Title:

Mitigating Business Risks: Proactive Environmental Compliance

Presenter: George Valaitis

Date: June 14, 2013

AB SCIEX

AB SCIEX at a Glance

- **AB SCIEX**
  - **global sales, service and support**
  - **North America:**
    - **research and design**
    - **some manufacturing**
  - **Asia:**
    - **primarily manufacturing**

- *Environmental Mgmt Focus:*
  - *fabricated parts, OEM hardware and components*
  - *reagents and consumables*

AB SCIEX DFMA Success – API 2000

API 3200 MD Series

- **Launched, 2013.**

- Based on API 2000 Platform

API 2000

- **Launched 1998**

- Design optimized with BD DFMA S/W.

- Known for performance, reliability, ease of Mfg and modular design.

- **Ensure That Environmental Compliance Related Legislation Around The World:**

  - **Does Not Adversely Affect AB SCIEX's Ability to:**

    - **Ship Existing and Newly Developed Analytical Instrumentation Solutions**

      - **To Current And Future Global Customers and Markets.**
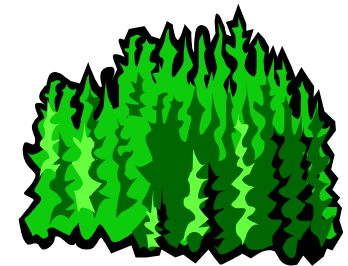
Agenda

- **Purpose**

- **Environmental Compliance Landscape**

- **AB SCIEX PEC Program Pillars:**

  - **Organizational**

  - **PEC Related Infra-Structures**

    - **System Based Approach**

    - **Efficiency Improvements**

    - **Integrating GSC**

    - **External Expertise**

  - **Quality Management System**

- **Measuring Success**

- **Summary**

- **Highlight importance of embedding "Design for Environmental" requirements at concept stage:**

  - **To mitigate current and future business risks:**

    - **While maintaining/reducing product cost.**
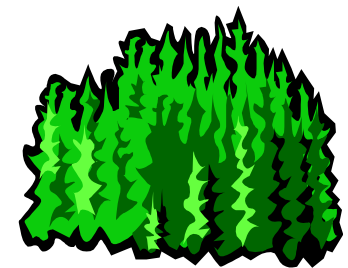
• Global Environmental Landscape

Green Peace View

- ## Spearheaded Primarily by <u>EU's initiatives</u>:
  - **To reduce the negative environmental impact of products and services.**

- ## Corporate Environmental Procurement Policies:
  - **Continue to gain momentum and acceptance.**
  - **Used to base purchasing decisions on level of compliance to their policies.**

To Gain Competitive Advantage

Global Environmental Landscape

- **RoHS**

RoHS   RoHS II

Well defined and limited.

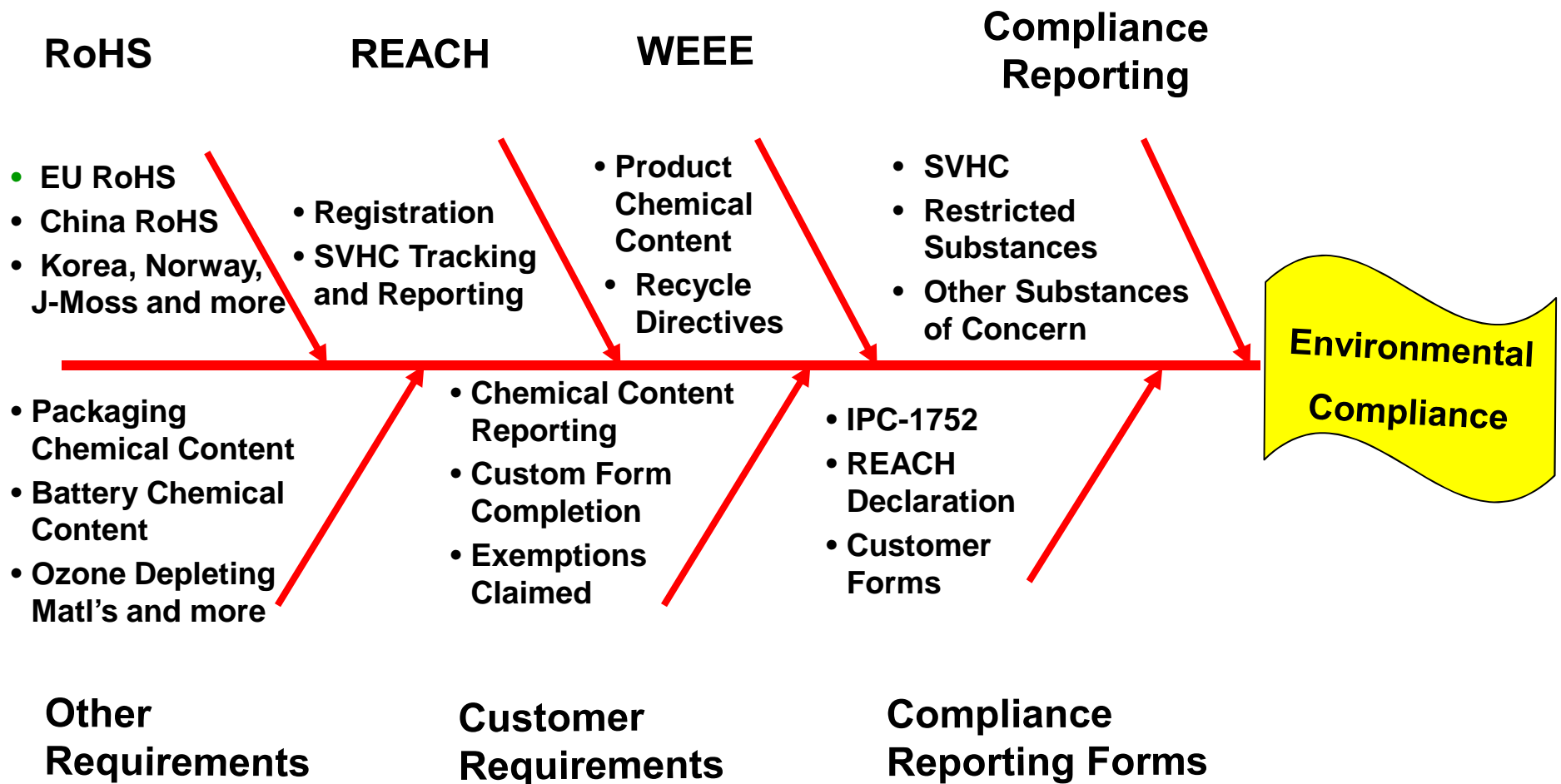- **REACH and Other Directives**

2010   2011   2012   2013

Continues to grow and expand globally

Environmental Challenge Will Not Go Away

The Road to Compliance Reporting

AB SCIEX

RoHS

- EU RoHS
- China RoHS
- Korea, Norway, J-Moss and more

Other Requirements

- Packaging Chemical Content
- Battery Chemical Content
- Ozone Depleting Matl's and more

REACH

- Registration
- SVHC Tracking and Reporting

Customer Requirements

- Chemical Content Reporting
- Custom Form Completion
- Exemptions Claimed

WEEE

- Product Chemical Content
- Recycle Directives

Compliance Reporting Forms

- IPC-1752
- REACH Declaration
- Customer Forms

Compliance Reporting

- SVHC
- Restricted Substances
- Other Substances of Concern

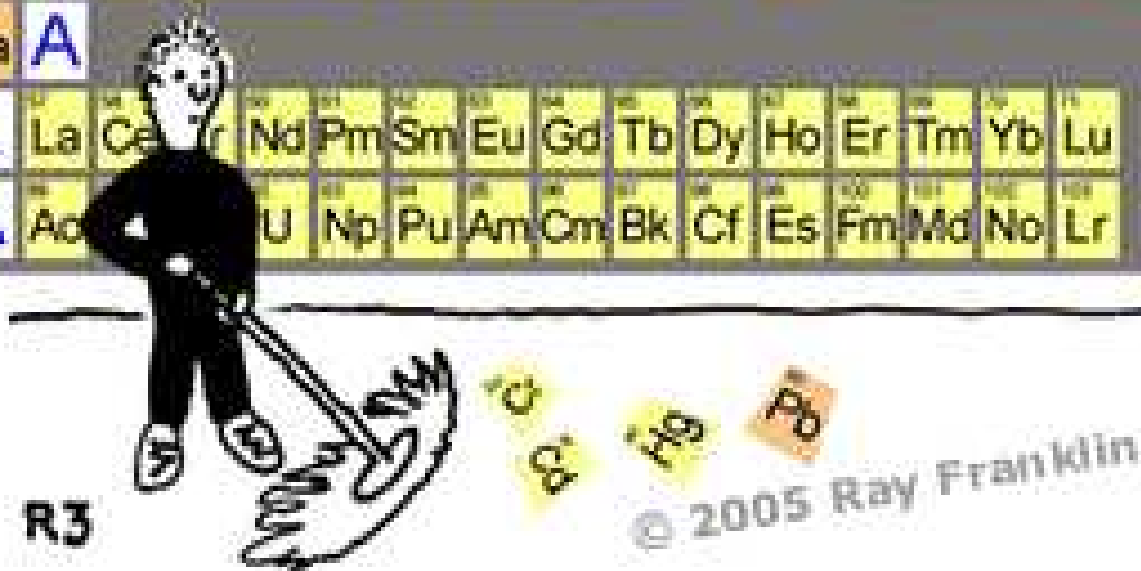**Environmental Compliance**

- **Cost of Compliance versus Penalties in EU:**
    - **Penalties generally higher than cost of compliance.**

