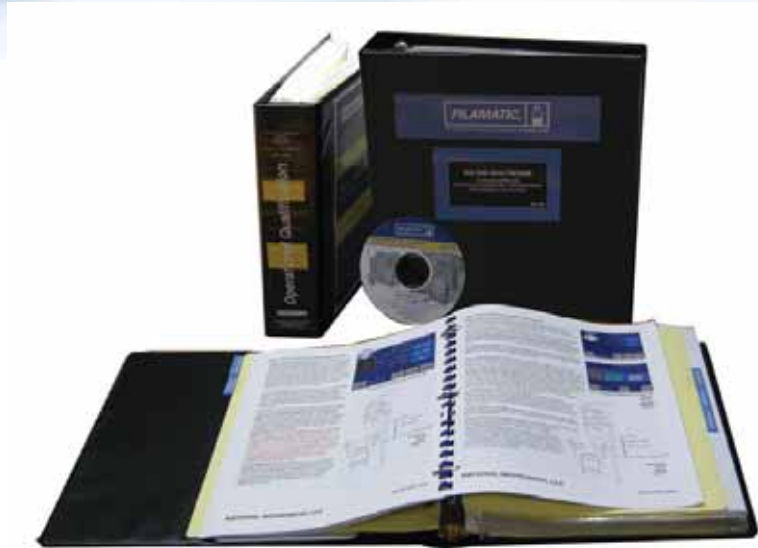


# IQ & OQ Validation Documentation Packages



- Prepared by Filamatic's Regulatory and Functional Experts to Complement Your New Machinery Acquisition
- Available in Customized Configurations that Offer the Maximum Flexibility in Terms of Specification Requirements and Degree of Desired Assistance
- Leverages Expertise of Experienced Engineers that are Knowledgeable in FDA Compliance Issues and Filamatic Machinery
- Facilitates Ease of Installation and Operational Integration for Newly Purchased Machinery

# IQ & OQ Validation Documentation Packages

## **IQ** Installation Qualification

- Provides an organized installation plan executed after a new machine arrives at the customer's facility
- Contains broad compilation of critical experiments and documentation instructions; for example, FAT protocols, collection/archiving pre-construction drawings, "asbuilt" construction drawings, and operating manuals
- 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
- Defines materials that will run on the machine, preventative maintenance regimen, and complete control system documentation

## **OQ** Operational Qualification

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

Filamatic's service team is dedicated to on-site visits for installation, maintenance, repair, operator training and retrofits. Our Service Agreement helps new and existing customers maintain mission critical equipment at the lowest possible cost. To learn more about the Filamatic Service Agreement, email [info@filamatic.com](mailto:info@filamatic.com) or call 866.258.1914.

