Device Regulation in an International Milieu

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International Device Development

The Scene

- U.S. Marketplace: 40% of approved device firms manufacture abroad
- U.S. Device Manufacturers have a positive trade balance
- Device Development
  - Studies conducted world-wide
  - Post Marketing Vigilance is a world-wide network
  - Application formats are becoming harmonized
  - Inspectional Methods are converging

International Forces

Business Forces

- Market Factors/ Reimbursement
- Intellectual Property
- Manufacturing Factors
- Import / Export Laws
- Regulatory Factors

International Forces

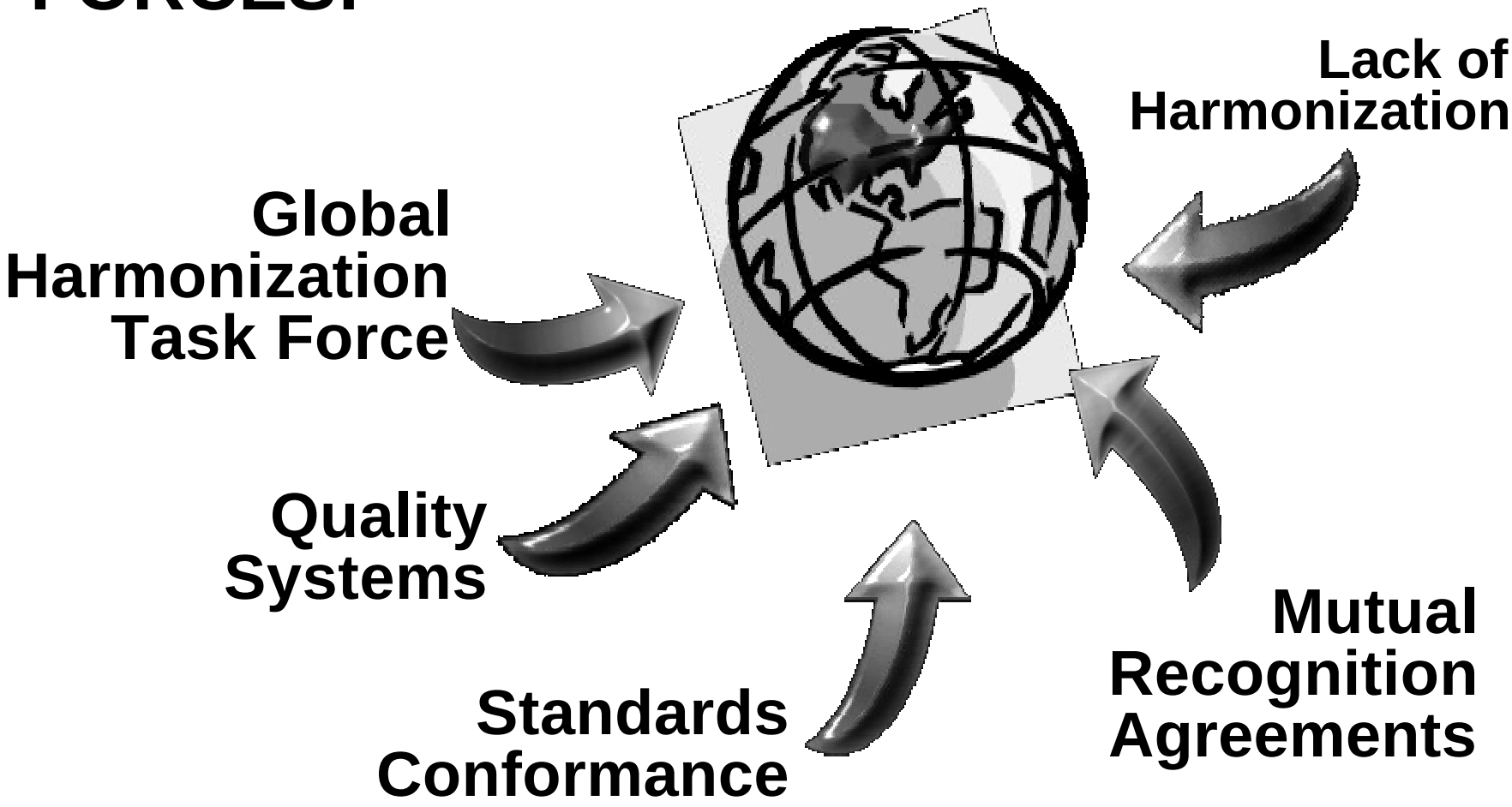
Complex Regulation

for example in the United States:

- Device Authority:
  - FDA, FTC
- Hospital and Clinical Laboratory
  - FDA, HCFA, CLIA, MQSA, JCAHCO
- Trade Authorities
  - FTC, WTO
- Other Authorities
  - FCC (wireless, telemetry)
  - NRC (Nuclear radiation)

International Device Regulation

FORCES:



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

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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

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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

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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

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.

