Automation of Stability Data Reporting and Trend Analysis at CSL Behring

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About CSL – we are active worldwide

60+ Countries worldwide

Over 8,500 annual Revenue bio. US $

8 Manufacturing Sites

25,000+ Employees worldwide

R&D Investments of 2,900 bio. US $
in 5 years drive promising new products forward

1,700+ R&D Employees

220+ Plasma donation centres throughout Europe and North America

Connecting Pharmaceutical Knowledge
About CSL Behring

18.000 +

employees worldwide

- Global leader in plasma therapeutics market
- Headquarter in King of Prussia, USA
- Develops, manufactures & markets biotherapies for:
  - Coagulation disorders
  - Immunological disorders
  - Pulmonary therapies
  - Wound healing therapies
  - Critical care therapies
- Operates one of the world’s largest plasma collection networks.
Stability Studies - Purpose

• Stability Studies are conducted in order to verify product stability over shelf life.

• Samples of these batches are stored under several different conditions and stability indicating parameters are measured regularly during the storage.

• The results are reported and a trend analysis has to be done.
Stability Data Reporting

Available data → Manual typing → Individual data sheet → Copy/paste into tables → Trend analysis → Paste graphs into reports → Stability study reports

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Paperless Project

**Goal:** «Automate stability data reporting and trend analysis within STATISTICA and validate the process»

**Steps:**

I. Guarantee data availability in Data Warehouse
II. Process data in STATISTICA
III. Implement trend analysis and outlier testing in STATISTICA
IV. Integrate audit trail and electronic signature
V. Implement direct export into templates (word & pdf)
VI. Test and validate process
I. Data availability in Data Warehouse

Data Warehouse (Microsoft SQL Server)

Source Systems

Data Analysis Tools

Shiny

TIBCO® Statistica

Statistica Warehouse

Source Systems:
- JAG
- SAP
- LABWARE
- TrackWise
- Excel
II. Data processing

User Input*

- Data from table 1: Specific data for Stability Study
- Data from table 2: Final product testing
- Data from table 3: Additional testing

Intermediate data 1

Intermediate data 2

Final data

Reference data sheet

Defines per product and country, what parameters need to be included

* Stability Study Number(s), Batch Number(s) and Number(s) of additional samples
III. Trend analysis and outlier testing

- User activates trend analysis
- Trend analysis (with one or several batches)
- Optional outlier testing
- Trend analysis done without outlier
- Linear or non-linear regression
- Dixon outlier test
**IV. Audit trail and electronic signature**

- **User 1** generates data.
- **User 2** reviews the audit trail and approves it.

- 21 CFR Part 11 compliant
- Approved data and any further outputs are locked.
V. Export into templates

- Approved data tables
- Approved trend graphs

Export into predefined templates
User receives word document and encrypted pdf
VI. Testing and validation

Workspace in STATISTICA

- User requirements
- Risk assessment
- Test case

Successfully tested and validated
Benefits

- Reduction per stability study report with 3 batches: ~1 working day (reduction of 35%)
- Release people from non-added value jobs
- More time for scientific tasks and data evaluation (investigate unexpected trends, etc.)
- Improvement of quality (of data and report) - less error prone
- Establishment of large historical database