



PLA 3.0 – Latest Developments

CASSS Bioassays 2025, 4/8/2025

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About PLA 3.0

End-to-end Bioassay Management Software developed for

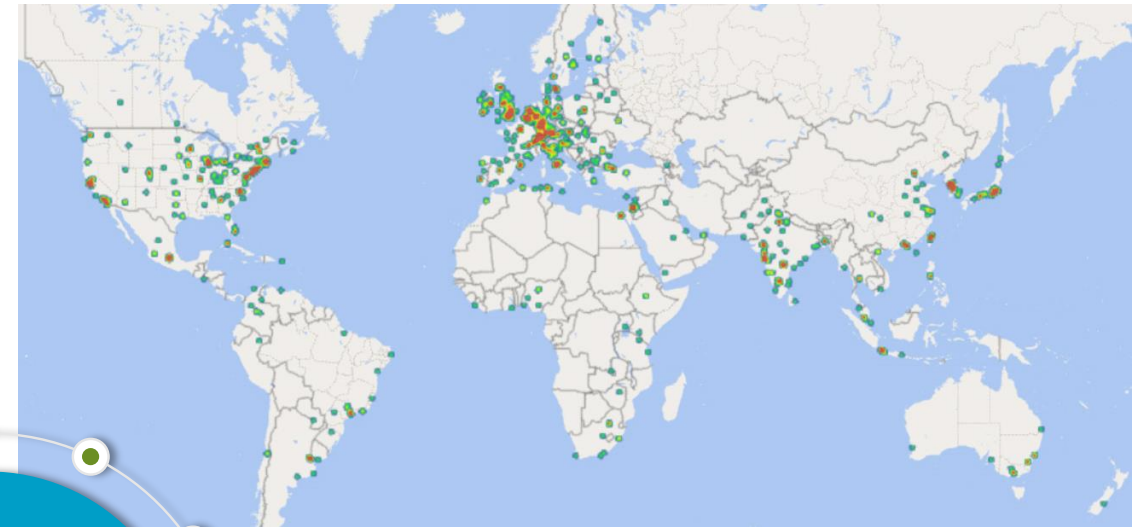
- › Pharmaceutical industry
- › Biotechnology companies
- › Gene and cell therapies
- › Regulatory authorities

Used by

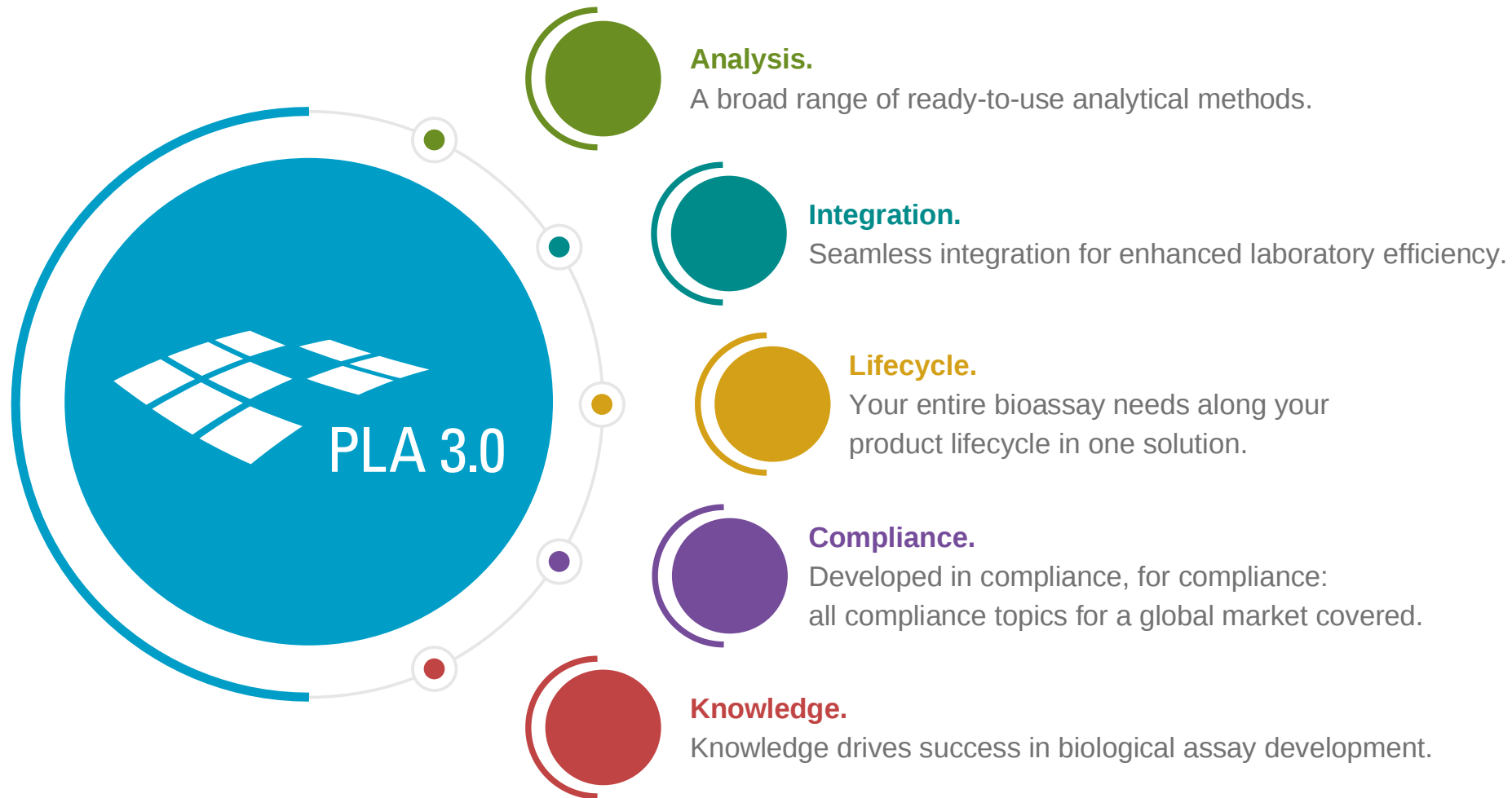
- › all top 100 biopharmaceutical companies
- › 1,000+ organizations in 80+ countries
- › 10,000+ estimated end-users

