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Corporate Responsibility Association

Webinar Series

"Global Supply Chain Dynamics and the Changing Risk Management Agenda"

Welcome!

Your membership signifies leadership in the community and your participation will further the CRA's mission to promote the practice and profession of Corporate Responsibility in service of good business. The CRA is your association and we encourage you to take full advantage of all member benefits.

Vision: To promote the practice of sustainability and responsible organizational behavior as good for both society and driving organizational results.

Mission: Promote the practice and profession of corporate responsibility in service of good business. Educate and engage leaders at all levels to use corporate responsibility to reduce risk, improve operational efficiency, save money, attract talent, and encourage innovation.

Value Proposition

The four core values of the association are:

Professional Development – a place to go and learn, tools for benchmarking, defining a focus on the industry

Networking – the opportunity to meet others with similar issues and concerns

Communication Channel – the opportunity to tell your story and make the world aware of what's working in your organization

Access – Unique Member to Member exchange opportunities

We are becoming a model for many organizations – an association others will aspire to be.

CRA Thought Leadership Councils:

- Rankings & Ratings
- Professional Development
- Diversity & Inclusion
- Brand & Reputation Management
- Responsible Supply Chain

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Allie Williams, IOM

Executive Director – Corporate Responsibility Association

Contributing Writer – *CR Magazine*

SHAREDXPERTISE – REDEFINING MEDIA

*Publishers of **CR Magazine**, **HRO Today**, and **HRO Today Global***

*Organizers of the **COMMIT!Forum** and **HRO Today Forum Events***

*Managers of the **Corporate Responsibility Association** and the **HRO Today Services & Technology Association***

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Corporate Responsibility Association (CRA)
**Global Supply Chain Dynamics and
the Changing Risk Management Agenda**
Part One - Wednesday, November 19, 12 Noon EST



Art Stewart – *Moderator*

Management Consultant – ArtStewart.com/CR Writer, Speaker and Educator



Tim Valko – *Executive Director, Global Supply Chain; Amgen*



Colin Lafferty – *Vice President/Operations, Supplier Quality Management;
VWR International*

Supplier Member; Rx-360 International Pharmaceutical Supply Chain Consortium



Jeff LaBarge – *Partner, Food & Beverage/Agriculture Practice; Nixon Peabody*

How Risk is Calculated is Changing

Drivers:

- ✓ Competitiveness (new rules of engagement)
- ✓ Business continuity
- ✓ Reputation equity

Competitive concerns vary widely depending on industry, product/service, manufacturing context, market dynamics. New or changing *rules of engagement* producing pressure to:

- ▶ Reduce wasted asset utilization
- ▶ Enhance sales and operations planning
- ▶ Minimize avoidable risks

Paradigm shift: Doing business now requires a *holistic view* with end-to-end visibility of the supply chain.

- ▶ Balance driving revenue with lowering costs
- ▶ New orientation from cost compression and containment to one that re-engineers business process for new value creation

How Risk is Calculated is Changing

Many existing (or old-school) supply chain models:

- ✓ Can greatly impact component/raw material access, production, distribution and integration
- ✓ Enable the most subtle of factors to create a ripple effect
- ✓ Restrict whatever decreasing direct control sourcing companies still have
- ✓ Increase exposure to: Geopolitical unrest, terrorism or natural disasters which, in turn, can inject fear into networks and create significant uncertainty in supply availability

New models of supply chain partnerships:

- ✓ Relieve infrastructure constraints
- ✓ Reduce bottlenecks
- ✓ Strengthen efficiencies
- ✓ Generate far greater margins and solidify longer-term commitments
- ✓ Help protect revenue certainty on all sides of the value equation

Questions to Guide Your Organization Toward a More Responsible Supply Chain Strategy