- **Enforcement:**
    - **Still in early stages.**
    - **Generally:**
        - **Agencies assist first before assessing penalties.**

Q 3
© 2004 Ray Franklin RoHSwell.com

"But we were RoHS exempt. REACH EXEMPT!"
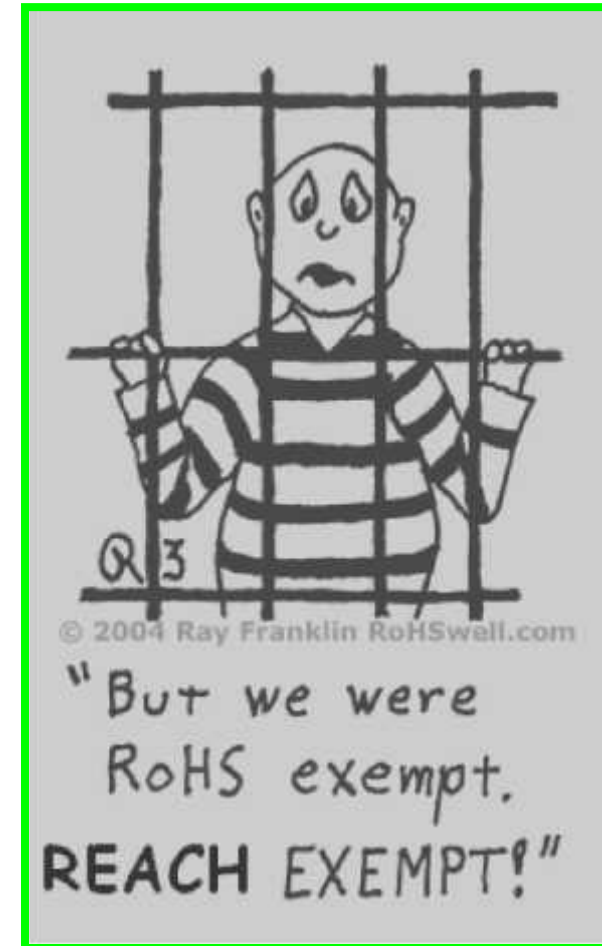
- **AB SCIEX PEC Program**

Scope of Challenge Details – API 5500

- **Total Unique Parts – 2500**
  - **Electrical Components – 1500**
    - *90 % FMD Data in MCC.*
  - **Mechanical H/W – 600**
    - *~ 50 % RoHS/REACH Components Compliant Already.*
  - **Fabricated – 200**
    - *Key Challenge Areas:*
      - *Paint, Plastics, Finishes etc.*
    - *Materials & H/W Spec'd by AB SCIEX.*
    - *85 % FMD Data in MCC.*
  - **OEM – 50**
    - *Key Challenge Area:*
      - *Obtaining Material Declarations.*
    - *No FMD Data in MCC to Date.*
  - **Assemblies 150**
    - *Contract Assy Supplier Assessing.*
    - *90 % FMD Data in MCC*

Data Collection Summary:
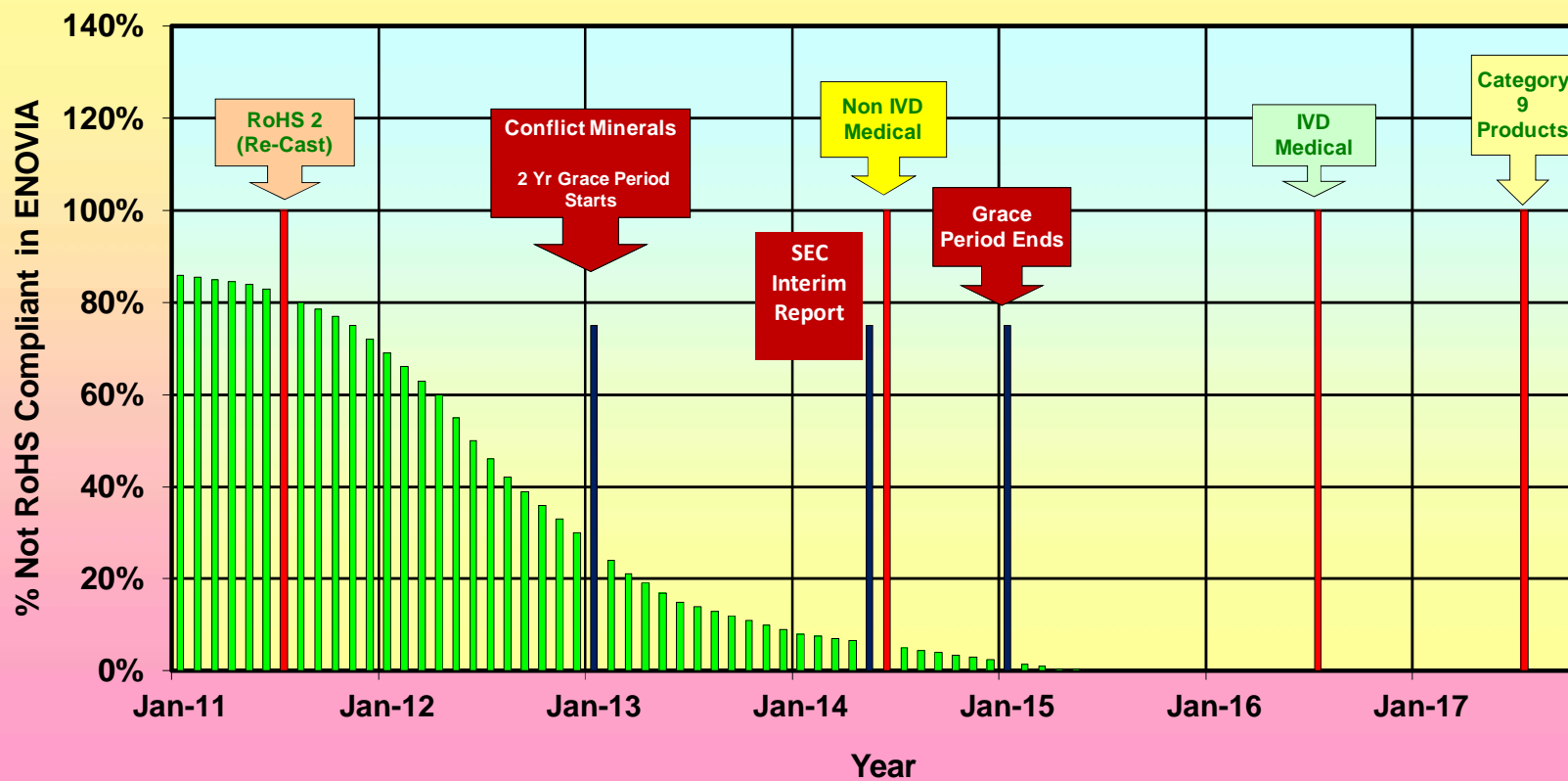
- **80 % Data Already Available, & MCC Ready.**
- **Effort Required for Remaining 20 %.**
- **Similar Mapping To Other Systems**

