INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

SERVICES QUALITY MANAGEMENT MEDTECH

The set-up and maintenance of a quality management system according to ISO 13485 / QSR are an indispensable requirement to be active in the medical engineering sector. We support you in all important steps of a (re)certification or adaptation of the QMS to new requirements and offer you comprehensive services.

Your Advantage

You can benefit from our vast experience as a self-certified and practically consulting company as well as from the practice know-how of some employees as experts/auditors. With our tailor-made service you decide on the pacing and the volume of our services, from a non-recurring coaching through to the extensive outsourcing of the quality management tasks.

Our Services

Coaching
Coaching during the setting up of the QMS to the point of support and review of certification. This includes in particular:
Identification of the processes to be described
Support in the interpretation/implementation
Monitoring/support in the preparation of expertise of system and the certification audits
Formulation of the conform description of the value-added process with focus on „design and development“ including risk management

Design dossiers / Technical documentation of products
Compilation of GAP–analyses related to design dossiers based on the latest CE and FDA requirements
Active support in closing of possible discrepancies
Review in terms of content / revision of dossiers

Q-Tool® as a possible document management system
Based on our own experience we have developed a document management system „Q-Tool“ which is tailor-made to the requirements of ISO 13485 and enforces discipline in a simple way without restriction of the flexibility you are accustomed to by Office Suite. Please see our separate factsheet about Q-Tool®.

Your contact

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