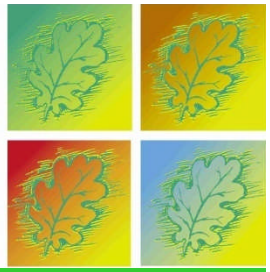
Regulatory and Statutory Compliance: It's Everybody's Business!

Diana Lough
Cavendish Scott, Inc.

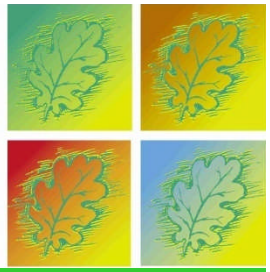
What is Regulatory?



- Of or relating to regulation

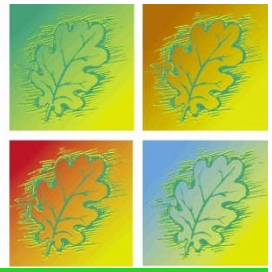
- 1.a law, rule, or other order prescribed by authority, esp. to regulate conduct.
- 2.the act of regulating or the state of being regulated.

What is Statutory?



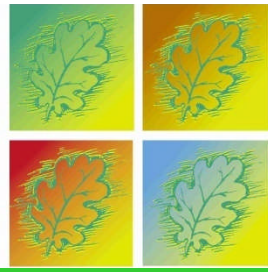
- the written law established by enactments expressing the will of the legislature, as distinguished from the unwritten law or common law.
- A law or group of laws passed by a legislature or other official governing bodies.
- Approval, license, permit, etc. for engaging in a certain activity under it's ruling legislation.
- A legally mandated requirement that must be complied with by the party to which it applies.

What is compliance?



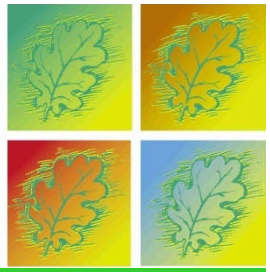
The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a product with a legislative or regulatory requirement or a recognized standard.

What is a Regulatory Authority?



- (US definition) Independent government commission charged by the legislature with setting and enforcing standards for specific industries in the private sector. The theory is that a commission of experts on the industry being regulated is better equipped to regulate it than the legislature or executive departments. Designed to operate with a minimum of executive or legislative supervision, agencies have executive, legislative, and judicial functions, and their regulations have the force of law.

Non-Compliance: What happens?

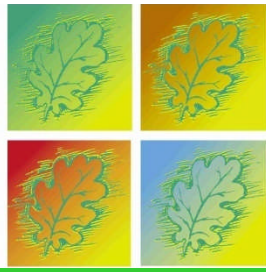


- Time and Resources = Money!!

- Prevent shipments
- Product confiscated
- Product held at customs
- Product removed from point of sale
- Fines
- Plant confiscated
- Criminal prosecution

Impacts on a Typical Quality Management System

Documentation



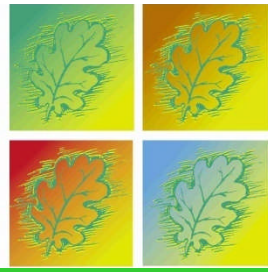
Product Specific:

- Drawings, schematics, specifications
- Technical Dossiers / Technical Files

Process Specific:

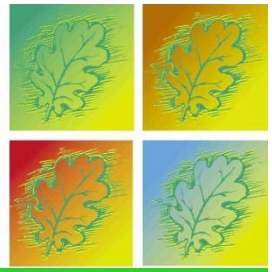
- Reporting Adverse Events
  - Your customers
  - Medical Devices: FDA, Health Canada, EU Notified Body
  - Consumer Products: US Product Safety Commission, EU General Product Safety Directive, etc.
- Product Recalls

Records



- Know what you have and know where they are!
- Product Specific:
  - Product Qualification Testing
  - Manufacturing Validations
  - Inspections and Material Certifications
  - Third Party Test Reports
  - Technical Dossiers and Technical Files
  - Notifications and Regulatory Correspondence
  - Distribution Records
  - Licenses, Registrations, Permits
- Process Specific:
  - Recall Records