RoHS, Conflict Minerals Compliance Targets AB SCIEX

Opco Compliance Targets & Deadlines - 2012 to 2017

Program Building Blocks
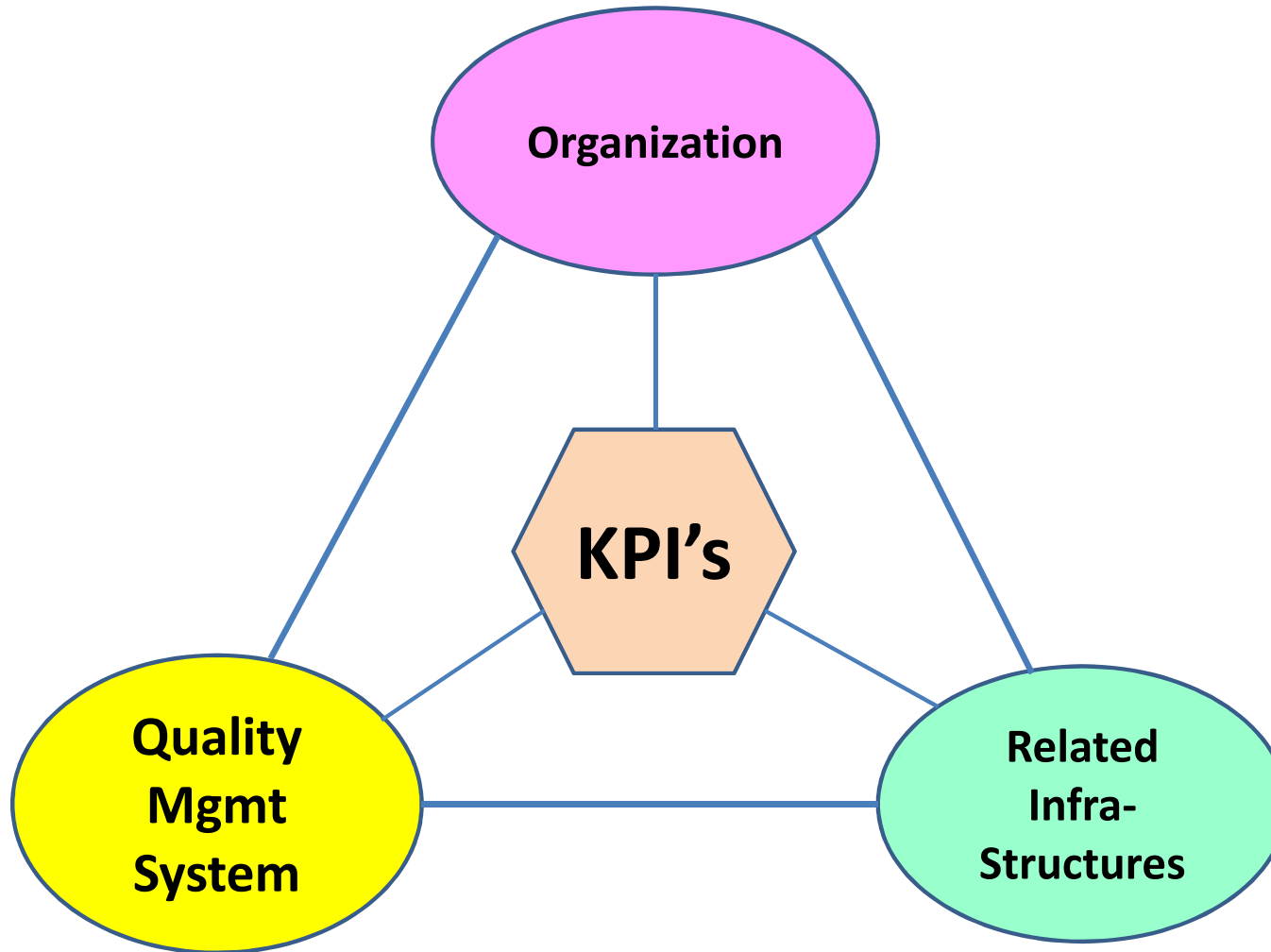
Implementation Strategy

Site, Product Specific Environmental Regulatory Compliance Mgmt Approaches

Integrated Compliance Program

Fully Integrated Environmental Regulatory Compliance Mgmt System

2010 State

2013 State
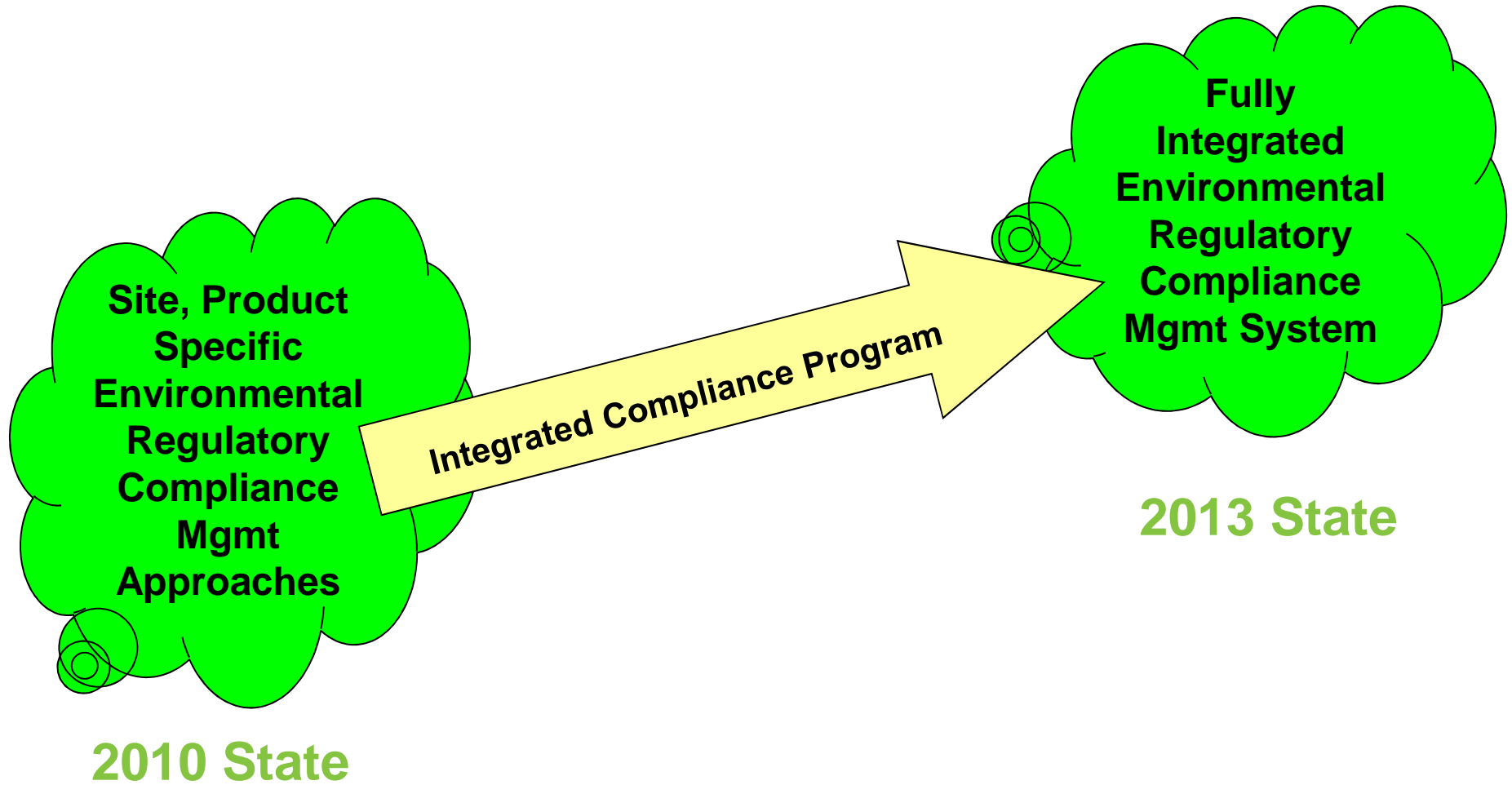
Environmental Regulatory Management Vision

- **Product/Part Specific Based Documentation:**

  - **More suitable for smaller organizations.**

- **System/Process Based Documentation:**

  - **Most suitable for larger organizations**

  - **AB SCIEX approach set up to:**

    - **"Drive compliance from within"**

- **Organizational**

AB SCIEX RoHS Steering Committee - 2010
(Chaired by Vice President, Quality Assurance)

