# Overcoming data management challenges

## Getting to grips with your data model is essential for meeting your GHS obligations

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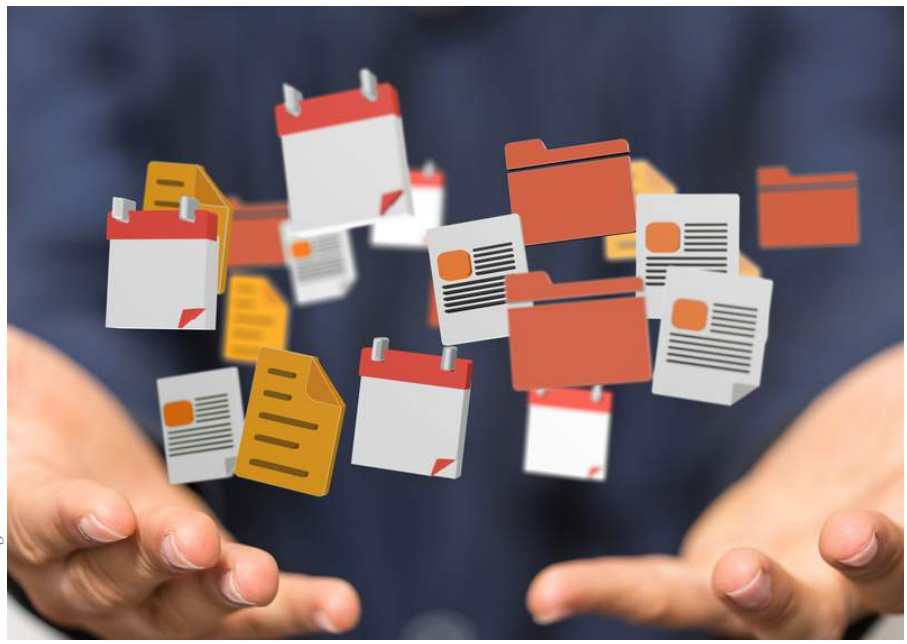
The dynamic regulatory landscape undoubtedly presents businesses today with many challenges; however, the complexities and challenges of regulatory compliance can be alleviated by utilisation of systems, data and tools. Data, however, plays an especially critical role, as it often serves as the foundation of compliance initiatives or as an essential input into systems and tools.

Clear, accurate data is the backbone of any system, and can be the decisive factor in the success of your entire operation. Given the role of data in collection, review, to final analysis, it's vital to establish a process as early as possible.



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**Meeting GHS obligations requires access to current data on your products and individual components**

### Understanding GHS data requirements

In order to successfully manage your organisation's GHS obligations, it is imperative that you have access to current and relevant data for your products and your individual components. In this digital age, data is becoming increasingly accessible; however, having access to a multitude of data sources can make it more challenging to properly assess and determine its relevance to specific products.

To address these challenges, it is important to ensure that experts in your organisation understand the backbone of GHS and how specific elements will drive classifications. Under GHS, companies are not required to test their substances or mixtures for health and environmental hazards, as the criteria for determining these hazards is test method neutral. This means that various approaches for determining classification are valid as long as they are scientifically sound and validated across international criteria. The challenge here is in aggregating and reviewing the data, so that as a company you can drive the classification you believe is accurate for your product. It is also essential to properly store the relevant data and ensure that it is easily retrievable, should it be necessary to substantiate and support any decisions.

While this may seem like an overwhelming task, it is more easily executed when broken down into several steps. The first step in the GHS process is to define and understand your data model. This will allow you to understand the relevant components and raw materials, which make up your product, so that you can determine which data points will be necessary to drive your classifications.

Required data elements, at the substance and mixture level include:

» hazard classifications of components. Companies must make a decision about this data point. Will you self classify all components or trust supplier classifications?

» physical and chemical data (section 9 of the safety data sheet (SDS));

» stability and reactivity data (section 10 of the SDS);

» toxicological information (section 11 of the SDS);

» ecological information (section 12 of the SDS); and

» transport classifications (section 14 of the SDS).

In addition to leveraging data to drive classifications, individual countries have a variety of regulatory lists that must be assessed to determine hazardous ingredients and additional disclosure information in section 15 of the SDS.

