

The SGS logo is displayed in a white box with a thin black border. The letters 'SGS' are in a bold, black, sans-serif font. The background of the slide is a photograph of the United Nations Secretariat Building in New York City, with a row of international flags in the foreground. The sky is clear and blue.

SGS

TRENDS IN REGULATORY COMPLIANCE FOR MEDICAL DEVICES

MEDICAL DEVICE SUPPLY CHAIN COUNCIL
SCOTTSDALE, AZ
16 NOVEMBER, 2011

THE WORLD'S **LEADING** INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY.



- 1878 - Founded in Rouen, France, under the name of Goldstück, Hainzé & Co.
- 1919 - Registration as Société Générale de Surveillance in Geneva, Switzerland.
- More than **53,000** employees in over **140** countries
 - Europe, Middle East & Africa: 24,400 employees
 - Americas: 12,100 employees
 - Asia/Pacific: 16,500 employees
- A Global network of over **1,255** offices & **365** laboratories

DELIVERING **TRUSTED** TESTING, INSPECTION, VERIFICATION & CERTIFICATION

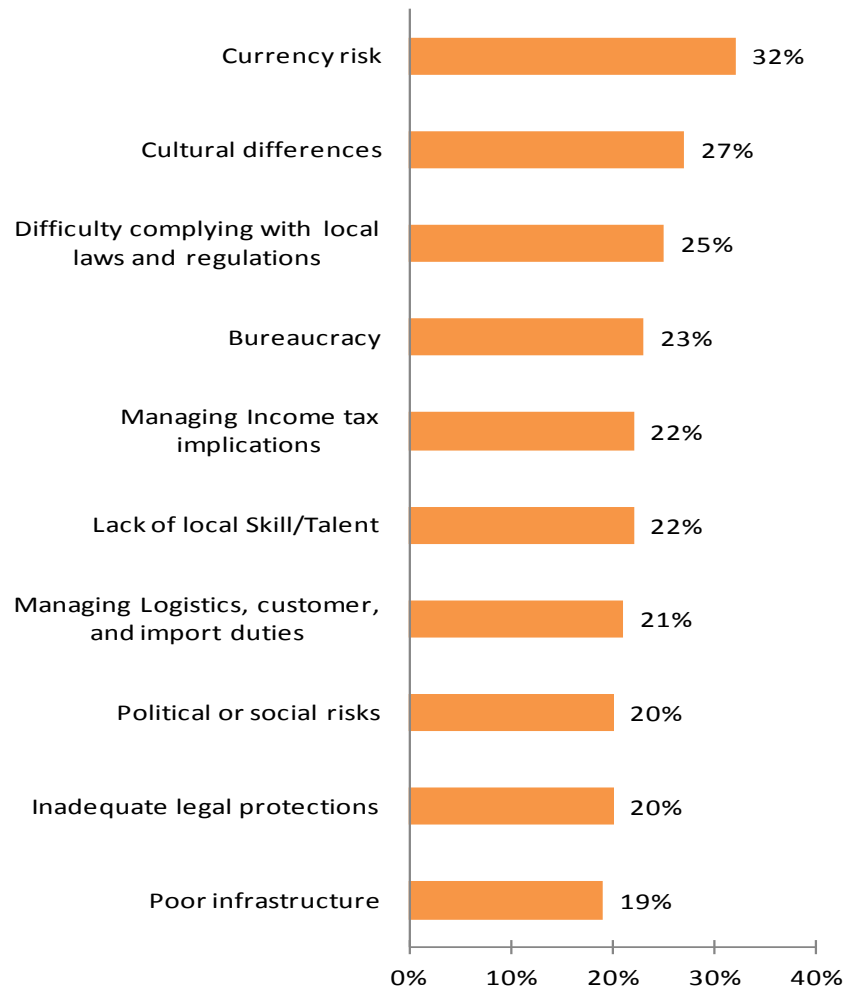
SERVICE DIVISIONS

“Customers and authorities demand better quality and reliability in the supply chain.”



