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Best industry practices - Audits and inspection

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Notified Bodies are accredited by their Competent Authority to conduct the conformity assessment of Medical Device manufacturers within audits and inspection. Therefore, Notified Bodiesaudits cover all the missing Quality Management Systemrequirements. With significant new requirements regarding the QMS, strategies regarding Regulatory Affairs need to be embraced. To manage a certified QMS against the new Regulations, companies need to ensure process repeatability systems including Continuous Improvement methods. Then, to support this approach, internal and external audits, so as Inspection are deployed. According to ISO 19011, ISO 9001 and ISO 13485, audit process approach is simple. Three steps, which are measurement, analysis and improvement, linked with 10 SOPs, as a minimum, bring companies to success with Notified Bodies, Certificates and Regulation.

In parallel to the Notified Bodies view, companies focus on the design of an effective QMS with limited resources. To develop, manage and monitor an effective QMS is always something critical. It is a daily challenge to adapt guidelines to activities and rules to current situations. Consequently, to facilitate improvements and quality habits, a best practice is to organize an open internal Quality System audit process conducted in the spirit of cooperation, with audit teams. Each audit program has an Audit Manager responsible for effectiveness of the audit program. It includes scheduling audits, assignment of audit teams and review of audit reports. The Audit Manager assesses audits with respect to escalation of issues to Management Reviews.

Biography

Kahl Melodie has completed her Master in Quality Management at the age of 25 from the Engineering School UTC in Compiegne, France. She published an article on Good Laboratory Practices in Nanobiotechnology. First, she worked as a Biomedical Engineer in French Military Hospitals and then, she went in the Swiss Medical Devices Industry. She had several years of experience in Quality Assurance and Regulatory Affairs Management, within Medical Devices for Dentistry, Orthopedic Surgery and Immunohematology. She is also certified Lead Auditor by IRCA (International Register for Certified Auditors). She works as a Quality Assurance and Regulatory Affairs Independent Consultant.

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