

FILAMATIC NEWS

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National Instrument Company Introduces Comprehensive, Customized Validation Packages to Help Customers Comply with Tougher FDA Regulations



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FOR IMMEDIATE RELEASE

National Instrument Company (NIC), manufacturer of **FILAMATIC**® liquid filling and modular compact monobloc systems for the pharmaceutical and biotechnology industries, has introduced a new series of documentation packages to help customers maintain best industry practices amid the rising tide of regulatory activity.

“We have structured these packages in a number of customizable configurations to offer our customers maximum flexibility in terms of both specification requirements and degree of external assistance. Our aim is to give our customers a way to comply fully with FDA regulations without having to turn to costly outside consultants,” said Joshua F. Rosen, Manager of Strategic Planning.

FILAMATIC® documentation packages include Installation Qualification (IQ) and Operational Qualification (OQ) protocols. Customers may choose to specify any or all of the services NIC offers.

For customers that are not accustomed to developing IQ or OQ documentation, our packages can provide one or more blank

protocols in a generic format. The blank configuration allows customers to use the protocol forms to design and draft experiments relevant to the specific **FILAMATIC**® system they use. Other packages add detailed experiments and instructions designed and drafted by NIC technicians to support a customer’s specific **FILAMATIC**® system.

“Whether our customers need customized support for acceptance testing, installation, qualification or validation, it’s critical that they have experienced technicians they know and trust to deal with compliance issues. No one knows these systems better than the people who design and build them,” said Mr. Rosen.



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Validation Packages



The IQ protocol provides an organized installation plan that is used after a new machine has arrived at a customer's facility. This is a broad compilation of critical experiments and documentation instructions that start with the FAT protocols and include the collection and archiving of all signed pre-construction approval drawings, "as-built" construction drawings, and operating manuals. Further documentation details every important aspect of system installation, use, and maintenance – from uncrating, rigging, inspection and calibration of the system to verification of materials of construction and surface finishes. The completed protocol provides the customer with a comprehensive archive containing specifications of materials that will be run on the machine, a preventative maintenance regimen, and complete control system control documentation including PLC programs and logic diagrams.

The **FILAMATIC**®OQ protocol provides an organized plan for verifying the operational capability of the subsystems associated with a newly installed unit. The experiments and resulting documentation verify that the IQ protocol was performed and approved and that the system interacts properly with upstream and downstream process steps. In addition, the protocol documents all standard operating procedures including preparation procedures for components, change parts, and fluid pathways, along with operational and quality control procedures. Customers also receive documentation indicating that any environmental control issues associated with the new system have been addressed. Further experiments include the testing and qualifying of the control, container handling, liquid dispensing, gas purging and, if applicable, closure handling systems. Plus, detailed procedures are provided for cleaning and disinfecting the system, particularly its fluid pathways.

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