- What are the priority factors for risk (new regulations, energy cost exposure, resource utilization, financial and human capital)?
- What governance frameworks need to be established to uncover conflict and appropriately resolve it?
- What incremental and game-changing sustainable business strategies can help maximize economic, human and ecological capitals (i.e., creating a sustainable supply chain)?
- What can you do to help evolve your company's culture to a truly collaborative way of working?
- What metrics and incentives would help promote big-picture thinking?
- How do you cultivate a supply base whose values align with yours – especially in corporate, environmental, and social responsibility?
- How can you engage suppliers in an ongoing dialog that supports your innovation?
- How do you ensure that your suppliers proactively manage total quality standards for their raw materials as well as those of their own suppliers throughout the chain?
- What steps can you take now to personally transition your sourcing organization to a driver of value, versus a manager of costs?
- What internal tools and specialized knowledge are needed to integrate sources of new value?



Pioneering science delivers vital medicines™

Reducing Risk in Product Supply Amgen Operations

Tim Valko, Executive Director, US Supply Chain
November 19, 2014

Safe Harbor Statement

This presentation contains forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and most recent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of November 19 2014, and expressly disclaims any duty to update information contained in this presentation.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. The Company's results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments (domestic or foreign) involving current and future products, sales growth of recently launched products, competition from other products (domestic or foreign), difficulties or delays in manufacturing our products. In addition, sales of our products are affected by reimbursement policies imposed by third-party payors, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and health care cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and products liability claims. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers.

Risks to Product Supply can Cause Drug Shortages or Threaten Patient Safety

Drug Shortages

- A recent study (US FDA) has further highlighted drug and medical product shortages as a significant public health issue
 - Since 2005, drug shortages have tripled in the US
 - 80% involve sterile injectables, including cancer drugs and antibiotics
 - 68% are attributed to problems at the manufacturing facility, delays in manufacturing or shipping, or active pharmaceutical ingredient shortages
- Similar issues have also been experienced in the EU
 - e.g. chemotherapy agents and other injectables (Tirelli, et.al.)

Threats to Patient Safety

- Product integrity is vulnerable to illicit activity in all phases of the supply chain
 - Illicit activities include: theft, diversion, counterfeit, and intentional adulteration

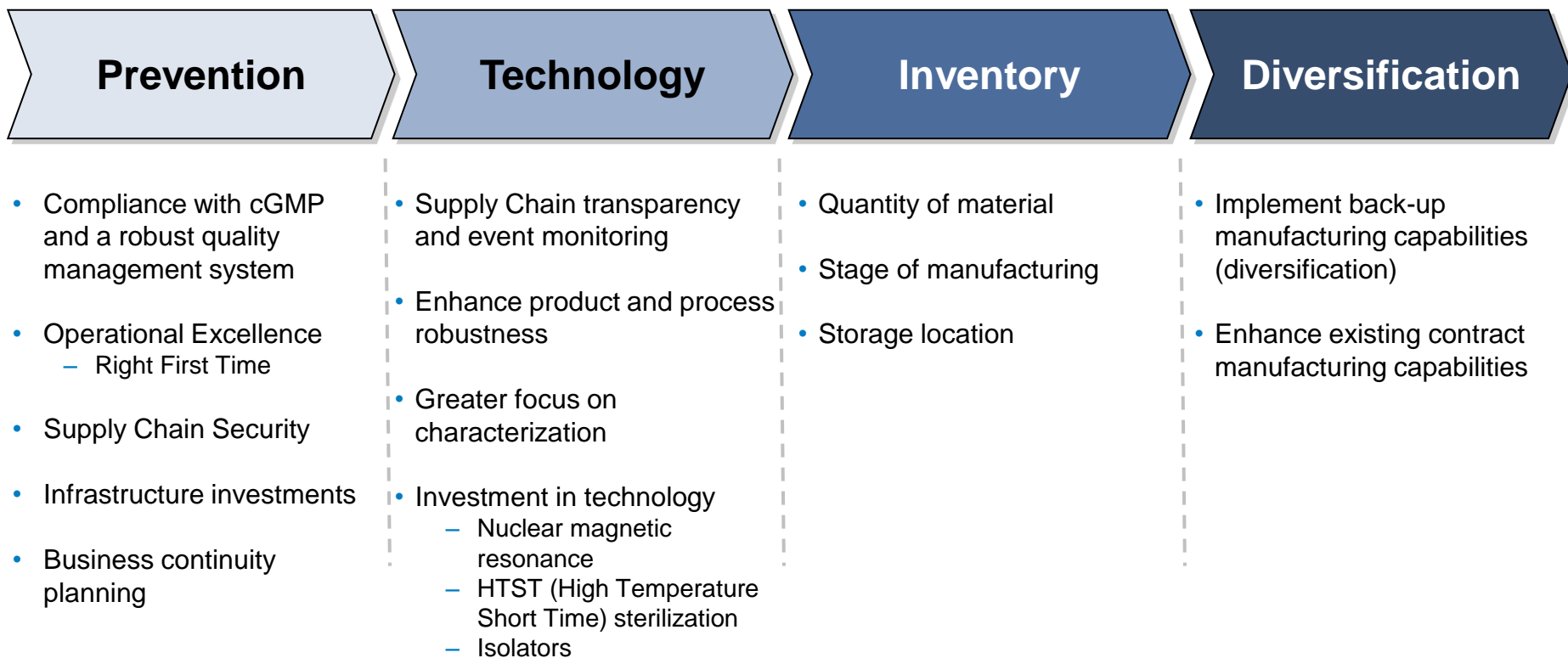
Companies have an obligation to take action to protect against these risks

