PTC® Live Global

CUST 206 - Ruck, Maul & Scrum: Material Compliance Doesn't Have to be as Dirty as Rugby

Katie Crawford
Regulated Materials Program Manager – Global Supply Chain

June 9, 2015

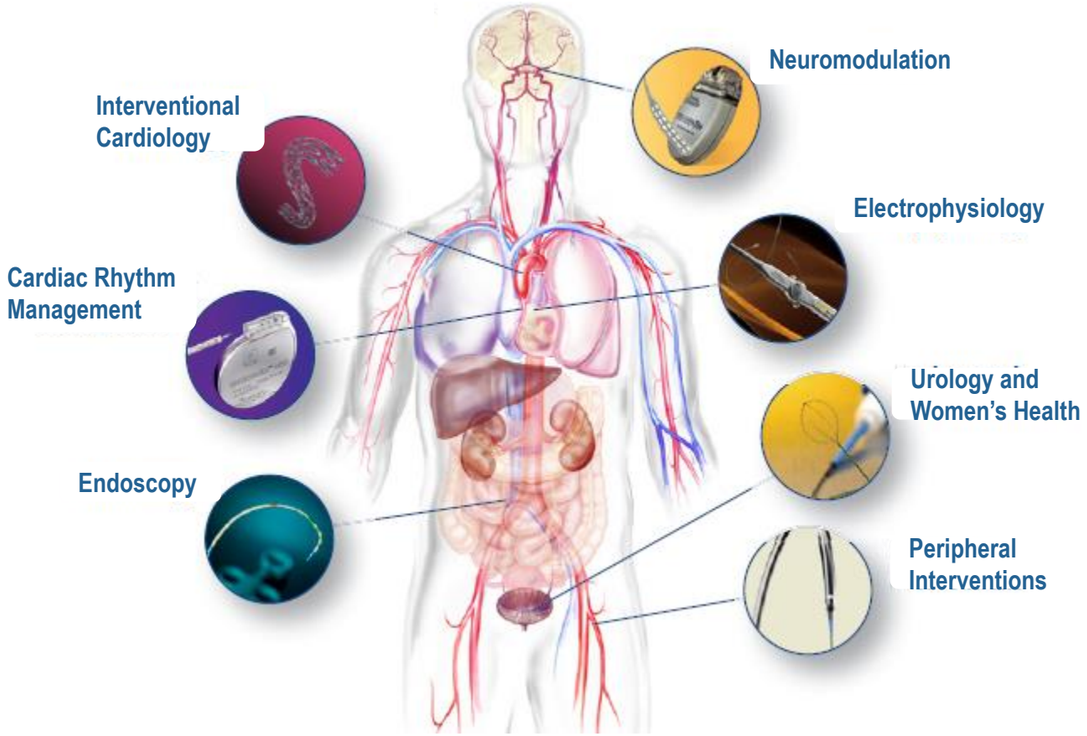
About Company & Team

Company: Boston Scientific Corporation (BSC)

- Katie Crawford
  - Regulated Materials Program Manager, Global Supply Chain

- Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices for over 30 years
  - 1 of the worlds largest medical device companies
  - Advancing the practice of less-invasive medicine providing patient's alternatives to surgery
  - Global Corporate HQ in Marlborough, Massachusetts (USA)
  - 18 manufacturing facilities worldwide
  - Market presence in approximately 100 countries worldwide

- Boston Scientific advances science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare.