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



PLA 3.0 – End-to-end Bioassay Management Software

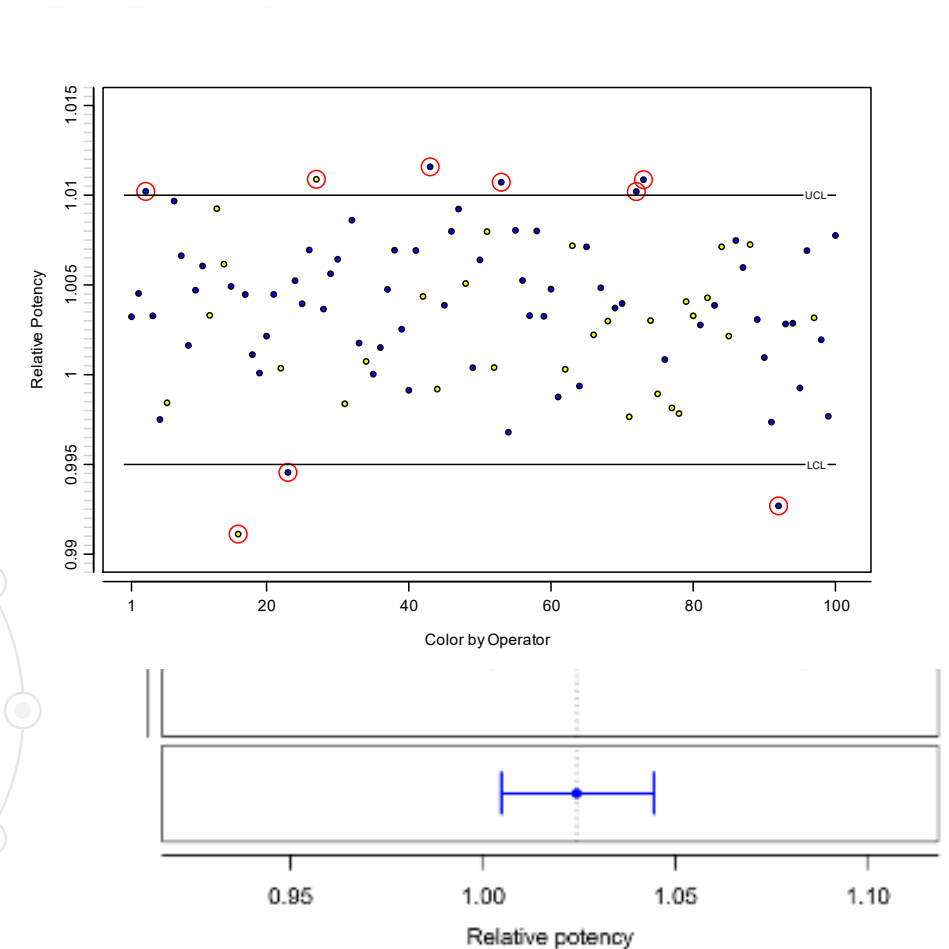


PLA 3.0 – Analysis

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)



