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Medical devices regulations in Southeast Asia: Example of Malaysia

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The Medical Device Authority (MDA) is a division in the Ministry of Health Malaysia (MOH) in charge of regulating medical devices in the country. The Medical Device Act 2012 and its regulations were enforced on July 1st 2013 with the objective to protect public health and safety. A transition period of 1 year is given to manufacturers, distributors, importers and LAr's to obtain their establishments licenses (30th June 2014) and 2 years to register their products (30th June 2015). This seminar will give some insight into product classification, product registration and establishment licensing.

Biography

Mr Kholti has over 15 years of experience in the Medical Device industry. He started his career in France where he had different roles in Manufacturing, Quality Management and Regulatory Affairs. He then travelled throughout Europe and Asia where he has successfully completed numerous manufacturing plants certifications as well as product registrations worldwide. Mr Kholti holds an MBA in « Medical Devices & Healthcare Management » and obtained a GCP certification from the Malaysian Ministry of Health in 2013.

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