RoHS Program Manager

RoHS Core Team,
Discipline Leadership

Product Conversion Projects Teams

RoHS Consultants and Collaborators

Related Infra-Structure
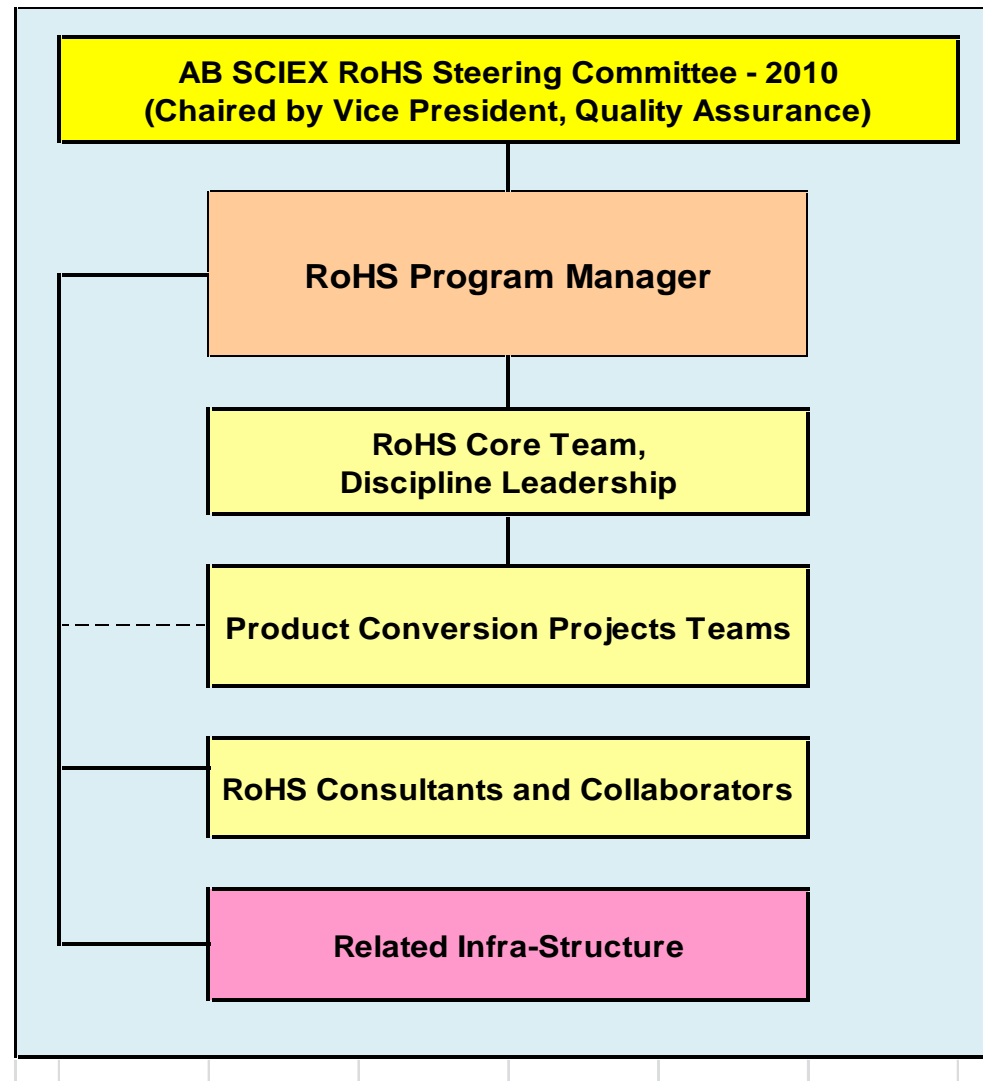
Multi-Level Management Structure

RoHS Steering Committee

AB SCIEX RoHS Steering Committee Make-up and Accountabilities

#	Key Stakeholders	Strategic (Timetable and Overall Budget)	Product Roadmap (Across Global Regions)	Regulatory (Regulatory Requirements)	Financial (Budgets)	RoHS Infra-Structure — Product Development	RoHS Infra-Structure — Supply Chain, Mfg	RoHS Infra-Structure — IT	RoHS Staffing Resource — Product Development	RoHS Staffing Resource — Supply Chain, Mfg	RoHS Staffing Resource — IT
	VP, QA & Regulatory Affairs, Chair, RoHS Steering Committee	X		X							
1	VP, Product Development				X	X			X		
2	VP, Manufacturing, Supply Chain				X		X			X	
4	VP, IT				X			X			X
5	Director, Product Management		X								

RoHS Program Update, October 2010

Current Status !

Overall Project `G`

1) **Concord RoHS Program** `Y` `G`

2) **Sunnyvale RoHS Program** `Y` `G`

Green = On Target: Will meet commitments
Yellow = Monitoring required: There is concern that the meeting of commitments may be in jeopardy
Red = Off track: Corrective action required if commitments are to be met
This month status colour is in the foreground last months status is in the background

This Quarters Achievements !

o **Released AB SCIEX versions of Environmental Spec Requirements Document.**

o **Completed MCC plans for launch in 2011.**

   1. **Completed RoHS/Obsolescence Conversions of 2700 PCBA parts for 100 PCBA's.**

   1. **Completed Firestorm Instrument Verification Process Improvement Reviews/Action plans.**

Major Outstanding Issues !

o **Ensure REACH & SVHC reporting deadlines do not impact product shipments into the EU.**

o **Maintain momentum around compliance program moving forward across AB SCIEX.**

Expectations Before Next Review !

o **Complete Discipline Specific RoHS REACH doc. Updates for GSC, PRM, QA, (Delayed from 3rd to 4th Qtr)**

   1. **Continue driving RoHS conversion of API 5500 products and prototyping in Singapore.**

   2. **Continue to Drive/Support updating of Concord and Sunnyvale Product Roadmap & Doc updates for RoHS, REACH. (Dec complete)**