Every Patient, Every Time

- It is a privilege to serve patients with grievous illnesses
- Ensuring dependable supply is at the heart of Amgen's social architecture
- We employ a broad array of tools to manage risk and prevent drug shortages
- We made significant investments to reduce risk; more are planned and underway

Amgen is committed to ensuring patients have access to high-quality medicines and is making significant efforts regarding supply chain risk mitigation

Amgen has Implemented a Comprehensive Approach for Managing Product Supply Risk



Amgen's risk management program is designed to prevent supply interruptions

Amgen is Working to Protect Patient Safety Through End-to-End Supply Chain Security

Supply Chain Processes

Plan / Source

- Supplier Relationship Excellence program
- Supplier lot genealogy
- Raw materials second sourcing
- Expanded raw materials testing

Make

- Quality System
- Serialization technology
- Overt and covert security features
- Warehouse security systems

Deliver

- Cargo security at pallet, truck, and carrier level
- Distribution channel audits
- Cargo tracking technology

Monitor

- Counterfeiting and illegal diversion signal detection
- Hoarding prevention
- Rx-360
- C-TPAT certification

Amgen Participates in the Rx-360 Supply Chain Consortium to help combat the threats of theft, counterfeit, diversion and intentional adulteration

Where is the Rx-360 Going?

2011 - 2012

SCS Management System
Cargo Theft Risk Management
Threats and Monitoring
Audits & Assessments of 3rd
Party Providers

2012-2013

Illegal Diversion
Incident Management
Serialization/Implementation
Discussion
Health Provider Education
Drug Shortages

2013-2014

Cargo Theft - High Risk
Upstream SCS
Africa Supply Chain
Traceability Data Exchange
Architecture (TDEA)
Serialization/Implementation
APEC efforts
Asia WG/SCS

White papers/tools deliverables

Knowledge Sharing; Education



Rx-360 Participation – Current Groups

Supply Chain Security Steering Committee

39 volunteers

20 companies

17 pharma

3 suppliers

Upstream Supply Chain Security

34 volunteers

20 companies

10 pharma

9 suppliers

1 medical device

Cargo Theft

20 volunteers

12 pharma

Africa Supply Chain

10 volunteers

8 companies

7 pharma

1 supplier

Traceability Data Exchange Architecture

73 volunteers

14 member
companies

33 non-member
organizations



To Serve Every Patient, Every Time

- Commitment starts with the top executives and has to be part of the company's culture
- Effective prevention of drug shortages requires a holistic and multifaceted risk management strategy
- Industry collaboration can help in building awareness and in developing mitigation strategies
- It is not easy or cheap to serve every patient, every time
- Regulators can have a major impact on the adoption by industry of supply risk management practices

