Product Stewardship Auditing:
A new look at an old discipline

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Maryann brings over 25 years of Product Stewardship program organizational skills, thought leadership, and scientific expertise in regulatory affairs, toxicology, occupational and environmental health, and microbiology to the table.

Throughout her career, she has provided services to multiple industry sectors. Maryann provides third-party audits, leads teams supporting acquisitions and divestitures and develops and provides training programs on new and changing regulatory requirements. Her work not only identifies areas of risk; it also celebrates best practices.

Maryann provides technical presentations for multinational companies and various technical organizations. She also serves as adjunct faculty in the Master of Science in Product Stewardship program at Indiana University, where she teaches a course in regulatory affairs.

Agenda

1. Traditional Product Stewardship (PS) Auditing
2. A New Focus
   - Mergers and Acquisitions (M&A)
   - Supply Chain
   - Sustainability and Corporate Responsibility
   - Emerging Issues
   - Customer Obligations
- PS Auditing Challenges

The Product Stewardship (PS) auditing discipline evolved out of Environmental, Safety and Health auditing to meet the specific challenges of product compliance. Over the years however, the discipline has developed further to cover compliance across the value chain, including supplied materials and considering downstream customer/ consumer uses. This evolution served to better address overall business risks. The results demonstrate the importance of PS in creating business value. To this end, companies are advancing their audit activities to include non-traditional assessments such as those associated with mergers and acquisitions and product sustainability and associated claims, while considering customer obligations and stakeholder expectations.

This session will provide insights into some new PS auditing considerations that not only substantiate chemical and product compliance and mitigate risks, but also identify means where PS can bring value an organization. The presentation will include examples of items to be considered in developing or expanding a PS audit program.

Traditional Products Stewardship Auditing

- Product Stewardship auditing sprung primarily from traditional EHS auditing.
- Rationale for performing an audit included:
  - Routine checks,
  - Identified risks (new regulatory requirements),
  - Expansion into new uses and/or new manufacturing or market geographies, and
  - New products and/or significant product revision
- Often incorporate an assessment of management systems and product compliance.

Purpose:

Manage Business Risks!

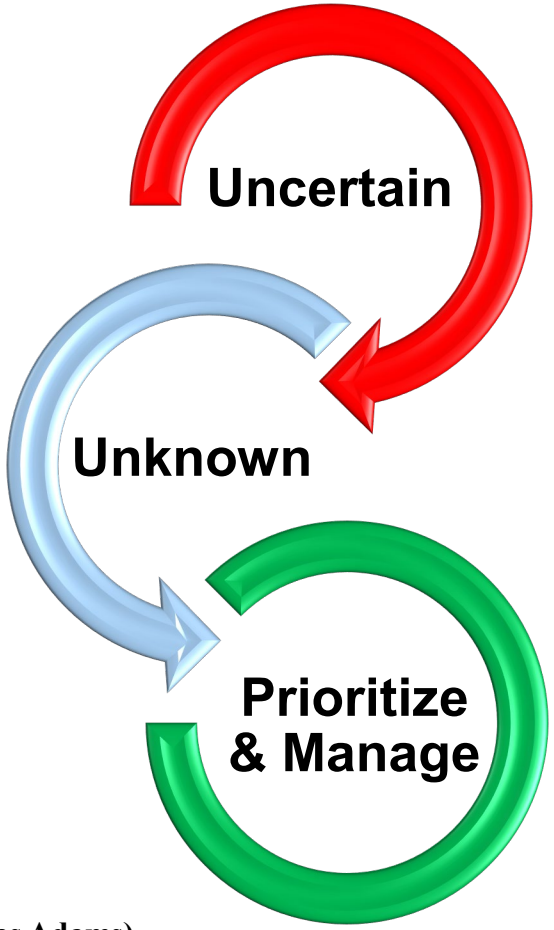
PS Auditing: Not a Universal Practice

- Corporate Risk Management Strategy may not deem PS audit necessary:
  - Based on business operations (actual or perceived),
  - No negative product compliance implications have occurred, and/or
  - Timing and costs associated with a PS audit is deemed unnecessary.

