

R&D Services - R&D Materials Team

Chris Johns, Director, R&D Services 8/23/2023

Acute Business Risks if Materials are Not Managed

(from presentation to J. Carlson 2009)

- **Can't make it**

- Sudden, unforeseen, raw material supply disruptions - Back order.

- **Can't sell it**

- Locked out of market through non-compliant chemistry in devices - Zero revenue.

- **Won't buy it**

- Customer preference for sustainable materials in devices - Loss of market share.

Our Ever-Evolving Regulatory World

EU Standards, Directives, and Regulations

Driving intense scrutiny of the *chemistry* of the raw materials (polymers, metals, lubricants, packaging, electronics) used in our devices

Pkg-Pkg Waste

DIR 94/62/EC
DIR 2005/20/EC
EN 13427: Pkg/Pkg Waste
EN13428: Minimize Design
EN 13429: Reuse
EN 13430: Recycling
EN 13431: Energy
EN 13432: Composting
ISO 11465: Plastic Marking
ISO 1043: Plastic Symbols
DIN 6120-1: Lbl Graphics
DIN 6120-2: Lbl Marking

Batteries

DIR 2006/96/EC
Battery Labeling

WEEE

DIR 2012/65/EU
DIR 2002/96/EC
EN 50419: Label

EU RoHS

DIR 2011/65/EU
EN 50581: Tech File
EN 62321: Measure
EN 62474: Matl Dec
TS 52476: Guide RoHS

China RoHS

Labeling of electronic devices required
Table of Toxic Substances in IFU

Med Electrical Equip

EN 60601-1-9: Envr Design

REACH

REG 1907/2006
Substances of Very High Concern, required to be in IFU customer communication strategy
Inventory Notification to Authority required.
Development of Safety Data Sheets (SDS)
Global Harmonized Standard (GHS) warnings in IFUs
Classification Packaging Labeling (CLP)
Hazard Labeling (if required in country)

MDD (Medical Device Directive)

DIR 2007/47/EC
EU MEDDEV 2.5/9: Latex
EN 15986: Phthalate
ISO 15223-1: Lbl Symbols

MDR (Medical Device Regulation), 2016

Classification of all substances in device including polymers and metals
Warning symbols required
Customer communications

Number of ***Chemicals*** of Concern:

REACH	- 200 for now
RoHS	- 10
CA Prop 65	- 1200 for now
EU MDR (doubles once they add Endocrine Disruptors)	- 1500 currently
CONEG & EU Packaging Stds.	- 3
SIN List / TedX / CoRAP / Other Watch Lists potentially	- 2000
Customer Concerns	- PVC, etc.

Our Customers Are Asking Materials Questions



vizient®

Are your products:

- BPA Free?
- DEHP Free?
- Latex Free?
- PVC Free?
- Heavy Metals?
- Recycle Content?
- Reusable/recyclable?
- How to dispose?



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Supply Chain	Regulatory	Internally Triggered	Standards	External Customers- Hospitals, NGO
Rspec System Compliance	Regulatory request for info	Regulatory restriction discovered in existing materials	Changes to material standards	Product Inquiry
Material Manufacturing Global Location Change or addition of location	New regulation or law (health or environmental)	Design Change Plan-CP0150	Changes to biocompatibility standards	Requests for substances for health impacts-Call Center
Material manufacturer change	Substances added to existing regulation	New product-CP0258	New Biocompatibility standards	Requests for environmental requests
Manufacturer change to Formulation	Selling into new countries after initial assessments/product release	NCR-material related-contamination, breakage	Obsolescence of std	
Process change- Lubricants, cleaners, oils etc. (Tier 1 or mfg sites)	Medical Exemptions removed from environ. regulations	Audit Support	New external material standards	
Manufacturing obsolescence - material no longer produced	Existing regulation discovery	Marketing request for info		
Material Manufacturing Location Change or addition of location (within same manufacturer)		Discovery of issues with existing materials during CP0258		
Industry shortages of ingredients-long lead times or cost increase		J&J requests		
External Mfg material or mfg. Changes		Sales request for info		
Manufacturer name change (sold off) no material change		Transfer lines-CP0198		
Raw material form change (e.g. stainless steels)				
Supplier business continuity event				

‘Material Events’

An ‘*event*’ is an internal or external occurrence that affects the materials our products are made from

~ **60** material events per month

Ethicon Cincinnati **Post** 2010

Consolidated Team of Material SMEs Focused Around a Material Database

● **People**

- SMEs with common G&Os, supporting each other
- Contractor support (including chemists) increases bandwidth
- Single point of contact for customer, Call Center, NPD and LCM material questions, using a single database for material selection
- Tracking emerging regulations, proactive response

● **Process**

- Design Control integration!
- Optimized workflow and processes, including supplier data acquisition process and controlled material specifications

● **Systems**

- Granta MI Platform (iMOE)

Life Cycle Materials

Stephen Torain, Manager



Meanwhile...

Materials Compliance is a MedTech-wide Issue!

- MedTech OpCos are realizing the urgent need for data and processes around materials compliance
- Some OpCos impacted by lack of material chemistry knowledge already
- OpCos are reaching out to Ethicon Cincinnati as an example of an established team, process and system.

Remember
this?

Can't make it

Can't sell it

Won't buy it

So...

How do we leverage the established team,
process and system to support all MedTech?

MedTech Materials Compliance 2.0

The MedTech Solution

New structure has two elements:

- Single data team centered around existing people, proven processes and an established data system, scaled up for all MedTech
- Single Product team *per campus* with the SMEs needed for the OpCos' products, the modification of design control systems, partnering with the Data Team

MedTech Materials Compliance 2.0

The good stuff – If you work with us:

- **Can make it, Can sell it, Will buy it!** – patient safety, environmental safety, compliance
- Huge cost savings through sharing material data (engineering properties, chemistry composition, biocompatibility), using a small, focused data team and a single instance of an established software tool
- Optimized material selection across MedTech – shorter design cycles, no compliance surprises
- Savings in Supply Chain through using a smaller palette of materials at higher purchasing volumes
- Standardizes process for rapid, compliant, onboarding of acquisitions and their products