) Decisions



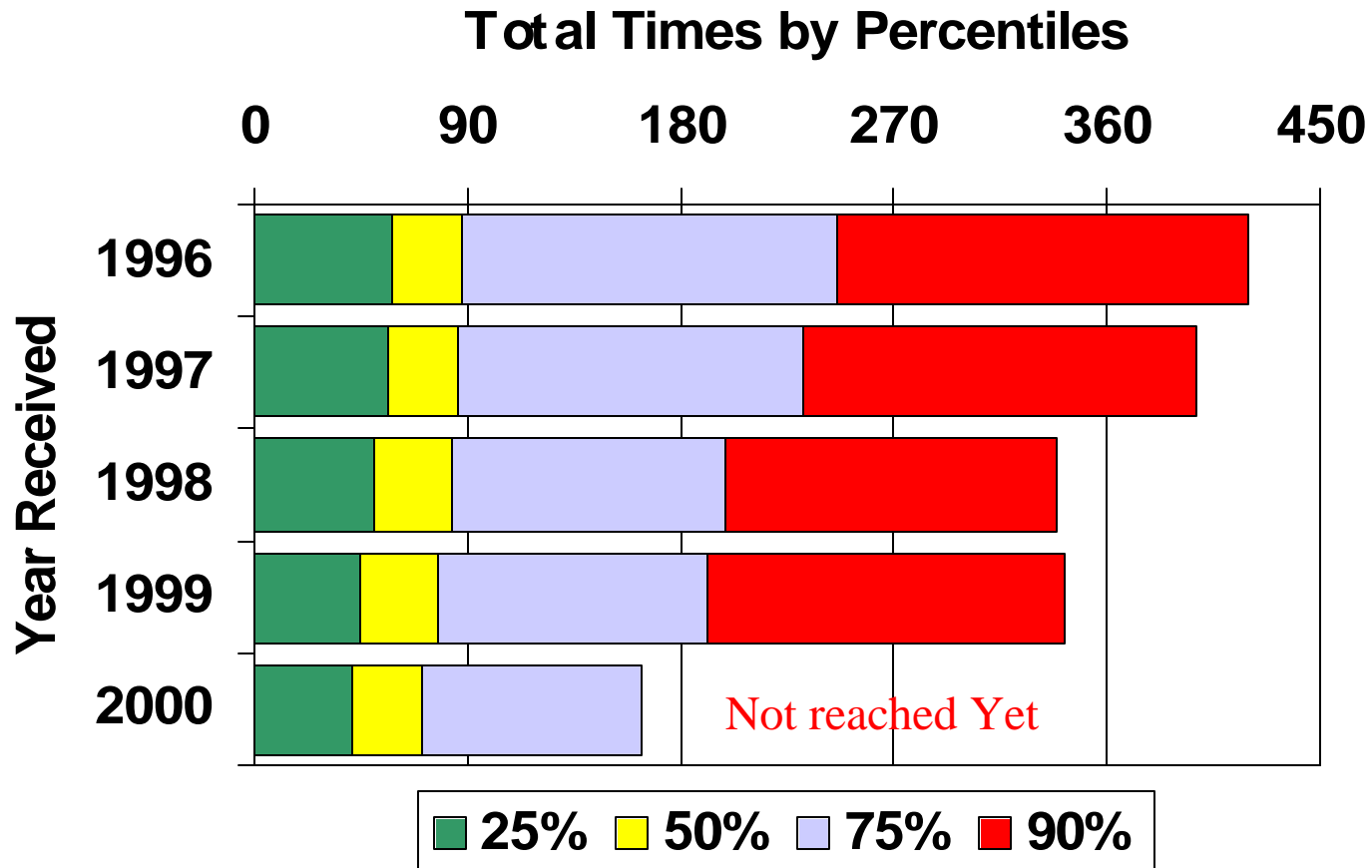
Performance

510(k) Total Decision Times



Performance

510(k) Total Decision Times



FDAMA Implementation

Dispute Resolution:

- Ombudsman: Les Weinstein
- Dispute Resolution Panel

Least Burdensome

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

First Year Experience

- Complaints: 24
- Disputes: 11

Complaint about or Dispute with:

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

- ODE: 23 (61%)
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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 1990
 - Orientation and Organizational Agenda
- Second Meeting Summer 1991
 - 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 FDA

- 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
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Meetings

	1998	1999	2000	Total
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Total	10	24	6	67

(24 reached agreement)

