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HOW TO ACHIEVE MATERIALS INVENTORY SAFETY, EFFICIENCY AND COMPLIANCE FOR LIFE SCIENCES

White Paper

DASSAULT SYSTEMES

Life Sciences organizations need to bring new high-quality therapeutics to market quickly to respond to patient needs specific to different diseases and geographies. But development time and costs for new therapeutics are high and efforts to comply with global and regional regulations as well as to ensure that therapeutics are safe, efficacious and compliant with specifications are significant. To speed time to market while reducing costs and regulatory risks organizations need to transform how therapies are discovered, developed and produced. Testing is a key to confirm therapeutic characteristics discovered during research, to identify and optimize formulations for production and scale-up, and to confirm the quality and efficacy of active ingredients and products. To achieve the required transformation and accelerate drug development, reduce costs and enhance compliance and quality, Life Science organizations must improve lab testing efficiency and safety and fully leverage the data they generate.

Inconsistent, inefficient and inaccurate materials inventory management processes are incurring higher risk and cost, and industries are investigating ways to address these challenges.

Laboratory incidents based on expired or inadequate storage of chemicals are one of the major risks in laboratory operations that can damage the lab, the people and the reputation of an organization. So proper chemicals and materials management is critical. At the same time the frequency with which federal, state and local safety regulations are being updated is not only increasing, but the regulations are also growing in number and complexity. This makes it confusing and difficult to ensure compliance. When the regulations concern chemicals, it is vital that the organization deploy efficient processes and systems that enable laboratory and Environmental, Health and Safety (EHS) personnel to easily comply with the regulations, ensure safe chemical management and produce accurate chemical inventory reports. Laboratories must be operated safely and in accordance with a variety of government regulations; thus it is important to avoid situations of safety risks and noncompliance caused when chemical inventory management is inconsistent or ineffective.

This white paper discusses the obstacles Life Sciences companies face in ensuring chemical safety and compliance and lab efficiency related to chemical and materials management. The paper will also discuss how different organizations have solved the challenge of mitigating compliance and safety risks while improving lab productivity.

CHALLENGES IN ENSURING MATERIALS INVENTORY EFFICIENCY AND SAFETY AND REGULATORY COMPLIANCE

There are four key challenges confronting research organizations and manufacturing facilities that utilize large quantities of materials (chemicals, consumables etc.) in their work processes and that create formulated products (batches, intermediates, solutions, etc.) in their laboratories. These challenges arise from inconsistent materials tracking, inefficient materials-related work processes, inaccurate materials inventory reports and high-risk, hazardous materials management mistakes.

Consistently Tracking Chemicals and Materials

Maintaining regulatory compliance of chemical inventories can be difficult when inventory ownership is poorly defined or shared. What often happens is that the site may use an inconsistent, nonstandard way to register materials, with the process varying from laboratory to laboratory or even from person to person. One lab may keep their materials records in a spreadsheet; the other may use a manual logbook. Further, personnel within the same lab may not be updating the spreadsheet every time a materials container is received or disposed. Such disconnected processes make it difficult to track materials container location, quantity or even whether it is stored correctly. Without this data, it is almost impossible to ensure safe chemicals management or produce accurate regulatory reports. The inappropriate tracking of materials can also lead to unnecessary production or purchase of materials when scientists require a material but cannot locate it in the system. And it will lead to more expired chemicals and therefore waste when more is ordered instead of using what is on hand. Unnecessary costs are the consequence. In addition, staff will waste time searching for materials, in the system or even physically, or they will unnecessarily produce or order new materials, which can negatively impact inventory management and scientists' productivity.

Efficient Materials-related Processes

A second key stumbling block is confusion over who is responsible for materials inventory reports. Typically, lab personnel order materials for their research, but EHS personnel are responsible for reporting those chemicals to the regulatory agencies. This disconnect produces a very inefficient process with no centralized system for managing chemicals receipt and tracking. EHS personnel collect the information for their reports not by checking a centralized system, but by repeatedly asking lab personnel to produce reports specifying the materials containers in their lab. This takes the lab personnel away from the research bench to repeatedly perform an administrative task that could have been avoided with a more efficient materials management process. EHS may in turn be required to perform frequent inventory counts to confirm or correct the lab inventory reports, resulting in excessive time spent on this non-value adding task.

