PLA MIGRATION & ARCHIVING TOOLKIT

PLA 3.0

MIGRATE ALL YOUR BIOASSAYS FROM PLA 2.0 / 2.1 TO PLA 3.0 AND IMPROVE YOUR ANALYSIS

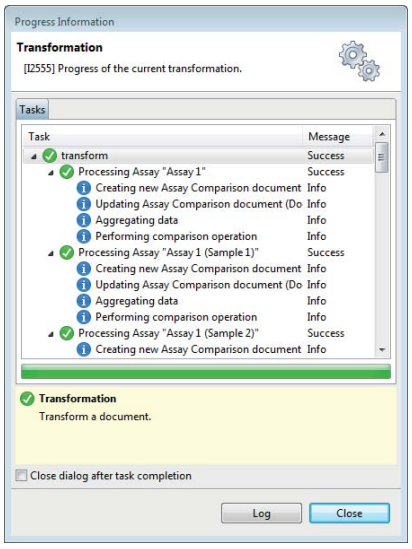
PLA 3.0
Software For Biostatistical Analysis

PLA 3.0

Migrate All Your Bioassays From PLA 2.x to PLA 3.0 And Improve Your Analysis

All of Your Bioassays in One Place

If you have spent any amount of time with PLA 3.0, you will know that it is superior to PLA 2.x by far. But that does not make your PLA 2.x assays any less valueable. In fact, those thousands or even tens of thousands of assays you created with PLA 2.x are a real asset worth keeping indefinitely. And that's exactly what the PLA 3.0 Migration & Archiving Toolkit allows you to do. You will have all your bioassays in one place: PLA 3.0.



Performing a bulk comparison on migrated PLA 2.x assays

Shorten the Re-Qualification of Previously Qualified Methods

With the PLA 3.0 MAT, you can migrate productive (and validated) PLA 2.x assays to PLA 3.0. The comparison feature shows you differences in the calculated assays (if any). You will therefore be able to reduce the re-qualification effort significantly, in many cases even dramatically. For many users, this feature alone is worth the entire price of the product.

Use Your Assay Archive to Improve Your Analysis

Two of the features that PLA 3.0 users value the most are control charts and equivalence margin development. And the more assays you have when you use these features, the better the results. By migrating your PLA 2.x assays to PLA 3.0, you add them to your assay archive, which will notably improve your results.

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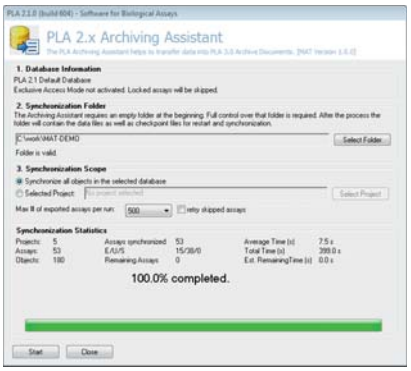
What Happens to Your Validated Installation?

Nothing. The PLA 3.0 MAT will do nothing that might compromise your validated PLA installation. The MAT consists of a small number of files that need to be added to your PLA installation, but existing files will not be altered. Therefore, your PLA 2.x installation remains validated.

Retire Older Versions of PLA Without Losing Data

By using the PLA 3.0 Migration & Archiving Toolkit to move your PLA 2.x assays to PLA 3.0, you will soon reach a point where you can retire PLA 2.x withour losing data. You could still use PLA 2.x for your established assays and smoothen your transition process, because the PLA 3.0 MAT can upgrade the data incrementially.



Exporting PLA 2.x assays

Migrate Your Bioassays Exactly As They Are

The PLA 3.0 Migration & Archiving Toolkit transfers your PLA 2.x data in three forms: assay data, calculated assay and report. The software also calculates every assay as it archives it. Your assay data will not change in the process. Even errors in your original data will remain unchanged.

Calculating Every Assay

In the migration process, the software will calculate each assay. Depending on the number of assays in your archive and the power of your computer, it could take several days to migrate all of your assays. We therefore made sure, that the entire process is able to restart, should it abort unexpectedly (e.g. in case of a power outage).