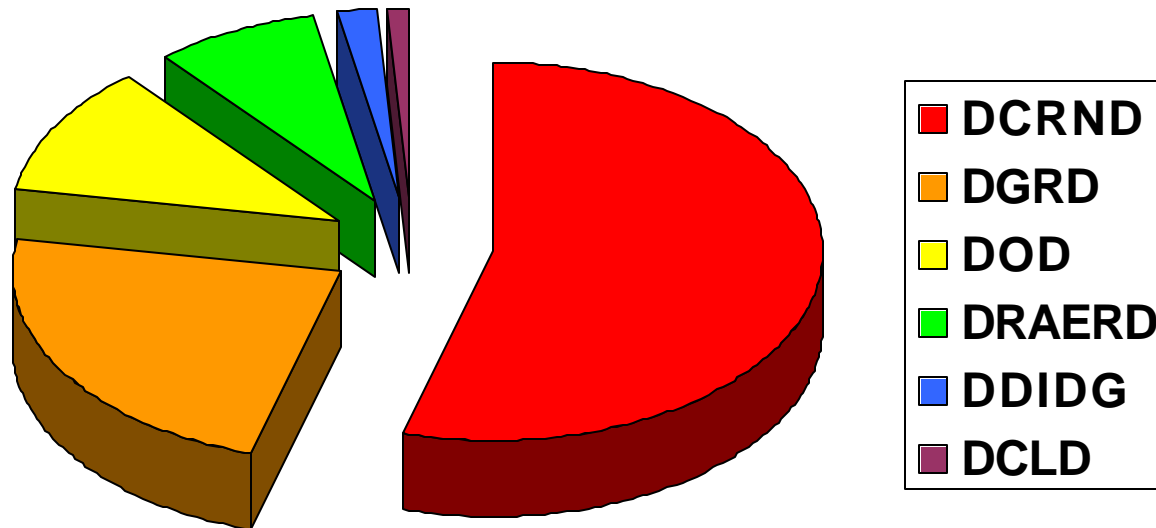
(14 reached agreement)

