INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

INDUSTRIALISATION ACCORDING TO ISO 13485 AND GMP

The high deadline and cost pressure on the development process frequently leads to a product that is developed according to the standard but the processes used for the serial production are not yet sophisticated enough. Part of the painful consequences are, along with a damage of the company's image, decreasing margins, the increase of vigilance cases, a warning letter from FDA, recalls of production lots or in an extreme case the recall of a product. We help you to avoid such consequences with our experience and knowledge.

Your Advantage

Sustainable cost savings, high ROI
Cost savings are a logical consequence of lean and consistently applied processes. We constantly strive to implement cost savings for our customers.

Low reject rates, fewer complaints
Important indicators for suboptimal processes are among others increasing reject rates at the receipt of goods (frequently an indication of inadequate product specifications or an inconsequent control of suppliers), extreme fluctuations in the process capability (frequently an indication of inexplicit SOPs) and a strong increase in the complaints by the customers. With optimized processes you will achieve a constant manufacturing situation, shorter lead times and a strict progress control.

Q-compatible and validated processes
We know the relevant norms and take your company-internal procedures into consideration. Assignments and results will be documented by us in such a way that you also pass severe audits through FDA or a Notified Body.

High delivery capacity
Risk potentials related to the continuous delivery of the market are revealed by risk analyses. We help you to reduce the risks to the extent that you will be able to ensure a high delivery capacity.

Our Services

Development of concrete measures
With the aid of a systematic analysis of the manufacturing process, the device master record (DMR) and important parameters (reject rates, manufacturing costs, complaints by your customers) as well as the identification of the legal and normative requirements for your product we compile a specific package of measures with a proposal for the prioritization.

Implementation including validation
We implement the measures taking into account the regulatory, quality and cost relevant aspects according to your priorities. Naturally we also issue the necessary validation.

Establishment and controlling
In a final stage the measures will sustainably be established through training and practice. Through suitable bench marks we make sure that the process reliability and process efficiency will be continuously tracked and improved if necessary.

We support you selectively in your trainings or concrete sub-operations through to the handling of entire projects.

Your contact

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