- **PEC Related Infra-Structures**

Centralized Component Engineering
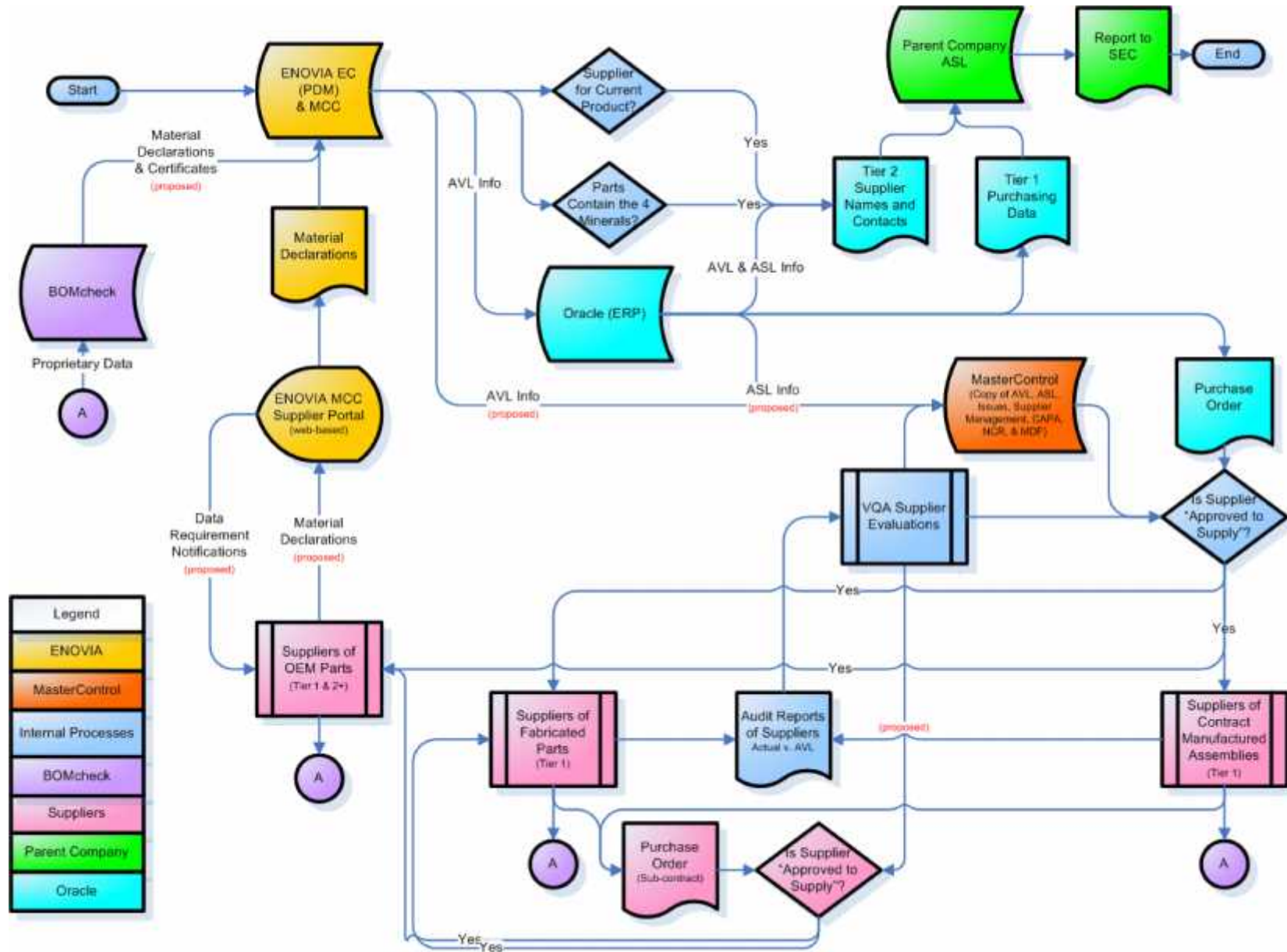
- ## Vision:
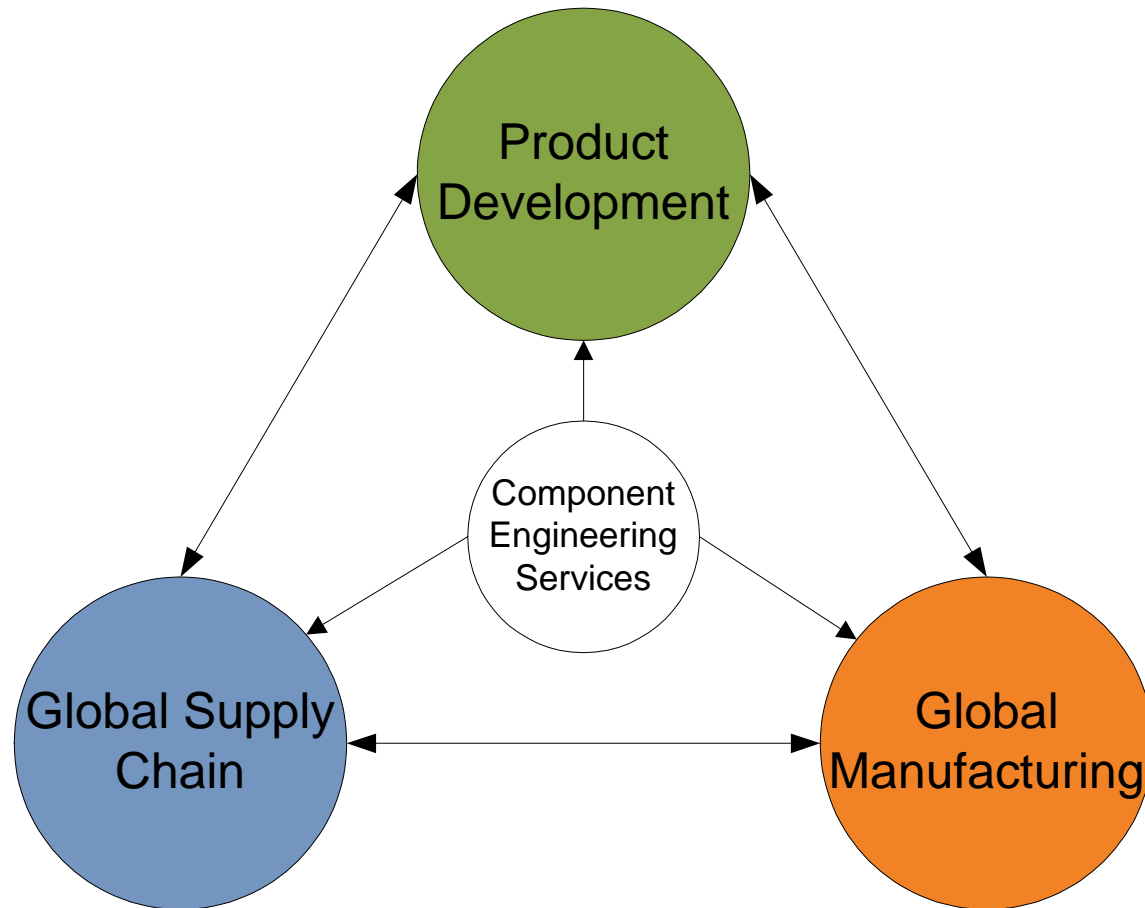
- ## AB SCIEX:

  - ### Centralized Material Compliance Central (MCC):

    - #### For 200+ Users.

    - #### 400,000 Parts

  - ### Integration to:

    - #### ENOVIA Engineering Central (EC),

    - #### CAD tools: CATIA and PADS PCB

    - #### Total Parts Plus (obsolescence mgmt)

Implementation & Redesign Costs
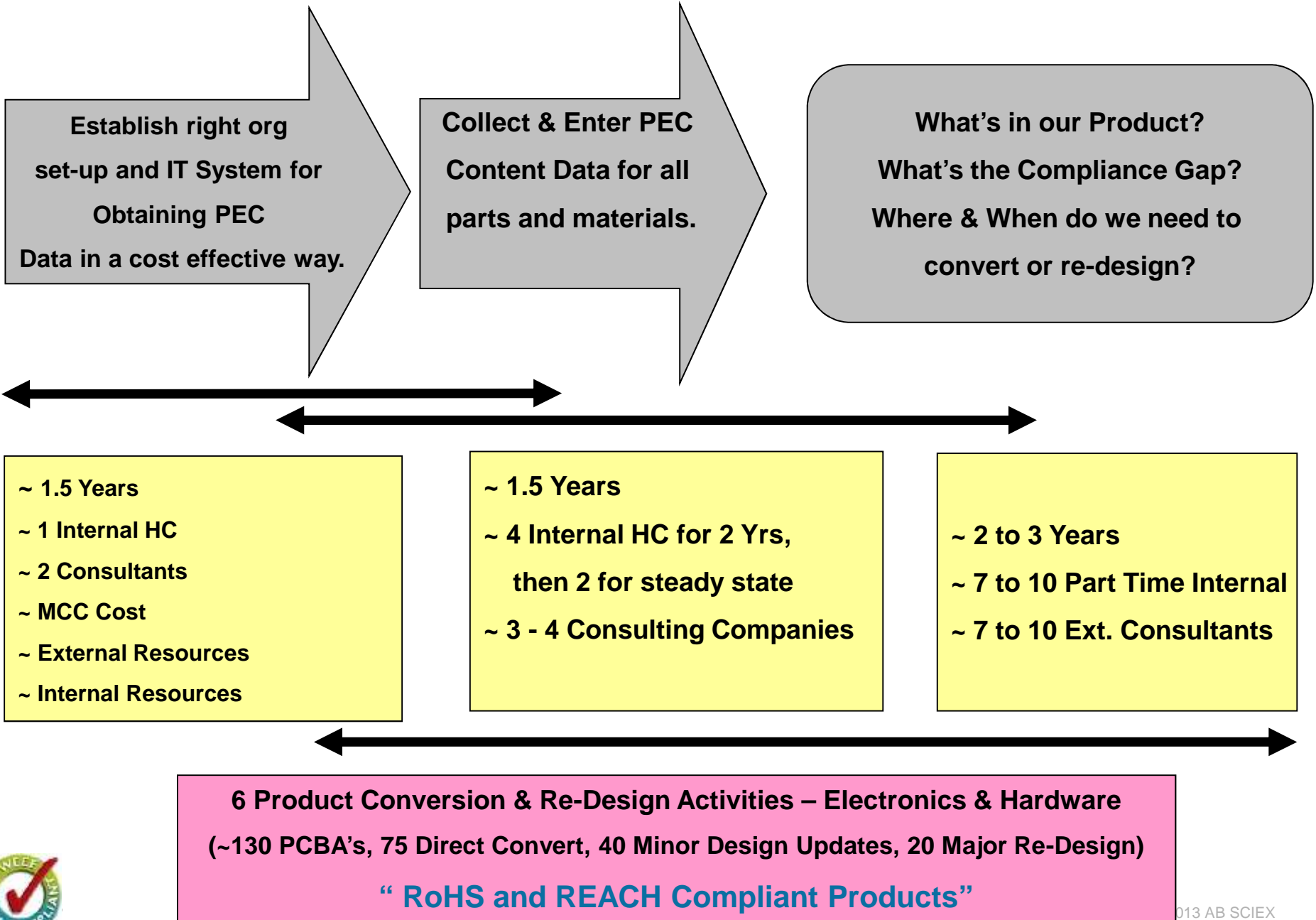
Establish right org set-up and IT System for Obtaining PEC Data in a cost effective way.

Collect & Enter PEC Content Data for all parts and materials.

What's in our Product? What's the Compliance Gap? Where & When do we need to convert or re-design?