Using Standards to Support SE Decisions in 510(k)s

- FDAMA intended to
  - Encourage using FDA-recognized standards
  - Provide a formal option but not limit past practices
- Declarations are legally binding & enforceable
- Cross-cutting standards used most often
- Least burdensome approach

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

Mutual Recognition Agreements

- MRAs do not harmonize requirements, standards or even tests.
- The goal of MRAs is to allow conformity assessment bodies (CABs) in various regions to do testing and certification that will be recognized in other regions as well as in their own.
- It is expected to lead to the reduction of requirements for multiple accreditations and certifications and the reduction of related costs.

MRA: Scope

Inspections/Audits

- All devices regulated by both parties

Product reviews/evaluations

- For EU CABs, 97 devices covered by FDAMA Third Party Program [510(k)]
- For US CABs, all devices regulated by both parties

Vigilance Reports

- All devices regulated by both parties

MRA: Where are we?

- Both sides evaluated and nominated potential CABs
- We are starting to receive information on EU CABs to evaluate, especially for conflict of interest and qualifications
- Before sending US CAB information to the EC we are awaiting assurance that information will be held confidential

MRA: Where are we?

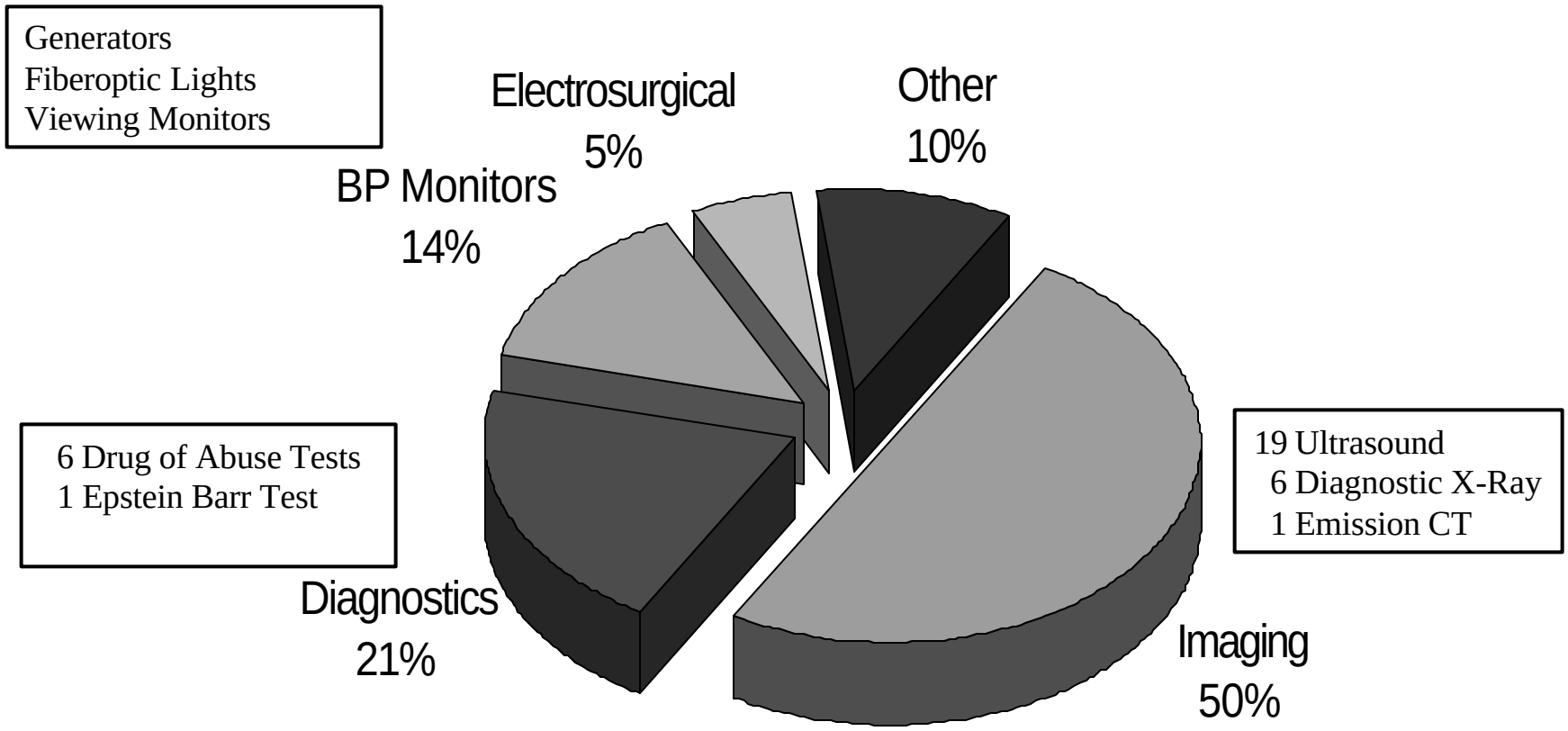
Training EU CABs

- Classroom training on 510(k) reviews, Quality System Regulation and FDA law, regulations, and procedures completed in 1999
- Practical experience (joint inspections) - 18 conducted by FDA investigators from October 1999 to June 2000

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

3rd Party Reviews: Who is using it ?



Fiscal Year 1999: 52 3rd Party Approvals