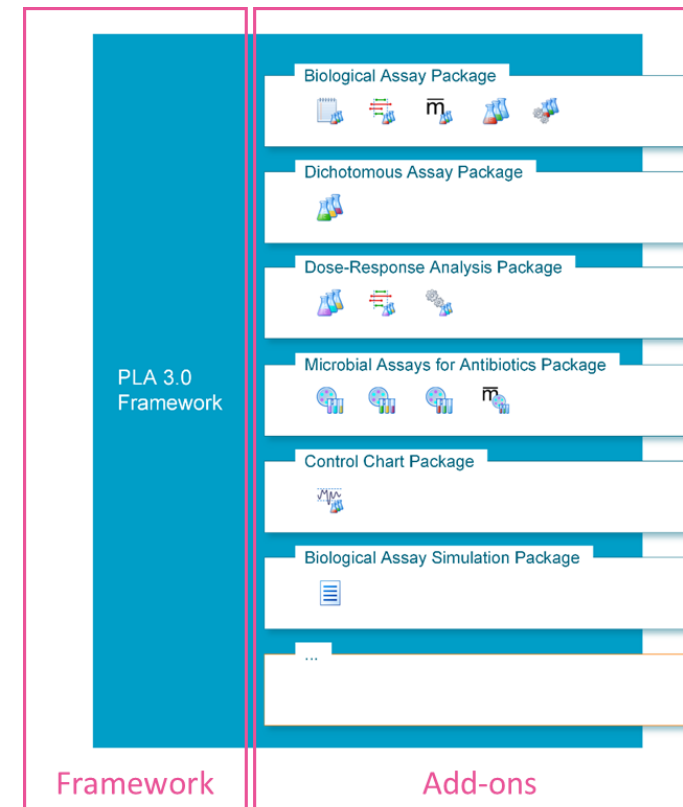
PLA 3.0 – Analysis: A modular system

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

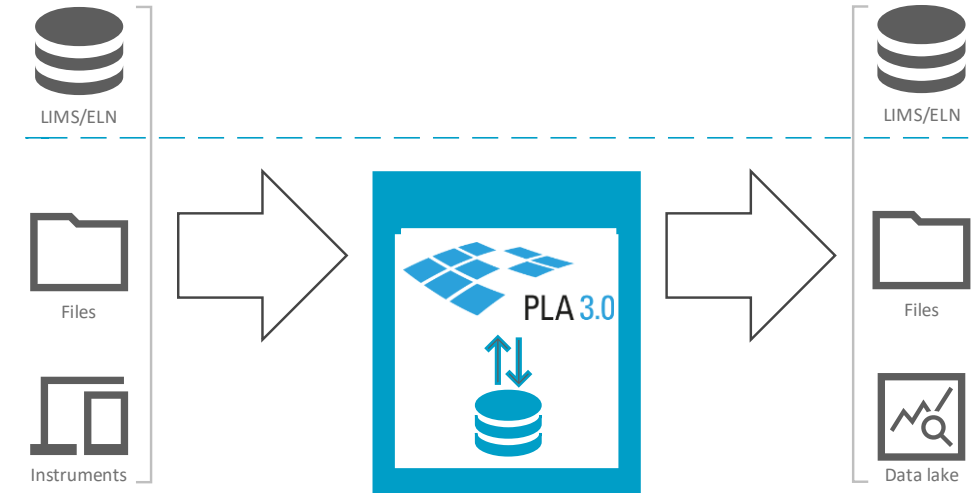


PLA 3.0 – Integration

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



PLA 3.0 – Lifecycle

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

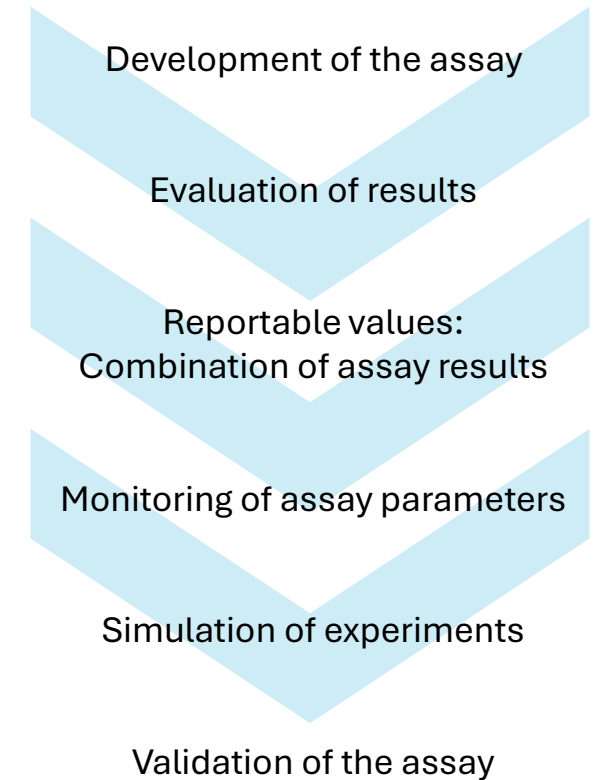
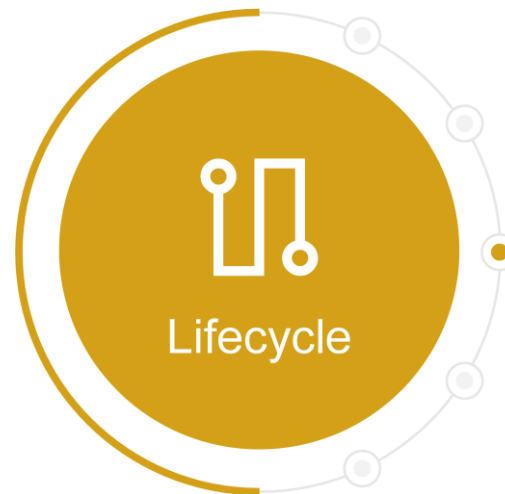
- › Studies
- › Analysis of Experiments
- › Equivalence Margin Development

› 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



PLA 3.0 – Compliance

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



PLA 3.0 – Knowledge

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




The screenshot shows the PLA 3.0 Academy website. The header includes the PLA 3.0 logo and navigation links: Home, Learning path, Courses, Library, Corporate offers, About us, FAQ, and Account. The main banner reads "PLA 3.0 Academy" and "START YOUR LEARNING JOURNEY TODAY." Below this, a welcome message states: "Welcome to the PLA 3.0 Academy. YOUR LEARNING PLATFORM FOR MASTERING PLA 3.0. Whether you're new to PLA 3.0, building on existing skills, or aiming to deepen your expertise, the PLA 3.0 Academy offers the resources you need to succeed. Start your learning journey today and take the next step in mastering PLA 3.0!" A "Get started" button is present.

Below the welcome message, three featured items are shown:

- PLA 3.0 Basics Webinar:** "Our introductory webinar provides a concise introduction to PLA 3.0." with a "Take me there" link.