Once you determine the specific data elements of relevance, the next step is to work out how and where to source this. It is also imperative to understand the various data and regulatory requirements on a country-by-country basis. If you are doing business globally, this additional measure can be a significant challenge as the regulations are generally published in the native language. It may be helpful to find a data provider, who can also provide

you with the full text of the regulation in a translated form.

If you are using an authoring software system to generate your SDS, it is still important to understand how the data will drive the output from your system – the rules are only as good as the data that the system leverages.

## Best practices

Companies can streamline their data management issues by utilising a combination of tools to manage vendor documents and raw material data. These tools can also be used to track regulatory changes, understand their implications and effectively manage the changes for your organisation – ultimately helping mitigate risk.

## Establishing an effective business process

One of the initial challenges companies face is the accurate collection of data, as it often comes from a myriad of sources. Stakeholders may contend with regulatory data such as classifications, restricted substance or health-based data, such as occupational exposure limits (OELs), or lists related to carcinogenicity and sensitisation. In addition, there are various other sources that may come into play, such as physical, chemical, ecotoxicological and toxicity data, dangerous goods classifications, and supplier data.

As a result, databases can be particularly difficult to manage, especially when exacerbated by issues such as the migration of company-specific data, or too much or too little data from various sources. Understanding exactly which data to use can be a complicated process, but solutions such as an automated system can turn an otherwise time-consuming, error-prone process into a simplified affair. Whether through in-house experts or third-party solutions, it's essential to establish a procedure for maintaining data, as it provides a foundation for many compliance tasks.

It may also be helpful to perform a gap analysis. This can be a valuable exercise if it is conducted regularly – perhaps on an annual basis. This exercise can occur as internal business processes are reviewed, because even with the best laid plans things can change. Regulatory requirements may shift, resource allocations may change or new and additional services or solutions may be available to help meet your business goals.

A gap analysis is simply a comparison of actual performance with potential or desired performance. The first objective is to explore what the company is trying to achieve – what are the objectives of the project? Once that is defined, then the "who," "when," and "how" can be pinned down.

Once the "what"– or the goal – has been determined, the next step is to review existing process and then outline the desired outcome. From there, it is easier to understand how the process needs to change in order to achieve the desired outcome. Once the gap is understood, it is easier to develop and execute plans to fill it.

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When conducting a gap analysis, companies often find a lack of accurate and up-to-date content. This was especially true in the US, where both manufacturers of substances and mixtures had the same compliance date. This added an additional layer of complexity for US manufacturers as they were waiting on raw material data and classifications from suppliers to accurately assess their final products. Without this essential information, manufacturers then were forced to choose to either wait for their vendor documents, or to look for alternative data sources to meet their compliance deadlines.

Some companies referenced the following publicly available sites:

» Echa C&L Inventory registered substance database
» GESTIS
» eChemPortal
» Toxnet
» HSDB

Another issue facing manufacturers was suppliers disclosing additional ingredients as hazardous. These often have a downward effect requiring updates to the manufacturer's classifications as well as additional disclosures, such as OEL's and national level regulations, which may also have further labelling requirements. This is why it is imperative for companies to have a system in place for tracking vendor and regulatory data on a monthly basis. Doing so promotes a better understanding of the implications for their final products and their compliance obligations.

## The update process

Once a compliant SDS is generated, many companies may think their obligation has been fulfilled. However, generating a compliant SDS is only the first hurdle. Companies must also plan and create a process for keeping their SDS current and accurate.

In most countries where GHS has been adopted, an SDS must be updated when new information has been identified. This can be any information that may affect risk management or new information regarding potential hazards. This means that it is the manufacturer's obligation to monitor regulatory changes as well as publicly available scientific data that may impact the hazard assessments of particular products.

Individual countries may have specific time periods in which the SDS and label must be updated and distributed, so it is also important to understand each country in which you are shipping your products and their specific revision requirements. Most countries also require specific revision information such as versioning, issue and supersedes/revision date and many require the manufacturer to identify specific changes of relevance to their customers in section 16 of the SDS.

Monitoring and understanding these global requirements can be a significant challenge. However, with the proper tools, solutions and best practices, these issues can be streamlined and managed, allowing your company to limit risk and manage resources effectively.

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