Future Trends

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CDRH: Future Trends

- Standards
  - U.S.
  - International

Standards

Role in US Device Regulation

- Quality Standards
- Cross-product performance standards
- Product specific standards

Can replace portions of 510(k) applications

- E.g., A mechanical wheel chair 510(k) application can consist of declaration of conformance to 12 standards.

Can facilitate 3rd party review

Performance: 510(k)s - Alternatives

Type of 510(k)	Reviews Completed 12 months FY99	Average Total Time (days)	Reviews Completed 1st 9 months FY00	Average Total Time (days)
Abbreviated	75	99	75	60
Special	361	29	389	33
Traditional	4155	108	2637	115

Using Standards to Support SE Decisions 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

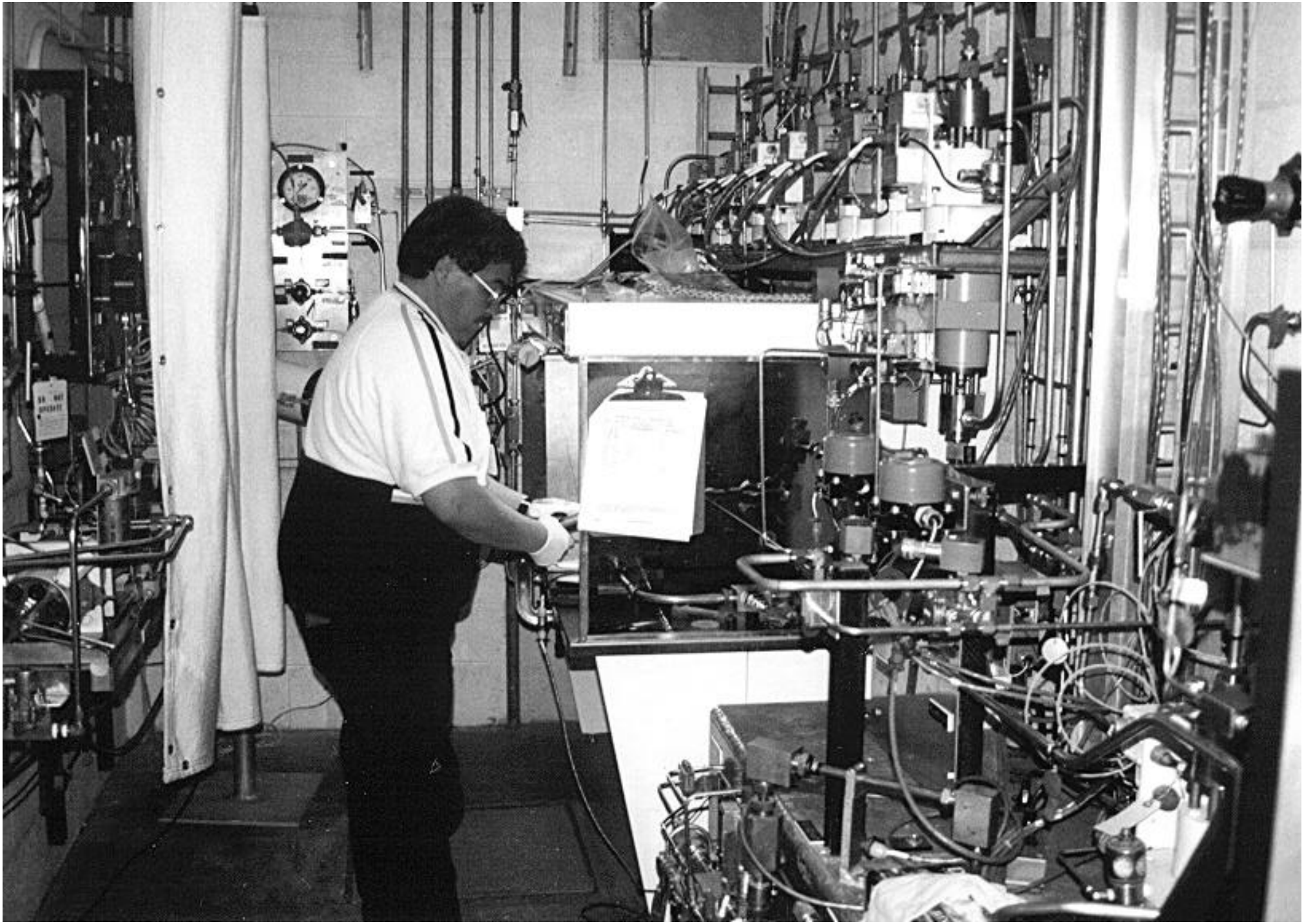
Problem Solving with Standards

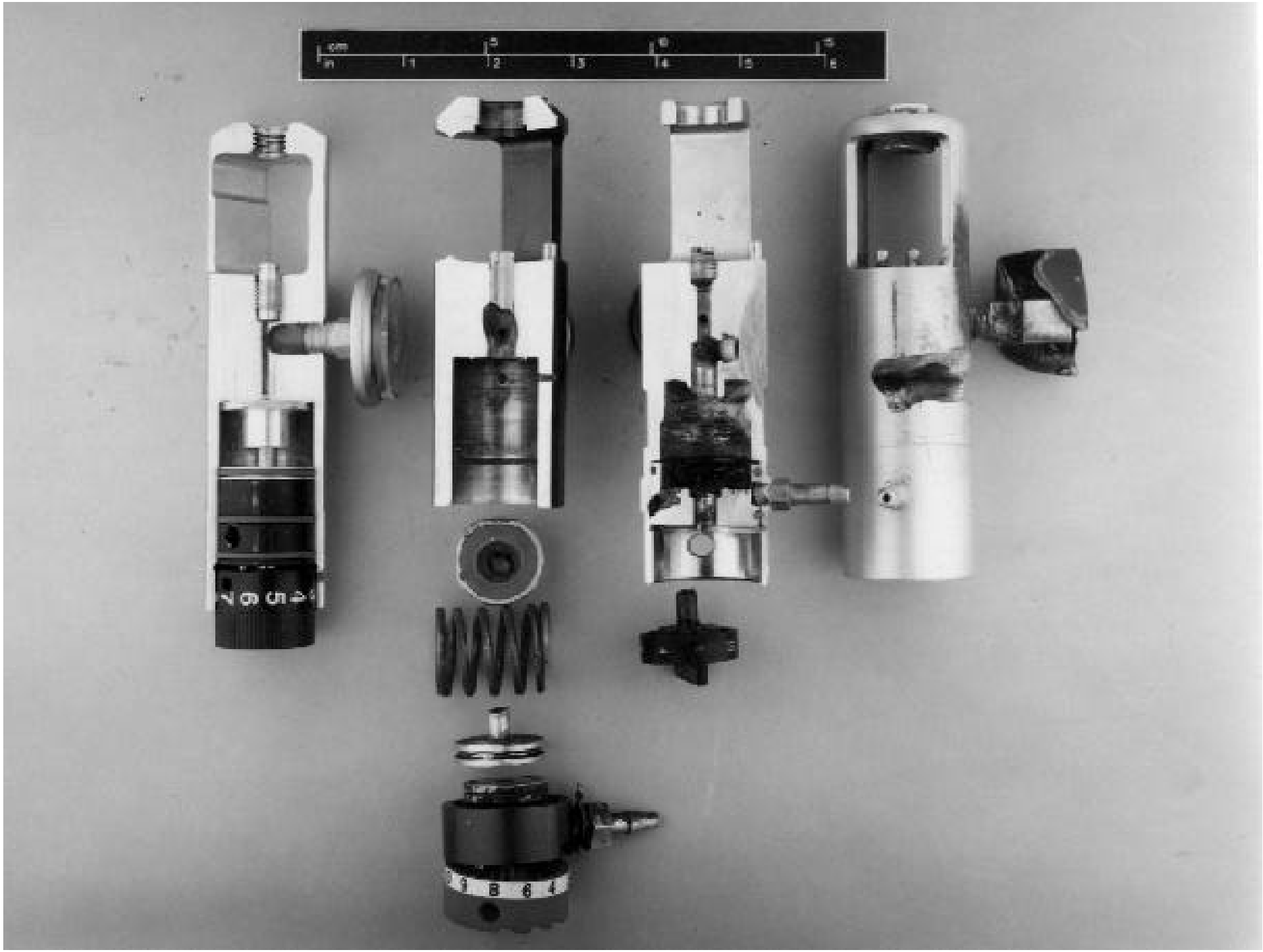
Oxygen Regulators

- Problem: Aluminum oxygen regulators are more susceptible to burning than brass, particularly with rough handling in an EMS setting.

? Solution: Go back to Brass??? (no)

Solution: Develop Ignition Standard and if a regulator can pass the standard it doesn't matter what it is made of.





Problem Solving with Standards

Medical Telemetry

- Problem: When digital television started coming on line in Texas it blocked out the signals from medical telemetry monitoring devices

- Solution: Standardize the frequencies to be used for EMF and get the FCC to set aside for medical telemetry.

International Standards Organizations

	ANSI	BSI	DIN	Centralized European			CDRH
				CEN	CENELEC	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	600+ Recognized

International Standards and FDA

ISO 9001 (2000)

- Where does it overlap with QSIT ?
- What can we learn from the ISO conformance inspections ?