Accurate Chemical Reports

The third challenge, hinted at in the previous paragraphs, is that the EHS reports provided to the regulatory bodies can be inaccurate as a result of inconsistent chemical tracking. This risk, if revealed during a chemical management audit by a regulatory agency—such as an audit by the Environmental Protection Agency (EPA) to confirm accuracy of Tier II reports—can subject the organization to greater regulatory scrutiny, fines and worse. Beyond regulatory compliance risk, the site safety may be at risk, even if unknowingly, when the exact quantity and location of materials are not certain.

Hazardous Materials Management

Finally, the highest risk that results from inaccurate materials management is the risk of incorrectly identifying hazardous

materials on site and thus improperly managing those hazardous materials. There are numerous regulations that specify how hazardous materials should be received, stored, tracked and disposed, as well as thresholds for the amount of hazardous materials that can exist on a site without reporting the over-threshold amount. Oversight of hazardous materials management is seldom deliberate, but this provides little solace when something goes awry.

It is important to note that disposition of outdated chemicals and containers is vitally important, whether the materials are hazardous or toxic or not. This is because the chemistry of some chemicals can change over time or after the container is opened. For instance, 2,4-Dinitrophenylhydrazine (DNPH, Brady's reagent), or the chemical compound $C_6H_3(NO_2)2NHNH_2$, is a shock explosive that requires care when used. It is usually supplied wet to reduce its explosive hazard, since it becomes a hazardous material when the material changes from a liquid to a powder. It is critical to ensure that disposal of expired and hazardous materials takes place correctly and in accordance with government regulations.

Further, there is often a high cost associated with disposing of expired chemicals as well as an increased safety risk. If an expired container of 2,4-Dinitrophenylhydrazine is discovered during an inventory count, activities must come to a halt, the lab closed, and a hazardous materials team called in to dispose of the container safely. This potentially dangerous situation can be costly and disruptive.

Finally, another key aspect of hazardous materials management is not providing the most recent information about materials through current Safety Data Sheets (SDS) distributed to the lab personnel who use them. Mandated by Right-to-Know regulations such as those promulgated by the Occupational Safety and Health Administration (OSHA) and the European Chemicals Agency (ECHA), the responsibility for providing and disseminating SDS information can fall under the responsibility of either the lab manager or EHS or both. This makes it a challenge to ensure that employees not only know how to access SDSs but also have the current versions.

SOLVING THE MATERIALS INVENTORY CHALLENGE

As with all science-based organizations, Life Sciences organizations must provide a laboratory environment where scientists can work safely and efficiently focusing on science instead of being distracted by non-value adding tasks or safety and compliance risks.

Avoid Chemicals-related Compliance Risks

The root causes of compliance challenges all have to do with chemicals. How the chemicals are received. How the chemicals are tracked. How they are stored and how they are disposed. These are all processes that can be resolved with a strategic decision to implement a single centralized solution that streamlines the workflows involved.

"Implementing a web-based chemical inventory management system has ensured that the materials containers on site are now managed safely and more effectively while relieving the laboratory scientists of workflow challenges and non-value adding activities."

With the goal of centralizing materials inventory management control, organizations can bring their materials management process under control with three key tactics. First, organizations need to track all materials containers using one simple, user-friendly system through which users can register all materials approved for use at the site upon receipt.

Second, they must implement a methodology that provides complete visibility for all safety information for each chemical and register that chemical for its specific hazard classes and categories. Such a system can be manual or electronic, but it is important to provide the data on demand, both for EHS professionals as well as for lab personnel.

Third, the materials management system needs to deliver a quick and efficient way to run inventory reports concerning the materials on site, detailing quantity and storage location. This is particularly important where hazardous materials and Controlled Substances are concerned, as some materials are strictly regulated and have maximum allowable quantities (MAQ) that may not be exceeded and/or require threshold reports.

