



# Auditing Your Global GHS Program

Employee health and  
product safety,  
stewardship, and  
compliance

Medical Department

Toxicology & Compliance Solutions

Occupational Medicine & Health Physics

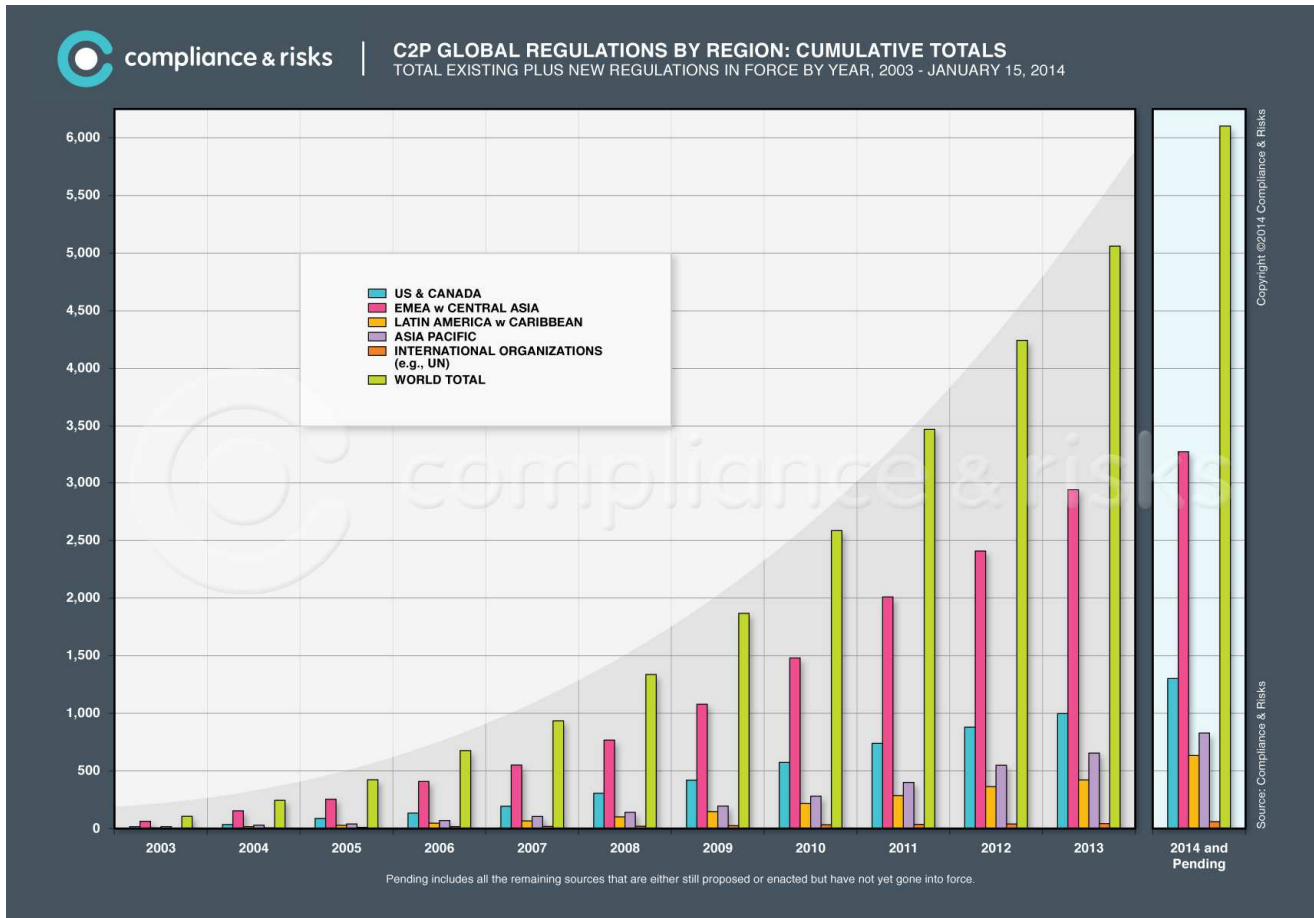
EHS Information Services

Operations

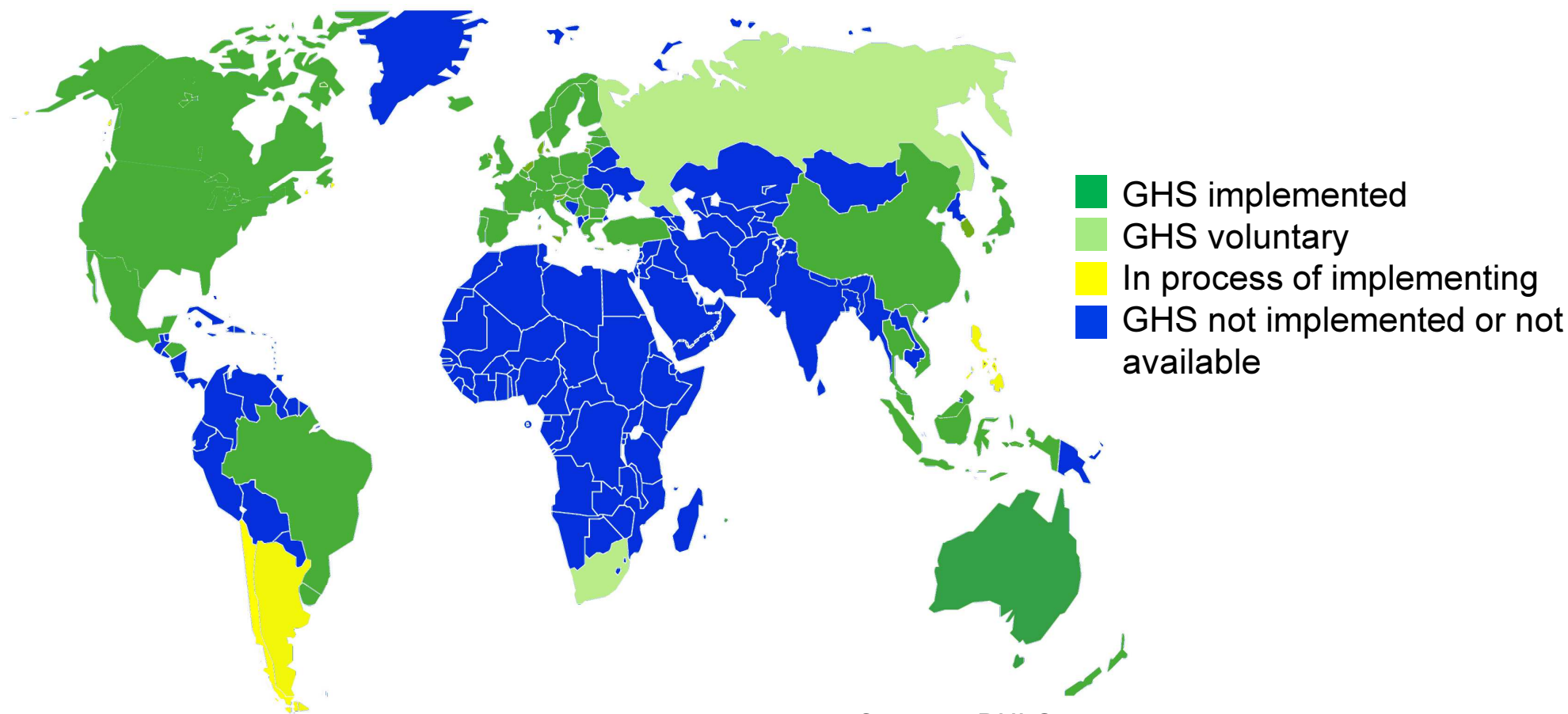


# Value Proposition of Auditing Your Global GHS Program

# Proliferation of Product Regulations Globally



# Proliferation of GHS Regulations Globally



# Reasons to Audit

- Routine audit schedule
- Identified risks
- Merger or acquisition
- Expansion into new markets
- Expansion into new geographies
- New or significant product revisions



