PLA 3.0

PLA 3.0 – Latest Developments

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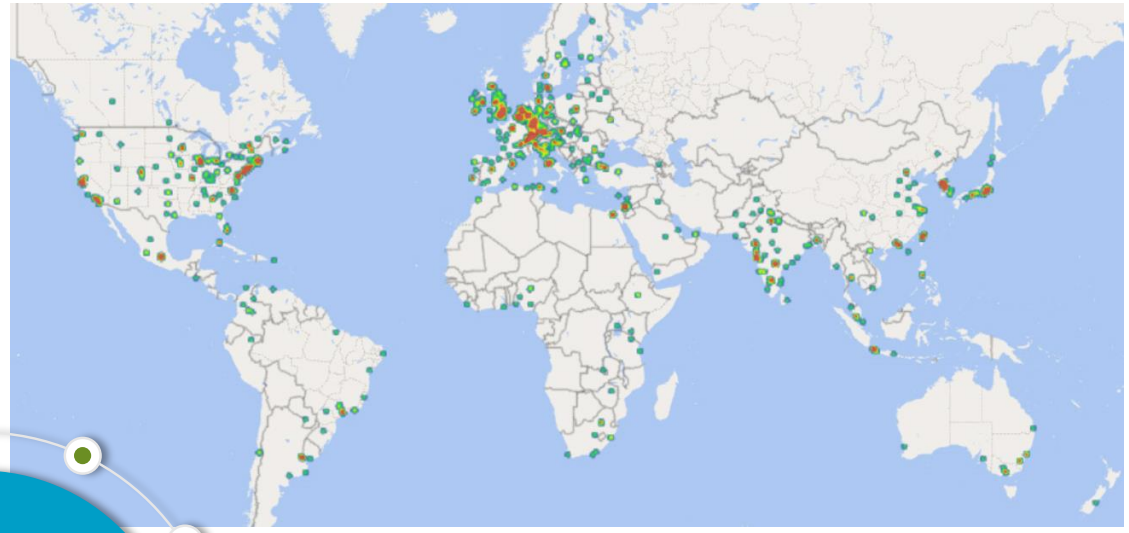
About PLA 3.0

End-to-end Bioassay Management Software developed for

- Pharmaceutical industry
- Biotechnology companies
- Gene and cell therapies
- Regulatory authorities



Used by

- all top 100 biopharmaceutical companies
- 1,000+ organizations in 80+ countries
- 10,000+ estimated end-users

Stegmann Systems

- Located near Frankfurt (Germany)
- 25+ years of experience in Biological Assay evaluation
- 45 employees, 30 developers, statisticians and scientists are directly working for PLA

Analysis.
A broad range of ready-to-use analytical methods.

Integration.
Seamless integration for enhanced laboratory efficiency.

Lifecycle.
Your entire bioassay needs along your product lifecycle in one solution.

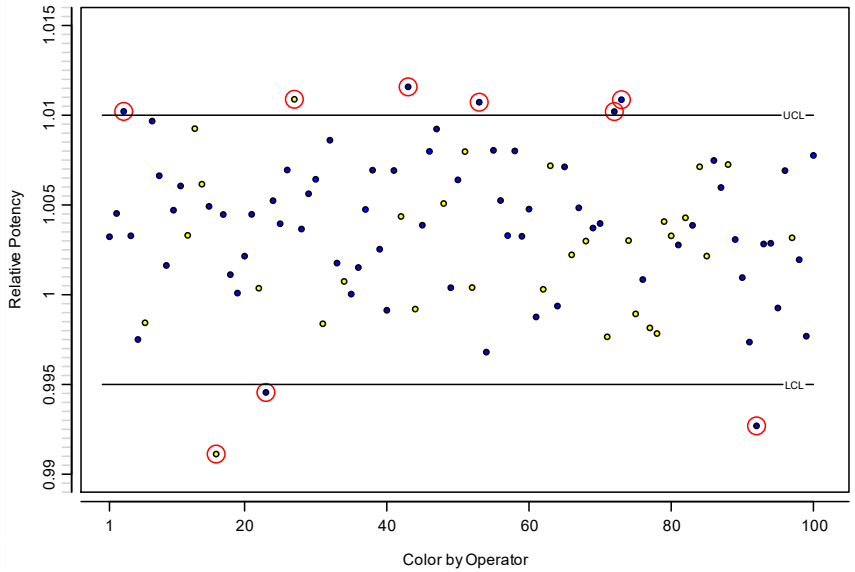
Compliance.
Developed in compliance, for compliance: all compliance topics for a global market covered.