HOW THE TOOLKIT WORKS

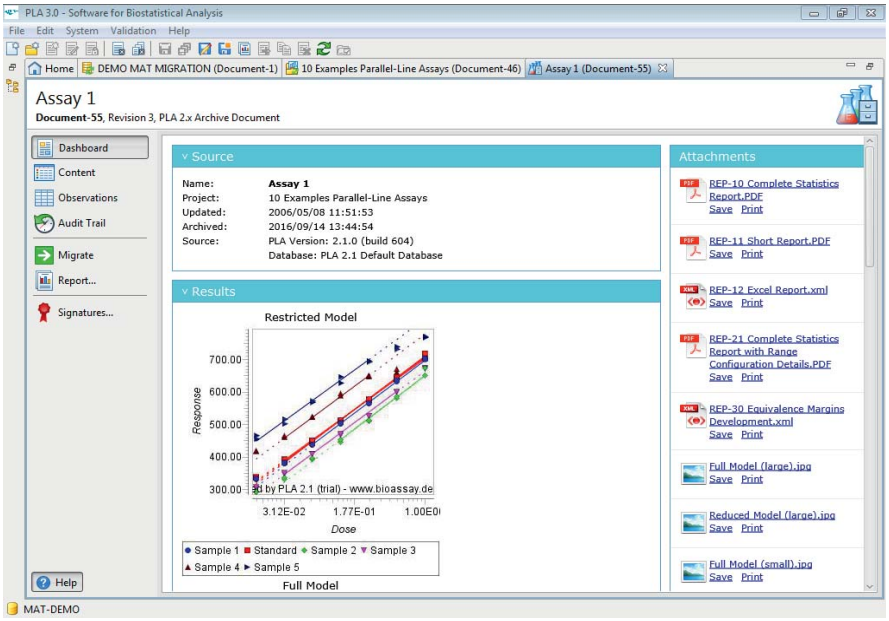
Switching from PLA 2.x to PLA 3.0 can be a big deal. Especially when you are working in a regulated environment, with validated assays and an archive that goes into the thousands. With the new PLA Migration & Archiving Toolkit the transition to PLA 3.0 is now easier than ever before.

We called it "toolkit" because the program is really a package of several distinct tools, each designed to complete a specific task. This might seem rather complex, but it was necessary because PLA 2.x and PLA 3.0 are two completely different programs. They were written in different programming languages. They can coexist on the same computer and you can import PLA 2.x assays into PLA 3.0, turning them into PLA 3.0 assays. But the PLA Migration & Archiving Toolkit goes several steps further.

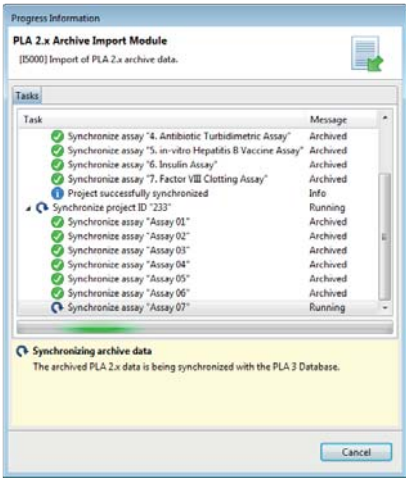
ARCHIVING

Bevor you retire your PLA 2.x installation and switch to PLA 3.0, you want to make sure that all your assays remain accessible no matter what. That is what the PLA Archiving Assistant will do for you.

So in case you face an inspection, either by your inhouse quality control or by external agencies, you won't have to look further than your PLA 3.0 installation to find everything you need.



PLA 2.x assay archived in PLA 3.0



Synchronizing the archived assays

SYNCHRONIZING

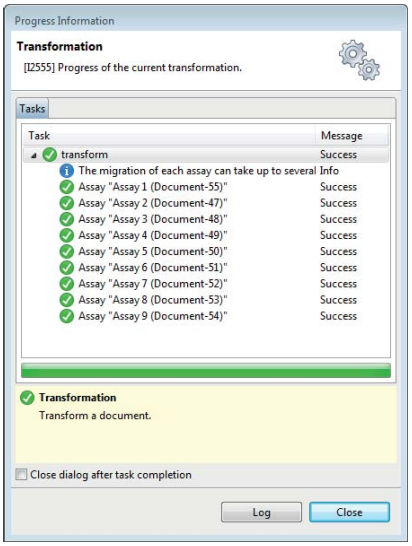
To make the transition from PLA 2.x to PLA 3.0 as smooth as possible, the Migration & Archiving Toolkit lets you to import your productive assays incrementally. On the first run, the software will copy the assays on a per project base. It allows you to synchronize all or only selected PLA 2.x projects with PLA 3.0. Initially, it copies all assays of the projects in question. On every subsequent run, it is going to transfer only new or changed PLA 2.x assays.

Synchronizing makes sense when you want to continue working with PLA 2.x while you are preparing to switch to PLA 3.0. Please note that synchronizing only works one way. It is not possible to move PLA 3.0 data to PLA 2.x.