Managing Risk

The Risk Management Paradox

It is imperative to get "there", but…
"there" can be a moving target.



"We demand rigidly defined areas of doubt and uncertainty!"

Vroomfondel (in The Hitchhiker's Guide to the Galaxy by Douglas Adams)

Evolution of PS Auditing

- Still managing Business Risks…but the rationale for performing a PS audit has evolved.
- As company's PS programs mature:
  - Regulatory compliance is expected,
  - Management systems to manage compliance are in often in place, and
  - PS audits can be used to inform business decisions.

PS auditing today often is used to assess the opportunity for business growth!

Mergers and Acquisitions

Assessing Value

In anticipation of potential sale

On the buy side

Business Valuation

- As more companies consolidate and divest the value of the overall company or a particular business unit (BU) may be of interest.
- A valuation audit can:
  - Inform the decision to divest,
  - Support the desired sale price point,
  - Identify:
    - Shortcomings in available systems, processes, or tools that make assessing compliance obligations a challenge,
    - Non-compliance findings, and
    - Emerging issue concerns.

Business Valuation Example

- Global Plastics manufacturer

Recently acquired multiple other companies

Increase market share from expanded and integrated product lines.

Next Step: Identify business for potential divestiture

Review current regulatory compliance status.	Investigate the value of the product portfolio based on a leading indicators.

Observations: Existing obligations and Emerging issues (EI)

Clear understanding and compliance with current obligations.	Some EIs likely to have an impact on the product line be valuated (directly or indirectly).	Other EI considerations had not been previously assessed.

M&A – Buy-side Audit

- At the time of a merger or acquisition, the company (or BU) being purchased will undergo an assessment led by the buyer's representative that generally includes financial performance, market position, potential synergies, and operational efficiencies.
- Ideally a PS assessment/audit is performed in conjunction with the entire M&A acquisition assessment prior to an acquisition.
- Unfortunately, PS is sometimes not considered a critical component of the M&A process and is:
  - Performed after the deal is closed, or
  - Not performed at all.

M&A – Buy-side Audit

- A lack of inclusion of PS during the M&A process may result in the post-sale identification of:
  - Insufficient processes and tools to determine compliance obligations,
  - A fundamental difference in risk management strategies,
  - Regulatory non-compliance, and
  - Obligations not uncovered in a traditional M&A audit that could have a significant negative impact.

M & A Buy-side Audit Example

Situation	Manufacturer of electric tools: little EU distribution	Company B makes similar products with EU distribution	Tentative purchase of Company B investigated to expand footprint in Europe
Actions	Existing Company A maintenance products substituted until compliance assessed	REACH obligations for new products addressed	1. The cost to complete compliance activities was determined and used to impact purchase price
Findings	Company B tools are compliant to EEE regulations	Company B maintenance products are not compliant with REACH requirement	2. Consistent with the Company A's risk management strategies, Company B's maintenance products were withheld from the market until compliance activities were complete

Emerging Issue Assessment

Emerging Issues

- Just because a product meets current regulatory obligations, future compliance and marketability can impact its ability to support long-term business goals,
- In advance of a potential acquisition of a pesticide manufacturer an assessment to valuate the future marketability of the included product line was performed.
- The assessment included a detailed review of current and proposed regulatory activities categorized based on anticipated timing of any required regulatory obligations or restrictions on use.

Emerging Issue Assessment Example

Ingredient	NA Revenue	Market(s)	Status of US Regulatory Impacts
Propiconazole (in Cu-Azoles)			Potential status change in 2-5 years • No currently identified issues within EPA Draft RA.
Imidacloprid			Potential status change in 1-3 years • Elimination of different uses, label changes, PPE requirements required to be submitted to EPA. Neonicotinic insecticides may be banned under the Proposed Toxic Pesticides Act of 2020
1-2-Benzisothiazoline-3-one (BIT)			Future US FIFRA status (2-5 years) • Concerns raised in preliminary RA regarding inhalation and dermal exposures via occupational use, residential use, or both. No current FDA initiatives identified to date. NGO identified potential issue with sensitization and contact allergies.