Tactics for Gaining Control of Materials Inventory

- Ensure cross-functional collaboration between the lab and EHS
- Identify materials inventory
- Define hazard classifications on-site
- List regulations that require compliance
- Identify existing chemical safety processes
- Conduct a gap analysis
- Develop end-to-end chemical safety Standard Operating Procedures (SOPs)
- Implement a real-time materials inventory system
- Identify and input applicable chemical and materials inventory into the system
- Train users in safe chemical management
- Conduct an internal chemical safety audit

Streamline Materials Inventory Management Workflows

Changing a well-worn workflow is disruptive, but if the workflow is broken then the problems it causes are also disrupting other processes. To bring materials inventory processes under control, organizations typically start by researching available software solutions and selecting the best fit. Once the system is selected, a complete review of the inventory management process is undertaken to streamline the process. Next, a thorough housecleaning and inventory of all materials on site is performed, and each container is bar-coded and entered into the new system. Finally, users are trained on the new system so that all future materials inventories are managed within the system.

One leading pharmaceutical company took a hard look at their materials tracking processes and decided to implement a materials tracking process improvement initiative. Laboratory management was responsible for overseeing some hundreds of materials containers on site and ensuring the accuracy of associated chemical safety and inventory data for regulatory requirements. However, materials management was completed manually as time permitted. When a quarterly physical inventory was conducted, repeated inconsistencies were found between the inventory reports and actual inventory on hand. The process involved laboratory scientists collecting the chemical data manually on spreadsheets that were then provided to EHS. This process was cumbersome, inconsistent and hard to manage.

Two key objectives were identified for the materials tracking process improvement initiative: (1) streamlining the scientists' workload and (2) ensuring the accuracy of materials inventory data. Implementing a web-based materials inventory management system has ensured that the materials containers on-site are now managed safely and more effectively while relieving the laboratory scientists of workflow challenges. Further, the organization realized numerous cost and time savings. Not only were they able to eliminate the quarterly manual inventory counts, disposal costs for expired chemicals were significantly reduced. With a real-time materials tracking system in place, the organization was able to reduce materials inventory on site by 30%, while performing at the same level. They estimated their savings at $75,000 per year.

Address Safety and Regulatory Requirements

Laboratories serving regulated industries are audited not only by regulatory agencies but also by their regulated customers. For a large laboratory, these audits can be frequent. When non-compliances occur, not only does it place the lab under a spotlight; it also puts enormous pressure on management and staff.

After a particularly intense audit, one specialty chemicals manufacturer cleaned up their lab and cleared all unsafe and noncompliant materials by implementing a materials inventory management system to track material lifecycle from receipt to disposal.

Previously, the organization tracked materials containers with spreadsheets, none of which were in a central place, nor were they updated consistently to indicate when materials were received or disposed. The critical customer audit became the catalyst for change providing the opportunity to implement a number of corrective actions.

After a thorough review of three different systems, the review committee selected a system that would meet all their functional requirements and ensure audit compliance. The functional requirements were straightforward, with barcoding containers and automatic report generation on the top of the list along with a system what would be easy to use and scalable.

The new system ensures that all materials containers are barcoded upon receipt and tracked in a central database that clearly indicates expiration dates. Automated reports list when material testing is required. If materials expire before use, the system reports this, so they can be disposed and taken out of the system. The result is improved cross-functional collaboration between the laboratory and EHS along with accurate reporting for regulatory agencies.

Implementing a materials inventory system has allowed the organization to gain control of their materials inventory and sail through audits with ease and confidence. Not only are they spending less on materials (since they are no longer over-ordering them), but the new system has streamlined workflows and eliminated non-compliances and corrective actions resulting from expired materials.

A Short List of Regulations Requiring Compliance

An inventory management system should assist in safety compliance and reporting efforts pertaining to a number of regulations organizations are subject to, including:

- EPA (Environmental Protection Agency)
  - EPCRA (Emergency Planning and Right-to-Know Act) Tier II Emergency and Hazardous Chemical Inventory Reports
  - Toxic Substances Control Act (TSCA)
- GHS (Globally Harmonized System of Classification and Labeling of Chemicals)
- OSHA (Occupational Safety and Health Administration) standards
  - Substance Specific Standards
  - 29 CFR 1910.1450 Toxic and Hazardous Substances
  - 29 CFR 1910.119 Process Safety Management of Highly Hazardous Chemicals
- CLP (Classification, Labeling and Packaging of Chemicals) (EC 1272/2008)
- REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) (EC 1907/2006)
- CSA (Controlled Substances Act)
- NFPA (National Fire Protection Association) Regulations

(see Appendix A for a more detailed list of regulations)

Track and Control Materials in Real-time

As organizations grow, business and operational processes evolve. Over time — particularly if the facility expands — items are moved, sometimes lost, sometimes misplaced. If that item is materials inventory, it can exceed the recommended shelf life or expiration date. Simply knowing what chemicals are on hand and where they are stored eliminates many management headaches and much regulatory scrutiny.

