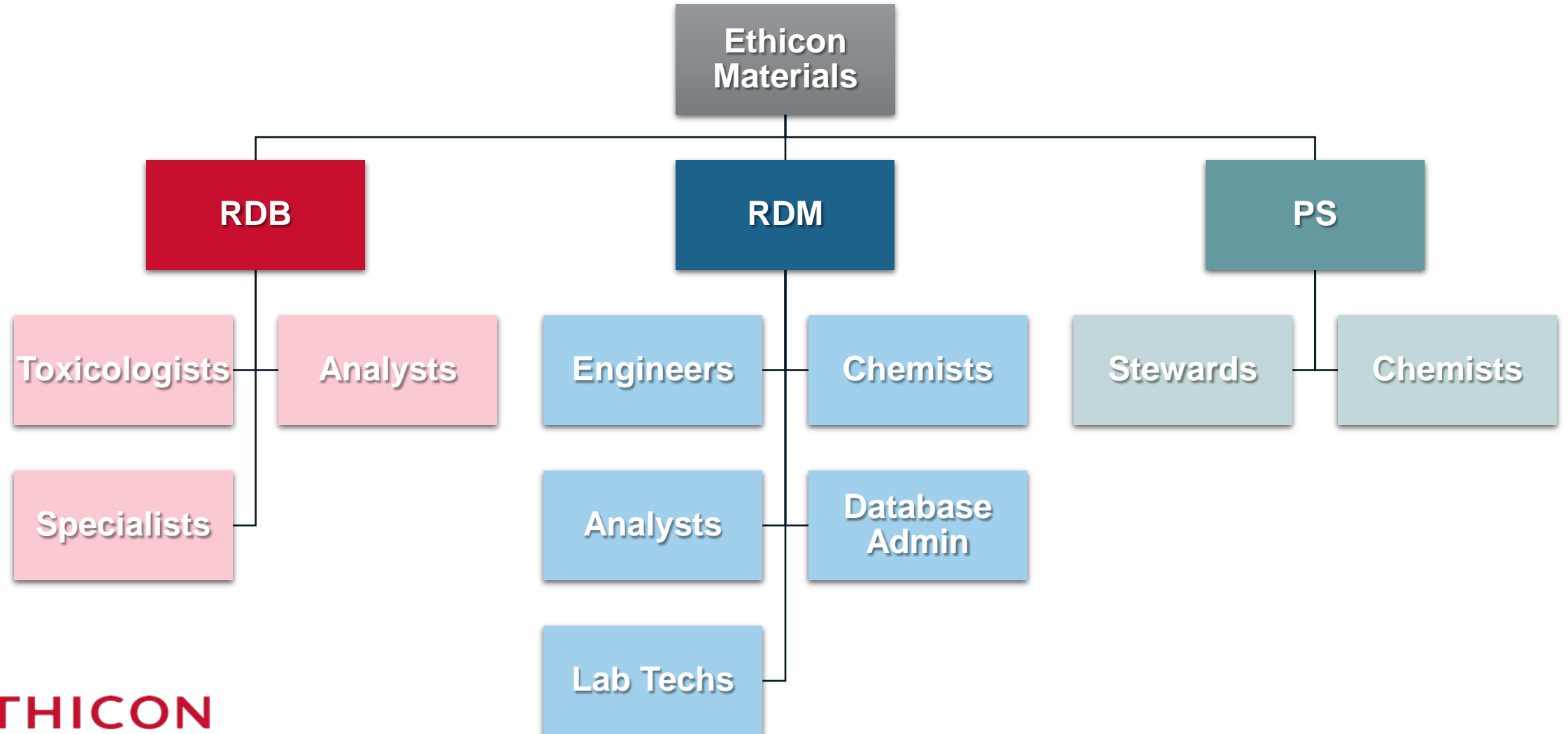
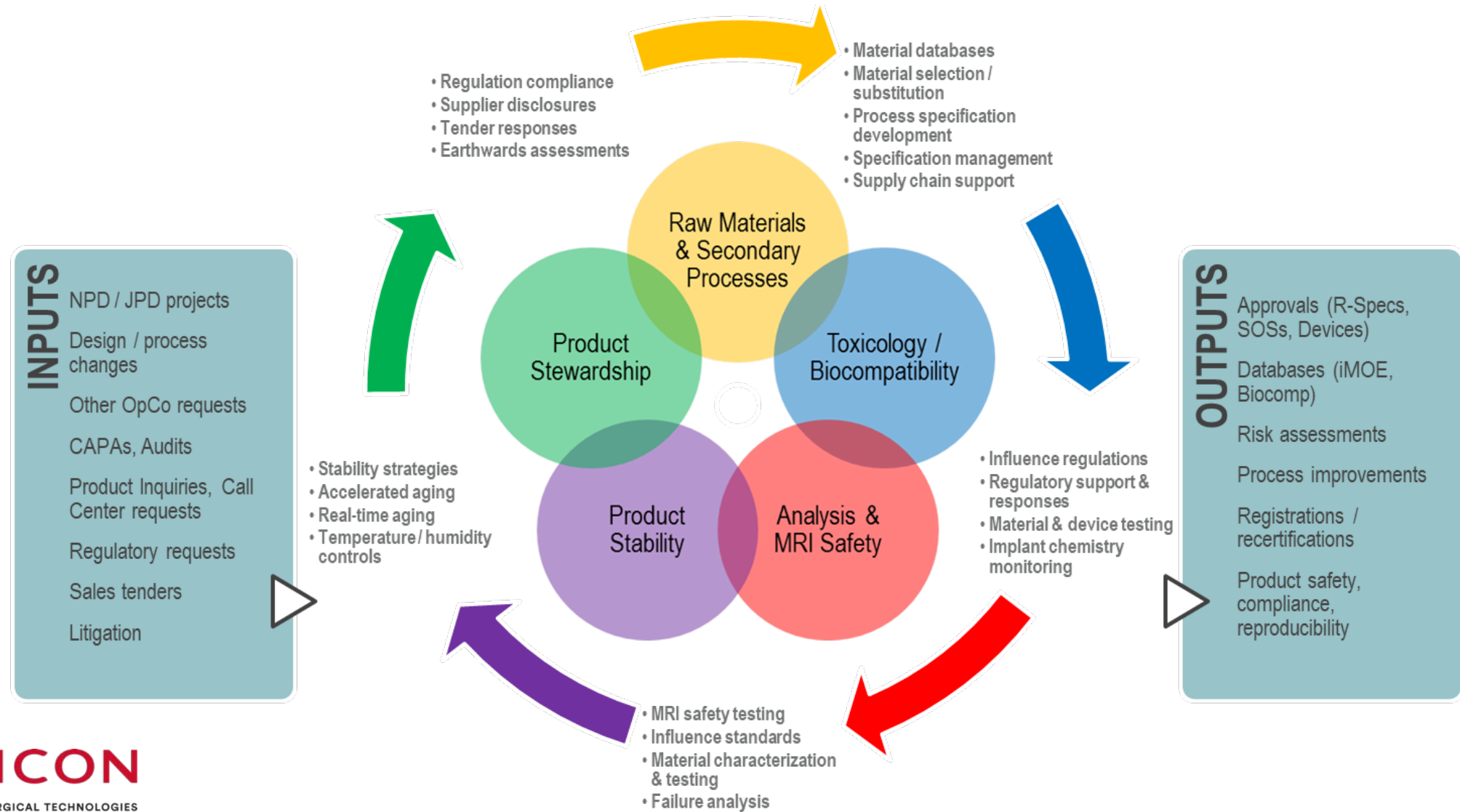