- Learning through the seasons:** "Our learning campaign supports your growth year-round."
- A scenic image of a mountain landscape.

To the right of the website screenshot is a circular knowledge map diagram. It features a central red circle with a white graduation cap icon and the word "Knowledge". Surrounding this are various colored circles, each representing a different area of expertise or a specific assay type, connected by a path of footprints. The areas include:

- Endotoxin assays*
- Regulatory compliance
- Advanced analysis
- Advanced actions
- Data import
- Control charting*
- Method development
- Database management
- Biological potency assays
- User interface
- Dose-response analysis*
- Work environment
- Assay layout preparation
- Rights and permissions
- Data input

Thank you!



<https://learning.bioassay.de>



<https://help.bioassay.de>

Free Webinar – weekly

PLA 3.0 Basics Webinar

THE IDEAL STARTING POINT FOR PLA 3.0 NOVICES.

Course objective

Get a brief yet comprehensive introduction to PLA 3.0 – free of charge!

This webinar introduces the key features of the PLA 3.0 platform and its add-ons. Learn about the basics of electronic documents and how to set up quantitative response assays.

In addition, we provide an overview of further analysis capabilities, such as dose-response analysis, microbial assays for antibiotics, and aggregating experiments.

Key features.

Basic concepts.

Biological assays.

FREE COURSE

Select a date

 SUITABLE FOR Novices	 DURATION 75 mins	 COURSE TYPE Live	 PREREQUISITES None
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