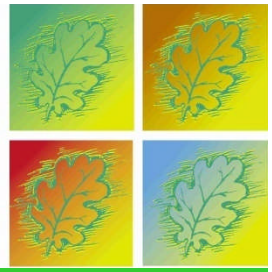
Management



- Plan for Compliance
  - Resources
  - Time (regardless of launch/delivery schedules)

- Promote Compliance (and not interfere)

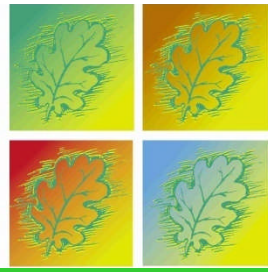
Resource Management



- Human Resources
  - Competence and training for compliance requirements
  - Assigned roles, responsibilities and authorities

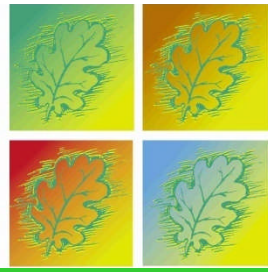
- Infrastructure
  - Environmental considerations for local ordinances
    - Waste stream, air pollution, noise nuances, etc.
  - Hazardous material handling and risk
  - Permits and licenses

Sales



- Requirements for the Destination Market
  - Product testing marks and/or licenses/registrations
  - In-country representation, may include identification on the packaging
  - Language translations for packaging and instructions for use
  - Packaging material restrictions
  - Material restrictions (RoHS, banned chemicals)
  - Country of Origin indication
  - Voltage and frequency, Plug style
  - End-of-life waste and recycling
- Systemic ability to block a sale

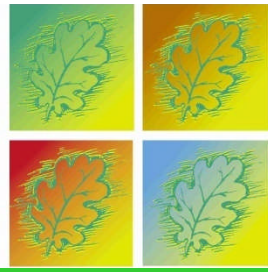
Design



- Basic product requirements and configuration – know requirements prior to 3rd party testing!
  - Banned materials and chemicals
- Product markings including safety, warnings
- Instructions for use including safety and warnings

- Design change process – impact on product currently listed/marked

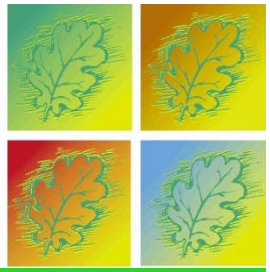
Manufacturing



QMS requirements and Factory Inspections

- Testing methodology and validation
- Inspections
- Raw material certifications
- Environmental conditions

Non-conforming Material and Goods

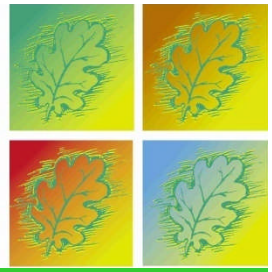


- Regulatory authority participates in Use As Is or Use with Restrictions dispositions

Shipping

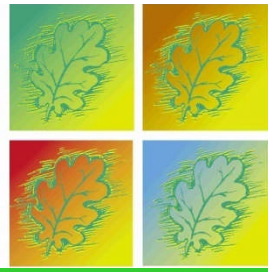
- Shipping documentation
- Container markings
- Pallet requirements

Post Market

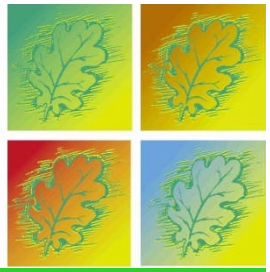


- Complaints – Reporting Adverse Events
  - Know requirements for types of events to report, timeliness, reporting format
- Product Recalls – voluntary or mandated

Where to go for help



- Government Web Sites
- US Government Export Portal: http://www.export.gov
- Consultants
- Professional Organizations (RAPS, etc.)



Thanks!

Any questions?