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# The European Medical Device Regulation, a curse or a blessing?

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It is not a secret that the European Medical Device Regulation entered into force on May 26th, 2017. Soon all medical device manufacturers, suppliers, authorized representatives and distributors must have the new Medical Device Regulation EC Certificate (starting from the 26th of May 2020 at the latest) for any new medical device to be placed on the European market.
By taking a deep dive into the regulation you will encounter a whole series of new requirements; such as Clinical requirements, Post Market requirements, UDI and Reclassification to only mention a few. The more you read the more questions come up while you try to decode what this means to your company.

"Isn't it too early to start now although we have 3 years of time?"
"Shall we wait for guidance documents to come up?"
"What does it mean for our sales organizations across Europe?"
"How shall we deal with suppliers and sub-suppliers who are not certified?"
"Will a start-up company survive trying to meet the clinical requirements?"
"How much will it cost us to be in compliance with the new Medical Device Regulation?"

Don`t waste the three-year transition time by waiting to get some of these questions answered.
For those who still haven't started yet, now is the time to start!
Three years might turn out to be a very short period of time, depending on the type of products you have, the quality of your technical documentation and the number of products you are dealing with.

Bringing up your economic operators and suppliers to the level of expectations might make you feel that the three years is not enough time.

Only once you start to understand the requirements, then you will see that the devil is in the details. Much work has to be done!

- Take it seriously but don't panic. Plan, do, check and act
- Perform a gap analysis on your processes and product documentation
- Identify which products and processes will need to be remediated
- Identify which products are unlikely to survive the new requirements
- Create a detailed overview for planning
- Create a high-level overview including high level summary of the new requirements for top management
- Get the Buy-in from your management
- Get top management support to make sure that this will be a company project and not only a Q&R project
- Set up a project plan and project team
- Prioritize the project and allocate resources
- Involve your notified body and make sure they will be certified, otherwise start the search for a new one

Depending on the perspective from which you are looking at it, the medical device regulation can be a curse but also a blessing. However, no matter if it is a curse or a blessing, the whole medical device industry is sitting in one boat and we all have to navigate through it.


***About QUNIQUE GmbH***

*QUNIQUE stands for Quality & Uniqueness. We focus on high quality and exceptionally customer oriented consulting services for the medical device industry.*

*QUNIQUE is an international operating consulting company with the head office in Switzerland.*

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