> "A web-based solution that utilizes familiar web browser screens and resembles typical work processes entails the least amount of training and the easiest adoption"

One industrial manufacturer had been evolving in just such a way. Eventually they found that using spreadsheets to track materials or a generic database to create special reports could no longer provide accurate chemical materials inventory data. As the organization grew from a small lab to more than 150 research staff in several buildings, the need increased for more accountability and better controls to enable enforcement of materials receiving and tracking.

The EHS team determined the need for a materials inventory system that would meet four key criteria: the ability to monitor chemical shelf life, track ownership, track material quantity and maintain SDSs in one system.

Migrating to a real-time system required a few key steps. First, they identified old chemicals and disposed them. Barcodes were then attached to all remaining containers to enable real-time tracking of not only expiration date and container location but also quantity, owner and Chemical Abstracts Service (CAS) number as well as associated hazard information. By tracking the expiration date in the system, the organization is now able to dispose chemicals within the appropriate time frame, thus reducing both waste and waste disposal fees.

Second, when they deployed the materials inventory system, they also implemented new procedures to ensure that the system processed all chemical transactions. They added a materials system check box to all purchase requisitions. Now, the researchers can easily check whether a material is in stock before ordering more — a simple fix that has resulted in a significant decrease in purchase orders for new materials. In this way, they have eliminated the duplication and reordering of materials that were already in-house.

Just by enabling better shelf life tracking and management, the materials inventory system has reduced the total number of containers on site by half—from 10,000 to 5,000 containers. Further, with fewer materials on site, the inventory material cost has dropped from $600K to $400K per year—a reduction of 33%.

Previously the company's reconciliation accuracy seldom exceeded 70%. Now they typically exceed 97% accuracy. The system they chose enables the organization to define material location not just by cabinet and shelf, but down to the drawer and container level, which in turn has enabled them to obtain a much higher level of accuracy on their reconciliations. Now whenever they want to know exactly where a material is located in the 8,000 square foot facility, they can find it immediately.

Implementing a real-time materials inventory system has enabled the organization to gain control of their materials inventory processes. It has also allowed them to reduce inventory costs and realize significant cost savings.

Drive User Adoption

The common denominator in all three case studies above is the implementation of a real-time materials inventory system. What all three organizations discovered was that providing a simple, user-friendly system which could accurately register all incoming or formulated materials drove user adoption, while also ensuring the accuracy of materials inventory data.

SELECTING THE RIGHT MATERIALS INVENTORY SYSTEM FOR YOUR ORGANIZATION

There are many criteria to consider when selecting a materials inventory management system. The most important prerequisite, however, is to create a functional requirements list that reflects your needs for the new system. Keep in mind that, because your existing processes are not working well, you will be updating these processes to take advantage of the materials inventory system's capabilities.

A best practices materials inventory system should accommodate all basic inventory tasks and leverage a "build it once, use it often" philosophy. The system should manage all the steps associated with registering a material, including receipt (data entry and barcodes), re-labeling, dispensing, storage and container disposal. Further, any materials inventory management system needs to be able to track materials with multiple chemical components, some of which may be hazardous and reportable to regulatory agencies.

With everyone able to use a single system, EHS can pull data for regulatory reports without requesting them from lab personnel, in turn enabling lab personnel to stay focused on research. This is one process change that everyone will like.