	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 Path to Market



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

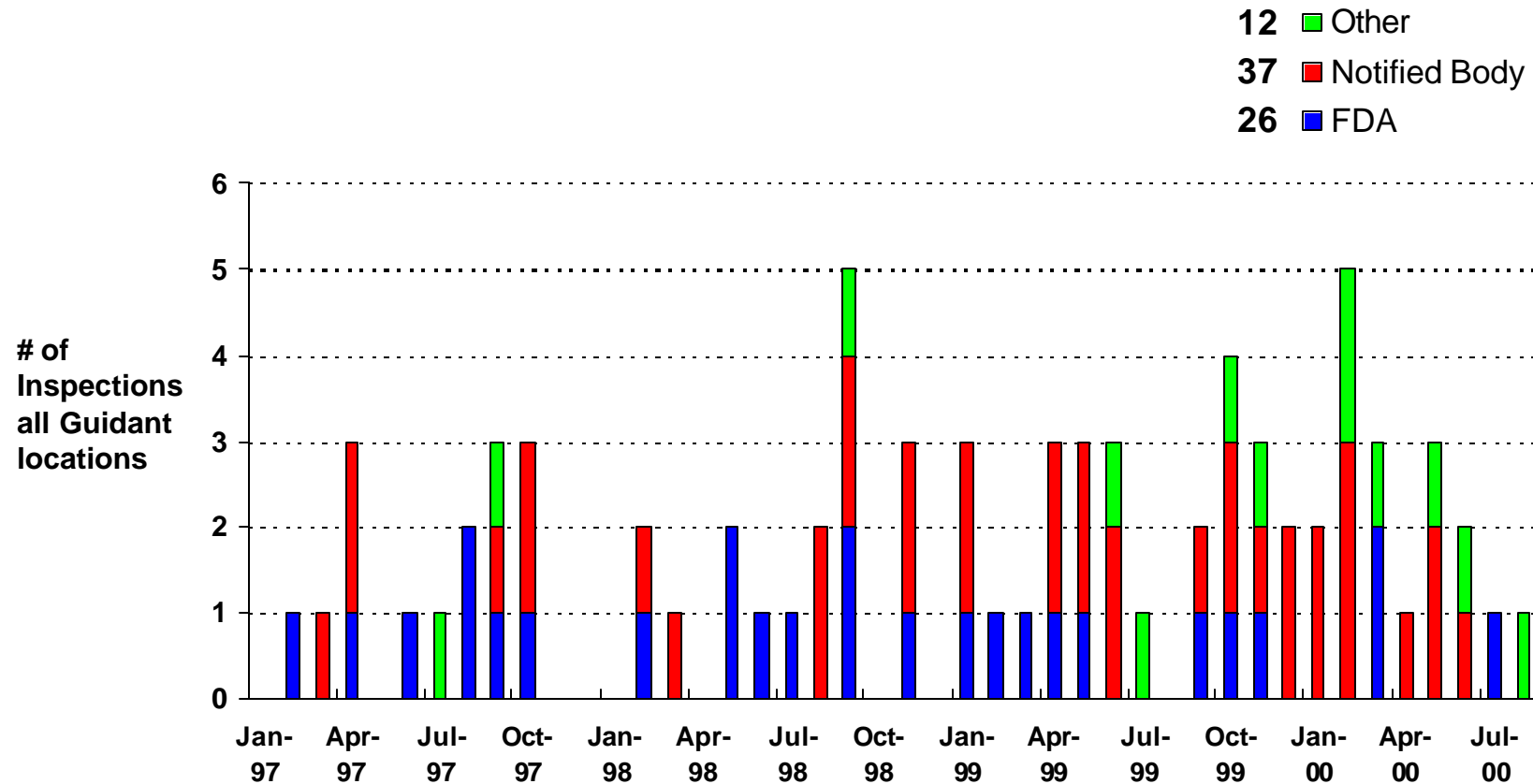
www.gh tf.org

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

