ZONE3® for Regulated Environments

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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. 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.

NOTE: ZONE3 Pro is required for access to all the functions described below.

User Access Permissions

User Access Permissions are linked to Windows® groups and the Windows® domain that each group is resident on. Users can be assigned permissions to launch specific software applications and may be further restricted regarding access rights within those individual applications. Within ZONE3, *User Access Permissions* can be set to allow or restrict access to specific functions of ZONE3 based on the individual user. These areas include:

- Project opening
- Project creation
- Project editing
- Saving images
- ZONE3 Offline
- System Properties
- Closing ZONE3
- Running projects
- Assist
- AutoID
- FeatureExtractor
- Tool Builder
- Probe/Laser Qualification Wizard
- Expiring Sensor Offset Qualifications
- Launching ICE™

Portal also allows setting specific software applications to be inaccessible to certain users, and for software to be launched automatically upon computer startup.

Locking Projects

ZONE3 projects can be locked by users who have the proper permissions in the Portal, to prevent any form of editing. Once an automated process that is part of a production or quality system has been validated, it may be locked and secured to prevent any further modification.

Audit Trails/Logging

Regulatory requirements for electronic records — for example, the dimensional inspection reports generated by ZONE3 — often need to be accompanied by computer-generated logging of the record's creation and modification. The Portal's *Log Viewer™* application allows viewing audit event records and log files for electronic records. These records consist of audit trail reports generated by ZONE3, ICE, and other QVI® software. Within the *Log Viewer*, you can quickly examine the most recent audit log file, open other log files, search for specific event records, and copy from or print log files.

LaunchPad

The *LaunchPad* application is a simplified yet highly configurable user interface that provides an operator view, where operators with only minimal training can securely launch and run programs. Setup instructions, documents, videos, barcode identification, etc., can be added to each program. Portal 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.
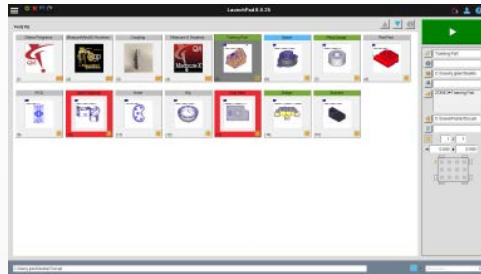
Task Based Programming

Task Lists are subsets of a master part program that can be run in lieu of the full program. Based on features selected to report, ZONE3 automatically identifies all steps required to measure the selected dimensions, including features needed for alignments and constructions. This allows existence of one master validated program, with many variations based on what is to be inspected/reported. Task Lists can also be used in conjunction with LaunchPad.

Error Handling

ZONE3 offers a series of settings for handling failed feature measurements and/or reports. For failures, you may choose to Continue, Assist, or End. Projects can also be configured to automatically capture and save images if out of tolerance or upon a measurement failure. Allowed recovery modes are accessible based on user permissions.

Failure Assistance Notes: If Assist is chosen for a failure, the operator may manually adjust finder settings and retry, or stop the program. If adjustments are made, the operator can add *Assignable Causes, Corrective Actions,* and *Notes* to be documented and reported to indicate the finder was adjusted, for traceability.

E-Signatures

ZONE3 can apply an electronic signature to PDF output of measurement results from the *Results Browser.* The e-signature can be in the form of Windows® user credentials or biometric data (e.g. a fingerprint). Signature approvals can be controlled based on user permissions.

Expiring Sensor Qualifications

The ability to set expiration dates for sensor qualifications assures the ongoing validated state of automated dimensional inspection processes. ZONE3 can react to expired qualifications in specific ways, e.g. whether to recommend or require requalification of an expiring sensor compensation.

