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#### Analysis of the regulations for medical devices in Europe & future perspectives

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This presentation aims to provide a structural & functional understanding of regulations for medical devices in the European Union. Medical Devices (MD) in the European Union are regulated by the European Commission based on their proposal in order to ensure the safety and efficacy of Medical Device, thus facilitating patient's access to device in the European market.

**MD s** are any instruments, appliances, software, implant intended to be used for medical purposes alone or in combination for diagnosis, prevention, prediction, treatment, replacement, of any disease, injury or disability or physiological/pathological state. **In-Vitro MD** is reagents, calibrators, instruments, software or system used alone or in combination to examine specimens (e.g.: blood & tissue) to provide further information for physiological/pathological state, congenital impairments, to track treatment response and to monitor therapeutic measures.

The New Medical Device Regulations (EU) 2017/745 (MDR) & In Vitro-Diagnostics Medical Device Regulations (EU) 2017/746 (IVDR) aims to give national regulators much more control & oversight of Medical device industry. Companies should proactively comply with these upcoming changes; if they do not then they could possibly result in losing their license to operate. Hence, it is very important to develop a new model for the industry to get them quick market access according to the new Medical Device rules.

In clinical practice, incidents including the breast implant and the hip replacements crisis have made it necessary to improve the regulatory & compliance approaches for the industry and hence raising a question about the quality aspect of the MD. Such incidents along with the understanding and addressing the critical factors of the pharmaceutical industry, namely the expectation of the patients and the requirements of the current legislations will determine of the quality of the MD.

Applying new approaches, by implementing the quality-by-design (QbD) could efficiently increase the quality of MD fitting in the ever-changing regulatory landscape. Tailoring the early development phases of MD by adding elements that are currently widely applied, but not yet included in the QbD model in a structured way would allow a more conscious development. In this way the continuous development & innovation of MD could be facilitated in the life cycle of the device.

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