INCOSE
International Council on Systems Engineering

SSSE Swiss Society of Systems Engineering

Systems Engineering in Medical Device Industry – Challenges and Opportunities

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QIAGEN is the leading global provider of sample and assay technologies. These technologies are applied in many QIAGEN in vitro diagnostic (IVD) medical devices. Increasing complexity of products and regionally required quality system regulations such as ISO 13485 (Europe) and 21 CFR part 820 (USA) demand a systematic life cycle management of a medical device manufacturer. Medical device and other manufactures of complex or safety-critical products can benefit greatly from well-established systems engineering processes and best practices to address those challenges.

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