Utilize Barcodes for Tracking

Any well-designed inventory system should enable your organization to avoid duplicate ordering and high disposal costs. Features like barcode labeling and tracking, remote inventory control and automatic e-mail notifications enable the lab or EHS to know exactly, in real-time, where materials are located and how much is available as well as when chemicals are set to expire, regardless of how many users and materials the system must accommodate. Utilizing barcodes for tracking materials, you can track even very small quantities in small vials by putting the vials in a small packet that is then barcoded. Without barcodes on every container, there is no truly effective means of identifying and thus tracking those containers.

With barcodes placed on materials containers upon receipt, the system can then provide a wide range of data, including not just quantity on site but also container location. By using barcodes to track containers, the system is able to provide

deeper functionality such as listing expired chemicals for a user (owner) and for a site. It can provide a mechanism for deleting individual containers or a series of scanned containers. It can create, edit and delete permissions for various operations in the system. It can accommodate parent/child or split container relationships and duplicate materials clean-up.

Manage a Wide Range of Users

It is important to consider who will be using the system. A large production line will utilize a dedicated production system with a dedicated team of users. A laboratory, however, typically does not have the luxury of staff that perform only one function. The optimal chemicals inventory system for a lab would thus be a versatile system with which anyone in the lab can interact at various defined permission levels.

For instance, the system should be able to define a system-wide administrator who oversees system configuration (users, locations, workflows, etc.). Certain specified users will be able to view and edit specific inventory based on group access. View-only users will have permission to access all inventory and safety details but will not be allowed to make any changes within the system. Whether your organization will use all these permission levels upon system implementation should not prevent you from requiring this capability in the new system. Your organization's needs will grow. Building in this type of scalability from the start will enable you to accommodate future change.

Leverage Current Technology

Obviously, a web-based solution that utilizes familiar web browser screens and resembles typical work processes entails the least amount of training and the easiest adoption. The downfall of many custom-designed materials inventory management systems is that they are too difficult to use. The result is that only a few people in the company have the knowledge and patience to use the system. Accuracy and timeliness of the materials inventory data suffer. Valuable time may be lost when experiments must be stopped because the necessary materials are not on hand. Analytical, Quality Assurance (QA), EHS and lab personnel should all be able to interact directly and intuitively with the system.

"Just by enabling better shelf life tracking and management, the materials inventory system has enabled the organization to reduce the total number of containers on site by half, from 10,000 to 5,000 containers."

A cloud-based environment helps keep costs down and improves the security of the system. It provides the real-time data visibility that both end users and managers across the laboratory supply chain need. Organizations can minimize the total cost of ownership for their deployment while decreasing the necessary IT overhead when the provider takes care of delivering application and security updates and ensuring performance. The dynamic infrastructure of a cloud-based system maximizes the flexibility to adapt to changing requirements regarding the number of system users. Ideally, the system has undergone a certification process (e.g., with an information security consulting firm) and a verification that a detailed framework for security design, implementation and management are in place, continuously monitored and improved. In times of increased cybersecurity threats, this certification process should also verify that a robust framework exists for information security risk assessment, threat identification and rapid response.

Quickly Respond to Incidents

Any time chemicals are used, safety is an issue. In the event of an accident, the correct information needs to be available immediately. A materials inventory system should provide details about exactly what materials are available and where they are. Safety information about chemicals should be readily available, whether as a SDS or as customized handling instructions.

In addition, the system should be able to identify toxic and hazardous materials so that these chemicals are stored and managed in accordance with environmental regulations, and the system should deliver prompt, accurate reports for the various regulatory bodies.

Further, a web-based materials management system that is remotely accessible ensures that accurate information about chemicals in a specific building will get to first responders — such as the fire department—during an emergency. Without remote and immediate access to data about the type and location of chemicals in a building, firefighters will not know what is in the building and will let the building burn to the ground.

Manage the Materials Lifecycle

The features described above specify the minimum functionality that a best-practices, real-time materials inventory system should provide. However, a robust, comprehensive solution should also manage the material lifecycle from "cradle-to-grave."

The materials lifecycle starts with receipt or the formulation of a material and tracks quantities, location changes and disposition. This capability is important because it allows the organization to have better accountability for and visibility into their materials inventory. By knowing and being able to track this aspect of operations, the organization is better able to estimate materials demands and establish accurate audit trails for every container. Whether the audit trails must meet regulatory Good Manufacturing Practice (GMP) requirements or not, the materials lifecycle workflows remain the same for any quality-conscious organization.