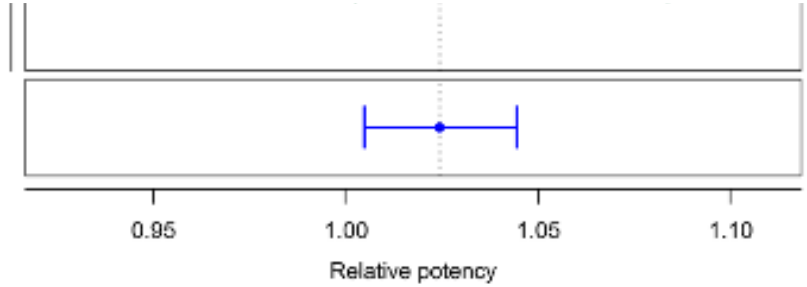
Knowledge.
Knowledge drives success in biological assay development.

A broad range of ready-to-use analytical methods.

Commercial off-the-shelf bioassay methods implement all guidance of all countries and industry best practices, ranging from single assay analysis to reportable values. The core capabilities of the software are enhanced with powerful development and monitoring tools. In addition, customer-specific modules can extend the software for specific needs.

- Potency assays
  (Parallel-line, Parallel-logistic, Slope-ratio, Quantal response ...)
- Content assays
  (Calibration curves, Interpolation, Curve analysis, ...)
- Impurity assays
  (Endotoxin detection assays)
- Development Tools
  - Method Development & Validation
  - Equivalence Margin Development
  - Simulations
- Monitoring (Statistical Process Control)





