Stéphanie Grassmann - Managing Director - MEDTECHXPERTS GmbH

"**MDR - Do's and Don'ts, It Depends**" covers the Medical Device Regulation (MDR; EU 2017/ 745) requirements for the economic operators (EOs including manufacturers, importers, distributors) in a pragmatic manner by listing the Do's and Don'ts to consider.

Bringing over 25 years of international experience in the medical device industry and research, as RA Manager, QM Manager, Clinical Affairs Manager, Senior Development Engineer, Stephanie Grassmann presents experiences from the field in the implementation of the MDR as EO in either the daily activities, specifically the implementation of the QMS requirements which also include post-market-surveillance and vigilance activities, or in the compilation of the required documentation for the CE marking of the medical device, the Technical File.

Numerous difficulties have been reported by many stakeholders, including the many interpretations of the MDR, leaving a non-level playing field and lots of frustration. Best practices, as well as tips and tricks may address some of these difficulties, of course, it depends.

Looking into the crystal ball, she will contemplate possible future changes to the MDR based on her interactions with CAs, NBs, EC policy officers, medical device manufacturer organization representatives, and key opinion leaders.