IV. DESIGN CONTROL UNDER EN ISO 13485 & 21 CFR PART 820

Design controls are a component of a quality system that covers the life cycle of a device to ensure that specified design requirements are met and the device will reach an acceptable level of efficacy and safety.
Design control begins with development and approval of device design inputs, includes the design activities and the associated manufacturing processes.
Design control applies to all changes to the device design or manufacturing process, including those occurring long after a device has been introduced to the market.

References
EN ISO 13485, U.S. FDA Quality System Regulations (21 CFR PART 820), EU Medical Device Directive (MDD 93/42/EEC) and new EU MDR , Canada Medical Device Regulations (SOR/98-282), local regulation.

The purpose is to enable you to establish and implement a system for design controls for various classes of medical devices for local market, the U.S. and Europe. Practical exercises will be used to ensure good understanding. Procedures and forms will be provided to implement a full design control system including :

- □ **Basic Terms and Concepts — The need for design controls**
- □ **Design Planning & Development**
- □ **Design Input**
- □ **Design Output**
- □ **Design Verification**
- □ **Design Review**
- □ **Design Validation**
- □ **Design Changes**
- □ **Design Transfer**
- □ **Design History File**

Our services include:

A. Design Control Training for Medical Device Companies
This training is conducted on-sites. The training session tailored to the needs of your organization regarding this sub-system.

B. Design Control Auditing for Medical Device Companies
Full or partial internal Design control audit - ISO and FDA QSR. We provide internal auditing services which allow for an independent review of this part of your quality system.

C. Design Control - System Implementation Consulting and maintenance
Gap analysis, design solution (custom made system), standard operating procedures, implementation, training, verification of effectiveness, and follow up.