ASK THE EXPERT

QUESTIONS WITH DANIEL ROBIDEAU

Quality Vision Services Inc.'s ISO Quality & Technical Manager discusses qualifying OGP systems for use in a regulated environment.

1 How can Optical Gaging Products (OGP) and Quality Vision Services (QVS, is a service branch of QVI/OGP) help your operation comply with FDA and CFR standards?

OGP® and QVS™ understand that medical device manufacturers must have processes that pass FDA audits. Despite many casual promises in the market, good manufacturers know that no metrology tool is "FDA compliant" on its own. It's the manufacturer's operations that must be qualified to FDA and CFR standards. At OGP, our equipment and software are proudly designed for use in FDA-compliant environments. Over the years, the QVS on-site service team has assisted thousands of medical device manufacturers with Installation Qualification (IQ) and Operational Qualification (OQ) of their OGP systems.

2 What does QVS's Installation Qualification (IQ) service provide?

QVS is an ISO 17025 accredited laboratory. All OGP systems installed by QVS comply to this accreditation. Following an accredited installation, QVS is capable of conducting testing to provide IQ – verification of documentation, environment, test equipment, artifacts, materials, lubricants, and equipment installation requirements. IQ helps customers meet CFR Part 820 requirements.

3 What does QVS's Operational Qualification (OQ) service provide?

OQ will provide verification of documentation, operational verification, process Failure Mode and Effects Analysis (FMEA), preventative maintenance schedules, and operational functionality forms. During the OQ, QVS runs numerous routines using accredited artifacts having measurements traceable to NIST or an equivalent National Metrology Institute to verify the system's ability to accurately measure using all installed sensors. OQ helps customers meet CFR Part 820 and CFR Part 11 requirements.

QVS can provide a suggested protocol for Performance Qualification the end user can follow to demonstrate the effectiveness and reproducibility of the process, and that the process works under a full range of conditions to be encountered in production.

4 What makes OGP's ZONE3 PRO metrology software useful in a regulated environment?

Compliance with complex regulatory requirements, such as FDA 21 CFR Part 11, requires much more than protecting passwords and restricting user access to files and folders on a corporate network. ZONE3® Pro software has built-in capabilities that directly support operational requirements of a regulatory-compliant environment.

User access permissions are directly linked to Windows® groups so specific users can be restricted from running or editing ZONE3 projects. For those with permission to run projects, audit trail reporting automatically logs all user actions.

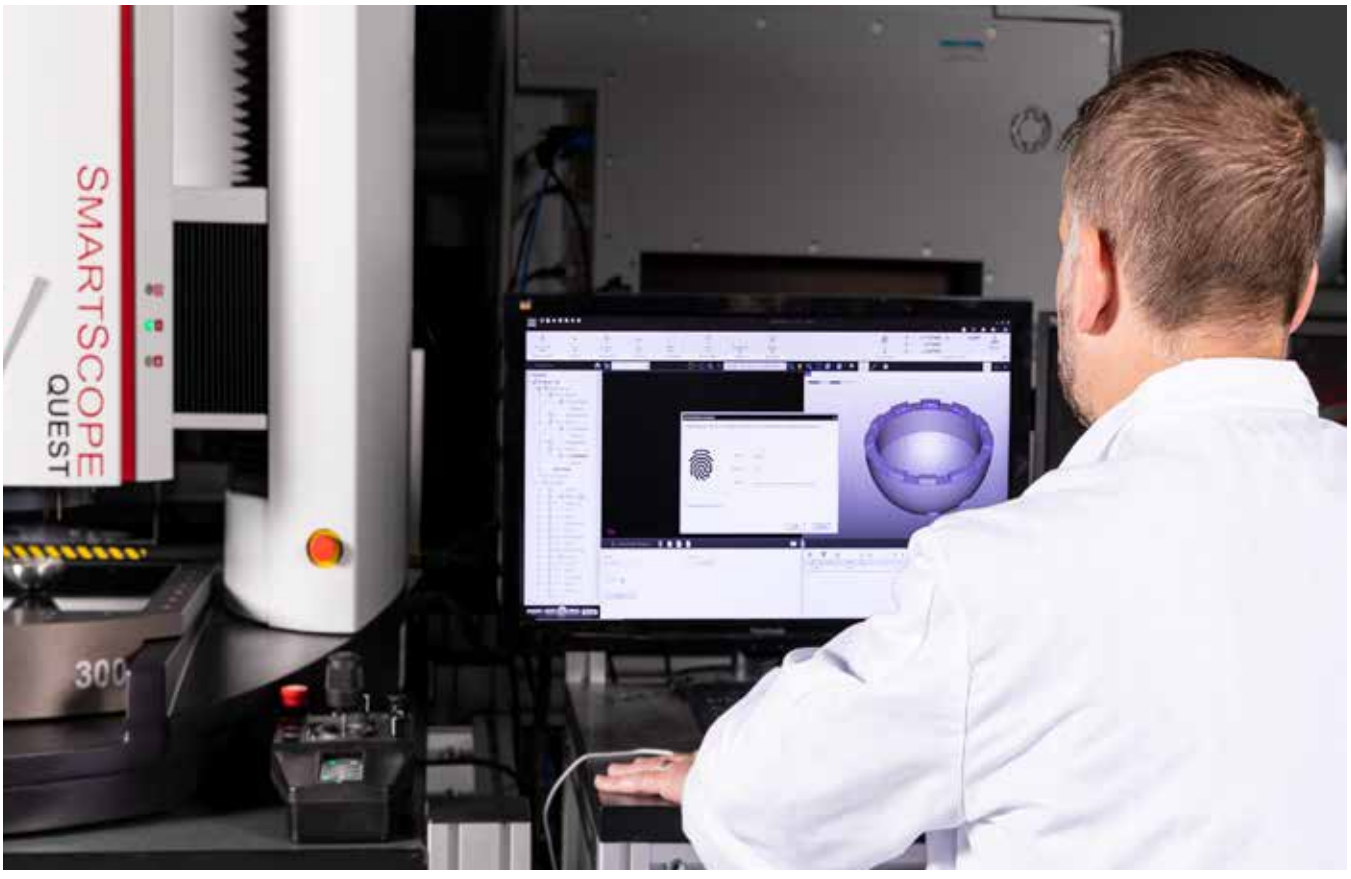
Electronic signatures of measurement results can be applied in the form of Windows user credentials or biometric data (e.g., fingerprint). Signature approvals can be controlled based on user permissions.

5 Is ZONE3 user friendly for operators?

ZONE3 Pro software contains LaunchPad, a simplified application with a highly configurable user interface that provides an operator view so those with only minimal training can launch and run programs. Setup instructions, documents, videos, and barcode identification can be added to each program.

User permissions can be set up to allow control over who is authorized to launch certain projects, the sequence in which projects are run, and the parameters within which projects may be executed.

FOR MORE INFORMATION:
http://ogpnet.com/zone3



ZONE3

Regulated Environments. When Results Matter.

Compliance with complex regulatory requirements, such as FDA 21 CFR Part 11, requires much more than password protection and restricting user access to files and folders on a corporate network.

ZONE3 Pro has built-in capabilities that directly support the operational requirements of a regulatory-compliant environment.

And even if you are not under the jurisdiction of any of the regulatory agencies, these ZONE3 capabilities may ensure adherence to your Quality Management System's internal requirements for a rigorous metrology environment.

Learn why ZONE3 is the software choice of leading manufacturers worldwide.

www.ogpnet.com/zone3

75 YEARS ogp

Confidence. When Results Matter.™