Locked UCP Database

The *Universal Configuration Provider* (UCP) is a system service that manages the measurement machine system database used by ZONE3. Access to these key system parameters may be restricted through password protection, ensuring consistency in the configuration and compensation of the measurement machine. This maintains the validated state of the automated inspection processes. In addition, modifications to the UCP database are logged in the Audit Trail.
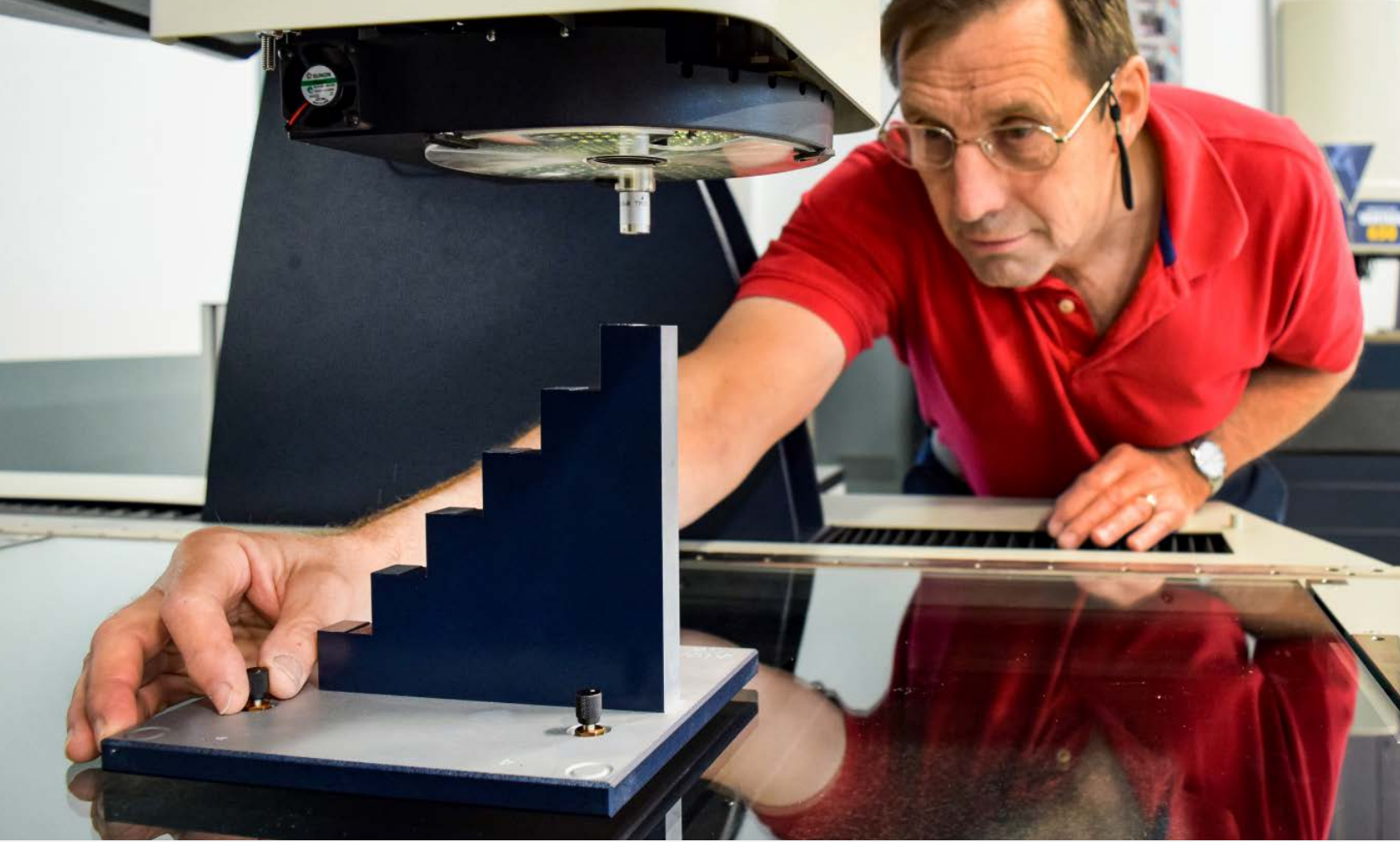
Supporting Documents, Products & Services

QVI® Systems in an FDA Regulatory Compliant Environment

This document provides information needed by users seeking FDA compliance when using a QVI measurement system.

QVI FDA Guidance

This document outlines the complete set of test protocols that customers can use to guide them through the IQ, OQ and PQ qualifications in 21CFR Part 820 & Part 11.

Equipment Installation Qualification (IQ) Service

The IQ includes analysis and report on verification of documentation, environment, test equipment, artifacts, contact materials and lubricants. Executor identification and deviation reports are provided. The service deliverables include completed documentation forms of equipment installation parameters that can be used towards compliance with FDA IQ requirements.

Equipment Operational Qualification (OQ) Service

The OQ service includes verification of documentation, Operational Verification, Process FMEA, Performance Evaluation, and a Preventive Maintenance Schedule. Executor identification and deviation reports are provided. The service deliverables include completed documentation forms of operational functionality that can be used towards further compliance with FDA OQ requirements.

Confidence. When Results Matter.™
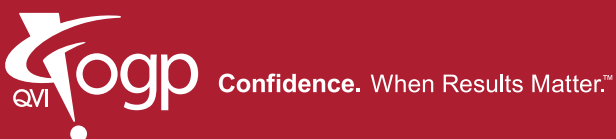
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