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Asia and ASEAN, what will be the result of all the harmonization effort going on in the Asian markets, and how should we as manufacturer deal with all these new regulations?

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Abstract

Asia is for Medical Device manufacturer the place to be in the future. In situations like now where financial situation allow little grow in Europe or USA, Asia have become the place to invest. Only 15 years ago, Asia – Pacific was a region where little regulation existed for Medical Device. These markets, Japan and Korea, have become less important than they were at that time. China, India or even less developed countries like Indonesia and Vietnam will increasingly become important. AS GHTF was initiated in 1992, the work towards harmonization were started, this resulted in that we created a set of harmonized "regulations", that was used by several countries as they through the last 10 years have introduced regulations for Medical Devices. Countries who were not part of this exclusive group (5 founding members), created their own Asian harmonization group, Further the ASEAN countries worked toward implementing their own Directive in their region. This session will be a real case session, where there will be focused on what your strategy should be to ensure that your documentation will increase the possibility that this documentation can be used for all your global submission, using harmonized template like STED (Summary of Technical Documentation) and/or CSDT (Common Submission Dossier Template). The session will highlight the different to these harmonized standards and those submission done in countries like China, Japan and Korea. It will explain why cultural understanding is essential for your company to succeed.

Biography

Toni Jorgensen has studied Chemistry and IT at Danish Technical University and University Of Witwatersrand in South Africa. After his MSc and PhD work he did a Pharma MBA and is a certified Lead Auditor. His Regulatory, Clinical and Quality/Compliance experienced started at Medtronic, and after this he has been in different leading position within the Medical Device & Pharmaceutical industry, in company such as Johnson & Johnson and Coloplast. The last more than 6 years he is working in Switzerland for Straumann, where he is the Global Vice President for Corporate Regulatory Affairs and Compliance. He has been participating in Medical device harmonization groups like AHWP (Asian Harmonization Working Party) and GHTF (now IMDRF) for more than 10 years.