



How to Manage Your Company's Regulatory Compliance Needs

How is Product Regulatory Compliance defined? At its essence, it means that your product meets all regulatory requirements that apply to it. Regulations are different based on industry, countries, states, and provinces you sell in and are constantly changing. This means you have to make sure you put serious effort into understanding which regulations apply to you. Compliance management can be harder than it seems on the surface. The good news is that there is technology that is made to specifically address this issue. The dilemma is “how do you go about evaluating these solutions?”, will they address the industry specific regulations for your company? Based on the multitude of options in this space, the decision really ends up being specific to your industry, your company's technology stack—ERP, PLM, etc.. However, the basic needs to be addressed are very similar. We break these up into the following 4 areas.

1. Regulatory Planning

As usual, everything starts with planning. If you take into consideration your industry, your product offering and the geographies you sell into, this capability not only allows you to see the current regulatory needs but also provides visibility into what is coming, in which industry, what geography and when. This step of preparation, is key in understanding the viability and potentially the added costs of entering new markets or even sustaining current markets.

1. Traceability capability

Traceability is centered around the ability to answer the basic question of “Is our product compliant to the industry/geography regulations?” With this question in mind, you need to understand the regulations and how they affect your product, its supply chain and the material used to create the product. This typically is stated as the “Traceability Matrix”. Defining what regulations impact your company and its product and how you are going to address it. Simply stated but very difficult to accomplish.

3. Reporting Capability

Another key aspect of regulatory compliance is the ability to report out to the regulatory agencies in their format and frequency, certification of how you meet their regulations. I can't stress enough of ensuring that the technology you decide upon is truly only as good as how well it can report and how frequently they update their capability to the new regulations and agency formats.

4. Company Specific Requirements

As we stated earlier, each company is unique in this field of regulatory compliance. Not only is it specific to your company's products and where you sell them in, but it is also very dependent on which current enterprise systems and processes you have embedded in your organization. Regulatory compliance solutions need to be integral in how you work day to day. To be beneficial it needs to be integrated into the product development process, the transactions you are involved in and the supply chain that supports the building of your products.

Regulatory compliance can make or break your company! If you are in need of starting or in the middle of evaluating regulatory compliance software, either reach out to us via email or give us a call. We can help you through this critical selection.

Next Month: Enabling Application Lifecycle Management as part of your PLM Journey