Introduction to Ethicon R&D Materials

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Manager, R&D Materials

Who is Ethicon Materials?



How does Ethicon Materials function?



What does Ethicon Materials do?

- New & alternate materials
- Medical-grade vs. industrial-grade
- Articles, lubricants, inks, & adhesives
- Electropolishing, anodizing, & passivating
- MRI safety & compatibility
- Heat treat processes
- Material composition
- Patient contact categories
- Biocompatibility, toxicology, & allergic reactions
- Aging studies & product shelf life
- Product storage conditions
- Material compliance and regulations
- Material standards (e.g. ASTMs, REACH, RoHS, ISO 10993)
- Failure analysis & chemical analysis
- Material database access & training (e.g. iMOE, Biocomp)
- *And many more!*

Why does Ethicon Materials do those things?

Chemicals of Concern	
REACH	200
RoHS	10
Cali Prop 65	1200
EU MDR	1500
CONEG	3
SIN List / CoRAP / Other Watch Lists	2000

Package Waste

- DIR 94/62/EC
- DIR 2005/20/EC
- EN 13427,28: Pkg/Pkg Waste / Minimize Design
- EN 13429,30,31,32: Reuse / Recycling / Energy / Composting
- ISO 11465: Plastic Marking
- ISO 1043: Plastic Symbols
- DIN 6120-1,2: Label Graphics / Markings

Batteries

- DIR 2006/96/EC
- **Battery Labeling**

WEEE

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

EU RoHS / China RoHS

- DIR 2011/65/EU
- EN 50581: Tech File
- EN 62321: Measure
- EN 62474: Matl Dec
- TS 52476: Guide RoHS
- Electronic devices labeling
- **Toxic substances table in IFU**

Medical Electrical Equipment

- EN 60601-1-9: Envr Design

REACH

- REG 1907/2006
- **SVHC labeling**
- SDSs
- Global Harmonized Standard (GHS) warnings in IFU
- Classification Packaging Labeling (CLP)
- Hazard Labeling

Our regulatory landscape is ever-changing!

EU MDD

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

EU MDR

- **Classify all substances in device**
- Warning symbol labeling
- Customer communications

Why does Ethicon Materials *really* do those things?

Our materials must be managed to prevent and mitigate acute business risks:

- Sudden, unforeseen, raw material supply disruptions ► Backorder
- Locked out of market through non-compliant chemistry in devices ► Revenue loss
- Customer preference for sustainable materials in devices ► Market share loss

Can't Make It

Can't Sell It

Won't Buy It

Why does this stuff matter to Ethicon Materials?

Our Credo

We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

ETHICON

Johnson & Johnson SURGICAL TECHNOLOGIES

Thank you for being strategic business partners.