

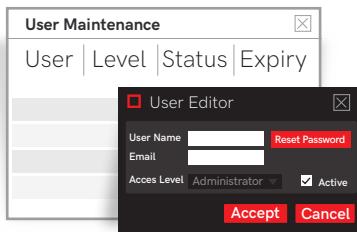


GlobalVision Compliance Add-On



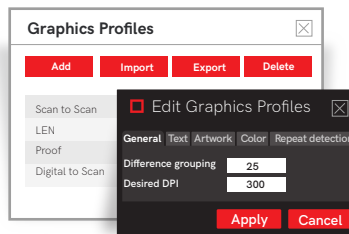
Software Controls for FDA 21 CFR Part 11 Compliance

The GlobalVision Compliance add-on lets you configure your system to meet both Annex 11 and FDA 21 CFR Part 11 guidelines for use in the pharmaceutical industry.



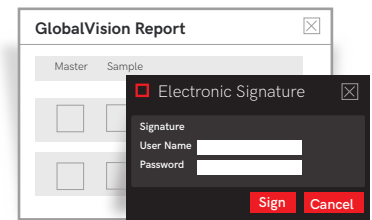
User configuration

- A hierarchy of access levels
- Non-reusable user IDs and passwords



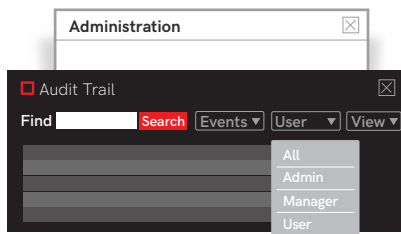
Inspection profiles

- Custom profiles that only admins and managers can create
- Structured workflows for a consistent inspection process



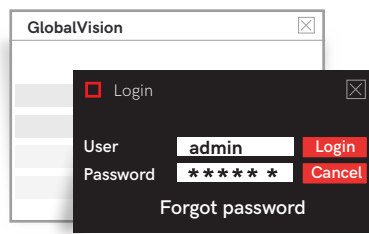
Electronic signatures

- Reports that are approvable only by specific users
- Signatures appear in Audit Trail and on physical reports
- Tamper-proof for greater data integrity and security



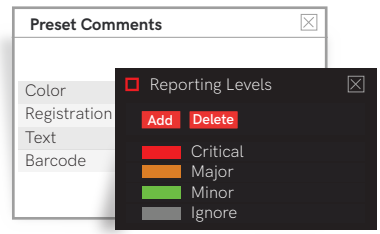
Audit Trail

- Restricted access to safeguard data
- Searchable, exportable data for easy review



Login management

- Log-ins, lock-outs, and time-outs
- In-depth administrative password management
- Simple and secure password recovery process



Administrative control over reporting levels

- Custom reporting levels
- Access to edit levels controlled by admins



ISO 9001:2015
certified



FDA 21 CFR Part 11
compliant



Annex 11
compliant



cGMP
compliant