PLA 2.0
Software for Analyzing Parallel-Line and Parallel-Logistics Assays
Parallel-Line and Parallel-Logistics Assays

Biological or potency assays are frequently analyzed with the help of the parallel-line or parallel-logistics (4- or 5-parameter fit) methods. These methods have major advantages over traditional single-point assays:

♦ The linear or sigmoidal dose-response correlation is not only assumed but confirmed in each calculation.
♦ The dose-response curves of the standard and sample preparations are confirmed to be parallel. Whereas in single-point analysis parallelism is a necessary requirement too, but cannot be proven.
♦ A dose-independent potency in terms of the standard’s potency is calculated for each assay, and its validity is statistically proven.

The complex statistical analysis of these methods requires an advanced software solution to be easy, flexible and efficient. This is the mission of our PLA 2.0.

Today's Requirements for Advanced Assay Analysis Software

Statistics

An advanced assay analysis software delivers state-of-the-art statistical methods, allowing fast and efficient assay analysis. The statistics used should be in accordance with the international guidelines, especially in accordance with the Pharmacopoeias (US, European, Japanese). Does your vendor provide scientific support?

Regulatory Requirements

However the requirements do not end up with statistics. The requirements are much beyond efficient data analysis. Your software should fulfill the regulatory requirements (e.g. GLP, GAMP, FDA’s 21 CFR part 11 and other international or local needs). The software vendor has to offer solutions for validation. Does your software support advanced security features, audit trails, direct support of IQ / OQ / PQ tasks? How is data being protected from manipulation by technical errors or mistakes?

Transfer Data and Assays between Projects, Sites and Companies

One of the most difficult tasks today is the transfer of your assay between different sites of your company, to and from contract research organizations or simply between different project stages.

Do you use software that can easily be validated when your project reaches advanced stages? Does your software support a validated transfer of data to other sites or service providers (e.g. CROs)? Is your analysis independent of your data acquisition systems software? Is it open to integrate with other acquisition software or target systems?

Advanced software is fit to manage these requirements.

Keep the life cycle of your assay development in mind!
Stegmann Systems is proud to announce PLA 2.0 — the successor of the well-known PLA 1.2 with over 200 installations all over the world. PLA is the commercial solution for assay analysis with the parallel-line and parallel-logistics methods.

Basics Features

- Proven statistics for the easy execution of parallel-line and parallel-logistics analytics
- PLA 2.0 is easy to learn, easy to use and to deploy
  - Intelligent design supports daily tasks
  - The user interface is designed for efficiency
  - Integrated installation of the whole system
- Set up templates to define your favorite methods
- Ad-hoc Data Analysis: Explore your assay on the screen and apply different methods to them.
- Advanced Data Management: Assay Data is organized in databases for fast and secure access. Set up any number of databases and share your data across the network.
- Assay Documentation Features allow you to document necessary meta data.
- High Quality Graphics
- Perfect and Secure Reporting. Standard calculation reports are created as secured Adobe PDF files. Report Templates for Microsoft Word and Excel are also available.
- Technical and scientific support by Stegmann Systems

Integration Features

- A large number of optional Import Modules is available to connect your acquisition system to PLA.
- PLA’s Enhanced Import Modules are able to execute even complex calculations on your input prior to setting up an assay inside PLA.
- PLA’s Enhanced Reporting System is able to report to virtually any target system (e.g., LIMS, Office)

Fit for the Enterprise

- PLA focuses the whole life cycle of assay development. You achieve maximum flexibility during development and maximum security when your assay reaches the production state.
- Electronic Signatures qualify your data records
- Digital Signatures using cryptographic tokens secure the integrity of your data records
- 21 CFR part 11 compliance, GAMP level 3 (commercial off-the-shelf software)
- A Validation Package is available. The extensive IQ, OQ and PQ tasks are automated.
Flexible Assay Setup
PLA allows you to define your assays very flexible. Define standards, samples and controls with up to 25 treatments and replicates. Optionally define the preparation of your stock solution or start at the raw material/bulk substances. Define any pre-dilution factors. Define any dilution scales. Assume standards and samples equipotent or assign a stated/labeled potency to your samples.