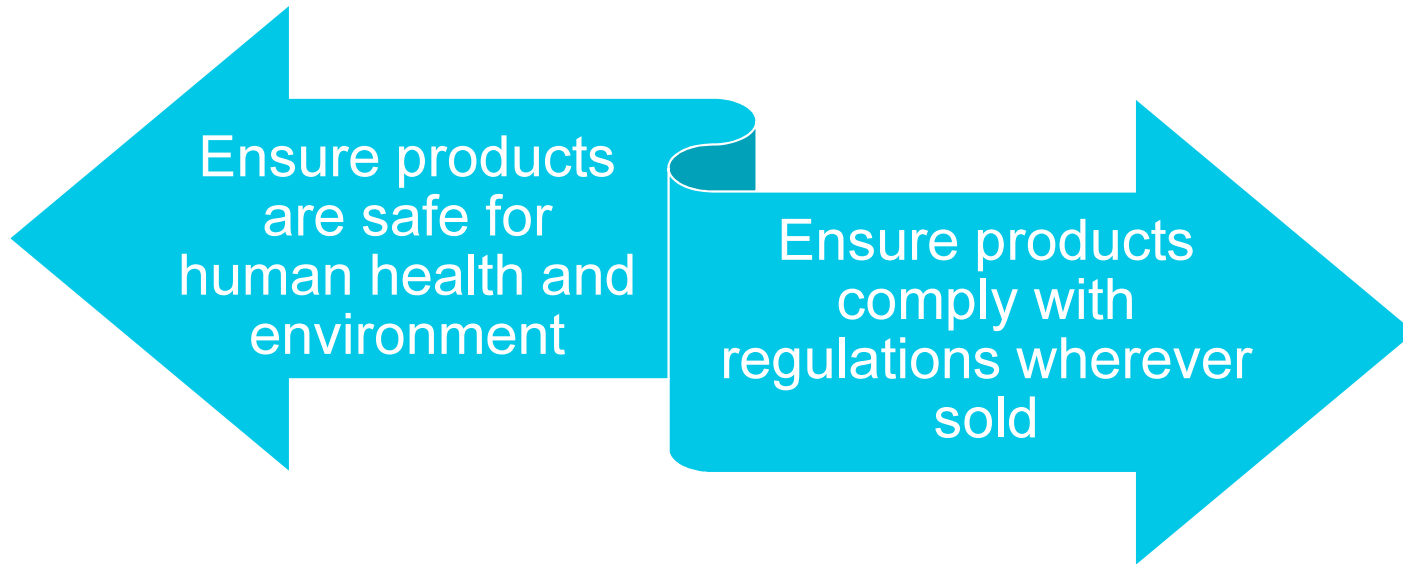


# Scope of Your Global GHS Audit Program

# Hazard Communication Audit Scope



# Hazard Communication Audit Scope





# Hazard Communication Audit Scope

- Implementations of UN GHS Guideline
  - US OSHA Hazard Communication Standard
  - EU Classification, Labelling and Packaging
  - Canada Hazardous Products Regulations
  - Total of 72 unique implementations of UN GHS Guideline
- Other non-GHS Safety Data Sheet and Labeling Regulations
  - Peru Safety Summary Sheet for the Transport of Hazardous Substances
  - Chile Consumer Protection Law
  - India Hazardous Substances (Classification, Packaging and Labelling) Rules

