Don’t Get Lost In The Regulations Storm

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Suppliers that are up to date and well versed on globally changing regulations and deadlines are better equipped to provide their customers with sound recommendations of products and equipment to use and processes to implement.

With the medical device industry expanding globally, it is more important than ever for device designers and manufacturers to ensure their products and processes are compliant with not only U.S. Environmental Protection Agency (EPA) standards, but also with REACH regulations in Europe. By consulting with suppliers early in the design stage, designers and manufacturers can rest assured that they are compliant from the beginning.

I can’t even count the number of times I’ve gotten a call from a customer (or prospective customer) who is well into their manufacturing process and realize they have a problem -- usually their chemistries aren’t EPA compliant or they chose a manufacturing process or even purchased or specified new equipment that wasn’t the most efficient. In most cases, if their chemistry is not EPA compliant, it is because they are using a process that was once compliant, but due to ever changing regulations, is no longer.

This situation is understandable. Medical device manufacturers and designers already have FDA regulations and gaining 510(k) approval to worry about, so keeping up with the constantly changing global environmental and chemical safety regulations can sometimes get placed on the backburner until it’s too late.

However, this situation is avoidable. Bringing vendors on board earlier who have expertise in the EPA arena can help specify an up-to-date process that will be compliant for years to come and can give the customer long-term peace of mind –

and potentially save significant time and money.

Changing Regulations and How Vendors Can Help

The REACH regulations that are currently being phased into law in the European Union will be fully implemented by 2018. The U.S. is in the process of implementing harmonized regulations similar to REACH so that the methodology of evaluating chemicals is done in a universally similar process both in the U.S. and the E.U. Also, California is implementing stricter clean air regulations by requiring that chemistries meet ever more restrictive VOC attainment levels. This rapidly changing landscape means that some manufacturers will be required to find alternatives for both suppliers of their chemistries and overall manufacturing process.

However, some changes have been a long time coming, and these are the kinds of situations that set certain vendors apart from the rest. One example in the U.S is the upcoming deadline of January 1, 2015 when HCFC-225 will no longer be produced due to its status as a Class 2 ozone depleting substance. Suppliers that have been keeping up with the EPA changes will be ready at that time with alternative products that do not contain HCFC-225. Furthermore, some vendors like MicroCare Medical, already offer alternative products and can assist with engineering expertise to use them immediately in conjunction with the appropriate process in anticipation of this upcoming regulatory change.

Suppliers that are up to date and well versed on globally changing regulations and deadlines are better equipped to provide their customers with sound recommendations of products and equipment to use and processes to implement. If certain regulatory changes are anticipated initially, sound decisions can be made that will help make smart investment decisions for the long term.

How to Choose the Right Vendor

So obviously, bringing your supplier on board early is only effective if you choose the right one. Vendors who lack the capability of navigating the globally changing regulatory landscape or providing EPA/REACH compliant products will only cause more problems. Asking a few simple questions up front can help determine a supplier who is the right fit. Some questions you would want to ask potential suppliers would be:

- Are your chemistries both EPA and REACH compliant?
- Does your supplier offer one basic chemistry option, or a variety of chemistry options?
- Are you able to validate something you know is going to be available over the long term?
- Does your vender have global supply and engineering capabilities?

- How will you ensure that I’m choosing the best process for my specific applications?

Vendors like MicroCare Medical can assist customers in making certain their engineering processes are both compliant with global regulations and are also efficient in meeting manufacturing standards. Again, if this is done right away during the design stage, rather than after investment is made in the manufacturing processes, it can end up saving time and money in the long run.

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Links:
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[2] http://www.microcaremedical.com/