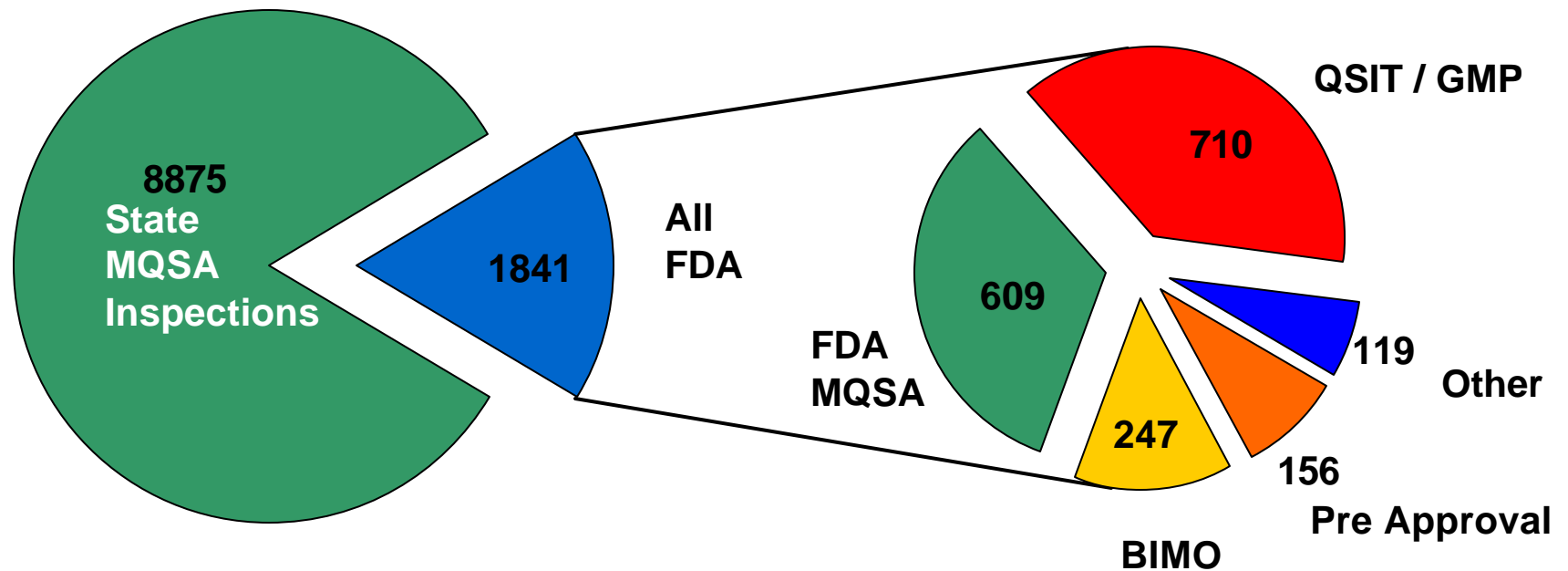
Guidant Global Compliance

Inspections 1997-August 2000



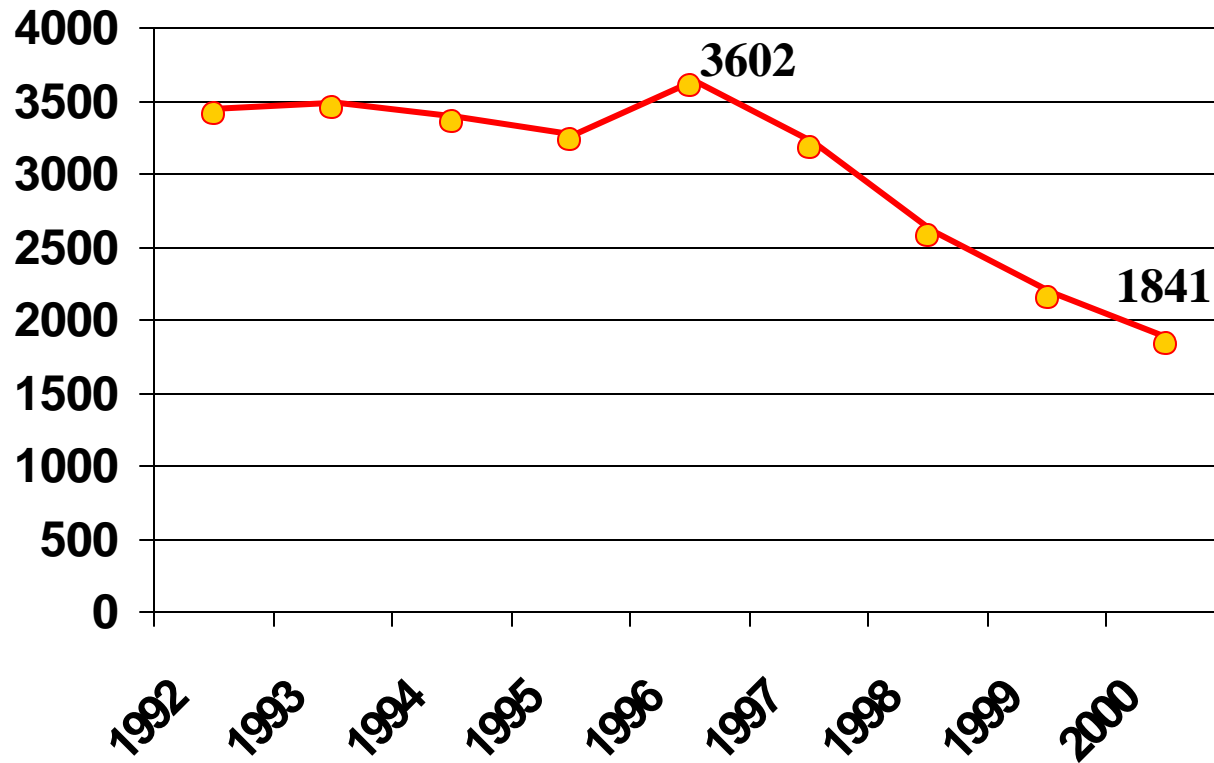
Courtesy Michael Gropp, Guidant

Resources



2000 Device Inspections

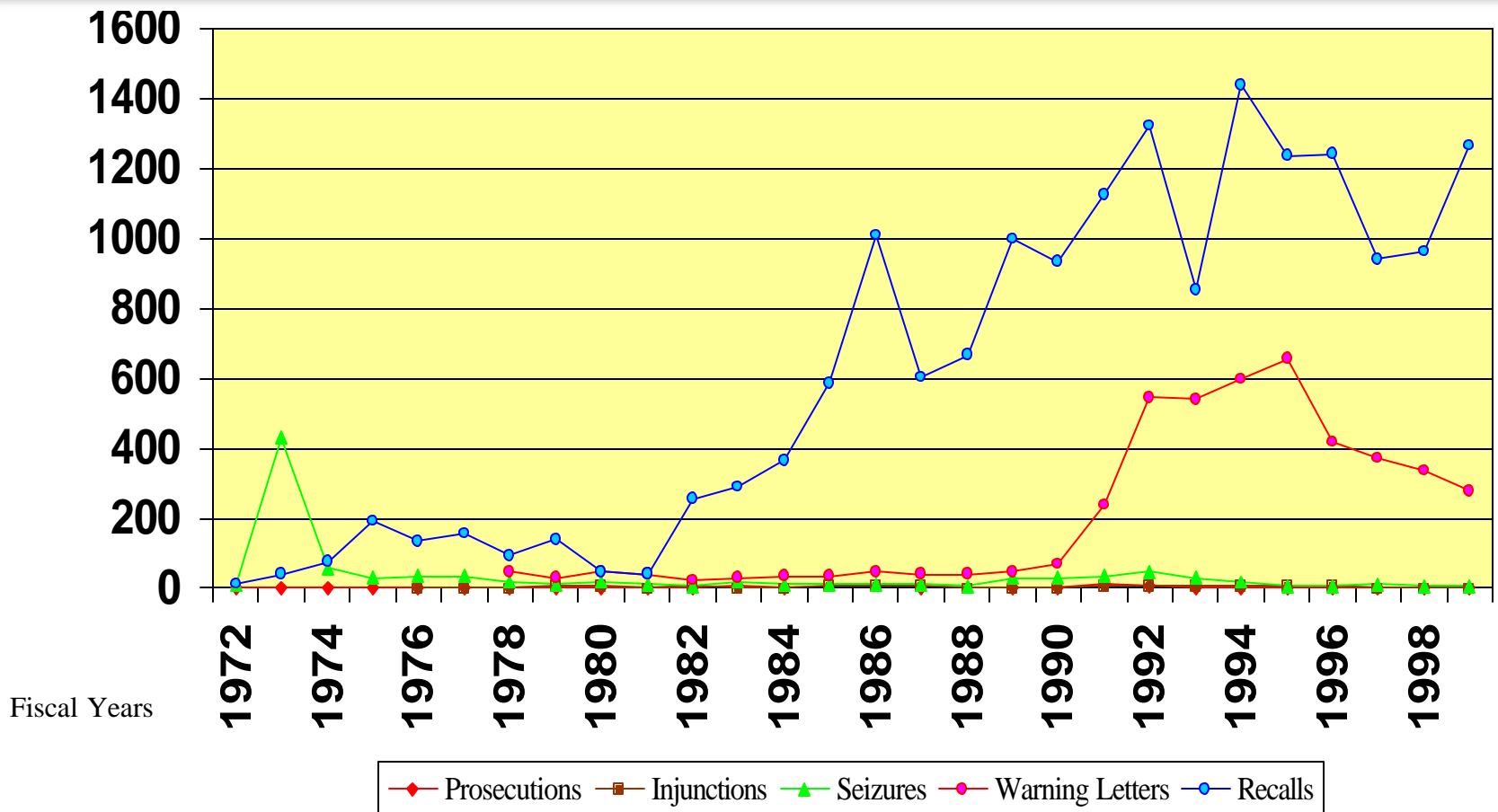
Resources



Device Establishment Inspections

Enforcement Action

Medical Devices and Radiological Health



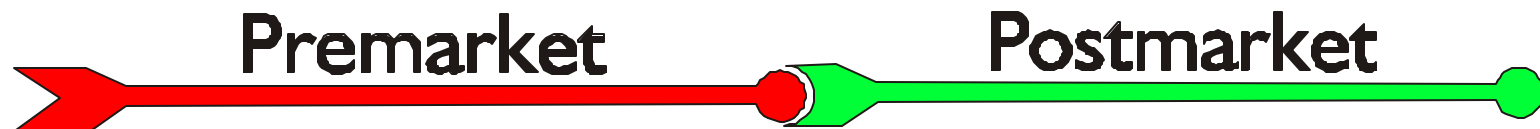
* Prior to 1976 Injunctions and Prosecutions were combined

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.

