



Machinery Installation Qualification (IQ) and Operational Qualification (OQ) Documentation Packages

**Prepared by our own Regulatory and Functional experts
to complement your new machinery acquisition**

Features/Specifications:

- Facilitates ease of installation and operational integration for newly purchased **FILAMATIC®** machinery
- Leverages expertise of experienced engineers that are experts in both FDA compliance issues and **FILAMATIC®** machinery
- Available in customizable configurations that offer the maximum flexibility in terms of specification requirements and degree of desired assistance



IQ Installation Qualification

- o Provides an organized installation plan executed after a new machine arrives at customer facility
- o Contains broad compilation of critical experiments and documentation instructions, e.g. FAT protocols, collection/archiving pre-construction drawings, “asbuilt” construction drawings, and operating manuals
- o Additional documentation includes aspects of systems installation, use, and maintenance – from uncrating, rigging, inspection and calibration of the system to verification of materials of construction and surface finishes
- o Defines materials that will be run on the machine, preventative maintenance regimen, and complete control system control documentation

OQ Operational Qualification

- o Provides an organized plan for verifying the operational capability of the newly installed machinery
- o Ensures that the system interacts properly with upstream and downstream process steps
- o Documents all standard operating procedures including preparation procedures for components, change parts, and fluid pathways along with applicable quality control procedures
- o Includes the following experiments: testing and qualifying of the control, container handling, liquid dispensing, gas purging, and closure handling systems
- o Offers procedures for cleaning and disinfecting the system