PLA 3.0 – Analysis: A modular system

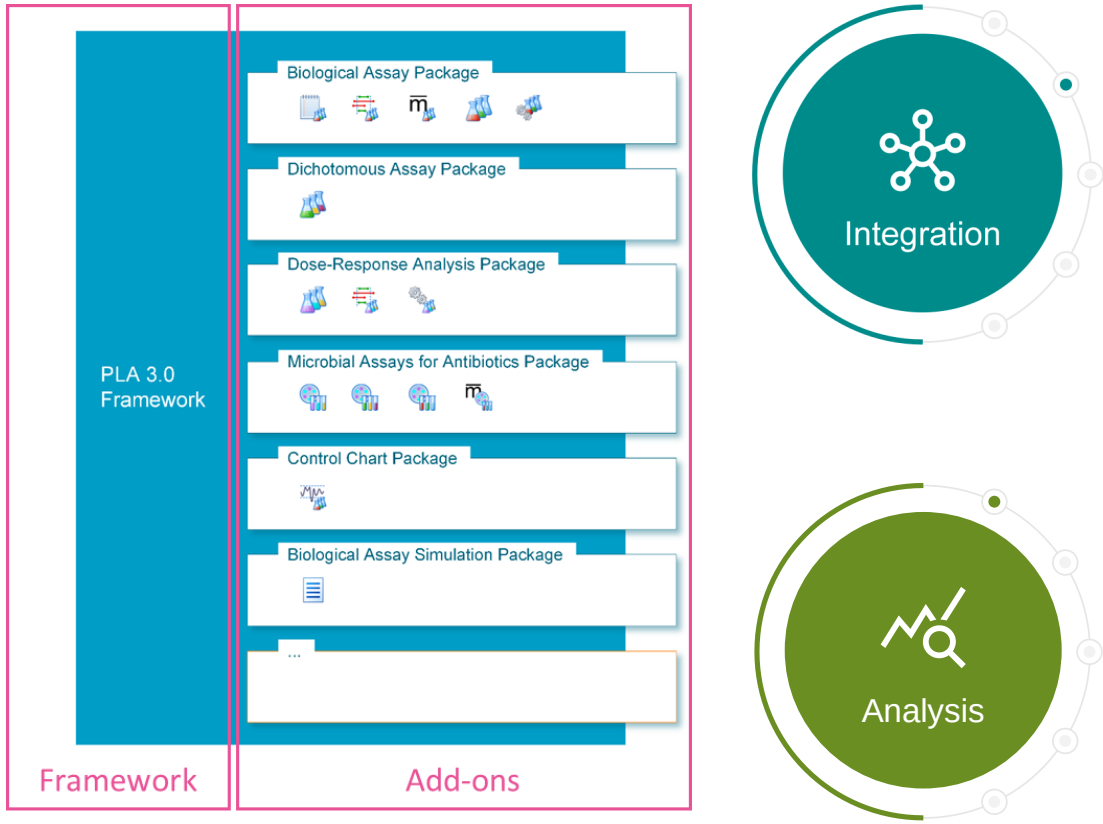
PLA 3.0 framework

- Security, validation & compliance
- Data management & integrity
- Account management

PLA 3.0 add-ons

- State-of-the-art analytical methods
- Supporting functionalities
- Customer-specific extensions

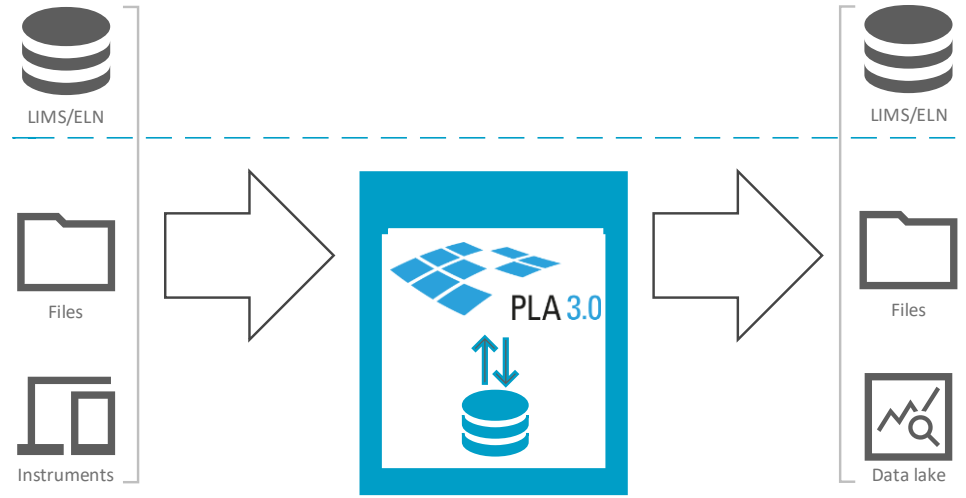
- Independent extensibility of PLA 3.0 platform and add-ons
- New capabilities with each version



Seamless integration for enhanced laboratory efficiency.

In the era of Laboratory 4.0, the seamless integration of digital technologies is crucial for optimizing efficiency, productivity, and data management in laboratory environments. PLA 3.0 facilitates this integration by connecting various analytical instruments and data systems, enabling advanced workflows and data exchange.

