



# **ASK THE EXPERT: EU MDR**

Q&A with Hilde Viroux,  
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## QUESTIONS DISCUSSED

- What are some of the biggest changes in the new MDR that will impact device manufacturers?
- What are some of the specific requirements medical device manufacturers will need to start preparing for?
- What challenges will medical device manufacturing companies face if they delay their preparations?
- How do EUDAMED and UDI fit into the new regulations?
- How will MDR affect small and mid-sized companies? What do these companies need to do to ensure a smooth and successful transition?
- How can HCL help medical device manufacturing companies through MDR transition and implementation?
- What advice would you give to growing medical device companies looking to navigate the ever-increasing compliance landscape?



### **What are some of the biggest changes in the new MDR that will impact device manufacturers?**

There are a lot of changes in the EU MDR that impact device manufacturers. Generating the clinical data for all devices, developing the required reports and updating technical files to be compliant with Annex II and III is where most of the budget will typically go. In addition, there is the requirement to trace hazardous substances in devices and identify them on the label. The new regulation also requires manufacturers to set up a proactive approach to following the performance and safety of the device throughout its lifecycle.

### **What are some of the specific requirements medical device manufacturers will need to start preparing for?**

Device manufacturers who have not yet started the implementation risk missing the boat. Even when they have optimal use of the grace period by extending existing MDD certificates, some QMS requirements need to be in place by May 2020, like post market surveillance. In addition, no new products can be launched under an MDD certificate after May 2020, so not being ready means loss of sales and reputation.

### **What challenges will medical device manufacturing companies face if they delay their preparations?**

The challenge is simple: No compliance with the regulation means that manufacturers cannot sell in Europe anymore. A late start in implementation will increase costs significantly as the work needs to be done in a shorter time frame and external experts are already scarce. Notified Bodies will be overwhelmed with MDR certification activities in 2019 and 2020, so if manufacturers have not yet booked their audits and tech file reviews they may not have the certificates on time.

## How do EUDAMED and UDI fit into the new regulations?

EUDAMED and UDI are set up to ensure the transparency and traceability of medical devices on the EU market. The challenge for manufacturers is identifying the data associated with UDI and establishing change control as Europe requires manufacturers to keep the data in EUDAMED up to date.

## How will MDR affect small and mid-sized companies? What do these companies need to be doing to ensure a smooth and successful transition?

The EU MDR does not differentiate in requirements between large and small companies. Small companies have to meet the same requirements as the big ones, however, the challenges for small companies are huge as they typically do not have the necessary budget and resources. In addition, small companies customarily use smaller notified bodies who are more likely to disappear or continue under MDR with a reduced scope.

Careful planning of MDD certificate renewal and product portfolio prioritization can help to spread the costs for MDR compliance.

## How can HCL help medical device manufacturing companies through MDR transition and implementation?

HCL has more than 18 years of experience with global medical device companies and has executed multiple remediation programs for standards and regulatory changes. The company's dedicated regulatory and clinical team leverages this engineering experience in current MDR programs with Top 10 medical device companies.

HCL has developed checklists for MDR's gap assessments and templates for the files and forms to be created, including labeling updates and hazardous substances evaluation. HCL can also perform additional device testing if required.



## What advice would you give to growing medical device companies looking to navigate the ever-increasing compliance landscape?

The complexity of the regulatory landscape is increasing. While some countries are reinforcing existing legislation, others are just now developing and implementing their own device regulations. Companies should either reinforce their regulatory teams or partner with someone who monitors the regulatory landscape to keep abreast of the changes in requirements.



HCL hosted a Lunch & Learn Roundtable Discussion at Generis' 2018 American Medical Device Summit in Chicago, Illinois. The session, "Ask the Expert - MDR and Lifecycle Management", was lead by the company's Associate Vice President, Hilde Viroux. Hilde addressed questions surrounding the uncertainty of EUDAMED and UDI, the transition period and how to obtain compliance.

HCL further discussed EU MDR in their workshop, "EU MDR Business Opportunity and Implementation Challenges." The session focused on the benefits of compliance and how challenges associated with the new regulation can be easily prevented.

**Find out more about HCL's services on their website.**

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