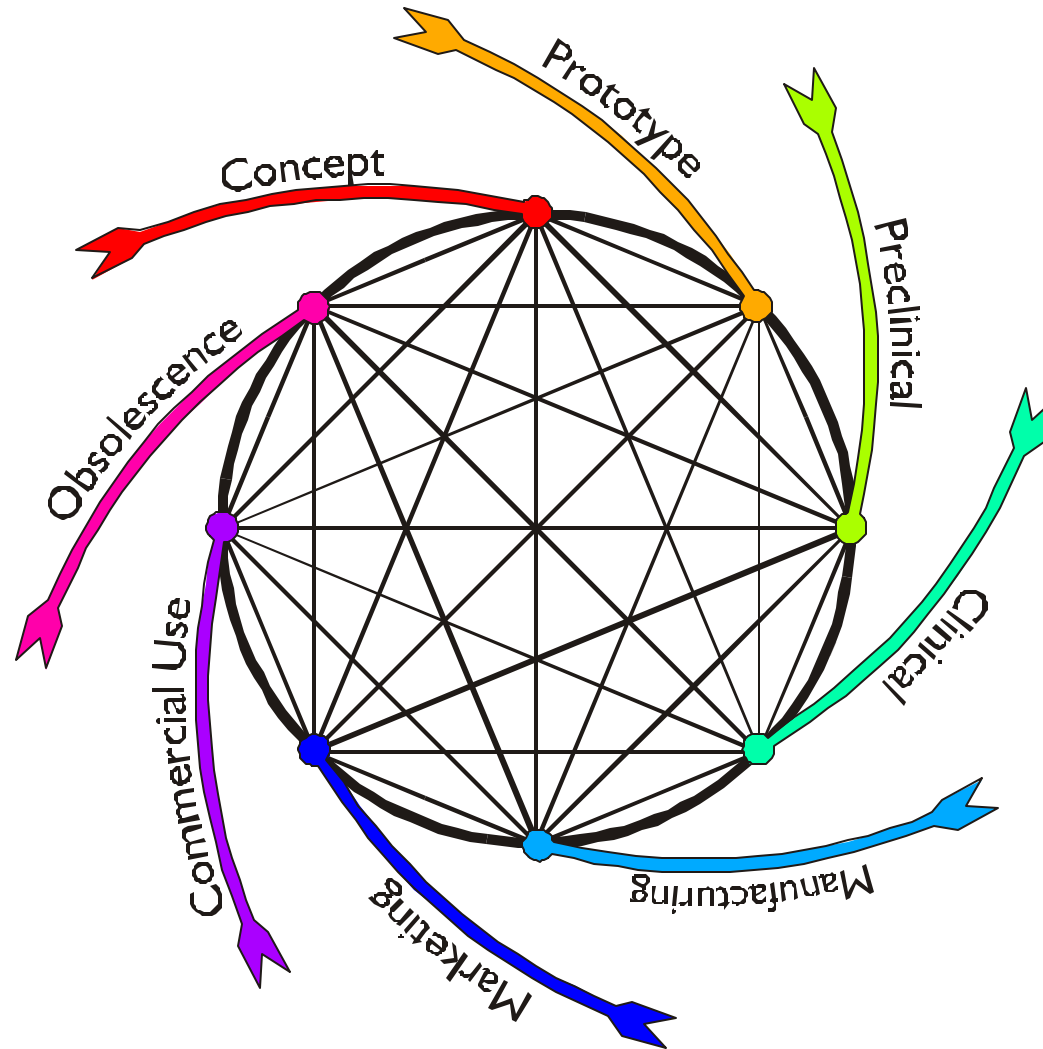
Consumer Protection



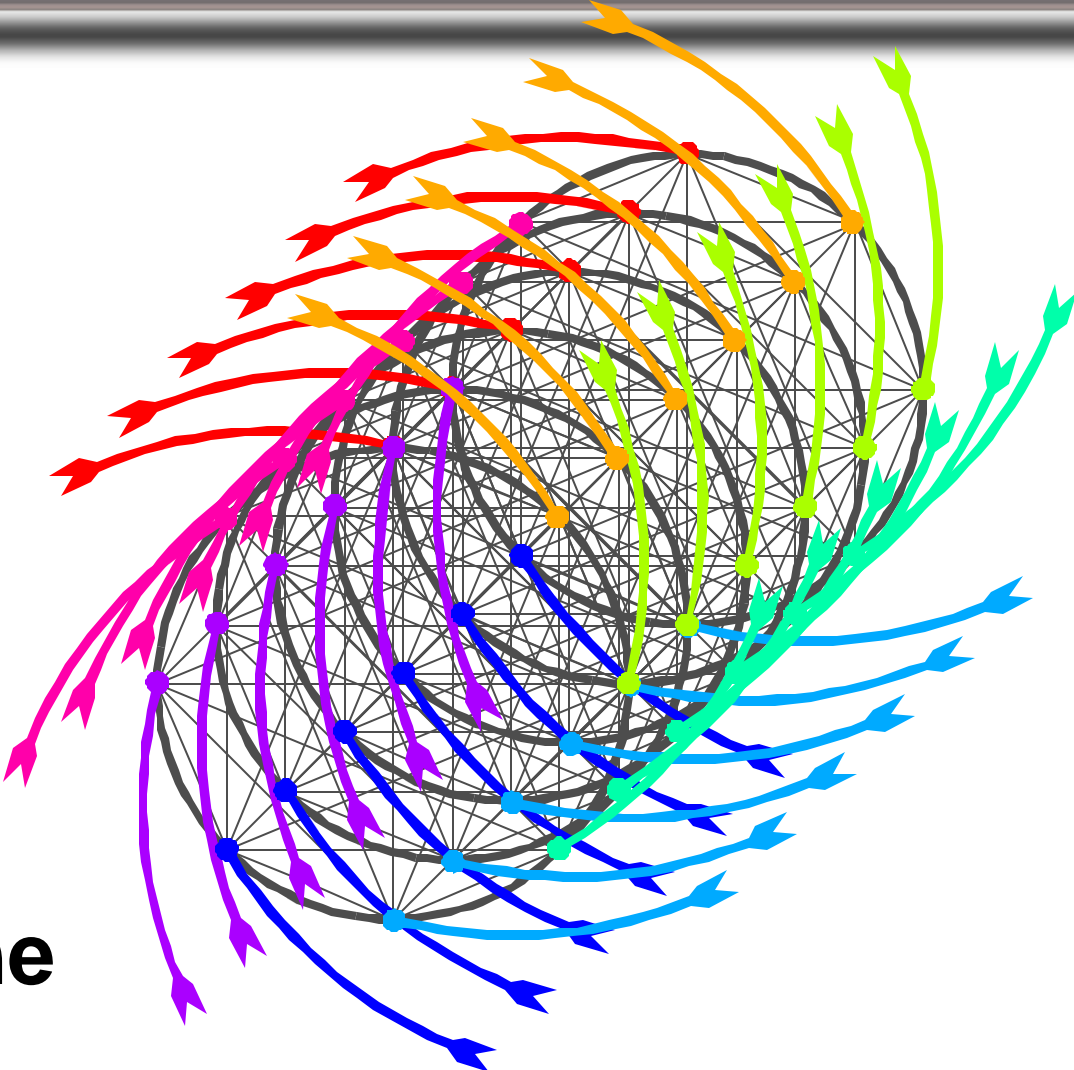
Safe experimentation
Premarket safety
Premarket effectiveness
Research Inspection