# Hazard Communication Audit Scope

## Sample Compliance Audit Criteria

- Product hazards are correctly classified per GHS criteria
- Safety data sheets are published for hazardous products
- Safety data sheets are distributed with hazardous product shipments
- Safety data sheets meet hazardous ingredient disclosure requirements
- Hazardous product labels include correct pictograms
- Hazardous consumer product labels include correct precautionary statements
- Safety data sheets and labels are in local language

# Hazard Communication Audit Scope

## Sample Quality Management System Audit Criteria

- Chemical data is stored in the company's centralized database
- All products sold are evaluated to determine whether an SDS is required
- The decision as to whether an SDS is required (and the basis for that decision) is documented
- SDSs are published to the company's electronic database
- Final label artwork is reviewed by a qualified hazard communication professional
- Hazard communication processes are documented in writing



# Preparing for Your Global GHS Audit



Obtain or Prepare Protocols

# Obtain or Prepare Protocols

## Internal Protocols

- Your company may have established internal expectations for hazard communication
  - Codified in a principle, policy, or standard
  - Written procedures
  - Formal internal audit expectations (self-assessments, evaluation tools)

# Obtain or Prepare Protocols

## Independent Protocols

- “Ready-to-use” protocols are available to purchase
  - Not available in all jurisdictions
- Custom-built protocols for deep dives into regulations
- EHS auditing firms have built their own protocols for their product stewardship auditors (including product hazard communication)

# Obtain or Prepare Protocols

Develop from scratch

- Regulatory knowledge of company's hazard communication specialists
- Methodical walkthrough of local regulations
- On-the-ground, practical knowledge of good hazard communication practices
- As starting point, can model after EHS protocols



# Obtain or Prepare Protocols

## Practical Challenges and Solutions

- No standardized SDS or label compliance protocols are currently available for the jurisdiction
  - Develop or obtain “model” protocol for GHS regulation in another jurisdiction – keep the structure, but modify the detail
  - Use “universal” management system protocol instead
- EHS compliance protocols available for jurisdiction, but regulatory coverage of SDS and labels not deep enough
  - Work with provider to expand the SDS and label requirements
  - Local language skills





# Auditor Selection and Qualifications

# Auditor Selection and Qualifications

- Selection of an audit team is based on their meeting the following major qualifications:
  - Auditing skills
    - Independent, objective, observant, detail-oriented
    - Writing skills
    - Interviewing skills
  - Local regulatory expertise
    - Direct compliance work
    - Auditing
  - Local language proficiency
    - Written proficiency – reviewing documentation
    - Verbal proficiency – interviewing

# Auditor Selection and Qualifications

- Other considerations for the composition of the audit team
  - Acceptance to client
    - May need at least one internal auditor to accompany team
  - Knowledge of the industry
    - Improved understanding of regulation applicability and impacts
    - Improved understanding of regulatory risks
  - Knowledge of the client

# Auditor Selection and Qualifications

## Practical Challenges and Solutions



- Ideal
  - Experienced product hazard communication auditor
  - Expert in local hazard communication regulations
  - Fluent in local language
- Very unlikely outside the United States!
- Practical
  - Find an experienced local EHS auditor that has also done some product hazard communication compliance work
  - Use an experienced U.S. product hazard communication auditor in an international location (either in-person or remote)
  - Pair an experienced local EHS auditor with a hazard communication compliance expert