Boston Scientific

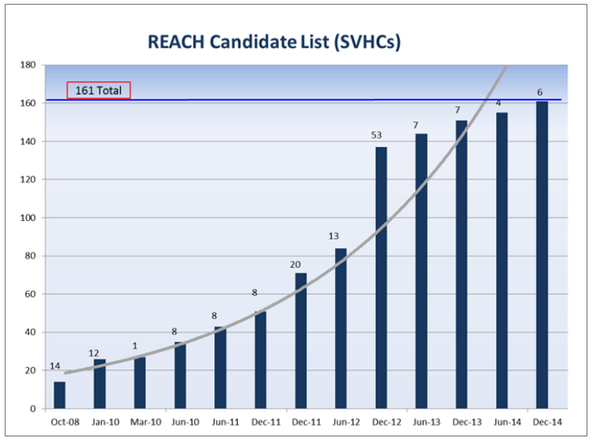
Advancing science for life™

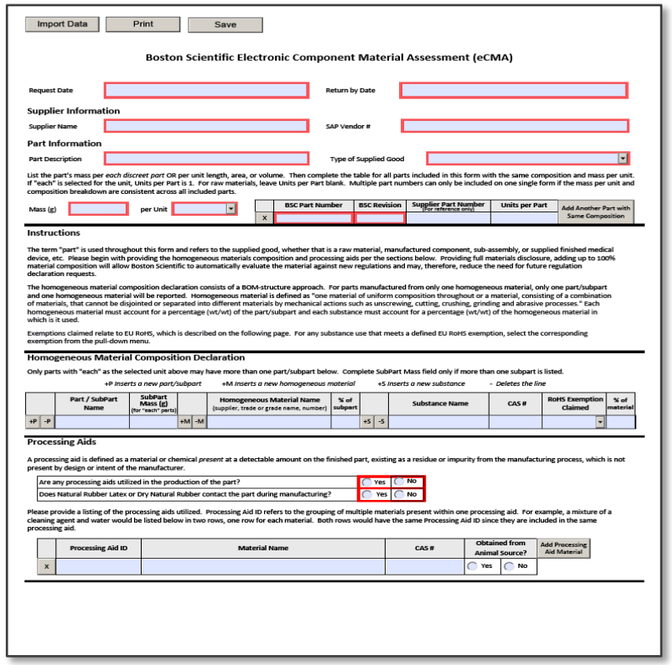
Summary & Review

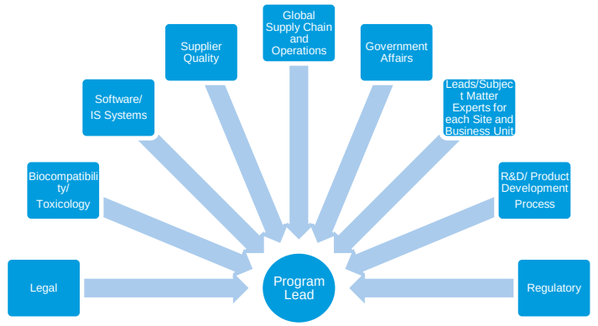
PTC® Live Global

Learning Objectives

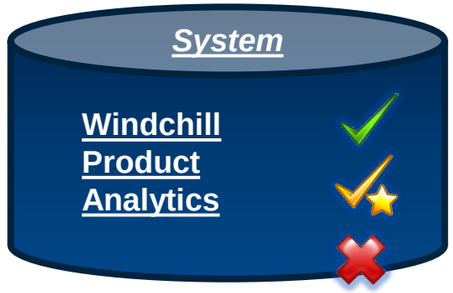
- ❑ Understand the challenging landscape of material regulations
- ❑ Discuss benefits of utilizing an automated data collection system (Product Analytics)
- ❑ Review a unique one-stop form for collecting material content from suppliers
- ❑ Describe best practices for optimized material information data collection







Developing a Regulated Materials Program



Define Need/ Requirements

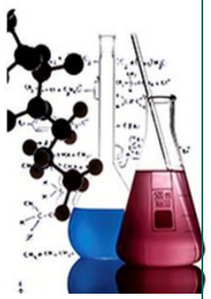
Build Team

Develop Process & Tools

Implement System and Data Collection

Sustain

CA.GOV OEHHA Office of Environmental Health Hazard Assessment

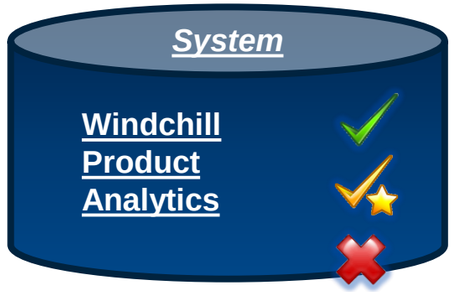


eCMA Process (and Form)

electronic
Component
Material
Assessment

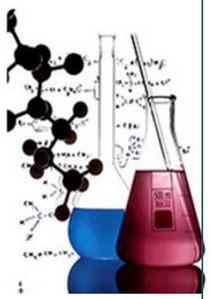
Developing a Regulated Materials Program

PTC® Live Global



Define Need/ Requirements → Build Team → Develop Process & Tools → Implement System and Data Collection → Sustain

CA.GOV OEHHA Office of Environmental Health Hazard Assessment



eCMA Process (and Form)

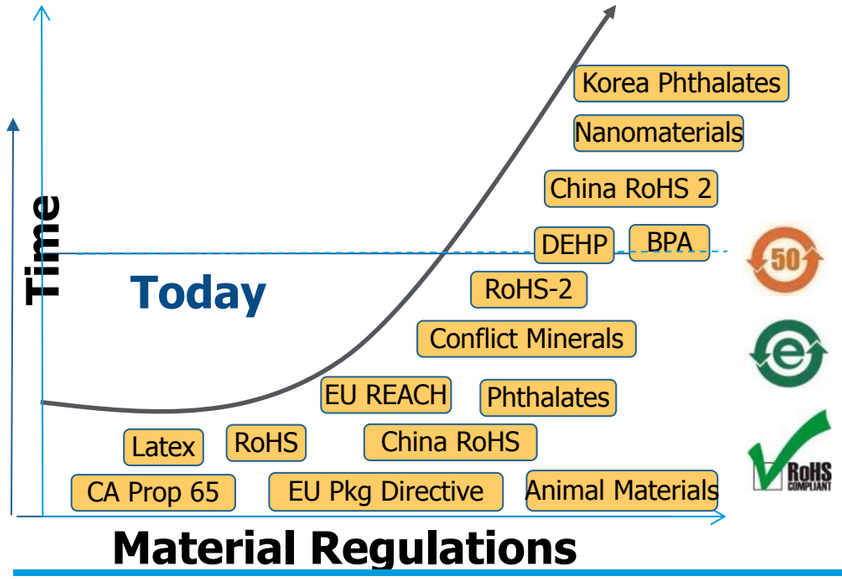
electronic
Component
Material
Assessment

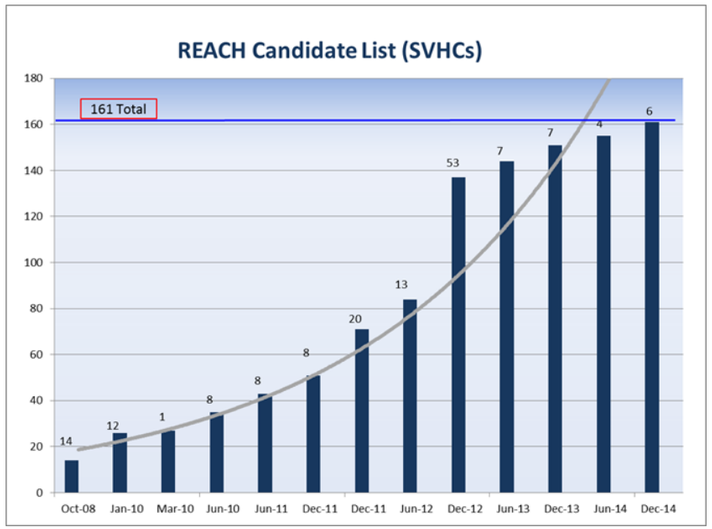
Why Material Compliance?