Poll Question #1

Rank your supply chain for responsible business practices:

- 1) Exceptional - leading the business/industry standard
- 2) Better than most - above average for our industry or market
- 3) Adequate but needing new approaches
- 4) Seriously inadequate - inherent risks
- 5) Dangerously exposed - vulnerable to liabilities



We Enable Science

Colin Lafferty

Vice President – Operations,
Supplier Quality Management;
VWR International, LLC
Supplier Member; Rx-360
International Pharmaceutical
Supply Chain Consortium

**CRA : Global Supply Chain Complexities and the
Changing Risk Management Agenda**



VWR Contribution to CRA Webinar : Global Supply Chain Complexities and the Changing Risk Management Agenda

- **Background on VWR**
- **Supply Chain Risks** as cited by Life Science Executives
- **Supplier Management** Processes
- Risk Mitigation via **Business Continuity**
- **Sustainability Charter**
- Corporate Responsibility **Audits**

Overview of VWR

We Enable Science

- Worldwide sales in excess of \$4.3 billion USD
- 4,000 Suppliers
- 120,000 Customers
- Over 8,500 Associates in 35 Countries
- Over 1,200 Customer Site Service Associates

We offer **reliable** and **transparent** supply chain **solutions** designed to decrease the complexity you encounter. **Manage** the risk you face by harnessing our global strengths:



Supply Chain Vulnerabilities Cited as the #1 Risk for Life Science Companies in the June, 2014 BDO Life Sciences Risk Factor Report

The *2014 BDO Life Sciences RiskFactor Report* examines the risk factors listed in the most recent annual shareholder filings of the 100 largest publicly traded U.S. life sciences companies listed on the NASDAQ Biotechnology Index by revenue. The risk factors were analyzed and ranked in order of frequency cited.

Top 25 Risk Factors for the 100 Largest U.S. Life Sciences Companies

2014 Rank		2014	2013
1.	Supply Chain and Supplier/Vendor Concerns	100%	93%
2.	Federal, State and/or Local Regulations	98%	100%
2t.	Intellectual Property Infringement	98%	96%
4.	Competition and Consolidation	97%	100%
4t.	Ability to Commercialize & Market Products	97%	96%
4t.	Volatility of Revenue/Stock Price	97%	92%
7.	Product Liability and Insurance Costs	95%	87%
8.	Ability to Attract and Retain Key Personnel	94%	96%
8t.	FDA Approvals and Compliance	94%	94%
10.	Legal Proceedings	91%	84%



The VWR Supply Chain Supplier Scorecard

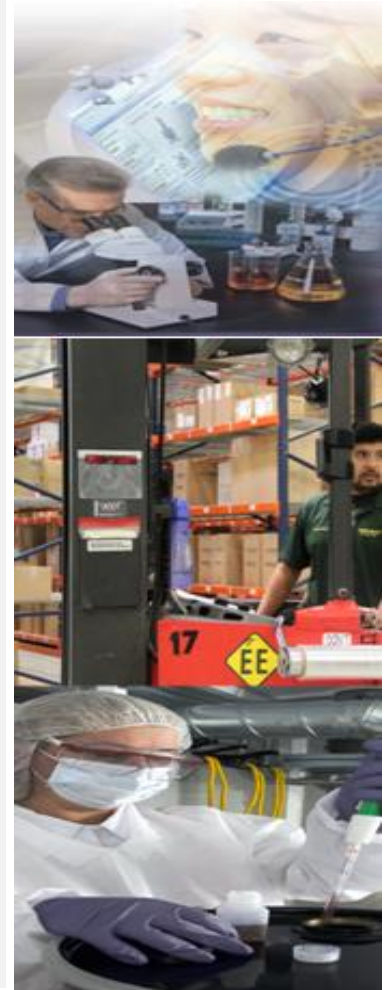
VWR Maintains a Robust Supplier Scorecard System Which Trends Supplier Performance.

