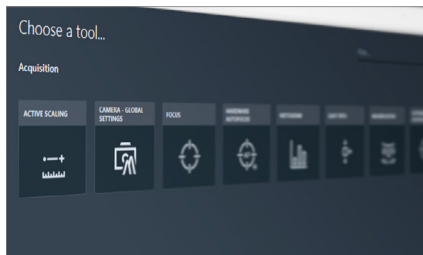


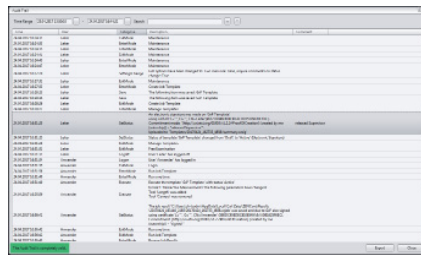
# Your FDA 21 CFR Part 11 Ready Software Module for Regulated Industries

## GxP Toolkit in ZEISS ZEN core

In the pharmaceutical industry or medicine production you generally need to work according to GMP or GLP. ZEN core with its GxP functionality allows you to customize, perform, and document your microscopy examinations in compliance with regulations such as FDA 21 CFR Part 11, Pharmacopoeia or EU EudraLex Volume 4 Annex 11 + 15.



The easy-to-follow GUI configuration accommodates tasks of all kinds and any complexity.



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



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

### Imaging Software Simplified

ZEN core is a powerful, yet easy to use, microscopy imaging software. You can set up individual workflows, from image acquisition all the way to a final report including analysis results. The user interface for the workflow is adaptive. That means, you can tailor it to your needs. ZEN core keeps it simple and efficient.

### GxP Function

The GxP Toolkit as part of ZEN core 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 or Pharmacopoeia. You benefit from:

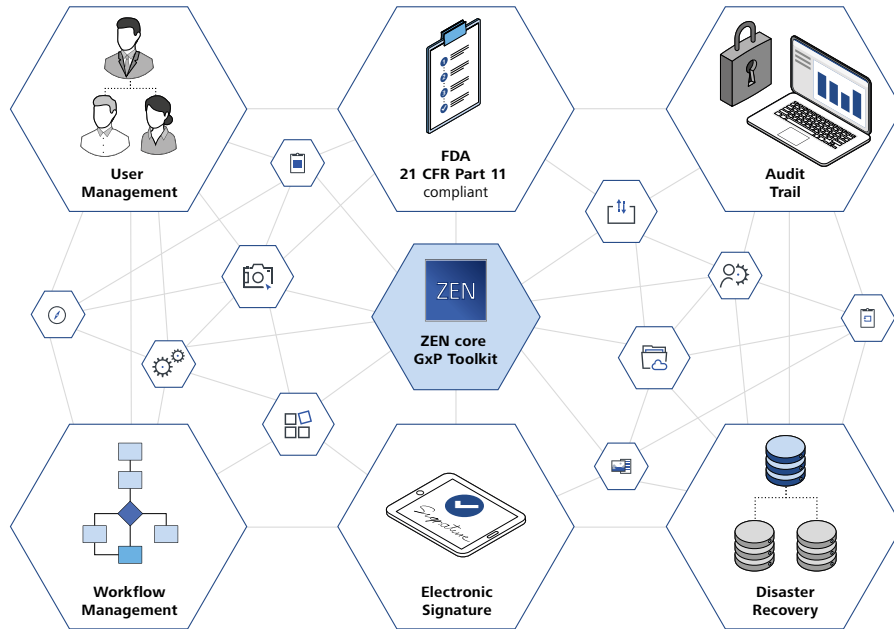
- Configurable user management
- Guided workflows
- Digital signatures
- A complete audit trail
- Checksum protection of your data

### 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 a supervisor. This makes sure, that only users with the respective permissions can use certain functionalities. It is also fundamental for releasing workflow procedures and electronic signatures.

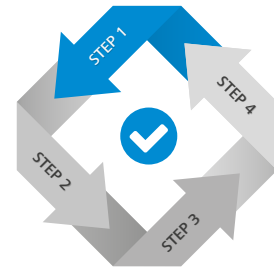
# GxP Toolkit in ZEISS ZEN core

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Every workflow can be made GxP compliant whether it is to characterize the particle size of powders, starch, or to check for the presence of contaminants or microbial load of production facility.

## Release Procedure of Workflows



Define a job, set up your imaging workflows, lock and hide microscope parameters according to your needs. These workflows guide your operators through a defined flow of consecutive tasks ensuring data repeatability and ease of use.

## Electronic Signature



Results and workflows are checksum protected and electronically signed.

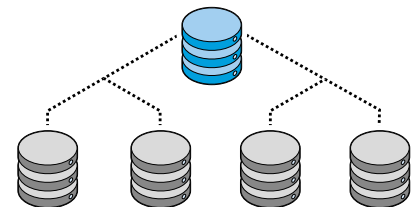
## Audit Trail

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 Trail is checksum protected and therefore prohibited from changes.

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

- 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

## Disaster Recovery



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



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Seeing beyond