Harmonization and Standards

- CDRH Participation in Standards Organizations
- Global Harmonization Task Force

Global Harmonization Task Force

Next Meets: September 18-22, 2000 Ottawa, Canada

Four study groups:

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

www.ghtf.org

Global Harmonization Task Force

Progress continues…

- 12 documents approved, from four study groups
- Formal operating principles being developed
- MOU between GHTF and ISO/TC210 Committee on quality management
  - Approved by ISO/TC210, awaiting approval by GHTF

MOU with ISO/TC210

The Task Force also agreed to pursue a formal liaison relationship with ISO's Technical Committee on Quality Management and Corresponding General Aspects for Medical Devices (TC 210), whose focus is to ensure the harmonization of quality system standards. The MOU was approved by ISO/TC210 in April 1999, and is awaiting GHTF approval. Goals of the MOU are

- Promote communication between the two organizations;
- Avoid duplication of work efforts where possible;
- Provide a formal and coordinated regulatory voice to TC 210;
- Promote the fit of international standards to worldwide regulatory needs where applicable;
- Utilize the expertise and resources of the TC 210 efforts to improve the efficiency of regulatory activities in the service of promoting public health; and
- Promote knowledge of the GHTF and its work to TC 210 and the national bodies that are involved in the regulation of medical devices.

Global Harmonization Task Force

Approved Documents

- Study Group 1
  - Essential Principles of Safety & Performance of Medical Devices
  - Labeling for Medical Devices
  - Role of Standards in the Assessment of Medical Devices
- Study Group 2
  - Comparison of the Device Adverse Reporting Systems in USA, Europe, Canada, Australia & Japan
  - Minimum Data Set for Manufacturer Reports to Competent Authorities
  - Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices
  - Global Medical Devices Vigilance Report
  - Charge & Mission Statement
  - Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative

Documents Published by GHTF include

- essential principles of safety and performance of medical devices on a global basis;
- the role of standards in the assessment of medical devices;
- a comparison of device adverse reporting systems in the European Union, United States, Japan, Canada and Australia;
- the management of information related to medical device vigilance reporting;
- adverse event reporting rules for device manufacturers, including minimum data sets for manufacturer reporting to competent authorities;
- design control guidance for medical devices, and
- guidelines for regulatory auditing of quality systems of medical device manufacturers.

Global Harmonization Task Force

Approved Documents

- Study Group 3
  - Guidance on Quality Systems for the Design & Manufacturing of Medical Devices
  - Design Control Guidance for Medical Device Manufacturers
  - Process Validation Guidance for Medical Device Manufacturers
- Study Group 4
  - Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements
  - Audit Language Requirements
  - Training Requirements for Auditors

CDRH: Future Trends

- Standards
- Knowledge Management

Knowledge Management

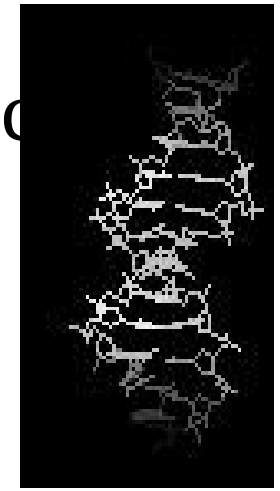
A CDRH Core Competency:
Science-based Regulatory Decisions

Know it	→	Core Knowledge
Figure it out	→	Decision Management
Look it up	→	Reference Systems
Consult it	→	Expertise Systems
Learn it	→	Training

Information Explosion Meets the Dissemination of Manufacturing Capability

Genetic Testing / Home Brew

- 710 Clinical or Research Tests World-wide
  - 301 in US
- 443 Laboratories World-wide offering Clinical or Research Tests
- 158 Laboratories in the US Offering Clinic Tests



Genetic Tests

Availability

- 710 Clinical or Research Tests World-wide
  - 301 in US
- 443 Laboratories World-wide offering Clinical or Research Tests
- 158 Laboratories in the US Offering Clinical Tests

Number of Labs offering the Top 30 Genetic Tests

74	Fragile X Syndrome
68	Hypercoagulability (Factor V Leiden Mutation)
59	
57	Prader-Willi Syndrome
42	Angelman Syndrome
38	Cystic Fibrosis
37	Hypercoagulability (Prothrombin Mutation)
35	Hemochromatosis
32	Huntington Disease
30	Myotonia Dystrophy
28	MTHFR Thermolabile Variant
27	Williams Syndrome
27	22q11 Deletion Syndrome
27	Duchenne Muscular Dystrophy
26	Medium Chain Acyl-CoA Dehydrogenase Deficiency
	Hemoglobin S
26	Tay-Sachs Disease
25	Miller-Dieker Syndrome
23	Smith-Magenis Syndrome
22	Hemophilia A (Factor VIII Deficiency)
22	Spinal Muscular Atrophy Types I/II/III
21	Gaucher Disease
21	Spinocerebellar Ataxia Type III
20	Canavan Disease
20	Spinocerebellar Ataxia Type I
18	Breast Cancer (BRCA1)
18	Sex-Determining Region Y
18	Spinocerebellar Ataxia Type II
17	Breast Cancer (BRCA2)
17	Cri du Chat Syndrome
17	Friedreich Ataxia