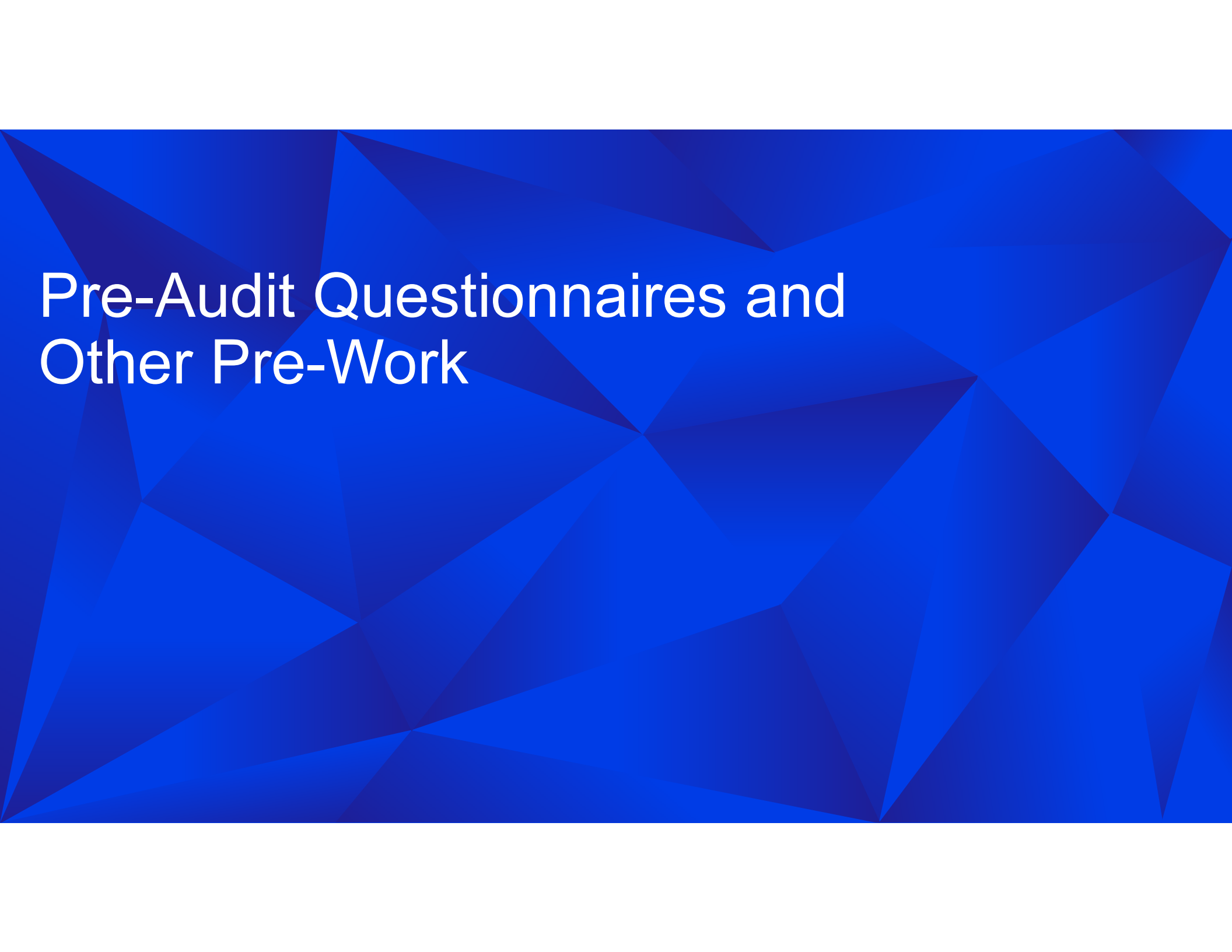
## Auditor CV for Mexico Product Hazard Communication Audit

### Audit

- Conducted EHS legal compliance audit for automotive manufacturing plant in Reynosa, MX
- Conducted EHS legal compliance audit for pharmaceutical manufacturing operation in Mexico City, MX
- Conducted EHS legal compliance audit for consumer product manufacturing operation in Acuna, MX
- Conducted an EHS and security audit of two engineered glass materials production facilities located in Tlalnepantla, MX
- Conducted H&S legal compliance audit for citrus grower in Chihuahua, Mexico, □
- Conducted an environmental audit in for heavy equipment manufacturer in Saltillo, MX
- Conducted EHS and transportation audit for pharmaceutical manufacturing operation in Xochimilco, MX

