INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

QUALIFICATION AND VALIDATION BASED ON ISO 13485 AND CGMP

In accordance to the COUNCIL DIRECTIVE 93/42/EEC and the 21 CFR 820 manufacturers have to assure that the process of manufacturing is specified with (1) precise process parameters and (2) the expected output. If the output of the process cannot be verified, a process validation is indispensable.
For the process validation, you can benefit from our experience in drafting and implementing Installation- and Operational Qualifications (IQ, OQ), Performance Qualification (PQ), Master Validation Plans (MVP) as well as compiling of documents requested.

Your contact

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Your Advantage

Q-compatible and validated processes
We know the relevant norms and account for your company-internal procedures. Assignments and results will be documented by us in great detail, providing you the opportunity to prepare and pass even severe audits performed by FDA, a Notified Body or customers.
You can benefit from our competent and experienced team, which provides services from on site support concerning conceptual work to operative implementation of complete work package.

Equipment supplier
You are the supplier for a manufacturer of medical devices and you would like to (or must) qualify the equipment delivered? We are very glad to support you. Our approach is based on the normative and legal requirements for medical devices and can be offered to the customer as an additional billable performance. The equipment qualification performed by ISS representatives takes place on site.

Our Services

Compilation of initial situation
In collaboration with the customer, several points are clarified and organisationally implemented within the first phase:
Forming of a interdisciplinary validation team
Identification and description of the processes
Decision on whether individual processes have to be verified and/or validated

Protocol development
Based on product- and process- requirements, the following questions have to be clarified for all qualification phases (IQ, OQ and PQ): what, how, how many, when shall be verified / measured. The definition of acceptance and reject criteria and the required documentation will be established.

Installation Qualification IQ
Within this process step, the equipment has to be tested for correct installation. Important IQ considerations are safety features, installation conditions, calibration, supplier documentation, etc.

Operational Qualification OQ
In this phase the process parameters shall be challenged to assure that they result in a product that meets all defined requirements under all anticipated conditions of manufacturing.

Performance Qualification PQ
In this phase the key objective is to demonstrate that the process consistently produces acceptable product under normal conditions.

Statistical methods and tools
In order to analyse your validation process, we provide support in the evaluation of the right statistical method. Our team of scientists and specialists is highly experienced in this field and will assist you with the right tools (Minitab, JMP, etc).

Reports
Each phase will be documented and compiled to a Master Validation Report at the end of the validation process.