- AGRICULTURAL
- AUTOMOTIVE
- CONSUMER TESTING SERVICES
 - SGS WIRELESS GROUP
- ENVIRONMENTAL
- GOVERNMENTS & INSTITUTIONS
- INDUSTRIAL
- LIFE SCIENCE
- MINERALS
- OIL, GAS & CHEMICALS
- SYSTEMS & SERVICES

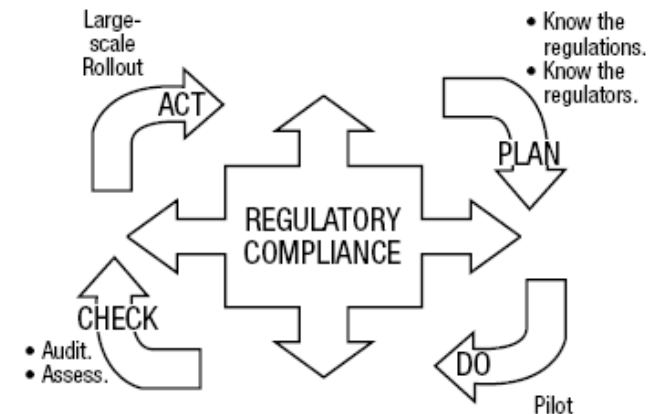
Trends in Global Regulatory Requirements for Medical Devices



Trends in Global Regulatory Requirements for Medical Devices

- Global Medical Device OEMs Take Compliance Seriously
 - It's a Cost of Doing Business
- Market is Highly-Regulated, but Transparent and 'Rules-Based'
 - At Least in Tier 1 Markets (FDA, etc)
- Goal: Regulatory Compliance is Only an Issue When It's an Issue
 - But - Tier 2/3 Markets have Emerging RA Programs
- Regulatory is Expensive
 - 1-2% of Annual Revenue
- Technology/Regulatory Changes
 - Wireless TeleHealth Systems
 - Material Management (RoHS/REACH)
 - Product Safety Standard (IEC 60601 3rd Edition)

Figure 1—Ensuring Continuous Regulatory Compliance



Regulatory Compliance Challenge

- Companies are challenged with a myriad of EHS regulations that apply across the global enterprise
- Finding information in a timely fashion is a constant challenge
- Uncertainty surrounding change in future regulations and the complexity of managing regulations across regions is a constant challenge
- Companies looking for ways to reduce cost of compliance, improve safety of people, products, and processes, and surpass corporate Sustainability goals.
- Companies re-evaluating internal controls, investing in solutions, and finding capable service partners
- A single instance of non-compliance can be disastrous to company image, brand value, and revenues
- Must transition from reactive, fragmented, and manually-intensive compliance to proactive, comprehensive, and automated continuous compliance framework
- Ongoing maintenance/monitoring of supply base and vendor-supplied products.

Systematic Approach Avoids Mistakes and Adds Value (Speed to Market / Risk Mgt)



Hazardous Substances:

- Lead
- Mercury
- Cadmium
- Hexavalent Chromium
- Polybrominated Biphenyls
- Polybrominated Diphenyl Ether

Limited % in Homogenous Materials:

- Metal
- Plastic
- Glass
- Ceramic
- Paper
- Resins / Coatings

RoHS 1 Enforcement was Weak (2006 – Present)

- EU Law - 2002/95/EC
- Supplier Attestations / Test Data Not Verified
- Loopholes
- Exemptions





- RoHS 2 Adopted by EU – May 2011
 - Became EU Law When Published in Official Journal of EC – July 2011
 - Mandatory Effect in EU Member States – Dec 2013
- Category 8 Medical Devices Come Into Scope of RoHS 2 – 2014
 - In Vitro Diagnostic (IVD) Devices in Scope 2016
 - Active Implantable Devices Remain Exempt
- Category 9 Monitoring & Control Instruments in Scope 2014
- Category 11 “All EEE Not Covered by Any Other Category” in Scope 2019



■ Examples of Category 8 Products

- Blood Pressure Meter
- Blood Analyzer (e.g., sugar, cholesterol)
- Endoscope
- Ultrasound
- CT/PET/X-Ray
- Thermometer
- Dialysis Equipment
- Infusion Pump
- Ventilator
- Defibrillator
- Pacemaker
- Surgical Tools (e.g., saw)
- Laser
- ECG
- Electric/Electronic Hospital Bed
- Anesthesia Equipment
- Dental Equipment
- etc



■ Examples of Category 9 Products

- Laboratory Devices
- Weighing Equipment
- Oven
- Centrifuge
- Heater/Chiller
- Chromatograph
- Spectrophotometer
- Video Monitoring Equipment
- Veterinary Products





- 2014 is Coming – Exemptions Expiring
 - Products Will Need to RoHS Compliance Baked In

- RoHS Compliance is More then Ever the OEMs Responsibility
 - Ties RoHS Data to CE Marking
 - Requires Manufacturer Declaration of Conformity (DoC)
 - Can You Rely on Component Suppliers' Data?

