



Think. Challenge. Excel.

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Implications of Global Regulatory Changes

Slides by Paul Brooks

Discussion between

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Objectives

- Introduction
- GHTF
- Regional Overview
 - North America
 - Europe
 - Asia
 - Australia
 - Latin America
- Thoughts & Considerations



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Global Regulatory Inconsistencies

- Medical device
 - Not always considered medical devices
- Classification
- Regulatory quality management system requirements
 - ISO 13485 acceptance / local variations
- Product technical documentation
- Adverse incident reporting
- Local inconsistencies & misunderstanding

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Global Harmonization Task Force (GHTF)

- Significant progress in developing documents
- Adoption by regulators
- Usefulness to manufacturers
- Asian Harmonization Working Party (AHWP)

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International Standards

- International
 - Quality system
 - Risk management
 - Clinical evaluation
 - Sterilization
 - Graphics & symbols
 - Electrical safety
 - Biocompatibility
- Local variations
- Manufacturers specifications

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Global RA Strategies & Tactics

- ‘Global’ manufacturers
 - Local offices and affiliates
 - Depth of expertise
 - Knowledge of available options – existing RA capital
 - Ability to influence and challenge
- Smaller manufacturers
 - Local agents, representatives, distributors

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Canada

- Health Canada - CMDR
 - Defined and established regulatory system
 - Resources in place
 - ISO 13485 based quality systems requirements
 - Recognition of third party registrars under CMDCAS program

http://www.hc-sc.gc.ca/dhp-mps/md-im/index_e.html

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Europe & CE Marking

- Medical device directives (AIMDD, MDD, IVDD)
 - Single common framework
 - Individual sovereign nations (Member States)
 - Local variations (registration requirements)
- Manufacturers regulatory staff must understand and interpret the directives

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Europe & CE Marking

- Amended MDD
 - Seminars / training opportunities
 - Largely clarifying requirements as expected by Member States
 - New classification definitions
 - Clinical data
 - Post market activities

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Europe & CE Marking Sources of Information

- European Commission
 - http://ec.europa.eu/enterprise/medical_devices/index_en.htm
- European Guidance
 - http://ec.europa.eu/enterprise/medical_devices/meddev/index.htm
- New Approach
 - <http://www.newapproach.org/Directives/DirectiveList.asp>
- MHRA (UK CA)
 - <http://www.mhra.gov.uk/index.htm>
- Eucomed
 - <http://www.eucomed.be>

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Europe & CE Marking

- Member States issue's / inconsistency's
- Turkey
 - Implemented EU styled regulations
 - Unique identifier requirements
- Non-EU countries accepting / using CE Marking
- Supporting letters from Notified Body – *certificate of free sale*

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Asia China

- SFDA – Medical Devices Registration
 - Re-registration of imported devices
 - Initial registration of imported devices
- The new Medical Device regulation was posted for comment and there are lots of concerns being given.
 - Estimate the regulation will take another year to finalize in this case.

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Asia Japan

- MHLW – Pharmaceutical Affairs Law (PAL)
 - Classification / Risk based
 - QMS Regulation
 - STED Technical Documentation
 - Government (PMDA / MHLW) & Third Party Review
 - Role of MAH
 - Product submission based

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Asia India

- Central Drug Standards Control Organization (CDSCO) is under the Director General of Health Services, Ministry of Health & Family Welfare (MOHFW), Government of India. CDSCO is the medical device regulatory bodies in India
- India system is running fairly efficient.
- India included devices within the framework of the Drugs & Cosmetics Act
- 6 Oct 2005 Gazette Notification – 10 sterile medical devices listed as drugs

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Asia Regulatory Evolution

- Hong Kong
 - Currently voluntary registration, mandatory registration program possible within 12 months
- Singapore
 - Three phase implementation program
 - Application & registration risk based varying timelines – full force by 2010
- Malaysia
 - Program under discussion, possible mandatory registration in 2009 with grace period

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Asia Regulatory Evolution

- Saudi Arabia
 - Royal Decree Feb 2007 established Saudi Food & Drug Authority, Medical Device National Registry released
- Philippines
 - Bureau of Product Registration, Certificate of Product Registration
- Thailand
 - Drafting new regulations – classification of devices likely to be revisited

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Australia

- TGA - Therapeutic Goods Medical Devices Regulations
- Implemented & established regulations
- Influenced by EU Directives
 - Utilization of existing EU regulatory approvals – clinical evaluation reports

<http://www.tga.gov.au/devices/devices.htm>

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Latin America Support & Advice

- Sources of information & support
 - US Department of Commerce
 - Local importers associations
- Visit & get to meet your partners
- Product registration & Power of Attorney
- Be prepared for uncertainty & unpredictability – unclear 'requirements'

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Latin America Support & Advice

- Some products in some countries may be under pharmaceutical regulations
- Local RA professionals who understand your language and local MD regulations
- Many regulatory agencies have portals in English

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Latin America Support & Advice

- Post-marketing surveillance programs
- Quality systems v Certificates of analysis
- Classification routes are different & not well understood
- Country of origin (regulatory v trade)

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Latin America Regulatory Evolution - Predictable

- Costa Rica & Colombia
 - Both postponing the enforcement of the new MD legislation (new enforcement date – Costa Rica April 2008 and Colombia December 08).
- Venezuela
 - Uncomplicated processes but burdensome.
- Uruguay
 - Simple process expected but long timeframes for approval (12 months)

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Latin America Regulatory Evolution – Less Predictable

- Argentina
 - New Government and a total change at the Ministry of Health.
- Brazil
 - New requirement to register an Orthopaedic product (knee-hip-spine).
- Mexico
 - Enforcement of a new regulation expected, all the manufacturers and importers to renew every single license in the market.

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Global Medical Device Nomenclature (GMDN)

- Global acceptance?

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GMDCAS

- International Accreditation Forum Working Group
 - ISO 13485 accreditation model
 - Common ISO audit / Common ISO report
 - Using GHTF guidance
- Meetings with GHTF
 - GHTF also meeting CASCO

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US Department of Commerce

- DOC Office of Health and Consumer Goods has medical devices regulatory profiles for about 35 countries (useful reports on <http://www.ita.doc.gov/td/health/regulations.html>)
- DOC ITA Commercial Service offices has domestic and overseas offices that can provide assistance to US medical device firms (list of offices and services provided on the www.export.gov).
- DOC ITA Commercial Service publishes ISAs (Industry Sector Analysis) and IMI (International Market Intelligence) sector specific reports (information on these reports on the www.export.gov).
- The DOC ITA Commercial Service also organizes industry specific trade promotion events (information on these reports on the www.export.gov).

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Sources of Information

- Trade Associations
- The web
- Journals - Clinica
- Consultants & Notified Body's

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Thoughts & Considerations

- Respect for local regulatory responsibility
- Solid local intelligence
- Validate from multiple sources
- Challenge inappropriate requests but know when to concede
- Set internal expectations
- Competitor 'stories'
- Distributors interests

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