Key Elements Include:

Measurable Data to Improve Supply Chain Integration

Quality Records such as Defects, Damage or Complaints to View Product Performance

Twelve Rolling Months of History.



VWR Maintains A Risk Based Supplier Audit Program

Key Focus areas include:

Subcontractor Management

Supply Chain Security

Packaging Labeling Integrity

Plant Security

Capacity

Change Notification

Sustainability

VWR Business Continuity Alignment



Crisis Management

Strategies and actions designed to protect people, property and business functionality, while preparing for recovery of critical processes.

Business Recovery

Resuming critical business processes in a reasonable timeframe and to a minimum acceptable level using alternate facilities, resources, personnel, technologies and/or processes.

IS Disaster Recovery

Resuming critical technologies (applications, communications and PCs/printers) based on business requirements.

Educating Suppliers on Sustainability

VWR Supplier Sustainability Charter

In 2013 launched a communication to suppliers defining VWR's sustainability expectations around ethics, health & safety, worker's rights, environment and governance



I acknowledge that I have reviewed this Sustainability Charter and understand VWR's expectations of suppliers.

Sustainability Charter

Sustainability Charter for VWR Suppliers

VWR is committed to sustainability by balancing People, Planet, and Performance in our operations. We strive to enhance the value of the Company over the long term in the interests of its owners, associates, and society as a whole by working together with suppliers and customers to seek and implement flexible and innovative ways to achieve our environmental, social, and economic objectives.

VWR's three priorities are:

1. **Social Impact (People)** - Focusing on associate health, safety, wellness, development and training, as well as community engagement in the areas where we work and live.
2. **Environmental Protection (Planet)** - Minimizing the use of resources, preventing pollution, and protecting ecosystem health.
3. **Economic Growth (Performance)** - Driving growth of the company through innovative projects and continual improvement.

In an effort to address sustainability throughout our supply chain, VWR has the following expectations of our Suppliers and will work with Suppliers to incorporate these values into their business operations.

Table of Contents

Social Impact	Section 1
Ethical Business Practices	1.1
Health & Safety	1.2
Workers' Rights	1.3
Environmental Protection	Section 2
Compliance and Training	2.1
Conservation of Resources	2.2
Waste Management	2.3
Governance	Section 3

VWR 2013 PSCI and SEDEX Audits

Pharmaceutical Supply Chain Initiative (PSCI)

The Pharmaceutical Supply Chain Initiative (PSCI) is a group of major pharmaceutical companies who share a vision of better social, economic and environmental outcomes for all those involved in the pharmaceutical supply chain. This includes improved conditions for workers, economic development and a cleaner environment for local communities.

SEDEX

Sedex is a not for profit membership organization dedicated to driving improvements in ethical and responsible business practices in global supply chains. - See more at: www.sedexglobal.com

- **Outcomes of Audit:** NO FINDINGS
- **Customer Remarks:** “You demonstrated a very high commitment to sustainability. It occurs very rarely that the auditors have no findings like in your case. You can take this as a clear confirmation that your standards are very high.”

Poll Question #2

Rank your CR program for overall organization impact:

- 1) Exceptional - leading the industry/market standard
- 2) Better than most - above average for industry/market
- 3) Adequate but needing new approaches
- 4) Seriously inadequate - inherent risks
- 5) Dangerously exposed - vulnerable to liabilities

TRACEABILITY ISSUES IN SUPPLY CHAIN MANAGEMENT FOR THE FOOD AND BEVERAGE INDUSTRY



JEFFREY LABARGE
NOVEMBER 19, 2014

WHY IS TRACEABILITY IMPORTANT?