~ 1.5 Years

~ 1 Internal HC

~ 2 Consultants

~ MCC Cost

~ External Resources

~ Internal Resources

~ 1.5 Years

~ 4 Internal HC for 2 Yrs, then 2 for steady state

~ 3 - 4 Consulting Companies

~ 2 to 3 Years

~ 7 to 10 Part Time Internal

~ 7 to 10 Ext. Consultants

6 Product Conversion & Re-Design Activities – Electronics & Hardware

(~130 PCBA's, 75 Direct Convert, 40 Minor Design Updates, 20 Major Re-Design)

" RoHS and REACH Compliant Products"
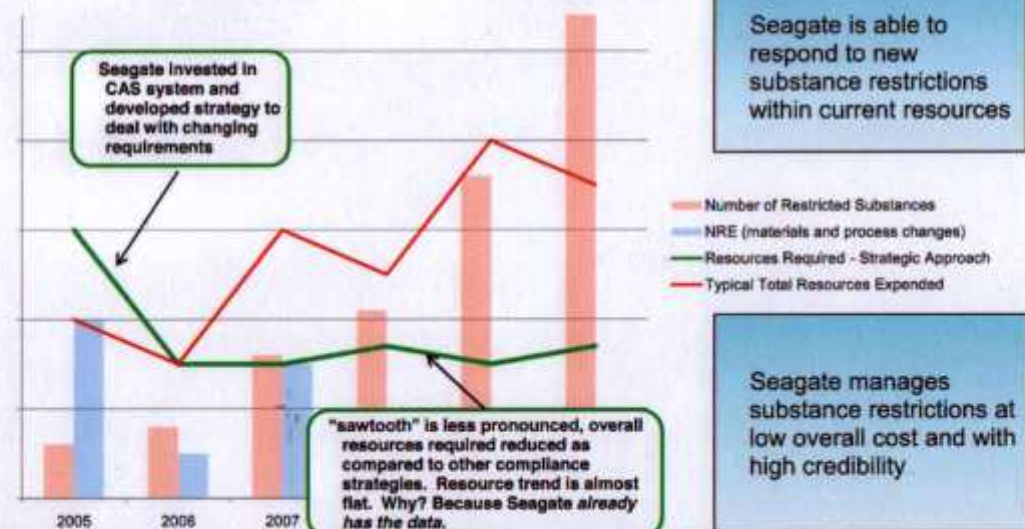
Reprinted from Greening Consumer Electronics, November 18, 2009, European Parliament Brussels, By Alexandra McPherson, Managing Director, Clean Production Action
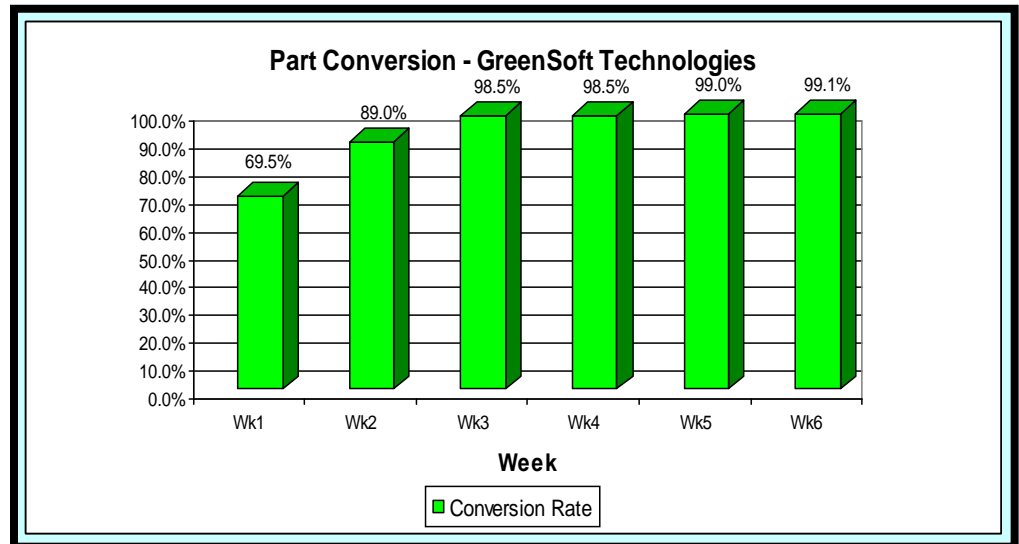
PCBA Conversion Cost Kaizen

Task	Kaizen, December 2009		Actual cost Per Part,
	Before Kaizen	After Kaizen	January 2011
Metric >>	Conversion Cost: (Per Unique PCBA Part)		
1 BOM Analysis	$60.00	$20.00	$6.00
2 Part Conversion & Sourcing, (Greensoft)	$300.00	$100.00	$10.00
3 PCBA Redesign, (Validate Parts, BOM, Review, Test, Release)	$1,900.00	$1,050.00	$540.00
5 Proto Development	$249.00	$249.00	$236.00
Total Cost:	$2,509.00	$1,419.00	$792.00

Greensoft Part Conversion Overview

AB SCIEX

- **1990's Vintage Design.**
- 1000 unique part numbers,
- 14 PCBAs.
- 2,145 Mfr P/Ns submitted for conversion.
- 2,126 parts converted to a compliant part.
- 18 of those parts are not fit, form, or function equivalent
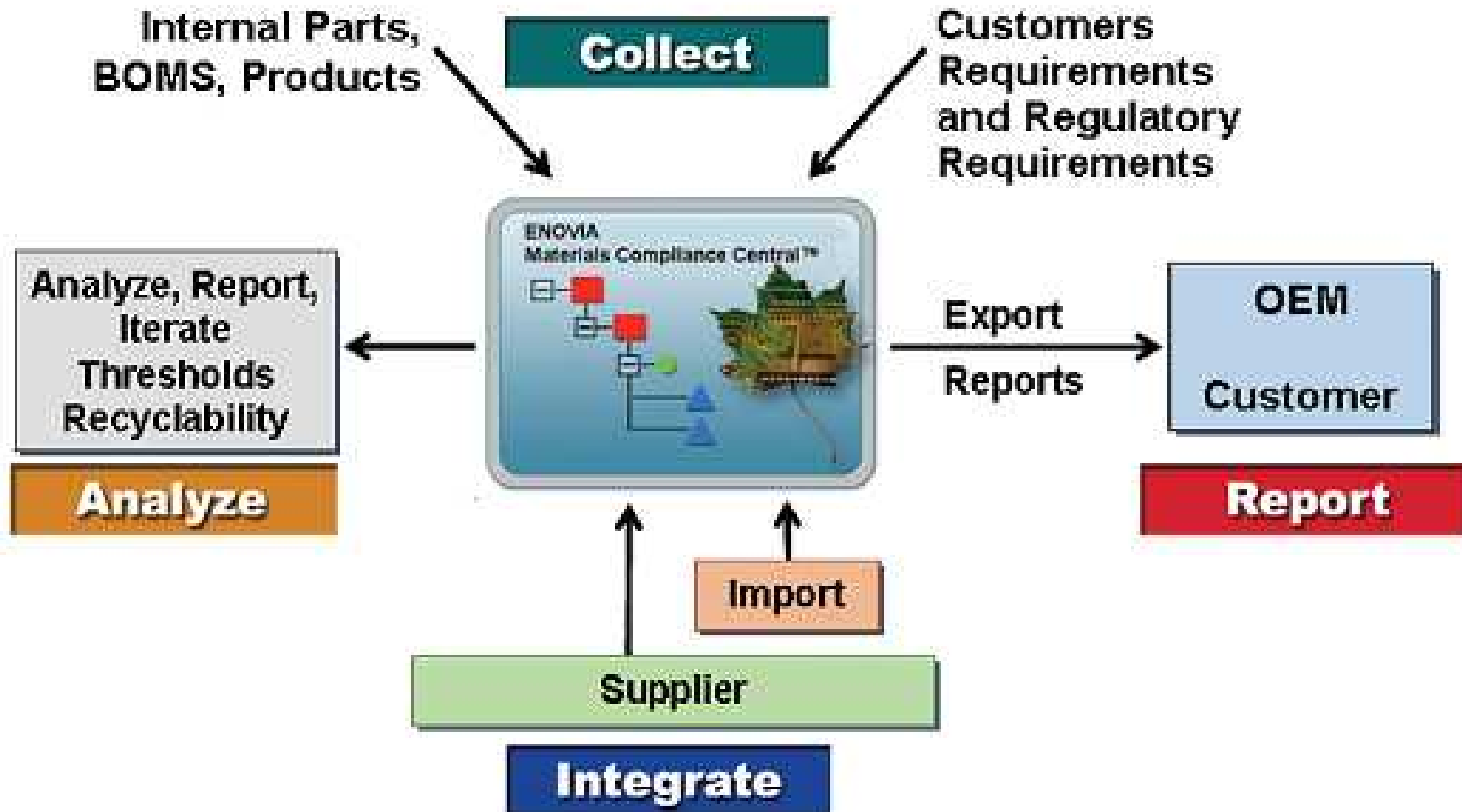- 19 remaining parts are mechanical.

