

PLA 3.0 Validation Package

OVERVIEW

Abstract

The PLA 3.0 Validation Package is an add-on that provides the features to qualify your PLA 3.0 software on your target computer system, compliant with GAMP. It contains functions for automatic installation and operational qualification (IQ and OQ) and supports your performance qualification (PQ).

The OQ data set for the Biological Assay Package includes several hundred datasets that can be run with the OQ functionality. The results of these calculations are then compared to digitally signed data sets.

More information:

www.bioassay.de/validation-package

Features

- Developed for regulated environments
- Functions for IQ and OQ, including printable certificates of qualification
- Support for PQ
- Extensive documentation with reference data

TECHNICAL SPECIFICATION

Type

Add-on for PLA 3.0

System Requirements

- PLA 3.0.4

Supported File Formats

N/A

Version

Specific to each version of the Biological Assay Package

Supported Systems

N/A

Supported Languages

English

DELIVERY AND SUPPORT

Release Date

05.05.2017

Scope of Delivery

- Software (download)
- User manual and Validation Package Documentation (PDF)

Support and Upgrades

You have access to our PLA support platform at: support.bioassay.de

Product No.

24020

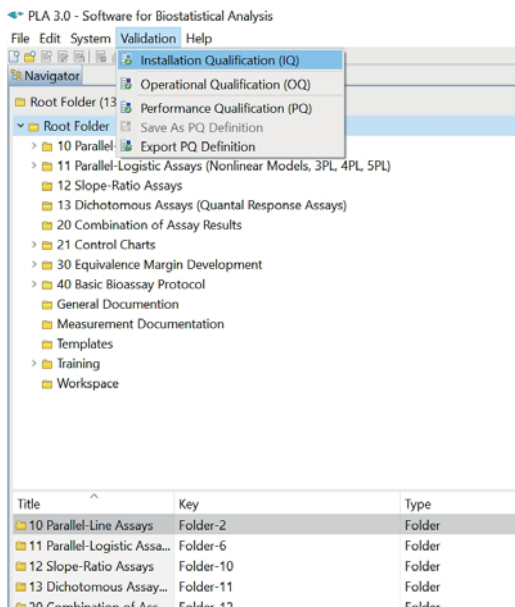
Lifecycle

We will provide support for PLA 3.0 and all related modules until March 15, 2024.

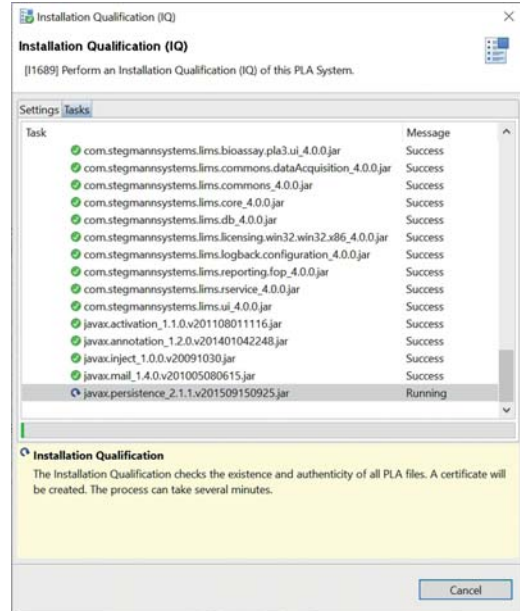
This module is covered by our PLA Support Contract. The first year is included and the contract can be renewed year by year. To find out more about its benefits, please go to: www.bioassay.de/support-contract

SCREENSHOTS

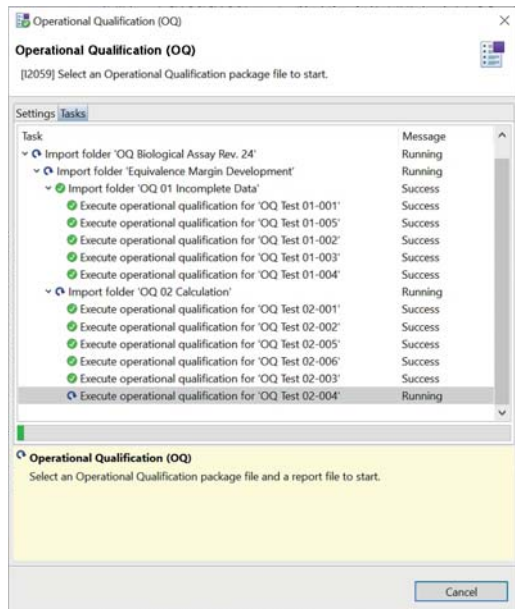
Selecting a qualification from the menu




Running the installation qualification (IQ)



Running the operational qualification (OQ)



Excerpt of the Certificate of Qualification



Certificate of Qualification

Operational Qualification (OQ) of the PLA System

Executed by: Administrator
 Started: 12.6.2017 12:45:32
 Stopped: 12.6.2017 13:47:26
 Computer Name: NBTRE01
 Database GUID: a2ad67a6-e67c-4466-b279-ddd399e9fcb4
 PLA Serial Number: 10014
 PLA Version: 3.0.4 (build 721)

Note: This Certificate of Qualification is valid only for the computer system on which the qualification process has been executed. The qualification process has to be repeated for every computer system which is running PLA.

OQ Dataset

Description: Creation of Operational Qualification package started by user 'Andreas Fromkorth' at 'May 5, 2017 8:36:10 AM'
 Creator: Andreas Fromkorth
 Timestamp: 5.5.2017 8:36:42
 Component Package: Biological Assays Package/24
 PLA Version: 3.0.4 (build 721)

The Operational Qualification (OQ) of the PLA System has been carried out successfully.
 The documented and expected results have been reproduced.