- Enforcement Increasing
 - Dutch VROM Inspectorate, Sweden Chemicals Agency (KEMI), etc
 - 9-30% of Field-Tested Products Failed Lead Test (2009-2011)

RoHS 2 HAS TEETH IN IT. OEMs NEED TO HAVE A SYSTEMATIC APPROACH TO RoHS COMPLIANCE.

Trends in Global Regulatory Requirements for Medical Devices – TeleHealth Systems

- Convergence of Medical + Wireless = TeleHealth Systems
- RF / Low Power Radio (2.4 GHz)
 - Wireless LAN (IEEE 802.11 a/b/g/n)
 - Bluetooth
 - Proprietary Communication Protocols
- Device OEMs Struggle with Radio Approvals
 - Similar But Different from FDA
 - Complex Applications
 - In-Country Testing
 - International Agency (Type) Approvals
 - Local Representatives



Result: A New Level of Regulatory Complexity

Trends in Global Regulatory Requirements for Medical Devices – Product Safety Update

- Global Product Safety Standard has been Updated - IEC 60601-1:2005 (3rd Edition)
- All Product Safety Files Must be Updated by Timetable Below
- Considerations:
 - Development cycle/product life of the medical device
 - Target global markets for the medical device
 - Resources available to update the certification files
 - Consequences of missing a deadline and failure to enter a market

REGION	CURRENT STANDARD	3RD EDITION ACCEPTED	TRANSITION DATE
EUROPEAN UNION	2 ND AND 3 RD EDITION	CAN BE USED FOR ER	June 1, 2012
UNITED STATES	2 ND AND 3 RD EDITION	FDA – YES OSHA - NO	June 30, 2013
CANADA	2 ND AND 3 RD EDITION	HEALTH CANADA - YES	June 1, 2012
CHINA	2 ND EDITION	NOT CURRENTLY	TBD
JAPAN	2 ND EDITION	NOT CURRENTLY	TBD
IECEE MEMBERS	2 ND AND 3 RD EDITION	CB CERTIFICATES CAN BE ISSUED	TBD

■ Brazil

- In-Country Product Testing is Required for INMETRO / ANVISA
- Exceptions: Active Implantables, IVD, some Lab Equip.

■ Russia

- Devices Classification is Same as EU (I, IIa, IIb, III)
- Medical Bureaucracy Can Be Frustrating to Deal With

■ India

- < 2005 – No Regulations
- Pending Legislation for 2012 Implementation
- US, Canada, EU Approvals May be Used Temporarily

■ China

- In-Country Product Testing is Required for SFDA Approval
- Device Classification May Be Different from US or EU
- Increases Approval Time and Cost



Recommendation: In BRIC and Other New Markets, Choose a Regulatory Partner with the Ability to identify Local Requirements and Provide In-Country Support

Trends in Global Regulatory Requirements for Medical Devices

Take Advantage of International Certification Programs:

- Certification Body (CB) Scheme
 - Harmonized Product Safety Testing to IEC Standards
 - One Test Used in Multiple Markets
 - Building Block for Device Approval in 50-75 Markets

Demand Your RA / QA Service Provider Deliver More:

- Local Regulatory Test / Audit = Fragmented Program
 - RA / QA Services Typically Bought Transactionally
 - Buy RA / QA Strategically Like Other Professional Services
 - Up to 1% of Annual Revenue Spent on 3rd Party Test / Audit Services
 - Find & Select RA / QA Service Providers Who Can Deliver Globally
 - Reduce Spend, Increase Program Alignment & Efficiency

Regulatory Knowledge Can Help Avoid Delays in Market Entry, Sales, Profit

- **SGS is the Largest Testing / Certification Body in the World**
 - \$5B Annual Revenue, over 1255 Global Offices
- **SGS Global Medical Service Delivers for Global OEMs**
 - Test, Audit, Inspection Services
- **SGS Supports Product Commercialization and Market Entry**
 - Enter Existing Markets Faster, More Efficiently
- **Consolidate RA / QA Services to Increase Program Performance**
 - While Reducing Total RA / QA Program Cost
- **SGS Services Promote Use of Quality as Product / Brand Enhancement**
 - Green / Sustainability / Social Responsibility Initiatives



REGULATORY TESTING
PERFORMANCE TESTING
PRODUCT SAFETY
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BATTERY
ENERGY STAR

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