### Compliance Support

- Reviewed and update labels, instructions, and guarantees to meet Mexican regulatory standards for pharmaceutical products
- Obtained NOM product certification for pesticide company
- Arranged testing and obtained NOM certifications for pesticide company
- Interfaced with downstream customers to communicate safety of chemicals for their intended end-uses
- Designed and implemented a Health and Safety program based on Mexican Standards
- Support introducing IT system for MSDS development
- SDS development and review for chemical and manufacturing industry
- Research and monitor regulatory updates and legal amendments of EH&S standards in Mexico



# Pre-Audit Questionnaires and Other Pre-Work

# Pre-Audit Questionnaires and Other Pre-Work

- You will generally complete three types of audit pre-work for a hazard communication audit
  - Pre-audit questionnaires
  - Data analysis
  - Document request
- You will also make practical preparations
  - Travel arrangements
  - On-site schedule





# Pre-Audit Questionnaires

## What is it?

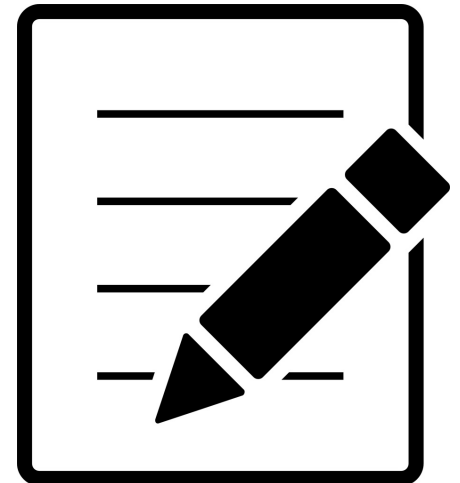
- Means to collect information to facilitate audit performance. It generally includes:
  - Basic location info
  - Summary of product portfolio
  - Roles and responsibilities, including names of assigned staff
  - Types and frequency of manufacturing operations
  - Types and frequency of product-related business processes
  - Hazard communication policies and standards
  - Overview of documentation systems



# Pre-Audit Questionnaires

## What is the purpose?

- Narrowing and prioritization of elements of protocol
- Development of specific audit schedule
  - How much time to allot to sections of protocol
  - Who to interview
- Direct input into audit report (e.g. introduction or background section)
- Preliminary identification of risk areas for nonconformance
- Feeds data requests and document requests
  - Pre-audit requests
  - Identification of documents and systems to review while on site



# Arrange Specific Schedule

- Important to create the schedule in advance
  - Ensure that allot enough time to cover whole scope
  - Ensure that critical staff are available during the audit
- Selection of interviewees based on pre-audit questionnaire
  - Staff responsible for product labeling and creation of SDSs
  - Product developers
  - Toxicologists, IHs, and other subject matter experts
  - Marketers
  - Management

Monday	Tuesday	Wednesday	Thursday	Friday

# Data Analysis

## What is it?

- Depending on scope of audit, a request for data followed by a detailed analysis to check for hazard communication applicability
- Examples of requested data:
  - List of products sold in last 12 months, with volumes
  - List by manufactured, imported, or outsourced
- Examples of analysis
  - Which of the products are hazardous
  - Which of the products have data in central systems
  - Which of the products have SDSs published to central document systems

