

For more information please visit

www.smartlogbook.com

to arrange a personal demo!

We are happy to offer the total package of validation including the test script generation according to customer requests and also data integrity related consulting and evaluation support.

Support and Demo requests:

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Please contact us for more information!



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SmartLogBook® electronic log book solution

SmartLogBook® was developed as a „tailor made“ solution to meet the requirements of the pharma industry and chemical laboratories. The input of records is possible using a web client or an iOS App being available for iPhone or iPad as well as an Android App for other smartphones and tablets. This client server solution can be implemented as a cloud based solution as well as in-house hosted service.

The data is stored in a referenced file structure and does not necessarily require the implementation of a database. However it will be possible to use databases as storage for log book entries in a further stage of development.

During development, the focus was to fulfill the high requirements in respect of data integrity and security, being obligatory for the pharma and chemical industry. To allow workflows with dedicated functions of the persons involved, users are grouped as „SystemOwner“, „Approver“, „Reviewer“ and „Author“. Using Microsoft Active Directory authentication is possible as well as local user authentication.

The numbers of Log Books being handled by a SmartLogBook® Server is just limited by the available hard disk space storing the log book related entries. The store is organized by objects with related elements to handle the information for each system element. Attachments like documents and pictures can be assigned to each log book entry individually. By defining workflows (modes) it is possible to address special requirements and different situations requiring documentation in the log book. By default the following modes are available:

Simple

Generate an entry and sign by e-signature (Username/ Password)

Advanced

Generate an entry and sign by e-signature (Username/ Password). The entry is routed automatically to a quality related person for approval by e-signature.

Complex

Generate an entry and sign by e-signature (Username/ Password). X-check by another person is required (System Owner / Quality) to approve this entry. This is intended to allow pre-approval of activities to be documented in the log book together with the documentation of the respective activity after being performed.



After finalization the information after implementation additional approval by responsible function (System Owner / Quality) is required to close the workflow of this mode.

e-Mail notifications can be activated to ensure automated notification of approvers to make them aware of Smart Log Book© entries awaiting approval.

Web Client

The Web Client interface is divided into two main sections: 'Master' and 'Details'.

Master Form:

- Language selection: En, De, Hr, Es, It, Fr, Ru
- Object Value Id: [Input field]
- Hide retired items: [Toggle switch]
- TestMaster1: VIE-Test1
- Active: [Toggle switch]
- Id: b9608352-0d96-4dc7-a0e7-27523ba8f082
- Object Id: VIE-Test1
- Title: TestMaster1
- Status: Active
- From: 22/09/2020
- To: 30/09/2021
- Text: Testing Master for evaluation
- Department: Validation
- Cost Center: 1234567890
- Site: AT-VIE1
- Room: EG/1/1
- System Owner: HS-AFN
- Type: Production
- Vendor: VendorTest1
- Created Date: 22/09/2020

Details Form:

- Module 1: Logbook entry [Text area, Max. 4000 characters]
- Module 2: Author signature [Sign button]
- Module 3: (Waiting for Module 2)
- Reviewer signature [Text area]

Bottom Panel:

- Buttons: SIMPLE, ADVANCED, COMPLEX, CANCEL

Picture 1: general design of Web Interface



Smart Log Book© creation is only possible using the web interface of Smart Log Book© and requires membership of the Smart Log Book© Administration group.

To support the handling during daily use the general design of the Smart Log Book© user interface is intentionally very simple and reduced to the required elements. For even more simplicity Smart Log Book© will support Nymi Band for authentication and e-signature.

The following languages are currently implemented in Smart Log Book© user interface: German, English, Spanish, Italian, French, Russian und Croatian.

It is possible to switch between this languages any time dynamically.

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iOS Client

The iOS Client interface is designed for mobile devices and includes the following screens:

Einträge (Entries):

- TEXT: Some description text
- ABTEILUNG: Quality/Maintenance
- KOSTENSTELLE: 2282764
- STANDORT: building 1
- RAUM: 1.14
- SYSTEMVERANTWORTLICHER: Robert Reviewer
- TYP: ELISA Reader

Details:

- MODULE 1 (schreibgeschützt): LOGBUCH-EINTRAG (4000 Zeichen) * Bernhard-Test-Advanced
- BILDER (max. 5): BILD 1
- MODULE 2 (schreibgeschützt): AUTOR UNTERSCHRIFT * Unterschrieben von: Ariel Author

CS mit ELISA Reader BioTek EL...:

- Objekt ID: [Input field]
- Abgeschlossene Ausblenden: [Toggle switch]
- Wählen Sie ein Datum: [Date picker]
- Neuen Eintrag hinzufügen: [Add button]
- 36 ÜBERPRÜFER UNTERSCHRIFT... (Robert Reviewer) Complex entry 2020/08/24
- 35 AUTOR UNTERSCHRIFT (Ariel Author) Simple

Picture 2: general design of iOS Interface



On iOS based devices (iPad/iPhone), Android devices and Laptops/tablets with camera capability QR-Code scan functionality can be used to ensure that entries are assigned to the correct system. Scanning the code located on the devices will automatically activate the proper log book and allows immediate documentation accordingly.