MIGRATING

When you consider the features of PLA 2.x on the one hand, and those of PLA 3.0 on the other hand, you might want to switch sooner rather than later. And that is where the migration feature comes in.

It lets you migrate productive assays from PLA 2.x to PLA 3.0. You can then continue these assays in PLA 3.0, benefitting from all the advantages this software has to offer. This will also put you in a position to retire your PLA 2.x installation without losing any important data.

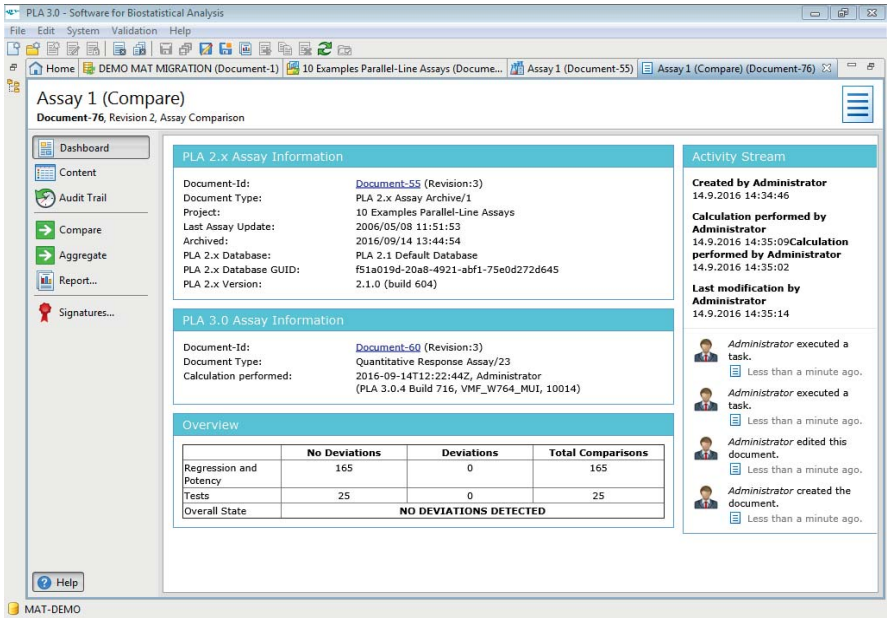


Migrating the assays

COMPARING

The feature to compare migrated assays with the original data in PLA 2.x is necessary because there are small differences in the calculations between PLA 2.x and PLA 3.0. These small differences may or may not lead to small diviations in your assays. But with the PLA Migration & Archiving Toolkit, you'll be on top of this.

It works like this: The new comparison package compares the original calculation results of the PLA 2.x assays with those produced by PLA 3.0 using the migrated assays as input. It then generates a report pointing out the differences (if any) between the calculation results of PLA 2.x and PLA 3.0.



Comparing the assay results

This report gives evidence that the PLA 3.0 method produces the same results as PLA 2.x and serves as input for fine tuning your PLA 3.0 method. In fact, for many users, this feature alone is worth the entire price of the product.

This way, the program also makes the re-qualification process of previously qualified methods in PLA 3.0 faster and easier, saving you plenty of time and effort.

PLA 3.0

SINGLE ASSAY COMPARISON REPORT

After comparing the assay results, the comparison package gives you a detailed report about the deviations (if any) between the values of PLA 2.x and PLA 3.0.

Standard vs. Sample 1

No deviations detected

Regression Model

Variable	PLA 2.x Value (Archived)	PLA 3.0 Value (Migrated)	Result
Regression Model	MODEL_LINEAR	LinearParallelLineModel	✓