Configuration
While the full curve fit describes the whole dose-response correlation, parallel-line assays focus the significant part of the dose-response relationship. PLA is able to locate the significant parts of the dose-response correlation automatically. There is a full featured range of control options to determine the optimal assay configuration.

Curve Fitting
PLA implements both Parallel-Line Assays and Parallel-Logistics Assays (4- and 5-parameter sigmoidal functions). For Parallel-Line Assays transformation functions for the response values are available to reduce heteroscedascity.

Outlier Detection
The Studentized Residuals Method, Dixon Test, Grubb’s Test and a test based on the standard deviation are available to exclude outliers from the analysis. Outlier Tests may be applied once or in a recursive manner.

Analysis of Variance (ANOVA)
Multiple variants for the Analysis of Variance of the fitting results are available. Hypothesis testing for the validity of a curve is applied. Standard confidence intervals or confidence intervals according to Fieller are calculated.

Equivalence Testing
An optional Equivalence Test based on the ratio of slopes or the difference of slopes is available as an alternative approach for parallelism testing. This helps to eliminate the problem of failing too many tests in very exact assays due to low variance of the response values.

Potency Calculation
Depending on the setup your calculation starts at the bulk substance, stock solution, or at the dilution scale level. Various types of potency factors are calculated directly (e.g. assigned, assumed or labeled potencies of your standard or your sample).

Combination of Assay Results
PLA is able to calculate weighted and un-weighted combinations of assay results according to the European Pharmacopoeia.
Validation and GxP Compliance

According to GAMP software has to be validated on the customer’s computer system. The software vendor is only able to verify the software in his labs. The optional Validation Package helps you to manage the tasks of installation qualification, operational qualification and performance qualification (IQ, OQ, PQ) fast and efficiently.

Integration

PLA has a full set of interfaces for the import of raw data from data acquisition systems, for the export of assay data to e.g. documentation systems and for the reporting into many target systems (e.g. Adobe Acrobat PDF™, Microsoft Excel™, Microsoft Word™, OpenDocument). Individual modules can be created at low cost.

Transfer of Data and Templates

PLA allows to transfer data and templates between projects, sites and companies in a secure manner.

The trustability and integrity of the data is assured by a combination of electronic signatures, that are preserved in the transfer, and cryptographically secured data transfers. PLA secures the information with the help of its own integrated PKI (Public Key Infrastructure). This operation is completely transparent for the user. It assures the secure communication of data and templates to different projects, sites or CROs.

Roles and Permissions

PLA comes with its own permission system. The user is assigned a typical role that gives him a specified access level to the project’s database. PLA differentiates Administrators, who are responsible for a PLA installation or database, PLA Users and PLA Inspectors. The latter are allowed to review data only.

Templates

PLA comes with a template engine for assays and methods. Templates can be defined on the user level or as mandatory templates. The administrator can prohibit the manipulation of sets of properties (e.g. method details) from manipulation by the user. In this manner you can realize standard operating procedures (SOPs) within PLA. Templates can also be signed electronically.
21 CFR Part 11 Compliance

Advanced Security Features

In accordance with the FDA 21 CFR part 11 PLA has its own security infrastructure that requires users to log into the system. User accounts and their roles are defined with an easy-to-use interface. The accounts and their roles are database specific.

In addition to this account management PLA is fitted with the full range of security options required by the 21 CFR Part 11. The PLA Administrator can define security policies for each database in accordance to regulatory or your company's need. The feature includes password complexity, password aging, password blocking and password history rules. You may also define inactivity locks to prevent unauthorized access to the system.

