How to Handle Process Validation Using theISO 13485 Standard in the Medical DeviceManufacturing Seaa

ISO 13485 allows organizations, specifically medical devicemanufacturers, to connect their quality management system (QMS)with medical device industry requirements. ISO 13485 offers significant benefits to organizations that manufacture medicalequipment and related services. It ensures a commitment to qualityand enhances organizational efficiencies.

Manufacturing facilities for medical devices use industrial processesto transform raw materials into semi-finished products and finishedproducts into semi-finished products. To show that the industrial process has generated an output that satisfies the requiredspecifications, the results are validated by an inspection or somepresent quality tests. What should we do with processes whoseresults cannot be verified? is a pertinent question. Processvalidation is the answer to this issue. Therefore, clause 7.5.6 of ISO 13485:2016 requires organizations to verify those processesfor which verification is not feasible.

Validation demonstrates the ability of industrial processes toconsistently produce the desired outputs. Processes that are 100%product output inspected by the organization or that fully validateprocess outcomes using a sound statistical justification can obviatethe need for validation. Organizations are required by ISO13485:2016 to certify processes like sterilization and sterile barriersystems as well as computer software that is utilized in themanufacture or service of medical devices.

Management of process validation by ISO 13485

An organization can ensure that the procedures can consistentlygenerate the desired outputs by undertaking validation.Organizations are helped by ISO 13485 since it requires thefollowing:

Identify processes with unverified outputs: Identifying procedureswhose outcomes cannot beconfirmed is the first step fororganizations to validate their processes. The company mustestablish alist of these ISO 13485 procedures where verification isdifficult.

Document procedures for validation of processes. A procedureexplaining the validation of processes should be documented bythe organization, along with clear roles and responsibilities. Byincluding a criterion that details the validation program's evaluationand approval process, an organization can record a procedure. Theequipment qualification, also known as installation qualification, verifies thatthe equipment is in compliance during installation and is accomplished with the aid of certified specifications from the equipment manufacturer. The initial certification of the machinery for thedelivery of essential services. Personnel qualification, practical performance evaluations, and othermeasures ensure that the operators who are responsible for operating the equipment are well-qualified. Any personnel with ISO 13485 training online certification, can manage and fulfil thisrequirement.

Procedures for validating software should be documented: The organization should develop a procedure with clear roles that outlines the validation of computer software used in the creation of medical devices and associated services. Depending on the level of risk that could have an impact on the product's capacity to satisfy the required requirements, the procedure may involve the frequency of software validation. All of the procedures must be included in the ISO 13485 documents for future reference. As well as records of the software validation results, along with the conclusion and, if necessary, follow-up activities from the validation, must be kept.

Procedures for validating sterile barrier and sterilization systems should be documented: The organization needs to create a procedure with clear roles and instructions for validatingsterilization and sterile barrier systems. A sterile barrier system shields sterilized medical devices from biologicalagents while they are being packaged, stored, and distributed. Sterilization is the process ofeliminating