PLA 3.0

PLA 3.0 – Latest Developments

CASSS Bioassays 2026, 4/29/2026
Dr. Ralf Stegmann, Stegmann Systems

We are a **Scientific Software Development Company**

- Frankfurt (Germany)
- ~50 employees

Our mission:

1. Develop the most powerful bioassay software → PLA 3.0

2. Contribute to the field of bioassay analysis

Former versions:

PLA 1.0 (released 1997)
PLA 2.x (released 2004)

Current version:

PLA 3.0 (modular framework, continuously improved)
PLA 3.0 is used by over 1,000 companies and regulators in 80+ countries

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Stegmann Systems' Role

PLA 3.0

Bioassays are very complex.

- require a specialized software environment
- Stegmann Systems is a software partner for the regulated industry

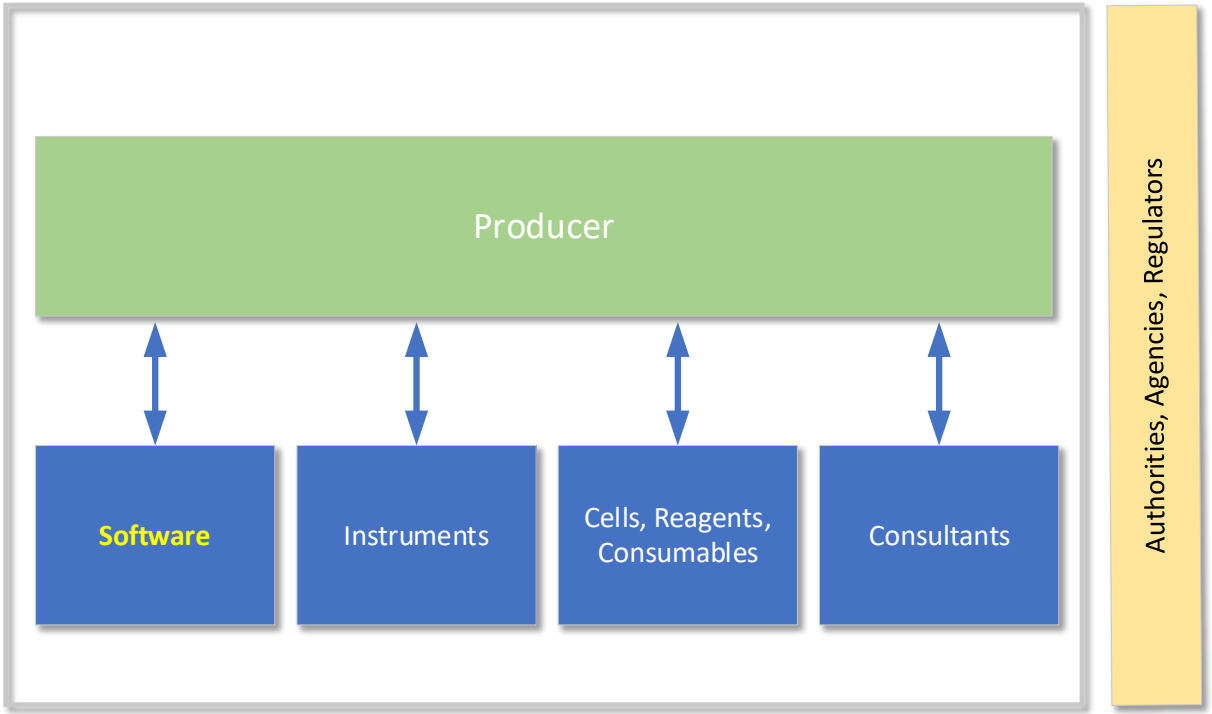
A software developer is not a consultant.
A consultant is not a software developer.

Strategic advantage: every partner has a clear role.

✓ Business risk reduced

✓ Compliance risk reduced

✓ Better quality



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PLA 3.0 – The End-to-End Bioassay Software

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.