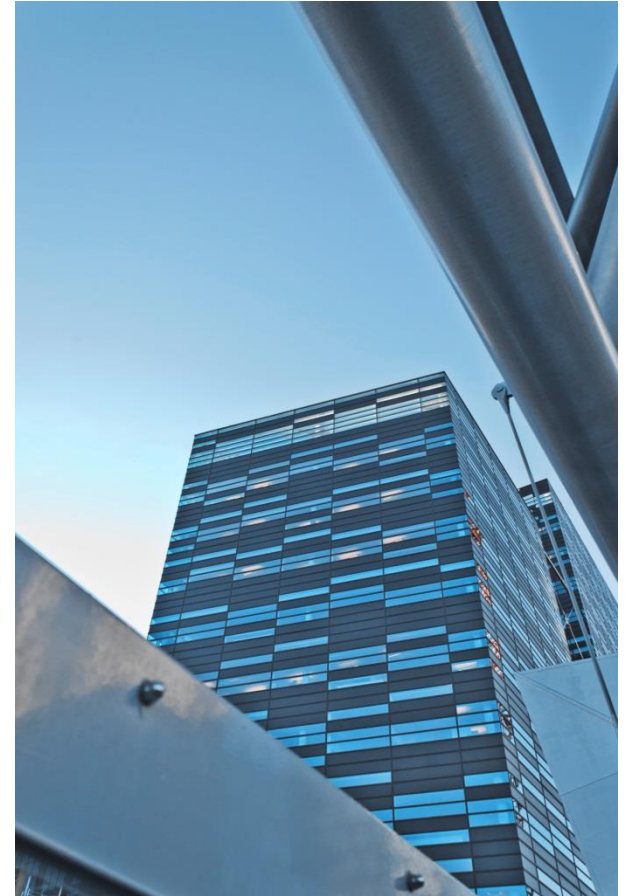
Legal/Regulatory Requirements

Substantiating Product Claims

LEGAL/REGULATORY REQUIREMENTS

– AN EXAMPLE OF WHAT IS AHEAD

- Food Safety Modernization Act.
 - Be Prepared for Change.
- More State Involvement.
 - State GMO Labeling Laws.



SUBSTANTIATING PRODUCT CLAIMS

- Food manufacturers have clearly realized that “healthy” food claims such as *all natural*, *gluten free*, *organic*, *sugar-free*, are appealing to customers and customers will pay more for those products.
- For example, the market for gluten free products alone was 10.5 billion in 2013, and is predicted to increase 48% to 15.6 billion in 2016.
- That increase in popularity has also lead to many consumer protection groups bringing lawsuits for false advertising.

LEGAL STRATEGIES FOR ADDRESSING TRACEABILITY ISSUES

- Contract Clauses.
 - Understanding the issue is key.
 - Contracting for your supplier's suppliers.
- Audit/Inspection/Samples/Notices.
 - Important ways to make sure that you know what your supplier is doing during the term of the contract.
- Questionnaires/Certificates.
 - Not just more paper.



Join in!
Questions and Comments



Tim Valko



Colin Lafferty



Jeff LaBarge



Art Stewart

Corporate Responsibility Association (CRA)
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Join us for Part Two:

Wednesday, February 11, 2015 | 12 Noon EST



Joel Sutherland

Managing Director – Supply Chain Management Institute
Adjunct Professor, Supply Chain Management – University of San Diego



Jeff Tanenbaum

Partner, Labor & Employment practice/Chair, Occupational Safety & Health focus
Nixon Peabody

Additional panelist to be announced.

Thanks to today's panelists!

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Colin Lafferty: Colin_Lafferty@vwr.com

Jeff LaBarge: jlabarge@nixonpeabody.com

Art Stewart: info@ArtStewart.com