Going beyond the minimal requirements for a materials inventory system frees the organization to focus time and energy on better managing their products and processes rather than on managing their inventory. A lifecycle-oriented materials inventory system provides numerous further benefits, such as additional levels for the materials data lifecycle and approval processes as well as permission control levels.

Ensure Safety and Internal and Regulatory Compliance

After ease of use, perhaps the most important capability of all is safety risk mitigation and regulatory compliance. Labs must operate safely and many of them also must operate in accordance with a variety of government regulations; thus, it is important to effectively and properly use the system.

Systems fail because they are not easy to use. Next to an inherent safety risk this touches on two issues: internal compliance and regulatory compliance. Internal compliance is driven by usability. If users find it difficult to use the system, they may use it incorrectly or only occasionally, so that a chemical might exceed its limits or be so far out of compliance that it impedes workflows. And the organization might not discover this until an audit takes place—a poor time to find out.

With regard to regulatory compliance, a system that is difficult to use can generate numerous problems. Not only should it be easy to receive containers into the system, it should be easy to manage inventory updates and container disposal. If material and/or hazardous waste is not disposed of properly, the facility is out of compliance.

In addition to ensuring that the system gets used properly and effectively, the organization needs to determine whether the materials inventory system can accommodate auditing and what types of audit controls it offers. The materials inventory system should support inspections by the fire department, EPA, FDA and/or OSHA by providing tools supporting compliance. It should accurately track chemicals and allow the design and generation of reports that document compliance at any time. For example, the system should assist with the preparations for OSHA audits or SARA and Tier II reports by supporting accurate and thorough as well as quick and easy reporting.

Real-time systems also provide complete visibility not only of the materials on site, but also all safety information for those chemicals. Upon receiving or formulating a material, the system can immediately register that material for its specific hazard classes and categories, providing data on demand for EHS professionals as well as lab personnel. A comprehensive materials inventory system can also associate the correct SDS with any chemical, so that both regulatory and safety requirements are satisfied.

With all materials captured within the system, the organization has a quick and efficient way to run chemical inventory reports. Furthermore, with hazardous materials captured in the system, it will be easy to comply with hazardous material safety mandates.

Accommodate Regulated and Non-Regulated Laboratory Environments

Document linking, audit trails and other security features are critical to labs that need to track samples and/or material classes which can include biologicals, chemical standards, excipients and intermediates. It is also important that the materials inventory system be adaptable to non-Good Manufacturing Practice (GMP) as well as non-regulated environments, if the facility combines both. Therefore, the system should seamlessly accommodate both GMP and non-GMP materials, enabling all users to see just the data that relates to their work or location based on their security profile.

SUMMARY

Many Life Sciences companies still rely on inefficient materials inventory management processes in their laboratories that inhibit scientists' and technicians' productivity, cause unnecessary waste and cost and make it difficult to ensure on-site safety and compliance.

Updating inefficient, marginally effective processes by implementing best practices allows organizations to improve process efficiencies and reduce operational costs, while also enhancing regulatory compliance and employee safety and protecting their brand reputation.

There are a few key takeaways from the information presented in this white paper. First, a best-practices materials inventory system enables your organization to perform regular inventory maintenance to purge hazardous materials from your site in a timely manner. Second, a barcode-based materials inventory system can track all materials (purchased or formulated) on site and thus ensure that inventory data and regulatory reports are accurate. Third, as a result of better materials inventory knowledge, the materials inventory system should also enable your organization to reduce onsite chemicals (particularly hazardous materials), thus reducing risk. Driving greater site safety and compliance reduces both risk and liability. In addition, most organizations realize considerable cost savings when they are able to understand, track and accurately

report materials inventory. Ordering fewer materials reduces purchasing costs. Fewer onsite materials reduce management and reporting costs. And a cloud deployment helps to minimize total cost of ownership.

By implementing best practices in materials management, Life Sciences companies can improve laboratory and scientific efficiency, lower costs and speed time to market. They can also reduce the risk of incidents, facilitate regulatory compliance, improve workforce safety and protect brand reputation.