Part Conversion - GreenSoft Technologies

Week	Conversion Rate
Wk1	69.5%
Wk2	89.0%
Wk3	98.5%
Wk4	98.5%
Wk5	99.0%
Wk6	99.1%

Results:

- **Completed 98.5 % conversion by week 3 !**
  - **Provided preliminary redesign assessment to Engineering teams at this milestone.**
- **Completed 99.1% conversion by week 6 !**
- **78% are RoHS2 (proposed) compliant.**
- **68% of the parts have Full Material Disclosure available.**
- **79% are SVHC1 compliant.**
- **Cost $8.00 USD per part**

Enabling Conflict Minerals Management

AB SCIEX

Internal Parts, BOMS, Products

Collect

Customers Requirements and Regulatory Requirements

Analyze, Report, Iterate Thresholds Recyclability

Analyze

ENOVIA Materials Compliance Central™

Export Reports

OEM Customer

Report

Import

Supplier

Integrate

Integrated Enterprise Data Management – Most Efficient Approach

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ENOVIA MCC

Example PCBA:
Compliance Status Icons
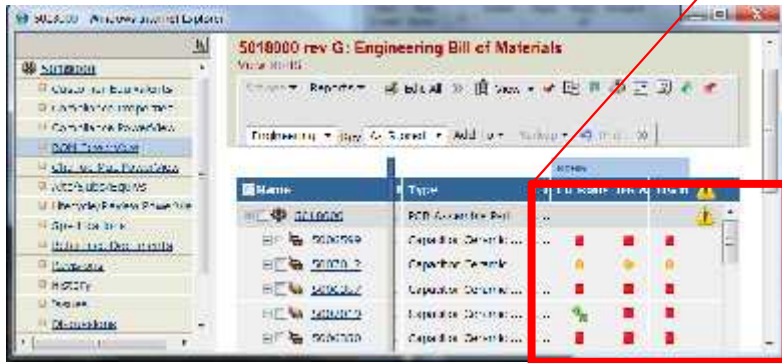
Example Component:
Compliance Properties View
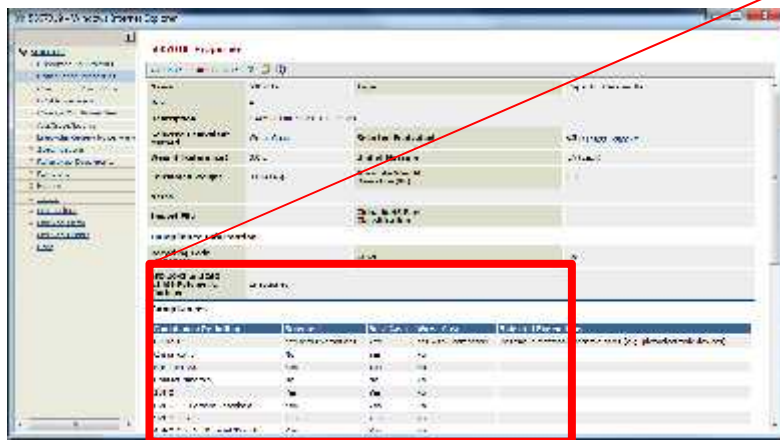
- **Efficiency Improvements,**

  PDV and Mfg

Firestorm Project Benefits

- **Through RoHS Conversions:**

  - **Improved overall efficiency of the PCBA design process.**

  - **Outsourced many of the routine PCBA development tasks.**

  - **Proactively mitigated existing component obsolescence issues.**

  - **New components now meet/exceed exeed product service life.**

  - **Updated legacy PCBA's to the latest lead free design standards.**

  - **Facilitated reliability improvements.**

  - **Up to 20 % cost savings/avoidance realized on specific PCBA's.**

 - **Streamlined the "Design for Environment" process across all disciplines.**

- **Integrating Global Supply Chain**

- **Costly and Time Consuming.**
  - **AB SCIEX:**
    - **Responsible for Regulatory Compliance.**
    - **Ask suppliers to comply.**
    - **Utilize different collection formats.**
    - **Absorbs all related costs !**
  - **Suppliers, Sub-Suppliers:**
    - **Education and training.**
    - **IP Protection.**
    - **Pass on related costs !**

Challenge - How to Close Supplier Collaboration Gaps

Tech Clarity Perspective
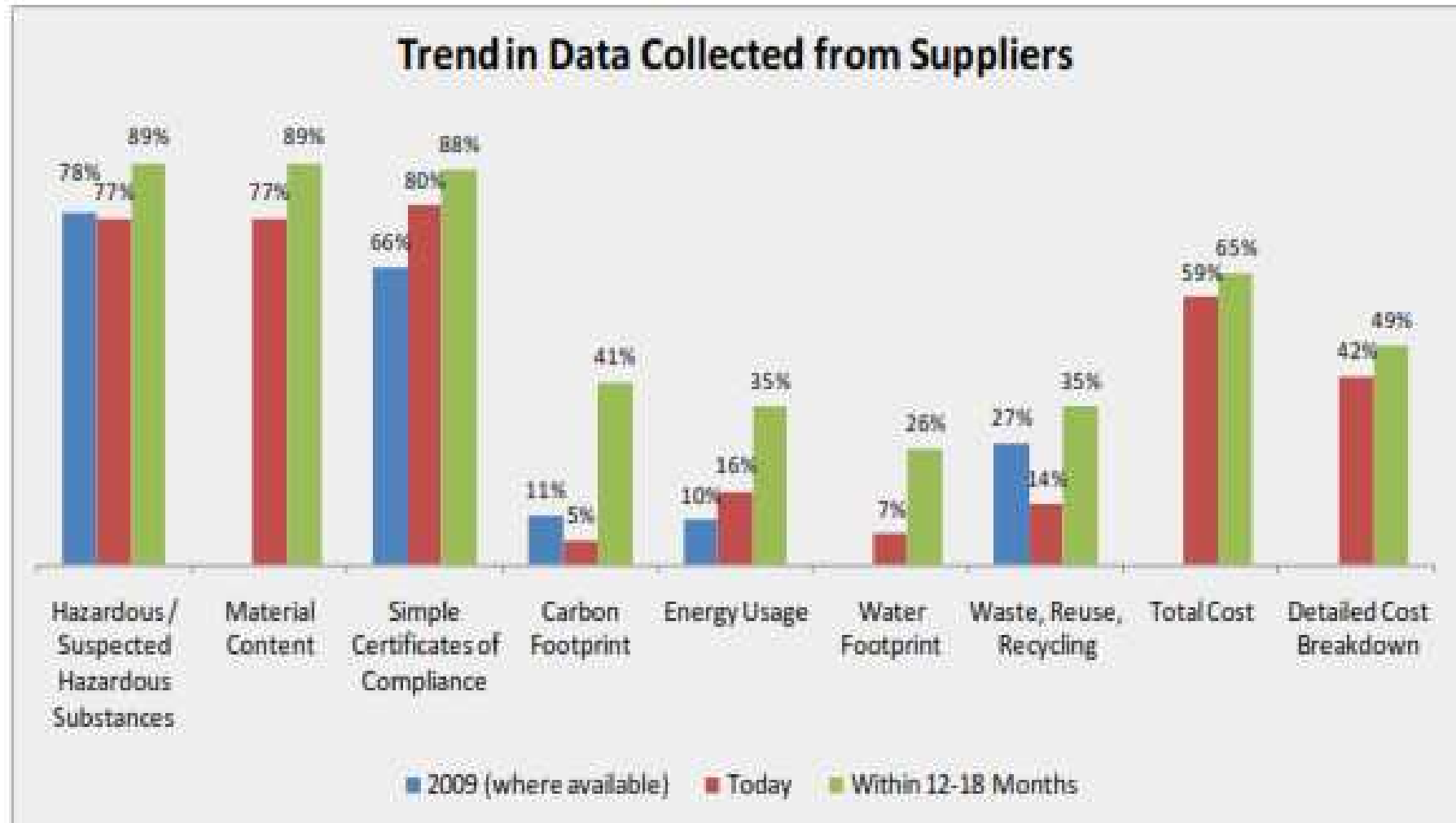
Challenge - How to Close Supplier Collaboration Gaps

Key Global Supply Chain Elements

- "Spec Environmental Requirements" Doc posted on AB SCIEX Website.