Order_Date	REQ_Date	Sales_Con	Price_Per	STTY	STTY_Sub	POTO_Ord
9/17/2014	9/26/2014	H	U	0	1	EACH
12/11/2014	12/22/2014	H	N	0	0	CASE
12/3/2014	12/12/2014	H	N	0	0	CASE
10/21/2014	11/21/2014	H	N	0	0	CASE
12/8/2014	12/19/2014	H	N	0	0	CASE
12/8/2014	12/19/2014	H	N	0	0	CASE
10/9/2014	11/7/2014	H	N	0	0	CASE
6/6/2014	7/22/2014	S	N	0	1	PADS
9/10/2014	9/18/2014	S	U	0	1	EACH
10/10/2014	11/14/2014	K	N	0	0	RLS
6/12/2014	7/18/2014	K	N	0	0	RLS
3/25/2014	5/7/2014	K	N	0	0	RLS
3/3/2014	4/10/2014	K	N	0	0	RLS
10/24/2014	11/28/2014	K	N	0	0	RLS
10/1/2014	1/9/2015	S	N	2	0	PADS
8/7/2014	11/17/2014	S	N	2	0	PADS
7/8/2014	10/6/2014	S	N	2	0	PADS
7/16/2014	10/27/2014	S	N	2	0	PADS
5/28/2014	9/12/2014	S	N	2	0	PADS
4/30/2014	8/8/2014	S	N	2	0	PADS
3/28/2014	5/28/2014	S	N	2	0	PADS
10/22/2014	11/26/2014	K	N	0	0	RLS
10/31/2014	12/5/2014	K	N	0	0	RLS
10/10/2014	11/14/2014	K	N	0	0	RLS
9/30/2014	11/25/2014	K	N	0	0	RLS

# Data Analysis

## What is the purpose?

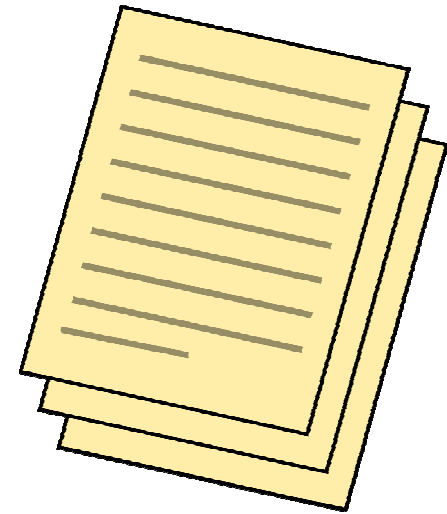
- What is the purpose?
  - Narrowing and prioritization of elements of protocol
  - Identification of nonconformances
  - Direct input into audit report (metrics on numbers of materials and their regulatory status)
  - Feeds document requests
    - Pre-audit requests
    - Identification of documents to review while on site

Order_Date	REQ_Date	Sales_Con	Price_Per	STTY	STTY_Sub	POTO_Drc
9/17/2014	9/26/2014	H	U	0	1	EACH
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10/1/2014	1/9/2015	S	N	2	0	PADS
8/7/2014	11/17/2014	S	N	2	0	PADS
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10/30/2014	11/14/2014	K	N	0	0	RLS
9/30/2014	11/25/2014	K	N	0	0	RLS

# Document Request (and Analysis)

## What is it?

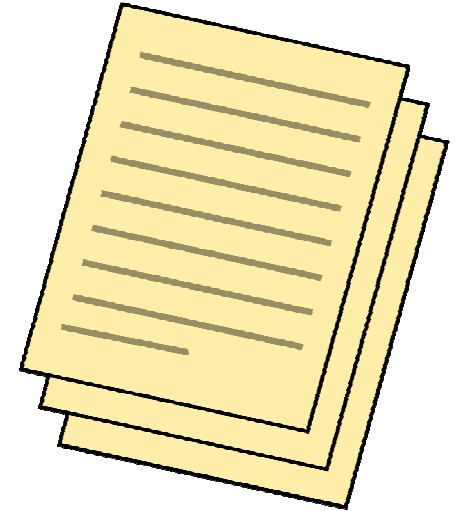
- An advance request for product regulatory documents to improve on-site efficiency
  - Written procedures
  - SDSs
  - Product labels
- Provide appropriate time deadline
- Document review optionally may be completed prior to on-site portion of audit