PTC® Live Global

Need: The rough and tumble landscape of material regulations

↑ Number of material regulations ↑ Scope of existing regulations ↑ Complexity of regulations





Conflict Minerals

Photo credit: Darc Red

A Changing Landscape

PTC® Live Global

Requirements: Types of Material Regulations

Environmental Regulations

Restriction of Hazardous Substances

Medical Device Regulations

Animal Materials

Other Regulations

Conflict Minerals

DRC Adjoining Countries

Angola	Republic of the Congo	Tanzania
Burundi	Rwanda	Uganda
Central African Republic	South Sudan	Zambia

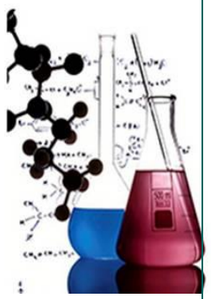
Developing a Regulated Materials Program

System

Windchill Product Analytics

Define Need/ Requirements → Build Team → Develop Process & Tools → Implement System and Data Collection → Sustain

CA.GOV OEHHA Office of Environmental Health Hazard Assessment



eCMA Process (and Form)

electronic
Component
Material
Assessment

Build Team

Best Practice: Agile, High-Performance

I improve the Quality of Patient Care and all things Boston Scientific.

Boston Scientific

GDM Global Direct Materials STRATEGIC SOURCING

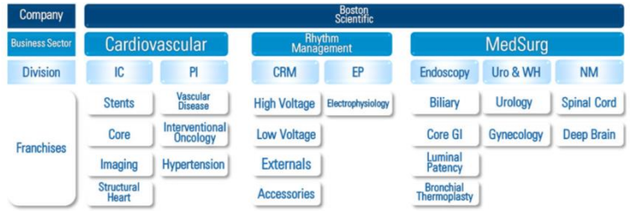
Supplier Quality

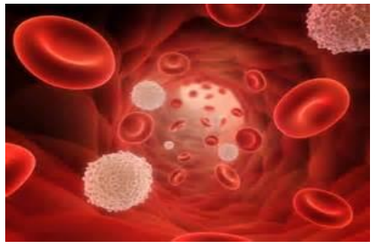
Global Supply Chain and Operations

Government Affairs

Software/ IS Systems

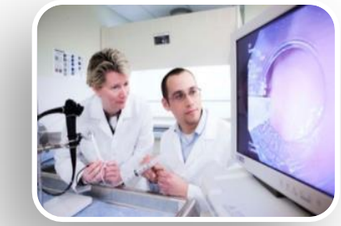
Site and Business Unit Leads / Subject Matter Experts





Biocompatibility/ Toxicology

R&D / Product Development Process

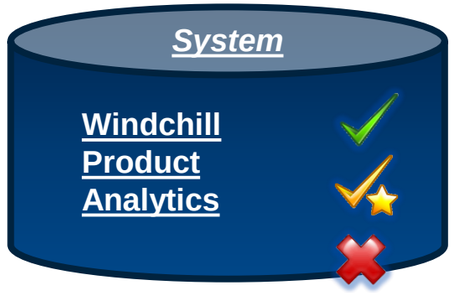


Legal Compliance

Program Lead

Regulatory Affairs

Developing a Regulated Materials Program



Define Need/ Requirements

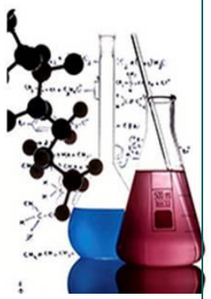
Build Team

Develop Process & Tools

Implement System and Data Collection

Sustain

OEHHA
Office of Environmental Health Hazard Assessment



eCMA Process (and Form)

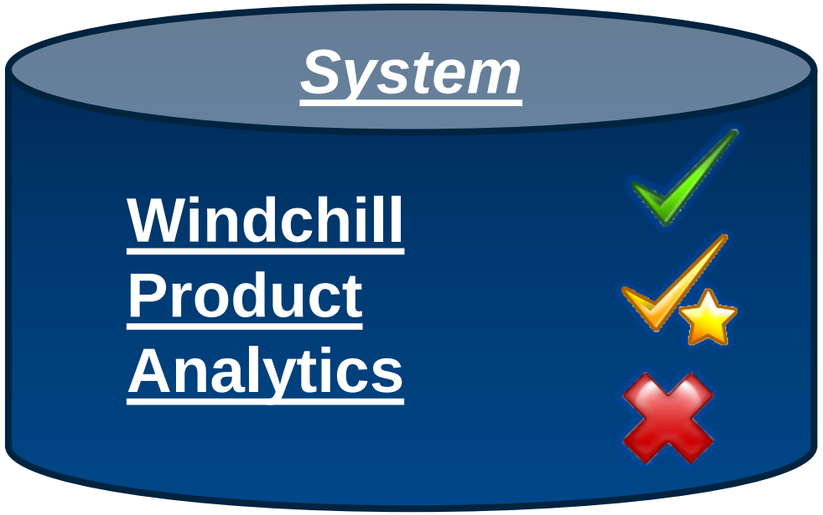
electronic
Component
Material
Assessment

