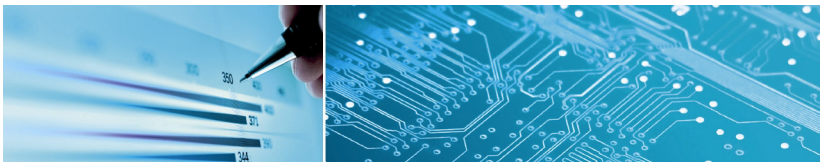
INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY



SOFTWARE DEVELOPMENT MEDTECH, FDA, ISO 13485, IEC 62304

For the SW development in medical engineering ISO 13485, the FDA requirements and meanwhile the standard IEC 62304 are mandatory. This set of standards has to ensure that the software in medical devices complies with the high requirements on the security of patients. This results in considerable extra costs for manufacturers which can be minimised by a good knowledge of the standards and a smart use of tools.

Your Advantage

Through our focus on medical engineering you gain a competent partner for your software development.
As we do not just write software but develop under consideration of the regulatory requirements and the relevant standards you will receive an adequate SW product which complies with the regulatory requests.
You can also outsource subprojects or validations to us. If you have a shortage in your resources, we support you in the timely completion of your product.

Our Services

SW development
We take charge of individual subprojects for your SW development. As we mainly develop for the medtech industry we know all the required processes and the involved tools are validated accordingly.

SW project management and subproject management
We take charge of the lead of the SW sector within bigger projects. We manage the corresponding subprojects and ensure that the development will be implemented and documented according to the standards of the new norm. If your QMS does not yet consider the new norm, the SW project can be implemented with our SW development process that complies with ISO and FDA.

SW verification and SW validation
The definition of SW in medical devices as well as the demands on their verification and validation are constantly changing. We keep pace with this development and take charge of the rule-consistent verification, validation and the corresponding documentation of your software.

Risk management and usability engineering file (ISO 14971 and IEC 62366-1)
We prepare the risk management file, planning, consulting or leading the activities as needed to get the complete dossier according to the valid standards for you.

Use of validated infrastructure & tools
In projects partially handled by us you have the possibility to use the validated infrastructure. This relieves you from the - meanwhile mandatory - validation of your tools and infrastructure and also ensures an efficient project process.

Assignment of rights of software
All source codes which we develop for you also belong to you. Exceptions will be agreed on separately.

Your contact

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