



PharmASSIST

Audit Trail Module (FDA 21 CFR Part II Compliant)



PharmASSIST's 'Security and Electronic Signatures' features comply with the requirements laid down in **FDA 21 CFR Part II:**

- Checking Schedules
- Signing Schedules
- Verifying Schedules
- Signing Samples
- Signing with Passwords Only
- Password Expiry Period
- Changing a Password
- Maximum Password Attempts
- Storing Previous Passwords
- Mandatory Password
- Locking a user account
- Securing a section of the system from unauthorised access

In addition to the aforementioned, PharmAssist's 'Audit Trail Module' keeps a detailed log of additions, amendments and deletions to the Master Files:

- Master Product
- Test Plan
- Item
- Product Type
- Location
- User
- Violations

For example, a user called 'Fred' changes the text of the tare violation message from "One or more tare values are outside the tare limits. Weigh another sample immediately." To "One or more tare values are outside the tare limits. Weigh another sample immediately and inform Supervisor." An audit trail is created which records: the date and time of the change, the internal code for the tare violation message, the type of change, in this example 'an update,' the data fields before the update and the data fields after the update.

PharmASSIST Audit Trail

Time	Date	File	User	Type	Reason
11/20/2011 12:25		KEP2002	Fred	Update	File Maintenance
11/16/2011 11:45		KEP2002	Tan	Update	File Maintenance
11/2/2011 15:50		KEP2002	AM	Insert	File Maintenance

Old Value	New Value
Code: KEP2002	Code: KEP2002
Name: PLACEBO TABLETS	Name: PLACEBO TABLETS
Type: Tablet	Type: Tablet
Additive weight/ingr. Tsp	Additive weight/ingr. Tsp
Sample Size: 25	Sample Size: 25
Target: 250mg	Target: 250mg
Plausibility: 25%	Plausibility: 25%
Upper open limit: 266.75	Upper open limit: 266.5
Lower open limit: 233.25	Lower open limit: 233
Upper action limit: 264	Upper action limit: 264
Upper warning limit: 262	Upper warning limit: 262
Lower warning limit: 240	Lower warning limit: 240
Lower action limit: 237	Lower action limit: 237
Shelf life: 12 months	Shelf life: 12 months
Barcode:	Barcode:
Cpk limit: 0	Cpk limit: 0
Recheck: No	Recheck: No

This screen shows an example audit trail for a product named, 'KER2002.' The top portion shows a list of audit trail items sorted in descending order of date and time. The lower portion shows the details of the selected item, the left hand panel lists the previous values, and the right hand panel lists the new values. Values that differ are highlighted.

The 'Audit Trail Module' also provides:

- Encryption of user passwords
- Enhanced security for File Maintenance

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