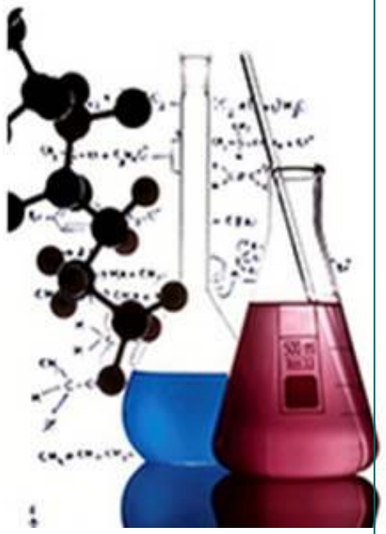
Develop Process and Tools

A sustainable solution includes teamwork between IS systems, business procedures and forms

Software System: PTC Windchill Product Analytics (WPA)

One-Stop Form: electronic component material assessment (eCMA)





eCMA Process (and Form)

electronic Component Material Assessment

Photo Credit Darc Red

PTC Windchill Product Analytics

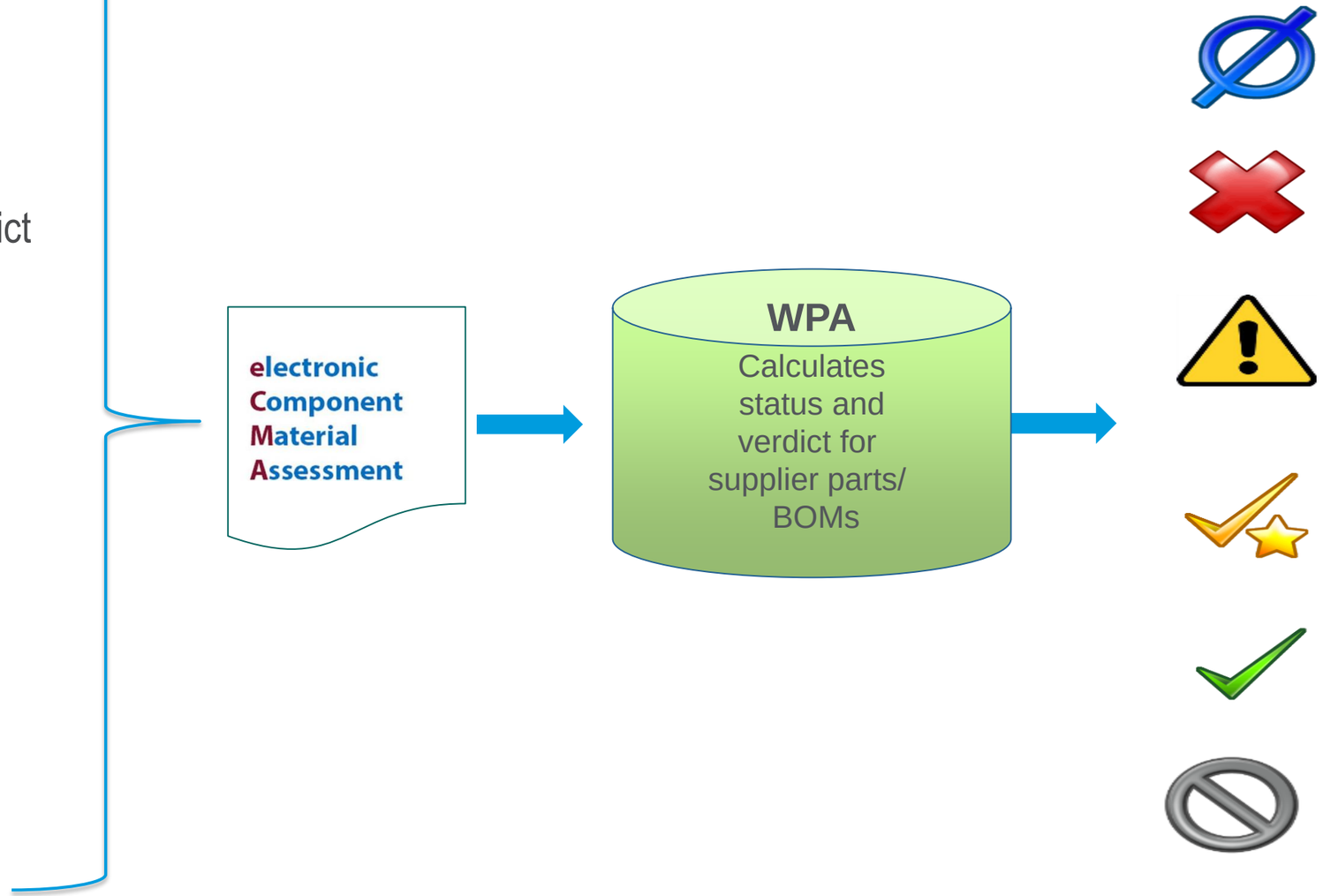
Key Tool: Software System

- *Quality:*
  - Comprehensive for material regulations
  - Material information requests/response tracking
  - Version history tracking
- *Efficient:*
  - Searchable system
  - User-friendly interface
  - Connection with PLM system & purchasing system
  - Connection to supply chain for material
- *Adaptable:*
  - Compliance specifications can accommodate rapidly changing and new regulations

