QUALIS STABILITY®

PRODUCT NOTE

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Qualis Stability a complete validated stability study management system

Qualis STABILITY is a web based stability management system designed based on guidelines provided by the FDA/ICH. Designed to meet the regulated laboratory handling a wide range of products, dosage forms that are manufactured for various international markets that need to cater to variety of regulatory needs across the globe.

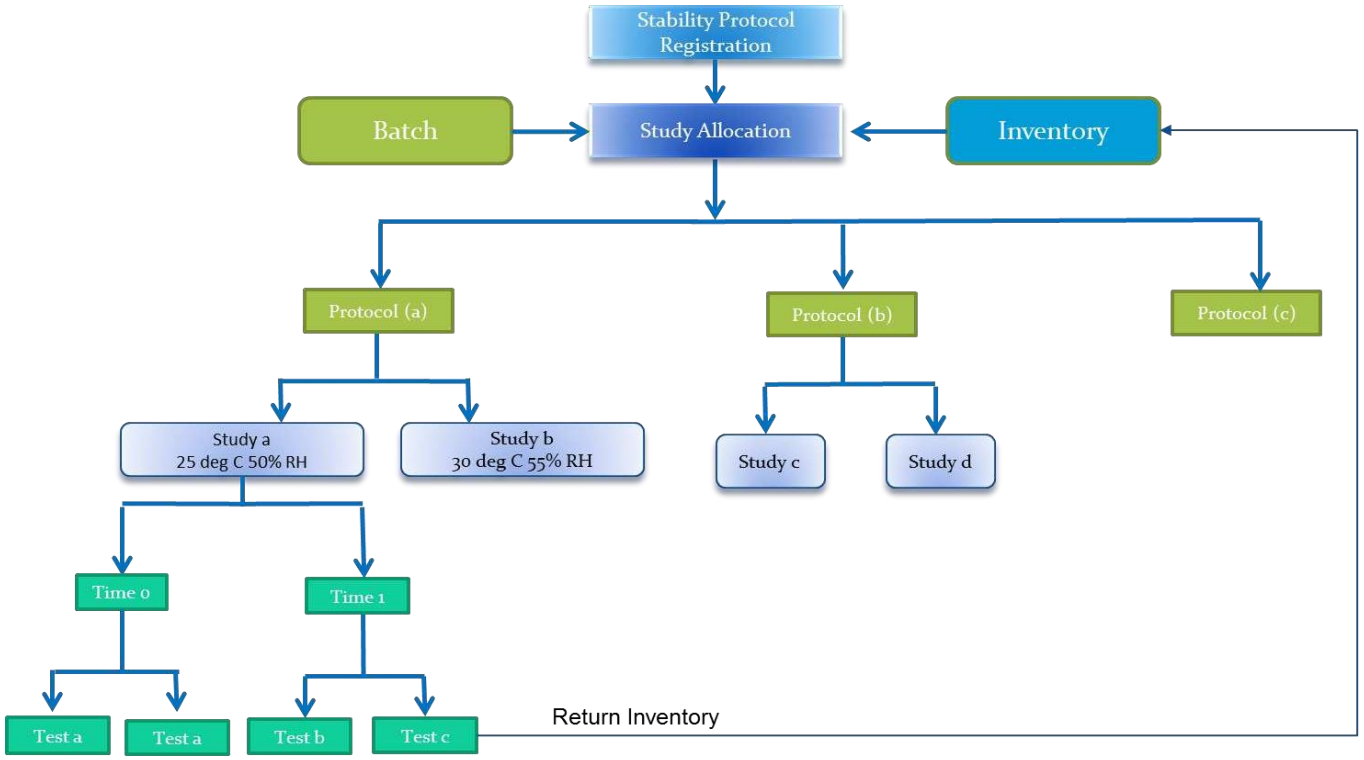
Introduction

Qualis STABILITY can be deployed and scaled up from a simple single user to multi-user environment system in any windows environment. It is a simple yet sophisticated software which is user-friendly with a simple workflow reducing the time and manpower spent on the stability study creation, approval and execution. It handles complete workflow of a typical stability study planning, including protocols with appropriate storage conditions, pull time periods with appropriate tests to be performed at various time points, re- cording of day to day stability test data results and generating reports for stability studies

Features

- A Web based stability management software that runs on any browser with a database for stability studies.
- A completely independent system that can manage stability protocols, conduct studies, maintain study conditions, chambers. inventory control for study sample consumption, sample registration, result recording, review and approval and study reports
- Works with MS-SQL Server or PostgreSQL database as backend
- Complete 21 CFR Part11 features with audit trail better compliance for regulated labs

Study Structure



Workflow

- Manage study protocols
- Manage Stability Chambers
- Storage Structure
- Manage Packaging

- Register stability Protocol
- Create Study
- Review & Approve Study
- Start Study

- Automatic sample pre-registration
- Pull sample list
- Job Allocation
- Results Entry
- Results Approval
- STF (Review & Approval)

- Query & Search
- Stability Protocol Report
- Protocol Inventory Report
- Study Test format Report

"Implementing e-"Stability helped in moving to electronic stability data management, automating data entry and report generation has improved our efficiency and regulatory compliance"

–Director of QC, Leading U"FDA approved laboratory

Chamber Management

Maintain storage chambers with temperature, humidity conditions, location and masters for racks & trays

Protocol Management

Maintain different study protocols and upload reference protocol documents

Protocol Registration &Study Management

Create study plans based on protocol. Register batches for studies with time points, tests, inventory etc. Review and approve plans. Generate study plan report

Registration (Pull samples), Job allocation, Results & Approval

After starting and execution of stability study scheduler system registers samples to be pulled at appropriate time. Complete the registration, allocation work for personnel, record results, approve and release results of stability tests

STF Report

Review and approve results generated for all time points and generate a final stability test format report

Reporting

Several standard reports are provided with the system including protocol report, inventory report, stability test format report and summary reports.

System Requirements:

"Server & Client (up to 5 concurrent users): Windows® XP, Vista, Win 7, Win 8 with 2GB RAM, 100GB HDD, SQL-Express or SQL –Server 2016 or higher, or PostgreSQL.

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