MedTech Global Product Stewardship

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NORTH AMERICA MGMC MEDICAL MATERIALS

Agenda

- **What is Product Stewardship?**
  - **Product Stewardship Boundaries, Roles & Responsibilities**
  - **Key Risk Drivers & Examples**
- **Increasing Frequency of Environmental Product & Packaging Regulations**
- **Questions**

The boundaries of Patient, Community, Environmental Compliance and Environmental Sustainability Requirements are blurring..

Environmental Sustainability / Supply Chain requirements such as carbon reporting, product digital passports, supply chain transparency, etc. Regulated by various environmental agencies and international organizations such as OECD, UN, etc.

Internally managed by multiple groups such as **the Office of Sustainability, Procurement, Finance, Trade Compliance**, etc.

Product regulations related to **market access** of finished products, with a focus on **patient safety** & **efficacy.** Regulated by agencies like Federal Food & Drug Adminstration (FDA), European Medicines Agency (EMA) etc.

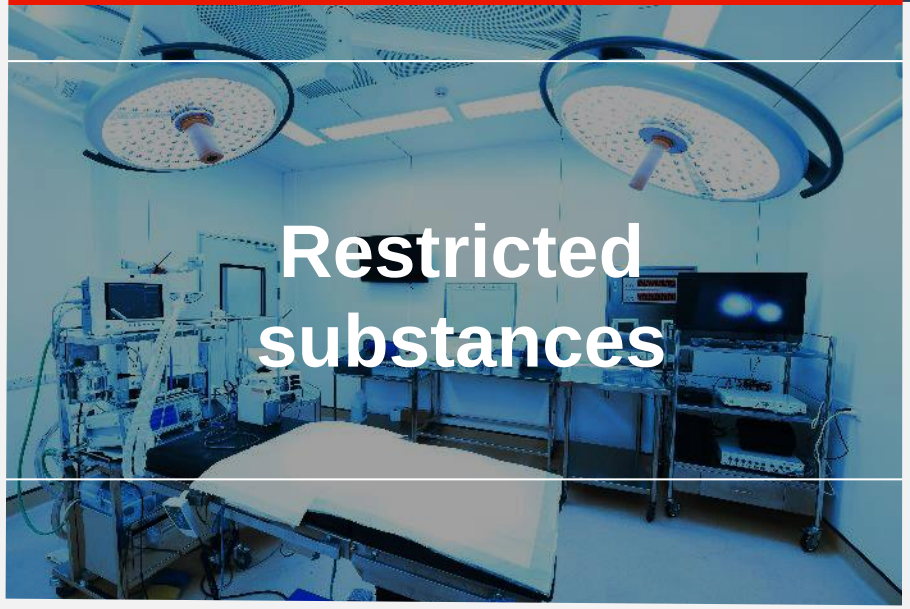
Internally lead by **Regulatory Affairs** & **Quality** (GxP).

Worker safety and facilty environmental requirements such as Personal Protective Equipment (PPE), discharges, etc. Regulated by EPA, Occupational Safety and Heallth Administration (OSHA) (and oher like agencies), etc.

Internally lead by **Environmental Health & Safety (EHS).**

Requirements to minimize the **environmental impact of** raw materials, process chemicals, finished products and packaging. Regulated by European Chemicals Agency (ECHA), EPA, etc. Internally led by **Product Stewardship.**

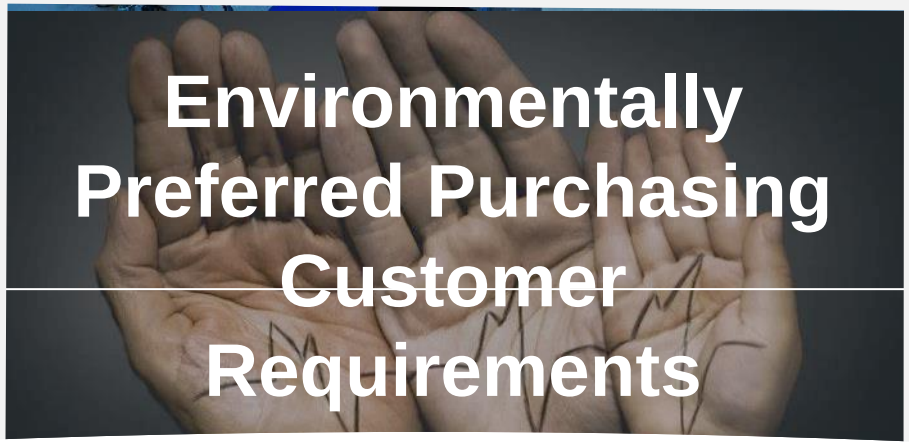
Global restriction of substances in Electrical and Electronic Equipment



Restricted substances

EU frameworks, built to grow

Packaging end of life fees and reporting



Environmentally Preferred Purchasing Customer Requirements

New End of Life regulatory models

Product Stewardship is the global team under Regulatory Affairs that monitors, tracks, informs and works with the MedTech businesses to manage global *environmental product and packaging requirements*

Key Risk Drivers & Examples

Can’t Make it (Supply Continuity)

Example - EU suppliers moving manufacturing out of Europe because of stricter product stewardship requirements

Can’t Sell it (Regulatory)

Example - Electronics regulations compliance tied to CE marking (if product does not comply with RoHS, etc., we cannot use the CE mark and sell the product)

Won’t Buy it (Customer Preference)

Example - Non-Governmental Org pressure moving customers away from purchasing products and packaging containing specific plastics (PVC)

Increasing Frequency of Environmental Product & Packaging Regulations

Exponential Increase In Emerging Product Stewardship Requirements