



PLA 3.0 EXTENSIBILITY CONCEPT PACKAGES, MODULES, REPORTS

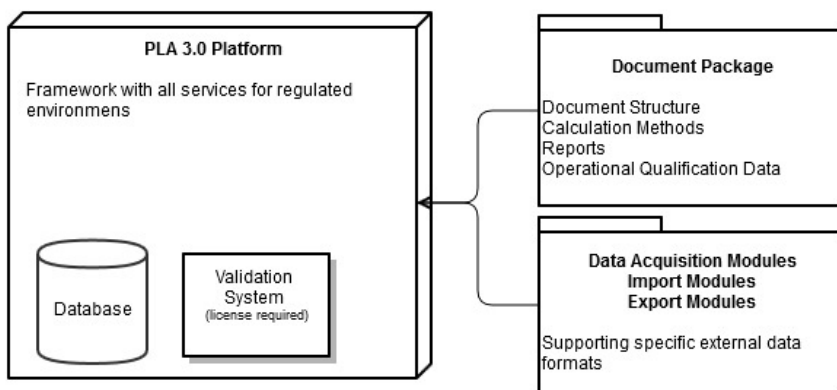
EXTENDING THE CAPABILITIES OF PLA 3.0

OVERVIEW

INTRODUCTION TO THE EXTENSIBILITY CONCEPT OF PLA 3.0

PLA 3.0 is an extensible platform for biostatistical analysis. Information unit in PLA 3.0 is the document. A document consist of the data for calculation, meta-data about the measurement and properties of the calculation. They are all covered in the document.

Documents are handled by the PLA 3.0 Platform. The platform does not have any knowledge about the structure of an document or the calculation defined for a document. The structure, calculation routines and reports are all delivered as Document Packages, which add the required knowledge into the system.



21 CFR Part 11 Compliant, GAMP compliant. Fit for GLP/GMP.

THE PLA 3.0 PLATFORM

The platform of PLA 3.0 covers all aspects for regulated environments:

- Database Engine with all features for document handling
- Editors to edit the documents according to their structure rules
- Security System to handle the documents according to FDAs 21 CFR Part 11
 - Protection of Electronic Records
 - Audit Trail
 - Electronic Signatures
- GAMP support for
 - Installation Qualification (IQ)
 - Operational Qualification (OQ)
 - Performance Qualification (PQ)
 - Template system to support the implementation of standard operating procedures (SOPs)

DOCUMENT PACKAGES DELIVERED WITH PLA 3.0

The PLA 3.0 Base System comes with three sets of predefined Document Packages.

- Biological Assays - adds all the biostatistical functionality for the analysis of Biological Assays
- Measurement Documentation - adds three supporting document types capable of documenting several aspects of a measurement
- General Documents - these are simple documents for notes, tasks, contacts and appointments.

Fully Fitted for Development and Analysis of Biological Assays without Extensions

EXTENDING THE CAPABILITIES OF PLA 3.0

There are several ways to extend the PLA 3.0 environment to fit your needs:

- PLA 3.0 Validation Package
- Document Packages for New Document Types and Calculation Methods
- Additional Reports
- Document Import/Export Modules, Data Acquisition Modules

PLA 3.0 VALIDATION PACKAGE

According to GAMP regulations the validation of a software is a customer and not a vendor task, which has to be performed on the target computer system. The PLA Validation Package has been created to minimize these validation efforts.

Stegmann Systems delivers PLA 3.0 as a verified software system. The PLA Validation Package automates several tasks in the process of validation on the target computer system.

AUTOMATED INSTALLATION QUALIFICATION

The installation qualification routines of PLA 3.0 verify all system components and deliver a certificate as well as a detailed report about the installation on the target system. It certifies that all required components are in place in the required versions.

AUTOMATED OPERATIONAL QUALIFICATION

The operational qualification routines are able to validate the calculation routines of a PLA 3.0 Document. The OQ data is delivered with the package. The Validation Package license is required to make use of the OQ data for qualification of a system. E.g. the OQ data set of the Biological Assay package contains several hundred datasets that can be run with the OQ functionality of PLA 3.0. The results of these calculations are compared to digitally signed data sets delivered with the document package. After the successful verification a certificate is being created.

PERFORMANCE QUALIFICATION

The performance qualification requires customer data to be verified. PLA allows the customer to create his own verified data sets. These data sets can be used for the automated qualification of additional computer systems and for the re-qualification after changes in the environment or when PLA 3.0 has been updated.

REPORT TEMPLATES

In PLA 3.0 a set of standard reports is delivered for many document types. These document types allow the reporting of any relevant calculation. Report templates require validation to report valid and trustable results.

If a customer needs a modified report type, Stegmann Systems delivers verified report templates. They are created based on the customers requirements and can contain corporate design elements. E.g. for migration projects these report templates can be designed in the fashion of an earlier inhouse solution.

Additional Calculation Types can be loaded into the system.

Automated qualification of the target computer system

Report Templates are quality critical components that require verification and validation.

ADDITIONAL DOCUMENT TYPES AND CALCULATIONS

Stegmann Systems can easily extend the collection of available Document Packages to match any need. The modular concept of PLA 3.0 allows any additional document type and calculation method to run on the PLA 3.0 framework in a 21 CFR Part 11 and GAMP compliant environment. With the Document Package a set of operational qualification calculations can be delivered to support the direct operational qualification of the new methods..

This extensibility makes PLA 3.0 a perfect for the migration of legacy software for biostatistical analysis into a modern and compliant environment. The migration project only needs to cover the data structure, calculation and reporting, while the PLA 3.0 framework delivers the compliant platform.

This makes migration projects very cost and time efficient.

DATA IMPORT

DATA ACQUISITION MODULES

Data Acquisition Modules are used to connect external systems directly to the data tables of a PLA 3.0 document. Typical examples are Data Acquisition Modules for Plate Readers. A plate reader delivers a stream of measurement values that need to be imported to the data table of a specific document in a GLP/GMP compliant way. Data Acquisition Modules are the most common import modules used by PLA. Currently over 40 different Data Acquisition modules are available.

Data Acquisition Modules are licensed by the supported external format. They are not specific to the target document type.

DOCUMENT IMPORT MODULES

Document Import Modules generate fully specified documents of a specific type. They are useful when an external format contains every information required to create a specific document. E.g. if a third party program deals with biological assays a Document Import Module can be set up in a way where a completely specified Quantitative Response Assay is delivered. In this case the Document Import Module converts all settings and creates the appropriate PLA 3.0 document.

Document Import Modules are licensed per external file format and target document type.

DOCUMENT EXPORT MODULES

Export Modules are available to export PLA 3.0 Document to a specific External Format. They export the PLA 3.0 Document and transform them into the target format. They can be used to connect PLA to other external systems (e.g. LIMS systems).

PLA 3.0 is the most cost efficient solution for the migration of old in-house solutions to current standards.

Connect PLA 3.0 to external systems.

Over 40 different Data Acquisition Modules are available.