An Adaptable System

Compliance specifications designed to be adaptable for changing regulations

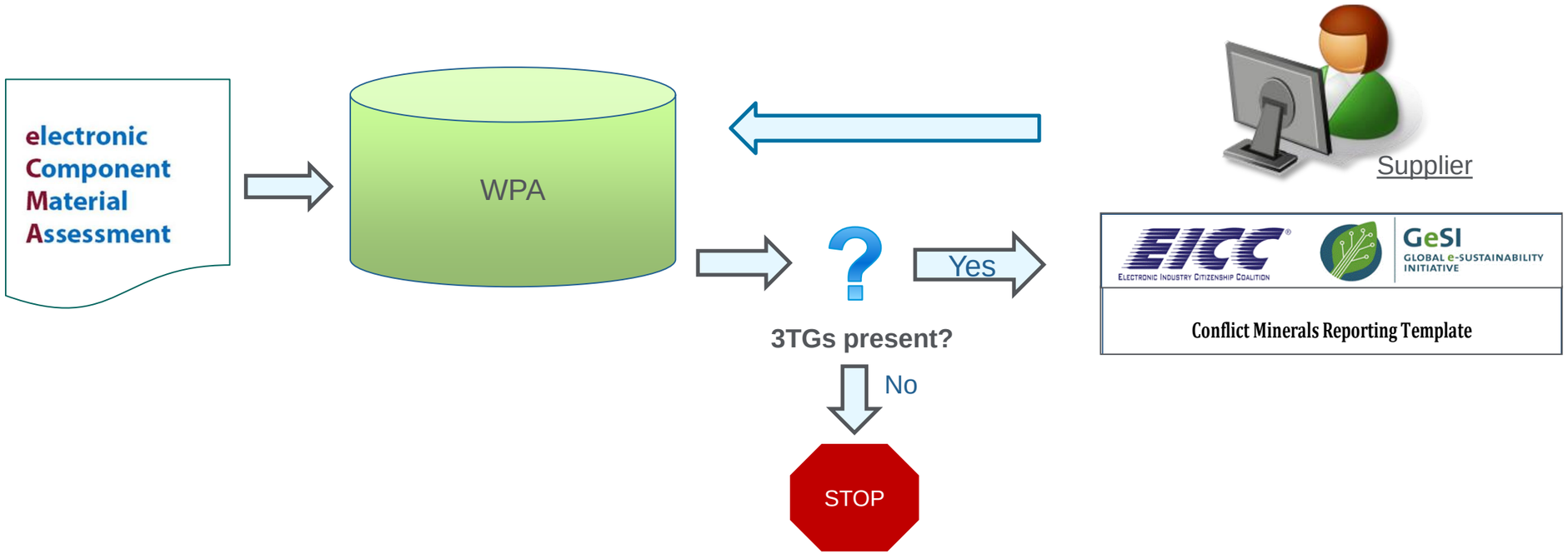
- PTC specifications
  - Managed by PTC
  - Updates available when regulation updates
  - Includes: EU REACH, EU RoHS, Conflict Minerals, etc.
- Customer defined specifications
  - Managed by customer (BSC)
  - Medical device regulations ‘
  - Customer business rules



An Efficient Quality System

Comprehensive for key material regulations. For example:

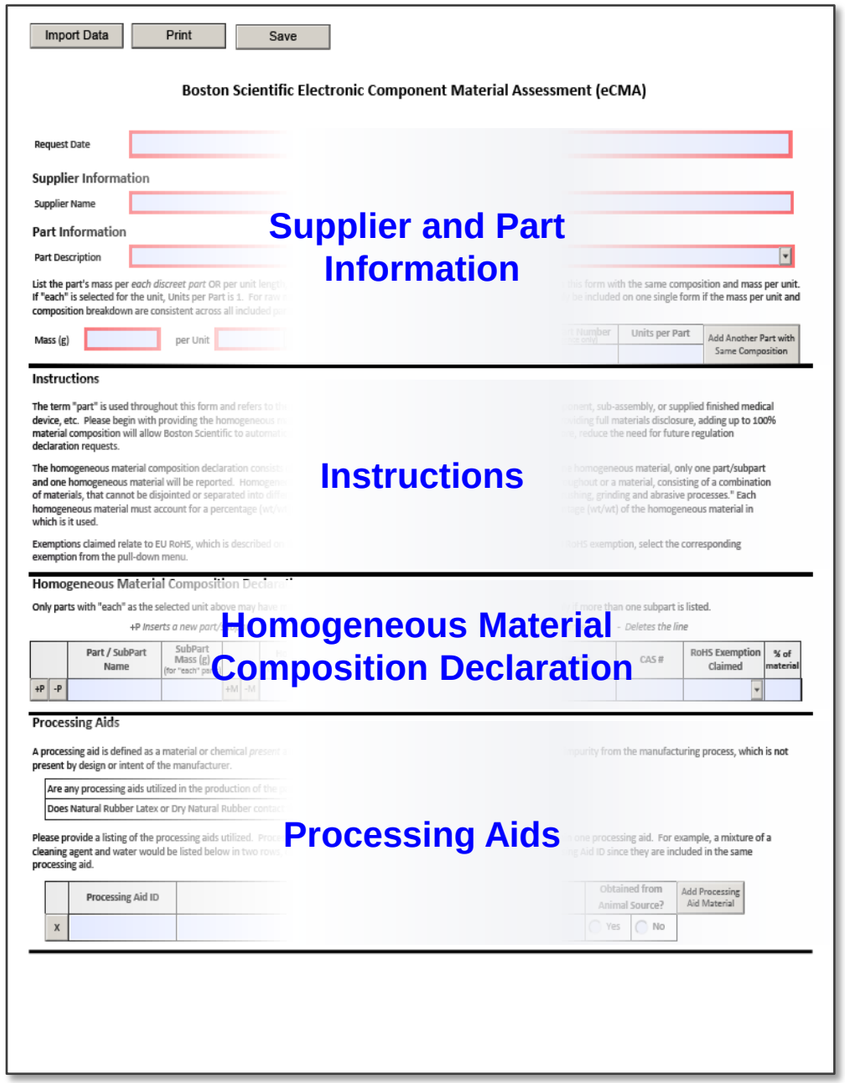
- Requests/response tracking
- Storage and revision history
- Validations performed on incoming data

