GxP Module in ZEISS ZEN 2 core
Your Software Module for Regulated Industries.

The GxP Module offers all functionalities that are needed for CFR compliance, such as an audit trail of all user activities.

The GxP module provides job templates for repetitive sample analysis in regulated industries.

Imaging Software Simplified

ZEN 2 core is powerful software for microscopy imaging, automated control of motorized ZEISS microscopes, and multi-modal workflows. ZEN 2 core provides a unified user interface for ZEISS microscopes and cameras. When you're running routine tasks with repeatable results, ZEN 2 core keeps it simple and gives you total efficiency.

GxP Module

The GxP module as part of the ZEN 2 core imaging software fits exactly to regulated industries such as the pharmaceutical or food industry. Profit from a variety of tools and functionalities combined with the required qualification and validation activities to make your system compliant to e.g. 21 CFR Part 11.

User Management & Roles

Precondition for a GxP environment is a user and user role management. You can configure the user privileges of the software as an supervisor. This makes sure, that only users with the respective skills can use certain functionalities.

- Audit Trail
- Release procedure of workflows
- Checksum protection of result data and workflows
- Disaster recovery

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GxP Module in ZEISS ZEN 2 core
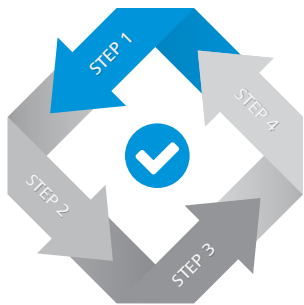## Your Software Module for Regulated Industries.

Audit Trail

In the Audit Trail, all interactions will be recorded (according to a risk based approach). Reproducibility and traceability of all end-result relevant actions are done. The Audit Trial is check sum protected and therefore prohibited from changes.

Beside others, following activities are recorded in the Audit Trial:

- Start up, shut down
- Login, logoff of users
- Change of parameters while running a workflow
- Creation of results in the archive
- Changes in the result archive
- Error messages
- Changes in user management

User Management / User Roles

Supervisor
Experienced User

Operator
Routine User

Job Mode

| Create & manage job templates | → | Run job templates |
| Browse job results | ← | Report job results |

Release Procedure of Workflows

STEP 1
STEP 2
STEP 3
STEP 4

Workflows will be released by using a defined release procedure. Using a checksum and electronic signature process ensures no changes in released – production ready – workflows.
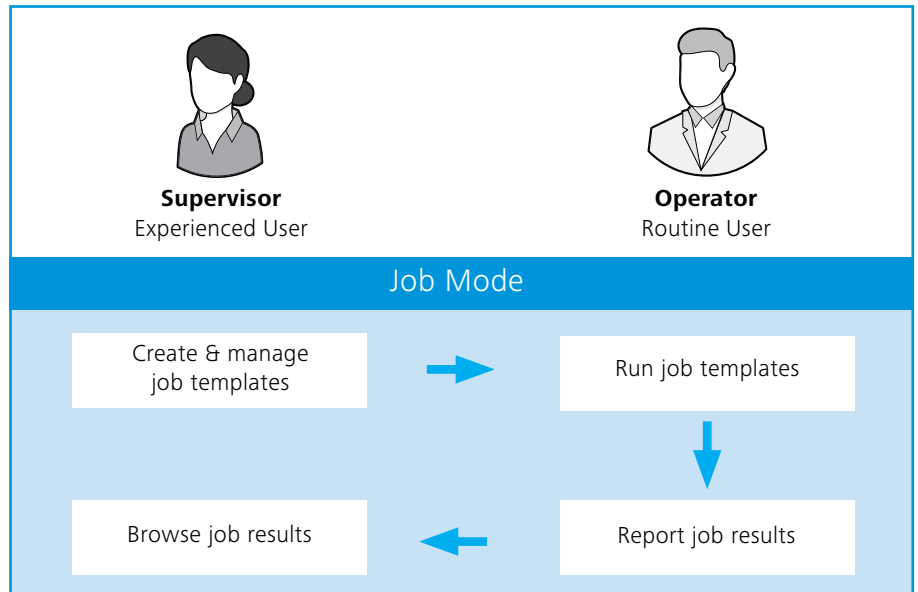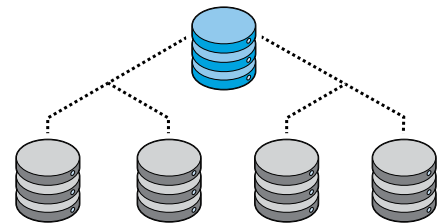
Checksum Protection of Result Data and Workflows

Verification of signature and files

Results and workflows are checksum protected and electronically signed. Unreleased changes and modifications are prohibited.

Disaster Recovery

Backup and restore functionality ensures a short in time production ready state in case of system breakdown.

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