Truthful promotion
Adverse Event Reporting
Postmarket studies
Manufacturing Inspection

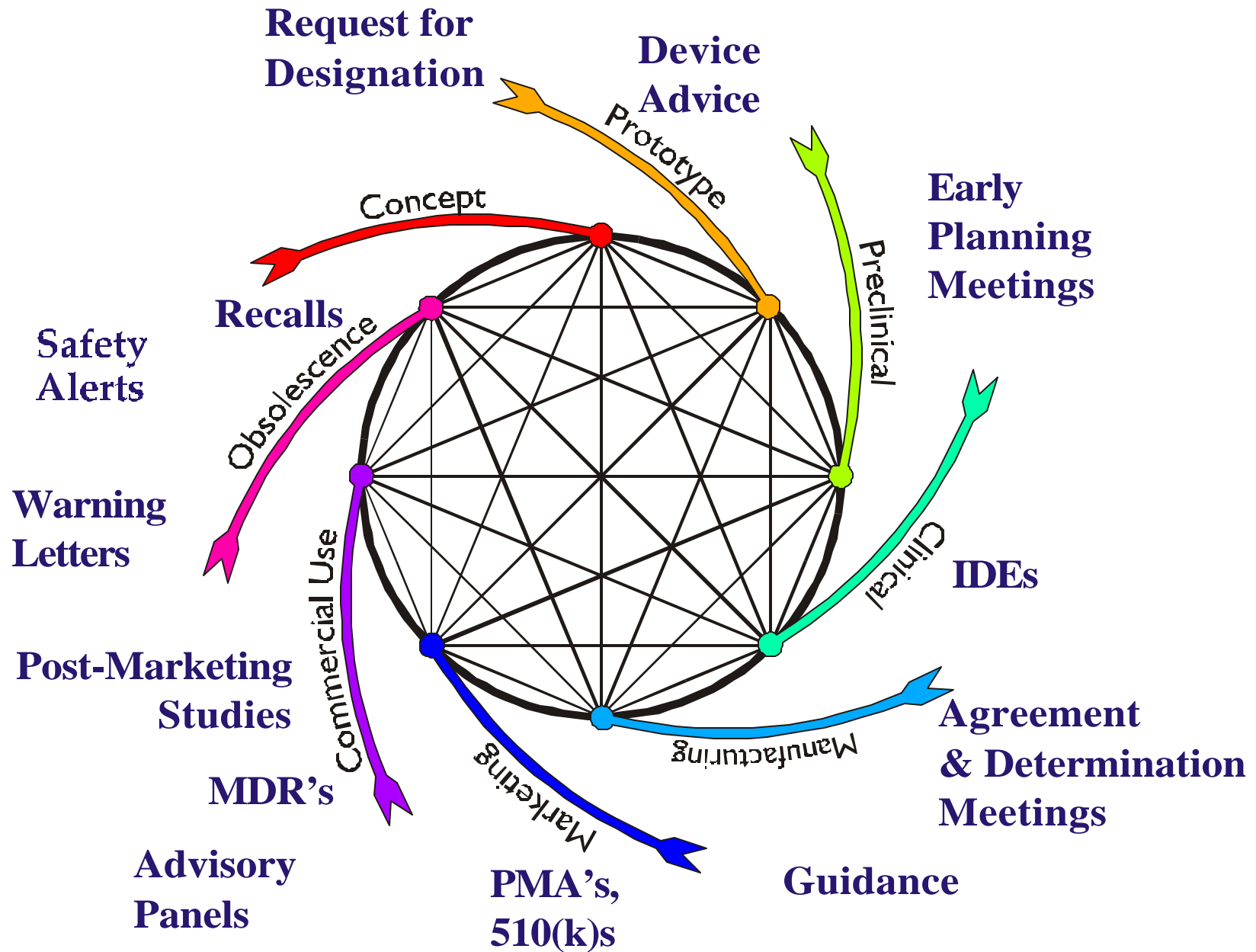
CDRH Vision - Total Product Life Cycle

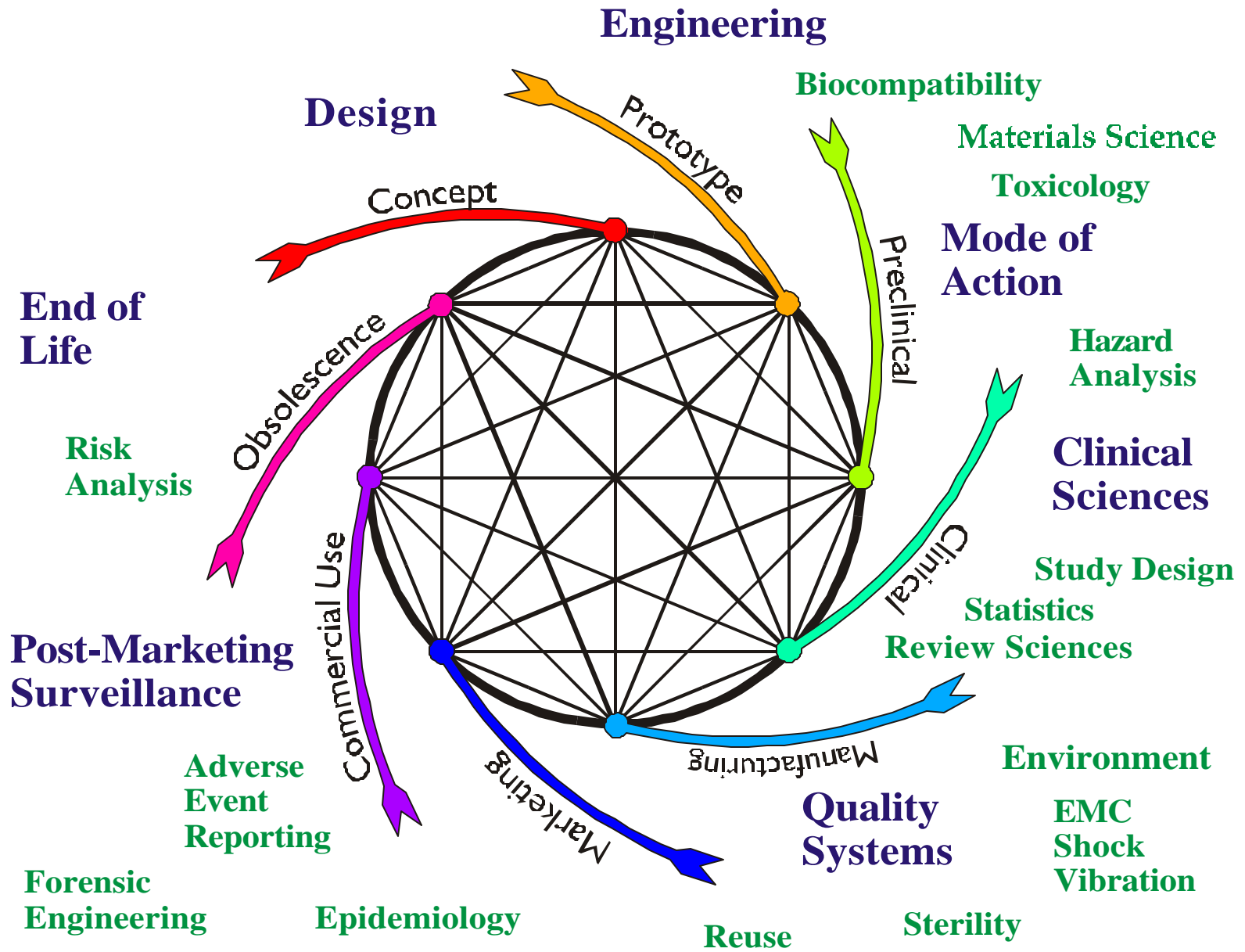


CDRH Vision - Total Product Life Cycle



The Pipeline





Center for Devices and Radiological Health

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”*

Center for Devices and Radiological Health

Vision:

Ensuring the health of the public throughout the

*Total Product Life Cycle
— it's everybody's
business*