VI.	**PROCESS VALIDATION INCLUDING SOFTWARE – TEST METHOD VALIDATION – CLEAN ROOM VALIDATION**
	Process Validation is required according to: 11 CFR Part 820.75, 11 CFR Part 820.70 (software validation), EN ISO 13485 (7.5.2). **Where the result of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures.** **Establish documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.** **References** **11 CFR Part 820.75, 11 CFR Part 820.70 (software validation), EN ISO 13485 (7.5.2), local regulations.**
	This sub-system is intended to assist medical device & pharmaceutical manufacturers with implementation of process validation system including Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ): establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements. ☐ **Sample procedures and forms** ☐ **Conduct of a validation** ☐ **Getting started** ☐ **Protocol Development** ☐ **Installation Qualification (IQ)** ☐ **Operational Qualification (OQ)** ☐ **Performance Qualification (PQ)** ☐ **Maintaining a state of validation** **Our services:** **A. Process Validation 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. Process Validation Auditing for Medical Device Companies** **Full or partial internal Process Validation audit - ISO and FDA QSR. We provide internal auditing services which allow for an independent review of this part of your quality system.** **C. Process Validation - System Implementation Consulting and maintenance** **Gap analysis, design solution (custom made system), standard operating procedures, implementation, training, verification of effectiveness, and follow up.**