By implementing the right Materials Inventory solution, Life Sciences organizations will be able to:

- Reduce time spent searching for misplaced or poorly located inventory by 5-10%
- Reduce time spent in researching materials by 30-45%
- Reduce time spent ordering materials by 30-45%
- Reduce inventory searching efforts by 50-75%
- Reduce delays resulting from to missing inventory by 50-60%
- Reduce inventory order requests by 30-40%

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APPENDIX A: CHEMICAL SAFETY AND MANAGEMENT REGULATIONS

Environmental Protection Agency (EPA) Regulations

- 40 CFR 355
- 40 CFR 370
- 40 CFR 371
- 48 CFR 22

EPA Acts

- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
- Clean Water Act, Sections 104(b) and 104(e)
- EPCRA (Emergency Planning and Community Right-to- Know Act)
  - Emergency planning, Sections 301-303
    - Emergency release notification, Section 304
    - Hazardous chemical storage reporting requirements, Sections 311-312
    - Toxic chemical release inventory, Section 313
- Toxic Substances Control Act (TSCA) Section 8(e)

EPA Guidelines

- Health and Safety Audit Guidelines: SARA Title I, II and III

UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

- EU: Classification, Labeling and Packaging of Chemicals (CLP) Regulation (EC 1272/2008)
- US: Occupational Safety and Health Administration (OSHA) standards

United States Department of Labor - Occupational Safety and Health Administration (OSHA)

- 10 CFR 835
- 29 CFR 1910
- 29 CFR 1926
- 29 CFR 61
- 29 CFR 63
- 29 CFR 68
- 29 CFR 970
- 29 CFR 1021
- 29 CFR 1910 (Hazardous Communications Act) (aligns with GHS)

Regulations that Address Fire Codes

- International Code Council (ICC)
- International Fire Codes (IFC)
- OSHA Substance Specific Standards
- OSHA Hazard Communication Standard (HCS)
- OSHA 29 CFR 1910.1450 Specific Hazardous Substances
- OSHA 29 CFR 1910.119 Process Safety Management
- Department of Homeland Security (DHS) 6 CFR Part 27
- American National Standards Institute (ANSI) Standards
- Compressed Gas Association (CGA) Standards
- Environmental Protection Agency (EPA) Regulations
- DEA Regulated Substances
- CDC Defined Select Agents

National Fire Protection Association (NFPA) Regulations

- NFPA30
- NFPA45
- NFPA45
- NFPA55
- NFPA400
- NFPA432

Further Regulations and Standards

- Canadian Environmental Protection Act (CEPA)
- Compressed Gas Association (CGA) Publications, P-1
- Department of Homeland Security - Chemical Facility Anti-Terrorism Standard (CFATS), 6 CFR Part 27
- Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) - Controlled Substances Act (CSA)
- Hazardous Waste Directive (2008/98/EC)
- REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) (EC 1907/2006)
- Restriction on Hazardous Substances (RoHS) Directive (2002/95/EC), RoHS2 (2011/65/EU), RoHS3 (2015/863)

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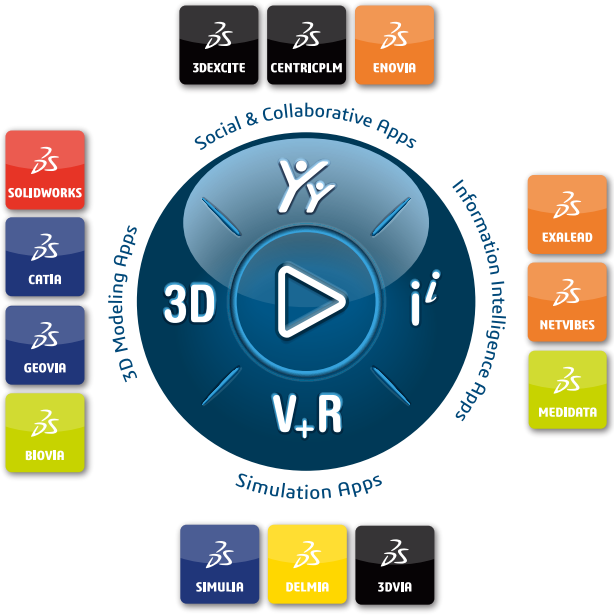

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