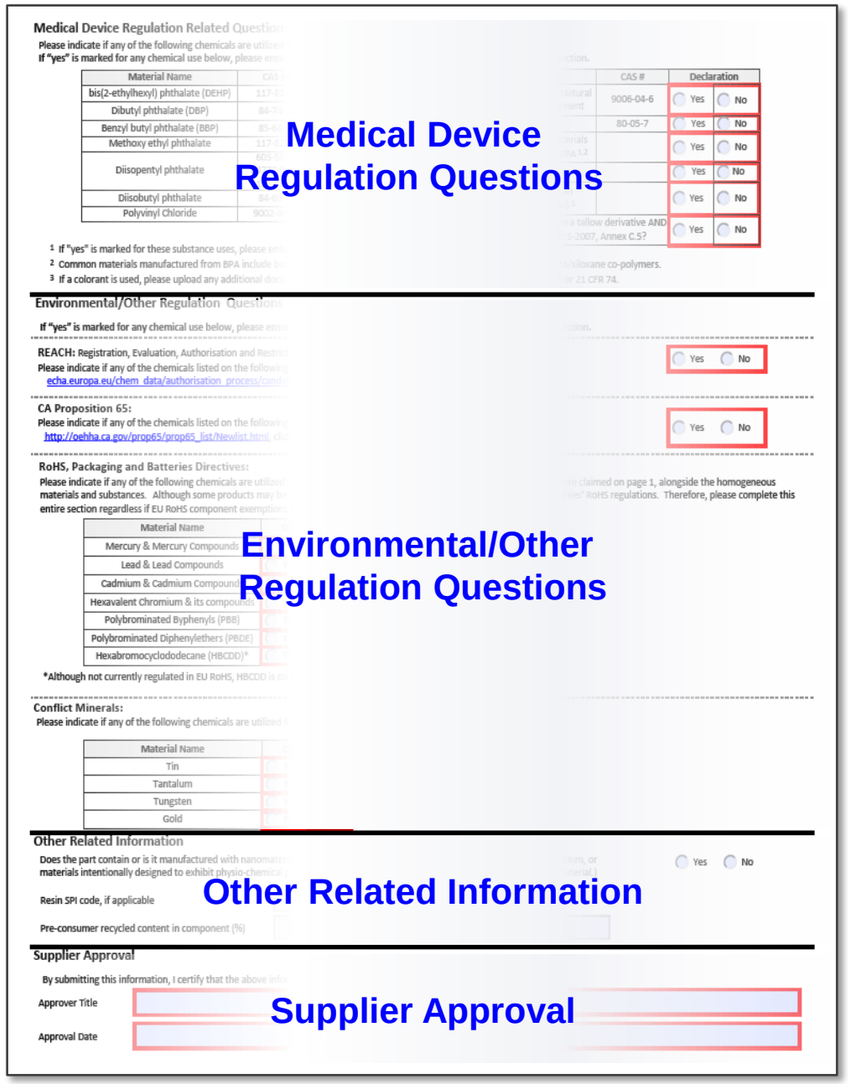


Electronic Component Material Assessment (eCMA) Form

PTC® Live Global

Key Tool: Boston Scientific's custom material declaration form





- *Comprehensive*:
  - Key regulations & substances
  - Processing Aids
  - Emerging regulations
- *User-Friendly*:
  - Auto-fill of part/supplier information
  - Validations for correct completion
- *Efficient:*
  - Multiple components on one form (when applicable)
  - Allows both Y/N declarations and ability to provide full material disclosure

Material Content Breakdown

PTC® Live Global

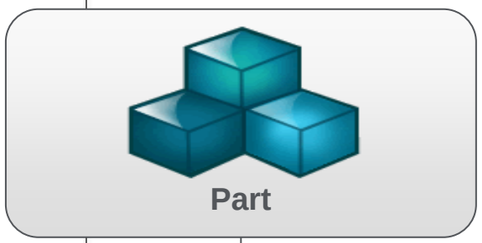
Key Concept: material content breakdown & full material disclosure (FMD)

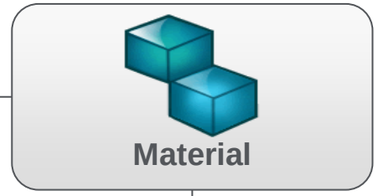
Homogeneous Material Composition Declaration

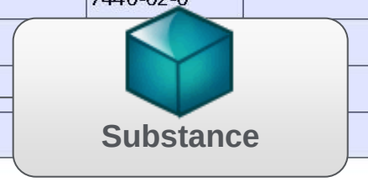
Only parts with "each" as the selected unit above may have more than one part/subpart below. Complete SubPart Mass field only if more than one subpart is listed.

+P *Inserts a new part/subpart* +M *Inserts a new homogeneous material* +S *Inserts a new substance* - *Deletes the line*

	Part / SubPart Name	SubPart Mass (g) (for "each" parts)		Homogeneous Material Name (supplier, trade or grade name, number)	% of subpart		Substance Name	CAS #	RoHS Exemption Claimed	% of material
+P -P	Outer Casing	1.9	+M -M	Polypropylene Casing	100	+S -S	Polypropylene	9003-07-0		85
						+S -S	Calcium Carbonate Filler	471-34-1		15
+P -P	Ink	0.1	+M -M	Water-based Ink	100	+S -S	Ferrous sulfate	7720-78-7		30
						+S -S	Water	7732-18-5		65
						+S -S	Gallic Acid	149-91-7		3
						+S -S	Gum Arabic	9000-01-5		2
+P -P	Ball Point	0.2	+M -M	Stainless Steel	100	+S -S	Iron	7440-89-6		68
						+S -S	Carbon	7440-44-0		0.08
						+S -S	Cobalt	7440-48-4		0.1
						+S -S	Chromium	7440-47-3		19
						+S -S	Copper	7440-50-8		0.3
						+S -S	Manganese	7440-96-5		2
						+S -S	Molybdenum	7439-98-7		0.22
						+S -S	Nitrogen	7727-37-9		0.1
						+S -S	Nickel	7440-02-0		9.125
						+S -S	Phosphorous			0.045
						+S -S	Silicon			1
						+S -S	Sulfur			0.03