Regression and Potency

Variable	PLA 2.x Value (Archived)	PLA 3.0 Value (Migrated)	Precision Class	Result
Intercept Standard (Unrestricted)	708.24	708.24	Regression Parameter	✓
Intercept Test (Unrestricted)	700.70	700.70	Regression Parameter	✓
Intercept Standard Error Standard (Unrestricted)	2.18	2.18	Standard Error	✓
Intercept Standard Error Test (Unrestricted)	2.33	2.33	Standard Error	✓
Slope Standard (Unrestricted)	64.429	64.429	Regression Parameter	✓
Slope Test (Unrestricted)	65.900	65.900	Regression Parameter	✓
Slope Standard Error Standard (Unrestricted)	0.720	0.720	Standard Error	✓
Slope Standard Error Test (Unrestricted)	0.952	0.952	Standard Error	✓
Intercept Standard (Restricted)	709.58	709.58	Regression Parameter	✓
Intercept Test (Restricted)	698.83	698.83	Regression Parameter	✓
Intercept Standard Error Standard (Restricted)	1.89	1.89	Standard Error	✓
Intercept Standard Error Test (Restricted)	1.77	1.77	Standard Error	✓
Slope (Restricted)	64.964	64.964	Regression Parameter	✓
Relative Potency	0.89165	0.89165	Potency Result	✓
Relative Potency Upper Confidence Limit	0.93097	0.93097	Potency Result	✓
Relative Potency Lower Confidence Limit	0.85414	0.85414	Potency Result	✓
Relative Potency Upper Confidence Limit (%)	1.0441	1.0441	Potency Result	✓
Relative Potency Lower Confidence Limit (%)	0.95793	0.95793	Potency Result	✓
Relative Potency Range (%)	0.086169	0.086169	Potency Result	✓
Selected Range Start (Test)	1	1		✓
Selected Range End (Test)	5	5		✓
Selected Range Start (Standard)	1	1		✓
Selected Range End (Standardt)	6	6		✓

Test Comparisons

F-Test (Hypothesis Test): Significance of Non-Parallelism

No Deviations

Assay Elements: Standard, Sample 1
Significance Level: 0.98

Variable	PLA 2.x Value (Archived)	PLA 3.0 Value (Migrated)	Precision Class	Result
Value	1.5194	1.5194	Test Result	✓
Critical Value	7.3880	7.3880	Test Result	✓

THE BULK COMPARISON REPORT

This is an excerpt from a bulk comparison report created with the PLA Migration & Archiving Toolkit after the assays have been migrated to PLA 3.0.

Assay 3

Archive Document ID: Document-48
Migrated Document ID: Document-69
Comparison Document ID: Document-87

	No Deviations	Deviations	Total Comparisons
Regression and Potency	58	0	58
Tests	6	0	6
Overall State	**NO DEVIATIONS DETECTED**		

Assay 4

Archive Document ID: Document-49
Migrated Document ID: Document-70
Comparison Document ID: Document-88

	No Deviations	Deviations	Total Comparisons
Regression and Potency	58	0	58
Tests	6	0	6
Overall State	**NO DEVIATIONS DETECTED**		

Assay 5

Archive Document ID: Document-50
Migrated Document ID: Document-71
Comparison Document ID: Document-89

	No Deviations	Deviations	Total Comparisons
Regression and Potency	58	0	58
Tests	6	0	6
Overall State	**NO DEVIATIONS DETECTED**		

Assay 6

Archive Document ID: Document-51
Migrated Document ID: Document-72
Comparison Document ID: Document-90

	No Deviations	Deviations	Total Comparisons
Regression and Potency	58	0	58
Tests	6	0	6
Overall State	**NO DEVIATIONS DETECTED**		

Assay 7

Archive Document ID: Document-52
Migrated Document ID: Document-73
Comparison Document ID: Document-91

	No Deviations	Deviations	Total Comparisons
Regression and Potency	58	0	58
Tests	6	0	6
Overall State	**NO DEVIATIONS DETECTED**		

Assay 8

FREQUENTLY ASKED QUESTIONS

How will Stegmann Systems support users of the toolkit?
The PLA Migration & Archiving Toolkit is covered by our PLA Support Contract for a minimum of 12 months. We recommend to renew this contract year after year to keep your software covered.

Why should I retire my installation of PLA 2.0?
Because we will not support PLA 2.0 after August 30, 2016. Each major version of PLA has a lifecycle of 10 years. PLA 3.0 will be supported until March 15, 2024. Besides, PLA 3.0 is superior to PLA 2.0 in many ways.

Which versions of PLA 2.0 are supported by this toolkit?
The PLA Migration & Archiving Toolkit works with all PLA 2.0 and PLA 2.1 versions.

Can the PLA Migration & Archiving Toolkit also transfer PLA 3.0 assays to one of the earlier versions?
No, that is not possible. The toolkit does not work the other way round.

What happens when the migration process gets interrupted?
We programmed the toolkit to pick up exactly where it was interrupted, so you will not loose any work.

How much does the PLA 3.0 Migration and Archiving Toolkit cost?
We will charge you a fixed amount plus a variable portion based on the number of PLA licenses you already have. Please request a quote.

Is there a discount for non-profits, such as universities or other research institutions?
Yes, we do offer a discount of 40% for non-profit organisations.

REQUEST A QUOTE

To request a quote, please send us an e-mail to sales@bioassay.de.

Do you have other questions about the PLA 3.0 Migration & Archiving Toolkit? Please contact us through the PLA Support Portal at **support.bioassay.de**

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