Current Issues for Medical Devices in the U.S.

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Paris via link-up, October 12, 1999

Current Issues for Devices in the U.S.

- FDAMA
- Reengineering
- Hot Issues
- Global Harmonization

Themes of FDA Modernization Act

- Interactive process for product review
- Decisive action
- Patient access
- Codifies reengineering
- Agency discretion, not mandatory requirements
- FDA review accountability/timeliness

FDAMA Accomplishments

- Completed 24 guidance documents and 6 final rules
- Recognized more than 400 consensus standards
- Exempted more than 60 Class II devices
- Approved 13 third parties for 510(k) reviews
- Designated >150 device types for 3rd party review
- Piloted Sentinel postmarket reporting

FDAMA Accomplishments (continued)

- Instituted interactive "determination" and "agreement" meetings with sponsors
- Rescinded 55 tracking orders
- Chartering advisory panel for scientific disputes
- Expanded stakeholder participation through open meetings nationwide

FDAMA Accomplishments (continued)

- Stakeholders meeting, live video teleconference
- Report to Congress, "Designing a Medical Device Surveillance Network"
- Drafted guidance on resolving scientific disputes
- Drafted guidance on least burdensome means to market

CDRH Reengineering

Team: cross-section of Center staff

- Understand stakeholders' needs
- Understand the process
- Assess the process
- Improve the process
- Pilot the process
- Implement and monitor the process

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

Reuse

FDA's policy is changing because:

- Types of single-use devices being reprocessed
- FDA laboratory findings
- Widespread practice but little data on safety or effectiveness
- Single-use labels not clearly meaningful
- Single-use labels don't identify vulnerabilities
- Patients are not informed -- experimentation?

Tissue-based Products

Concern about transmissible spongiform encephalopathies (TSE)

- Dura mater and Creutzfeltd-Jakob Disease
  - 1987 cases of transmission of CJD to donor
  - FDA requirements for processing human dura mater
- FDA meetings to address issues, increase knowledge
- International Workshop on Clearance of TSE Agents from Blood Products and Implanted Tissues

Global Harmonization

Four study groups:

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

Global Harmonization

8th meeting in September 2000

Hosted by Canada

Http://www.ghtf.org/default.htm