cencora

PharmaLex

Compliance and confidence with SMARTSTATS

Compliance and confidence with SMARTSTATS: Your SaaS solution for analytical procedures and stability reporting

Our SaaS solutions are the outcome of two decades of expertise and development and used by a broad range of biopharmaceutical companies with success. SMARTSTATS is an umbrella software consisting of modules that facilitate report writing in line with regulatory guidelines and authority (EMA/FDA/MHLW/...) expectations.

Key features

Automated validation reporting

Generate validation reports for your analytical procedures and bioassays, simplifying the submission process and saving valuable time.

Stability suite excellence

Accurately compute shelf life and internal release limits with our Stability Suite, producing submission-ready reports in seconds while following eCTD standards. Results are in line with ICH-Q1 requirements.

Trusted by industry

Our suite has been trusted by major biopharmaceutical companies for nearly two decades, with hundreds of reports successfully submitted to regulatory authorities.

Following ICH guidelines

Compliant with ICH-Q2(R2), ICH-Q14 and ICH-M10 guidelines, SMARTSTATS ensures integration and conformity for your reporting needs.

Easy qualification process

Enjoy the benefits of a fully integrated validation package with SMARTSTATS, where validation and maintenance are included in the license.

Standardization and efficiency

Allows standardized validation reporting across your organization, reducing human errors and saving costs and time in report writing.
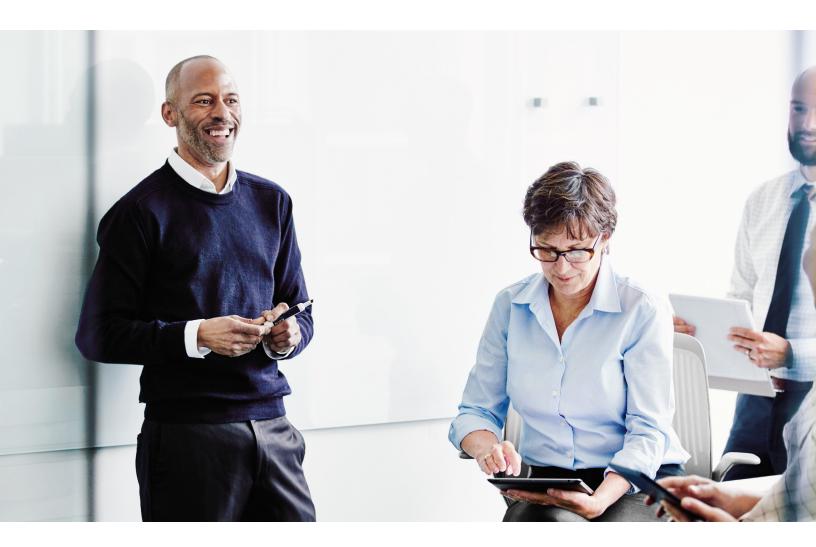
Beyond Excel

Go beyond the limitations of Excel with advanced statistical functionalities, qualified computations.

User-friendly interface

Designed by statisticians for non-statisticians, SMARTSTATS offers an intuitive and easy-to-use interface for best-in-class decision making.

Qualification

SMARTSTATS is qualified according to the 21 CFR Part 11 standards.

SMARTSTATS provides compliance to regulatory guidance and confidence in your results

Introducing our suite of smart software solutions designed to improve analytical method validation, bioassay validation, method transfer, and product stability evaluation.

Smartenoval **simplifies the reporting phase for validation of analytical methods, both relative and absolute, for various techniques such as LC, GC, EC, AAS, titration, UV, ICP and more. Features include**

- Compute accuracy, precision, and Total Analytical Error profiles (TAE).
- Optimized experimental design within the QbD framework.
- Generate reports compliant with ICH Q2(R2), ICH-Q14 and ICH-M10 as well relevant ISO regulations.

Smartseelva **validates bioassay, including ELISA, RIA, parallel line, parallel curve, slope-ratio, microbiological assays, qPCR, and others. Features include**

- Compute accuracy, precision, and Total Analytical Error for validation.
- Generate reports compliant with ICH Q2(R2) and USP 1033 standards.
- Potency module: generate reports for the qualification or validation of relative potencies assays for which analytical results are assumed following a lognormal distribution, in compliance with USP 1033.
- Optimized experimental design within the QbD framework.

Smarttransval **assesses method transfer feasibility between labs using the tolerance interval approach. Features include**

- Determine method transfer viability between sender and receiver labs.
- Generate comprehensive transfer reports for quantitative analytical methods.
- Assess risk of out-of-specification results at the new lab.

Smartstabelity evaluates product stability and estimates shelf-life. Features include

- Assess long-term stability and shelf-life.

- Compute release limits and predict degradation using the Arrhenius equation.

- Identify out-of-trend results and establish standard re-test periods.

- Generate reports compliant with ICH Q1E guideline.

Empower your analytical processes, streamline validation, and ensure product integrity with our suite of smart solutions.
Choose smart. Choose excellence. Choose SMARTSTATS!

Contact us
www.pharmalex.com/contact-us