- Suppliers rated on ability to provide PEC compliant deliverables.

- Purchase order "Terms and Conditions" updated:

  - Making compliance to AB SCIEX's Spec Environmental Requirements mandatory, except when exemptions are granted.

- Suppliers required to provide substance details on only those deliverables:

  - That do not have detailed AB SCIEX BOM's.

  - Where substances remain as a result of Mfg processes.

- Asking specific suppliers to join BOMcheck.

- Utilizing industry standard formats for PEC data processing:

  - IPC 1752 and/or IEC 62474.

- Addressing intellectual property issues and concerns.

- **Must achieve PEC requirements and cost goals in parallel.**

Consultants and Collaborators

- ## C2P, Compliance and Risks, (Paul Harvey)
  - Global regulatory intelligence on-line tools
  - Location: Oregon House, California

- ## BOMcheck, (Dr. Aidan Turnbull)
  - Provides framework to efficiently manage RoHS, REACH Conflict Minerals compliance.
  - Location: Wiltshire, UK

- ## GreenSoft Technology, (Larry Yen)
  - Environmental compliance content management tools and services
  - Location: Pasadena, California,

- ## Total Parts Plus, (Peter Robinson)
  - Proactive obsolescence management of electronic components
  - Location: Fort Walton Beach, Florida

Leverage External Capabilities Whenever Possible

- **Updating Quality Management System Documents**

QP-034 Functional Accountabilities

Functional Processes	5.0											6.0	7.0
	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8	5.9	5.10	5.11		
Business Information Systems (IT)			X	X		X			X				
Facilities and Infrastructure								X					
Field Service			X			X	X	X	X		X		X
Hardware Development and Test (incl. research, product transfer, regulatory engineering)	X	X	X	X	X	X	X	X	X	X	X		X
Human Resources and Communication								X	X				
Product Maintenance- Design Change	X		X	X		X	X	X	X	X	X		X
Logistics (Shipping)						X	X		X				
Manufacturing			X			X	X		X				
Manufacturing Engineering and Support			X	X	X	X	X		X				
Marketing		X				X		X	X				
Mat. Handling (Receiving, Incoming Material control & Stores)			X	X		X	X	X	X	X			X
Order Management and Planning													
Procurement and Global Supply Chain			X	X	X			X	X	X			X
Product Management				X		X			X				
Quality Assurance (General QMS processes)	X	X	X	X	X	X	X	X	X	X	X	X	X
Reagent/Consumables Development and Test			X	X	X	X	X		X	X	X		
Sales		X	X	X		X			X				
Software Development and Test (incl. Information Dev. and Product Sustaining)													
Technical/Customer Support			X			X	X	X	X		X		

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- **Measuring Success**

Success Metrics: "Top 10 List"

1	QSM and all related documentation updates have been completed.	✔
2	Access to the latest PEC regulatory compliance requirements.	✔
3	New products designed & released PEC compliant at launch.	✔
4	Communicating PEC requirements and deadlines to all suppliers.	✔
5	Manufacturing ensures all raw materials are tracked & compliant.	✔
6	Suppliers being categorized, measured and audited.	✔
7	Field related issues related to supporting compliant and non compliant products resolved.	✔
8	PEC training programs in place and underway.	✔
9	All existing products designated for shipment past compliance deadline have been updated to be Environmentally compliant.	✔
10	In case of a country specific audits, proof of compliance can be clearly demonstrated.	✔

Summary

- Promote and instill a "Design for Environmental" mentality.

- Generate a PEC Charter.

- Capture all BOM product parts, components and source suppliers into a electronic database.

- Keep all levels of management informed on compliance risks deadlines & costs.

- Integrate key elements and disciplines through efficient, sustainable approaches.

- Formalize data collection from suppliers & variety of sources/standards

- Balance the risks and costs associated with the reality of standards adoption and evolvement.

- Review product roadmaps around which products to continue, convert and/or retire based on ROI and/or NPV.

- Enable "Design for Environmental" approach through fully integrated, sustainable processes and systems.

- Ensure someone is given responsibility for PEC.

- Enjoy the journey !
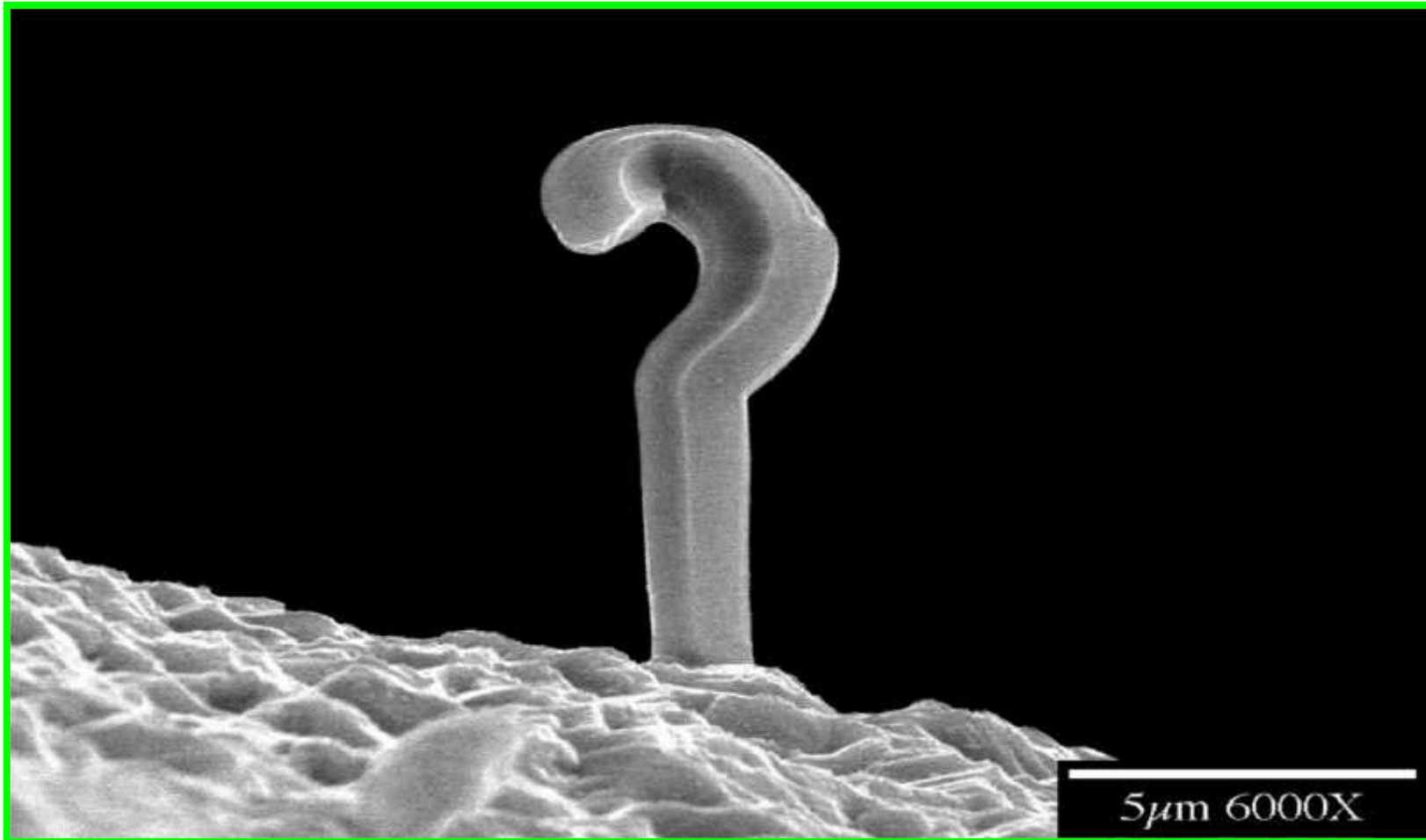
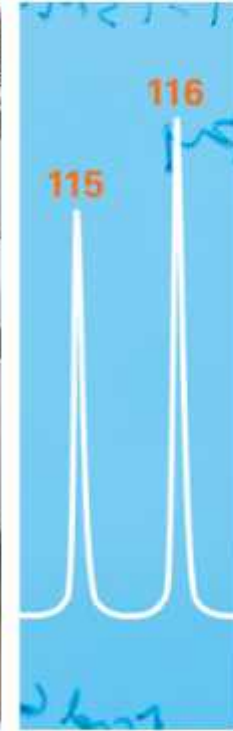**Slide Pictures and Illustrations from
Peter Bush, iNEMI Tin Whisker Workshop
at ECTC, 2004**

Thank You

AB SCIEX