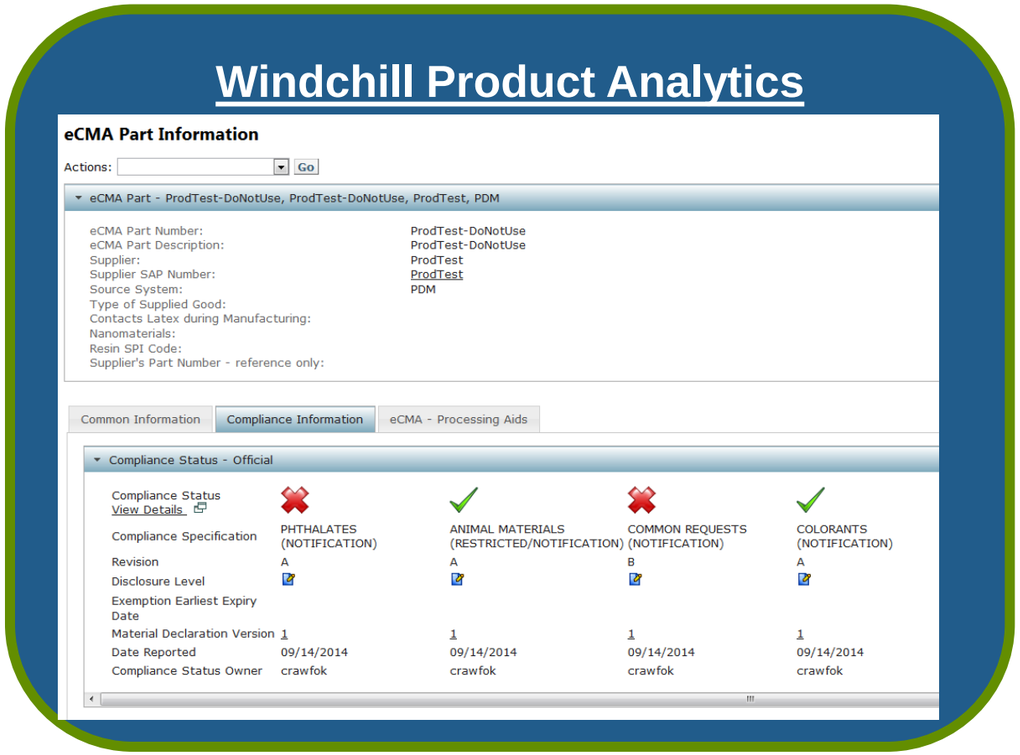




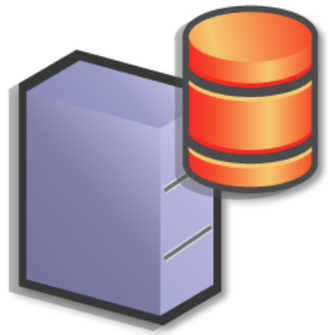
System & Form Together

PTC® Live Global

Key Tools Work Together



Portal (or Email)



BSC Employee:
- Send requests
- Review forms
- Run reports

electronic Component Material Assessment

Supplier:
- Receives requests
- Accesses forms & instructions
- Approve / submits forms

EICC Electronic Industry Citizenship Coalition | GeSI Global e-Sustainability Initiative

Conflict Minerals Reporting Template

Developing a Regulated Materials Program

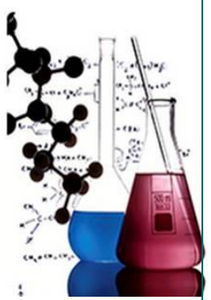
PTC® Live Global

System

Windchill Product Analytics

Define Need/ Requirements → Build Team → Develop Process & Tools → Implement System and Data Collection → Sustain

CA.GOV OEHHA Office of Environmental Health Hazard Assessment



eCMA Process (and Form)

electronic
Component
Material
Assessment

Best Practices for Material Data Collection

PTC® Live Global

Communication, communication, communication…

Who is the right contact?

Contacts | Locations | Alternate IDs | Documents

No.	First Name	Last Name
1	Raul	Otero
2	John	Wayne
3	Unknown	Unknown
4	Bob	Cat

What is needed?

- Material Declaration via eCMA Form
- Full Material Disclosure
- Conflict Minerals Information

electronic Component Material Assessment

EICC Electronic Industry Citizenship Coalition | GeSI Global e-Sustainability Initiative

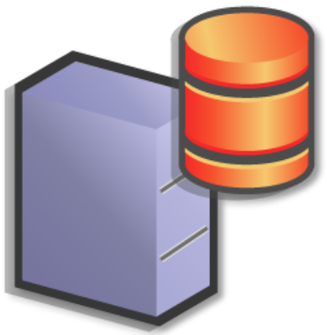
Conflict Minerals Reporting Template

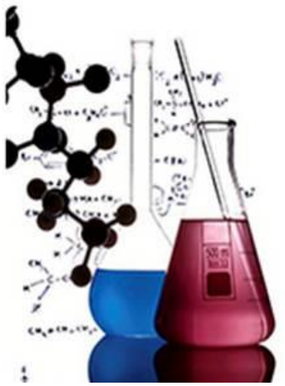
When is the deadline?

OCTOBER 2014						
SUN	MON	TUE	WED	THU	FRI	SAT
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

Where to go?