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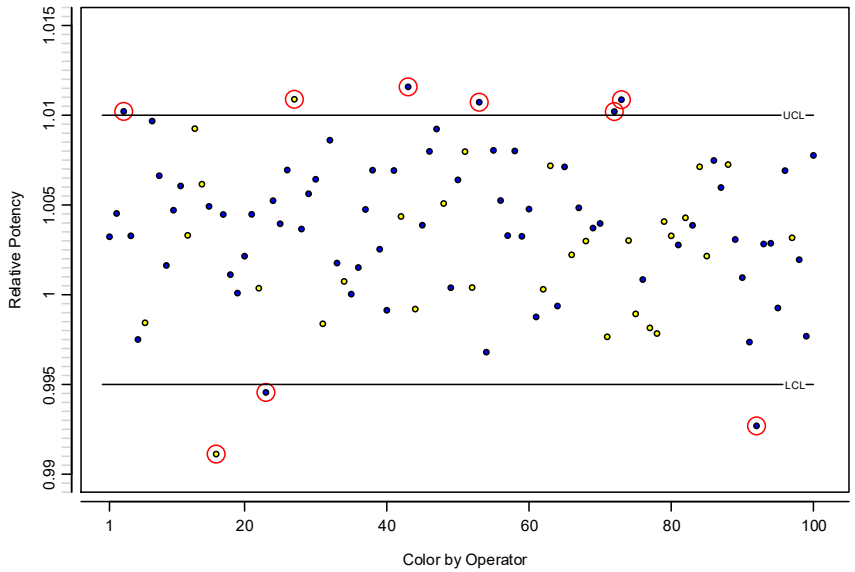
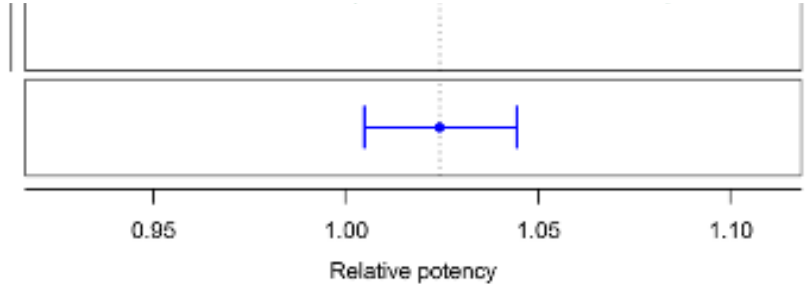
A broad range of ready-to-use analytical methods.

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)





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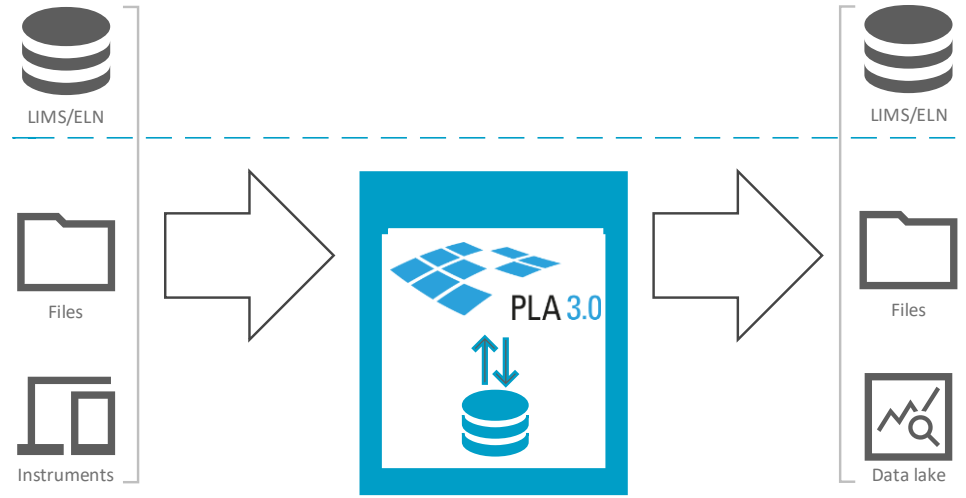
Seamless integration for enhanced laboratory efficiency.

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



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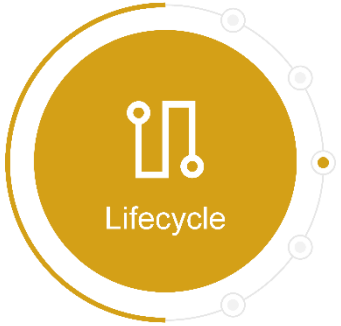

Your entire bioassay needs along your product lifecycle in one solution.

PLA 3.0 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 & Monitoring

Routine operations with defined Methods, Segregation of duties in the lab, Control charts

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Compliant with the global market

PLA 3.0 ensure your global market compliance with minimized efforts.

Analytical

National pharmacopeias (US, European, Chinese, Japanese), best practice statistical approaches

Technical

21 CFR Part 11, Eudralex Vol. 4 Annex 11, GAMP 5, ALCOA+, Data protection & integrity

Digital Sovereignty

All data at your premise and under your control!

Development compliance

V-Modell XT

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Knowledge drives success in biological assay development.

PLA 3.0

Expertise in analytical methods is key to developing and analyzing Biological Assays. We provide you to build and maintain this expertise in your team.

Academy PLA 3.0

Accelerate onboarding

Free weekly webinars

On Demand & live courses

Corporate Learning

+

Knowledge Center PLA 3.0

Increase lab efficiency

Best practices

Key concepts

Use cases

+

Support Portal PLA 3.0

Expert assistance

Technical, scientific & statistical support

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PLA 3.0 Upcoming Releases

- **PLA 3.0.8** – Usability improvements & functional enhancements, End of Q2 2026.
- Monte-Carlo Simulator for Quantitative Response Assays
- Method Validation Package
  - Mid of 2026
  - Demo at the **booth**

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