FDA Approved or Cleared Genetic Tests

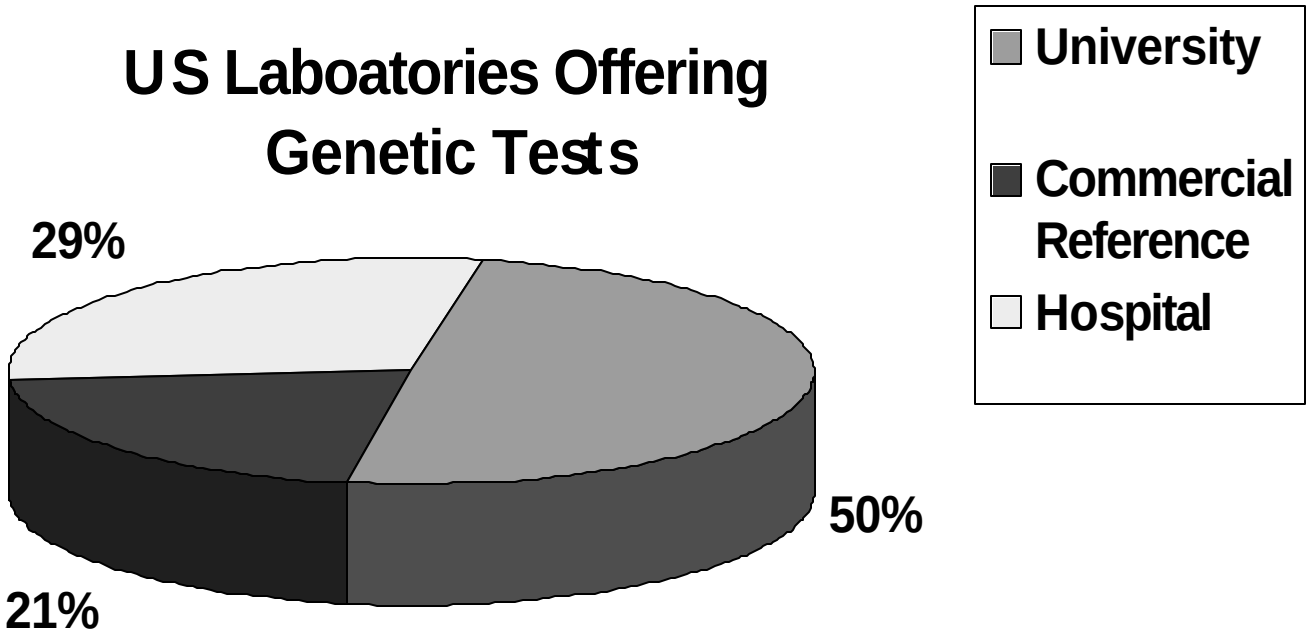
- AneuVysion Multicolor DNA Probe Kit
- Oncor INFORM HER-2/neu Gene Detection System
- PathVysion Kit (HER-2/neu)
- CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit
- CEP12 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit
- CEP X SpectrumOrange /Y SpectrumGreen DNA Probe Kit

FDA Approved or Cleared Genetic Tests

6

Genetic Testing Laboratories

158 Commercial Tests:



Comparison of Review Processes

	FDA	CLIA	NY State
Registration and Listing	By Device and Lab	By Lab	By Device and Lab
Informed Consent	As Appropriate		Yes
IRB Oversight	As Appropriate		
Analytic Validation	By Device	By Lab	By Device
Clinical Validation	For Novel Devices		Yes (but not requested to date)
Clinical Utility	For a utility claim (unusual)		

Center for Devices and Radiological Health

Mission:

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

The CDRH mission statement is both very straightforward, based on statutory responsibilities, and very close to the heart of why people work for the Center. The word protection is particularly close to the tongue and is part of our mission for both medical devices and consumer electronic products which emit radiation and where from x-rays to light rays to sound waves. There is also an explicit awareness that optimal protection of the public health from medical devices also occurs when safe and effective medical devices are made accessible, with high product integrity. Availability is facilitated by open processes and communication, with industry, the medical consumer and the public.