BSC Portal





Best Practices for Material Data Collection

PTC® Live Global

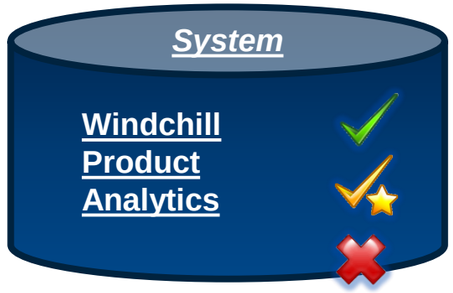
How to handle challenges

- No response from supplier?
- Incorrect contacts?
- Unable to obtain information?

- Escalation (internally, at supplier)
- Go to tier II or tier III suppliers
- Use other methods to obtain data

Photo Credit: Max Rugby

Developing a Regulated Materials Program



Define Need/ Requirements

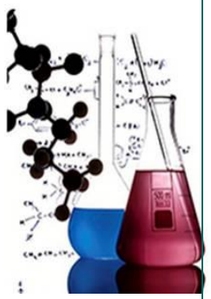
Build Team

Develop Process & Tools

Implement System and Data Collection

Sustain

CA.GOV OEHHA Office of Environmental Health Hazard Assessment

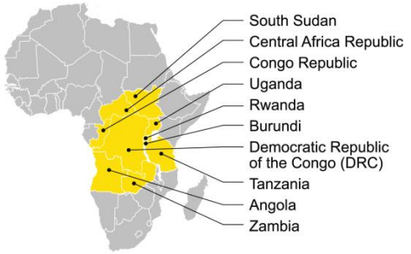


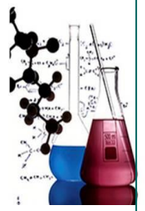
eCMA Process (and Form)

electronic
Component
Material
Assessment

Sustaining Regulated Materials Program

A Sustainable Program





eCMA Process (and Form)
electronic
Component
Material
Assessment

EICC Electronic Industry Citizenship Coalition
GeSI Global e-Sustainability Initiative

Conflict Minerals Reporting Template

Developing a Regulated Materials Program

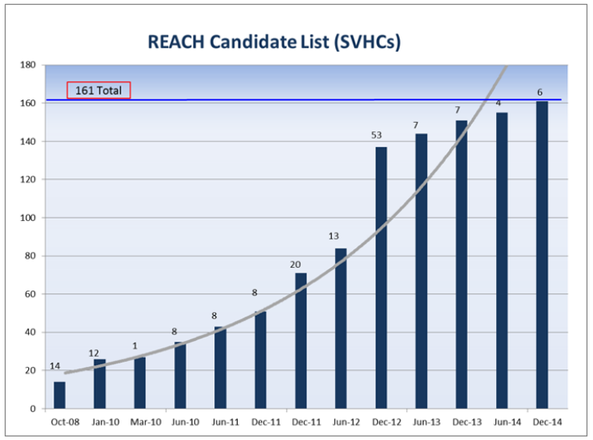
Q&A

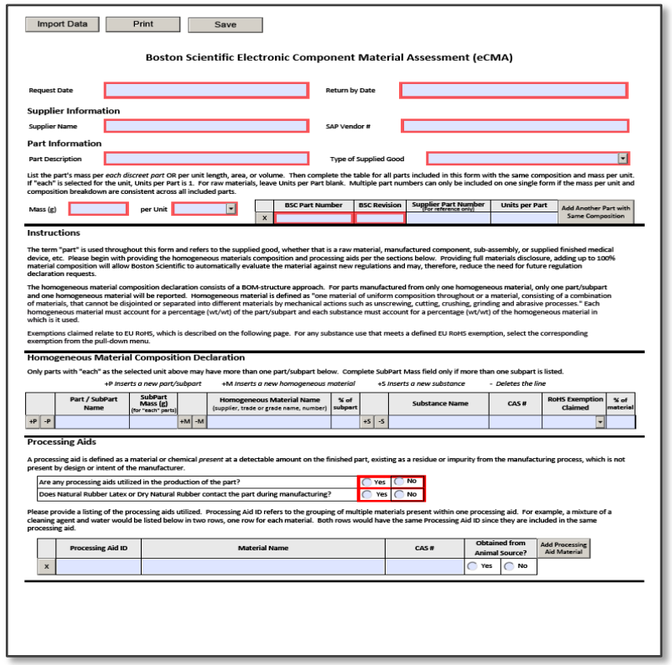
Summary & Review

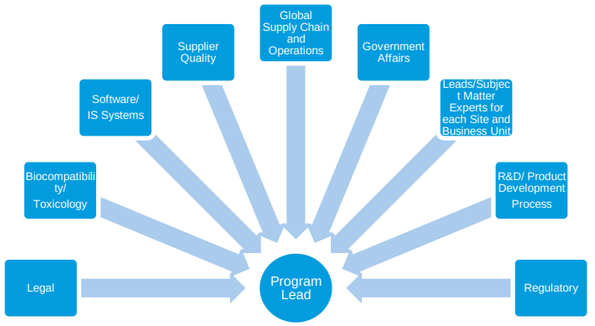
PTC® Live Global

Learning Objectives

- ✓ Understand the challenging landscape of material regulations
- ✓ Discuss benefits of utilizing an automated data collection system (Product Analytics)
- ✓ Review a unique one-stop form for collecting material content from suppliers
- ✓ Describe best practices for optimized material information data collection







- Your feedback is valuable
- Don’t miss out on the chance to provide your feedback
- Gain a chance to win an instant prize!
- Complete your session evaluation now

Photo Credit: Darc Red

PTC® Live Global

PTC® PRODUCT & SERVICE ADVANTAGE®