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Maintain the effectiveness of a QMS by using Lean Six Sigma approach

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Analysis of data, clause 8.4 in QMS according to ISO 13485, “shall provide information relating to characteristics and trends of processes and products including opportunities for preventive actions and suppliers”.

One of the biggest challenges for Medtech companies is to maintain the effectiveness of their QMS in accordance with ISO 13485, clause 8.5 “Improvement”.

Instead of top management’s one-sided focus on results (management by objectives), they should pay more attention to system- and process effectiveness and support the organization to use efficient statistical tools. But Top Management cannot only support the continuous improvements in an organization, they must actively participate in order to understand how to adjust system parameters (clause 6 “Resource management”), and hence expect the best output from the system (in relation to input). Management should use a QMS (Quality Management System) more as a BMS (Business Management System). “Internal communication”, clause 5.5.3, will be more efficient when the organization on all levels better understands how they could contribute to process efficiency rather than relating to financial key performance indicators. A product or service flows in an organization vertically not horizontally without taking any consideration to departmental hierarchy, which contributes to “Batch-and Queue”. By designing the system processes (clause 4.2.2 c) as a BMS instead of a QMS, the effectiveness could be maintained and improvements (= Money savings) will follow, which will benefit all stakeholders, top management, employees and owners. Performance management needs to adapt to a more flexible approach.

Biography

Peter Jehander has completed his MSc with majors in mathematical statistics and cost revenue analysis at the age of 25 years from SLU/University of Umea, Sweden. Peter holds the certificates Lean Six Sigma/Black Belt, American Society for Quality, IRCA/Lead Auditor ISO 13485, Kelmec Group, Ireland, and Lean Leader, Lean Enterprise Research Centre, Cardiff, UK. He is a Senior Consultant QA/RA of AF Technology AB. He has been working with QA/RA related projects for more than 15 years.

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