Electronic Signatures

Electronic Signatures can be applied to PLA's records. The application of electronic signatures is a requirement of the 21 CFR part 11. With PLA advanced data storage technology electronic signatures can even be moved between different installations of PLA (e.g. between your CRO and your company).

Audit Trail

PLA has its own Audit Trail that covers all changes of data and properties of your assay and of all security features inside PLA. The audit trail can be inspected on a per-database and a per-assay level.

Digitally Signed Electronic Records

PLA benefits from the XML industry standard for the storage of electronic records. This very flexible format has the main advantage that it is human readable, which is another requirement for compliance.

PLA makes use of the XML Signature 1.0 Industry standard to assure the integrity of all the data that PLA works with. The XML Signature Standard applies a digital cryptographic signature to each data package. With the help of this signature the integrity of the electronic records is checked every time PLA makes use of them. This integrity check prevents any unauthorized or unwanted data modification, e.g. by computer defects.
PLA 2.0 System: 
Optional Components

The main component of the PLA system is the PLA 2.0 Program. This package is fully featured and allows you to calculate and manage your assays. PLA 2.0 is able to deeply integrate into your environment. In addition several optional components are available for PLA. (These components are licensed once per site. If licensed they are available for all PLA installations on your site without additional charges). All Optional Components are automatically included in the Validation Package Installation Qualification process.

PLA Validation Package

The PLA Validation Package consists of extensive documentation and software. It contains the complete documentation of the Installation Qualification, Operational Qualification, Performance Qualification (IQ, OQ, PQ), and descriptions of the development process, certificates of quality, a 21 CFR part 11 statement. The IQ, OQ and PQ tasks are automated. The installation qualification and operational qualification with vendor data takes only minutes, and certificates of qualification are being generated automatically.

PLA Import Modules & Export Modules

PLA Import Modules connect PLA with your data acquisition software. They are currently available for over 30 different data acquisition systems. PLA Export Modules are able to connect PLA to other systems by exporting assays into specific data formats. Missing formats are developed on demand.

PLA Enhanced Import Modules

are specialized PLA Import Modules. They are able to execute complex calculations on your data input stream. Some of them generate separate documentation on these calculations. Sample Enhanced Import Modules are:

♦ Kinetic Calculations (Half-life times are calculated by the module with the help of a sigmoidal curve fit. The import module creates a parallel-line assay with the half-life times and documents their calculation.)

♦ Flow Cytometric Calculations (The import module selects a population from the FACS system and integrates it. The calculation is documented and a completely specified parallel-line assay is generated using the integrated population as response values.)

PLA Report Templates

The powerful report engine allows PLA to connect PLA to nearly any system. PLA Report Templates can be created or customized in various ways to fit your needs. The PLA base package contains Report Templates for Adobe Acrobat™ PDF files, Microsoft™ Word™ and Excel™.

System Requirements

Microsoft Windows 2000, XP or higher.
100 MB of free disk space.
Screen resolution: 1024x768 or higher

The retail version of PLA is delivered with a hardlock device that has to be attached to the parallel or serial port of your computer systems. The port will remain available for printers or other periphery.

Concurrent use licenses are available. PLA is Terminal Server aware (concurrent use licenses required).

Database Systems:

PLA supports the following database systems:

- Microsoft JET 4.0 Engine (max 3 concurrent users)
- Microsoft MSDE, Microsoft SQL Server 2005 Express Edition (available at no charge)
- Microsoft SQL Server 2000 or higher
- Oracle

Try It Now!

A full-featured 14-day trial version of PLA 2.0 is ready for download at

www.bioassay.de

Try it without risk!

A note to our valued PLA 1.x customers: PLA 1.x and PLA 2.0 can be installed on the same computer system. There is no unwanted direct interaction between both versions. They can be installed and uninstalled in any order. If you are upgrading you are entitled to run both versions on the same computer system. This allows you to keep your validated assays in place when upgrading to PLA 2.0.