# Document Request (and Review)

## What is the purpose?

- Improve on-site efficiency
  - Can be time consuming to retrieve documents during audit
  - Client staff needed for tours and interviews
- Identification of nonconformances
  - Request: Failure to produce the document when requested may constitute an audit finding
  - Review: Documents may have errors that constitute an audit finding
- Direct input into audit report (# documents reviewed)
- Assembly of document package for remote reviewer
  - Document reviewer may be a local expert that does not participate in on site audit



# Document Request (and Analysis)

## Practical Challenges and Solutions

- May sell thousands of products into jurisdiction
- No easy way to tell which are hazardous
  - Use quick screens such as product form, data flags, product category, trade name, units of measure in sales report
  - Send filtered list of remaining products with unknown hazard status to client
- Do not have resources to audit every product
  - Prioritize products based on system searches
    - Volume, system status, dated or missing documents
  - Audit random sample of prioritized products
    - Suggest 50-100 products
    - Ensure request is distributed across the supply chain
    - Typically use same list of products for SDSs and labels





The background of the slide is a complex, abstract pattern of overlapping triangles and polygons in various shades of blue, ranging from light cyan to deep navy. The shapes are arranged in a way that creates a sense of depth and movement, resembling a low-poly or crystalline structure.

# Conducting Your Global GHS Audit

# Conducting Your Audit

Good auditing practices apply to a product hazard communication audit

## Conduct opening meeting

- Auditor introductions, audit program background, audit scope, audit process, questions
- Product steward(s), R&D manager, EHS manager, site manager

## Use good interviewing skills

- Explain the process
- Paraphrase your understanding of responses
- Write down responses
- Use similar questions among interviewees

# Conducting Your Audit

Good auditing practices apply to a product hazard communication audit

## Ongoing communication of findings

- Informal
- At least daily

## Conduct closing meeting

- Audit scope review, findings, observations, performance levels, next steps, questions
- Findings include risk rankings and corrective actions
- Same attendees as opening meeting

# Conducting Your Audit

## Specific considerations for product hazard communication audits

- Conduct tours
  - Manufacturing
    - Product and process engineers
    - On-site EHS staff
  - Distribution center
    - On-site EHS staff
- No tour of product development lab



# Conducting Your Audit

## Specific considerations for product hazard communication audits

- Document review
  - SDSs and labels collected in advance and reviewed by third party auditor
    - Local language skills essential
    - Remote or on site
    - Review specific format and content requirements
    - **Hazard classifications**
  - Spot check of SDSs and labels while on site
  - Written procedures reviewed while on site

# Conducting Your Audit

## Practical Challenges and Solutions

- Expensive to travel to each jurisdiction that sells your products globally
  - Remote audits can be effective
  - Focus solely on document review (desktop audit)
  - Schedule back-to-back audits within a region
- Interviewees are same people that need to collect documents
  - Other than spot checks, request all SDSs and labels in advance





# After Your Global GHS Audit

## After Your Audit

Good auditing practices apply to a product hazard communication audit

### Provide timely report

- Risk ranking of findings
- Performance levels
- Management action plans

### Close findings

- Tracking
- Documentation to demonstrate closure
- Escalation process (if needed)



# After Your Audit

## Specific considerations for product hazard communication audits

- Establish timelines to obtain and review required documents not located during the audit
  - Delays in producing documents may result in findings
  - Cannot issue report until all documents reviewed
- For product hazard communication audits, tend not to have findings that require:
  - Stop sale
  - Product quarantine
  - Product recall
  - Self-disclosure to governing body

# Lessons Learned

What's next for our program?

- Document review process for hazard communication audits very effective
  - Now being used in general product stewardship audits
- Labels harder to audit than SDSs
  - Even with GHS, lots of hazard-related local label elements – so will continue to develop location-specific protocols
  - Develop better strategies to obtain labels
- Global program depends on centralized GHS classification of hazards
  - Certain jurisdictions, such as EU CLP, present unique challenges
  - Future audit of classification process

Thank you