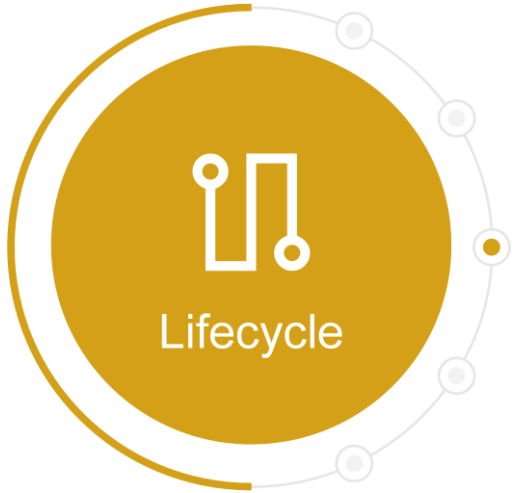
- Streamlined operations
- Integrity
- Compliance
- Advanced analytics
- Informed decision making

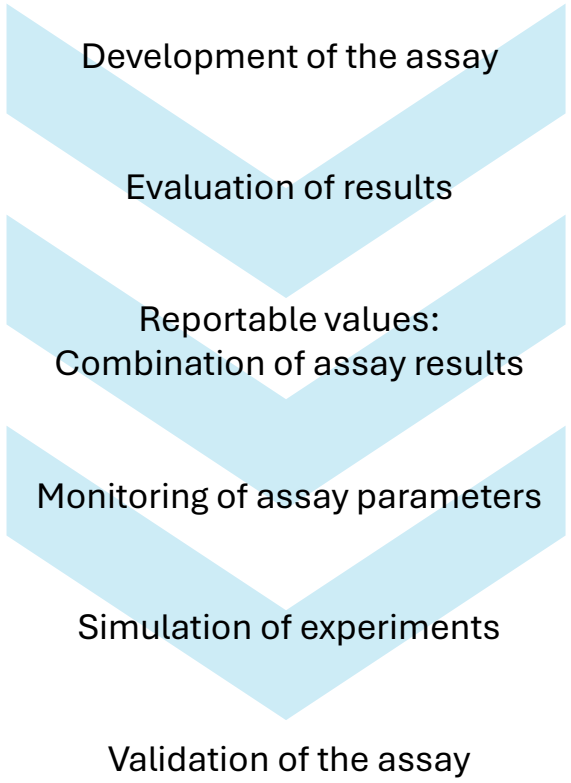


Your entire bioassay needs along your product lifecycle in one solution.

One software to handle your bioassay needs along the entire product lifecycle from research & development to manufacturing. Supports the ICH Q14 analytical procedure lifecycle for constant improvement of the analytical method, allowing for a seamless transition from development to manufacturing.

- Analytical Procedure Development
  - Studies
  - Analysis of Experiments
  - Equivalence Margin Development
- Analytical Procedure Validation
  - Validation according to ICH Q2 & USP <1033>
- Routine Use and Monitoring
  - Routine operations with defined methods
  - Segregation of duties in the lab
  - Control charts





Developed in compliance, for compliance: all compliance topics for a global market covered.

From analytical compliance to various national pharmacopeias (US, European, Chinese, Japanese) to technical compliance (21 CFR part 11, Eudralex Annex 11, GAMP5, ALCOA+), all compliance topics play a major role in PLA and ensure your global market compliance with minimized efforts.

- Analytical compliance
  - National pharmacopeias
  - Best practice statistical approaches
- Technical compliance
  - 21 CFR Part 11
  - Eudralex Vol. 4 Annex 11
  - GAMP 5, ALCOA+
  - Data protection & integrity
- Development compliance

Knowledge drives success in biological assay development.

Expertise in analytical methods and techniques is essential for successfully developing and analyzing Biological Assays. Ensuring predictable project timelines demands a competent and knowledgeable team. The PLA 3.0 Academy and PLA 3.0 Knowledge Center provide the foundation to effectively build and maintain your team's expertise.

- PLA 3.0 Academy to accelerate onboarding
  - On demand & live courses
  - Learning path from novice to expert level
  - Short videos
  - Weekly free webinar
- PLA 3.0 Knowledge Center to increase your lab's efficiency
  - Key concepts
  - Use cases
  - Best practices
- PLA Support Portal to receive expert assistance
  - Technical, scientific & statistical support

Thank you!

Academy PLA 3.0

https://learning.bioassay.de

Knowledge Center PLA 3.0

https://help.bioassay.de

Free Webinar – weekly