Supply Chain & Sustainability

Supply Chain

- The choice of supplier has traditionally considered:
  - Ability to provide necessary chemicals/components,
  - Costs,
  - Quality,
  - Reliability, and
  - Timing.
- However, global regulatory compliance obligations and sustainability metrics are resulting in companies reassessing their supply chains to mitigate regulatory obligations, environmental impact and carbon footprint.

Pharmaceutical manufacturer

- A Pharmaceutical manufacturer's regulatory affairs department wanted to assess their obligations relative to the implementation of the EU Waste Framework Directive and associated SCIP* for a product provided in a "pen-like" device placed on the EU market.
- Audit Findings:
  - Company operations associated with the product were in the in US and Europe.
  - Supply chain also incorporated toll manufacturers.
  - Active drug ingredient manufactured in the APAC region.
  - Final drug compounding occurs within the Europe
  - Incorporation into final drug package occurs in Central America.
  - Final product (pen and drug) packaging performed in a non-EU site with component locally sourced.

* Substances of Concern In articles as such or in complex objects (Products)

Pharmaceutical manufacturer

- Primary Objective – Assess regulatory compliance obligations
  - “Pen” components were not made in the EU
  - As the company was the importer of an Article (the Pen) in the EU, the company had the obligation to determine and meet any obligations to report information on SVHCs in the pen.
- Secondary Finding – Supply chain challenges
  - The supply chain incorporated the cross global transport of product resulting in:
    - Increased costs for shipping,
    - Increased carbon footprints, and
    - Increased time to market.

Given the findings, the company is working to meet its regulatory obligations **AND** better understand and consolidate its processes and supply chain.

Customer Requirements

Can't make it, Can't sell it, **People won't buy it!**

- Customers may have additional chemical/product restrictions that go above and beyond regulatory obligations.
- Customer obligations may:
  - Be based on sustainability considerations, customer internal determinations, or consumer perceptions,
  - Developed and implemented more quickly than regulatory obligations, and
  - May not have been considered during product development.

Auditing against customer requirements can be especially challenging.

Well not the audit per se…

Customer Requirement Audit

- **Similar to assessing for regulatory compliance**
  - Identify product composition
  - Confirm key customers with their own chemical lists
  - Determine where product compositions overlap with those lists
- **Findings may be more prevalent**
  - Existing products likely developed to meet regulatory obligations, not customer lists
  - Customer lists change more regularly
  - New customers may introduce new restrictions

Challenges

Business Buy-In

- For some companies even traditional PS audits are considered optional…or not considered at all.
- More influence beyond just compliance is providing additional motivation to consider PS when managing business risk for:
  - Traditional business operations,
  - M&A transaction, and
  - Assessing impacts to sustainability goals and market access.

Protocol Availability

- PS protocols are generally not available
  - Some may be available from consultancies, or
  - May need to be developed internally
- Audit goals define the content of the protocol
  - Regulatory obligations based on:
    - Supply chain,
    - Manufacture site,
    - End use, and
    - Market jurisdictions.
  - Sustainability goals, and
  - Customer obligations

Qualified Auditors

IDEAL

- Experienced LOCAL
- Specific (or broa xpertise
- Understandi ess implications
- Industr e
- Flu language
-

Unlikely to find outside U.S. and EU!

PRACTICAL

- Experienced non-local PS auditor (possibly remote)
- Experienced local auditor with PS compliance experience
- Pair experienced local EHS auditor with PS specialist

Key Take-Aways

PS auditing is alive and well…in fact it is becoming more prevalent across small and large companies alike

It supports not only the management of business risk, but also supports the bottom line.

Challenges may still exist in some companies.

PS auditing can identify risk and support the bottom line

Through traditional management systems and compliance audits

During the M & A Process

To assess the supply chain

To support sustainability goals

Challenges remain:

A lack of standard protocols for traditional PS audits still exists. This lack of protocols is exacerbated as the discipline evolves.

Audit findings may require you to pivot from the original audit scope.

Identifying auditors with specific (or broad) expertise can be challenging

PS Auditing

It’s all about identifying the known unknowns and the unknown unknowns.

So be ready to pivot and focus on items that can impact business risk and the bottom line to increase the importance of PS to your business

Thank you

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