PLA 3.0

# PLA 3.0

## FROM ASSAY SETUP TO INSIGHTS

Combination of assay results

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# 1 COMBINATION OF ASSAY RESULTS

Use Combination of assay results documents to perform combination calculations for independent assay runs, thus obtaining reportable values for the potency.

## What these documents do

Combination of assay results documents support you in evaluating assay consistency across mutliple runs. They let you combine independent potency estimates to improve the precision of the result and account for variations such as variability in cells or different operators. You can set up combination calculations for quantitative response and dichotomous assays.

These documents are commonly used in routine testing and trending scenarios, or as part of assay validation workflows.

## What you will learn

Combining assay results is a common task in regulated environments, especially when you need to report results from repeated assay runs or want to monitor them together. In this topic you will learn how to set up the combination calculation template that defines how PLA 3.0 aggregates the run results to calculate reportable values.

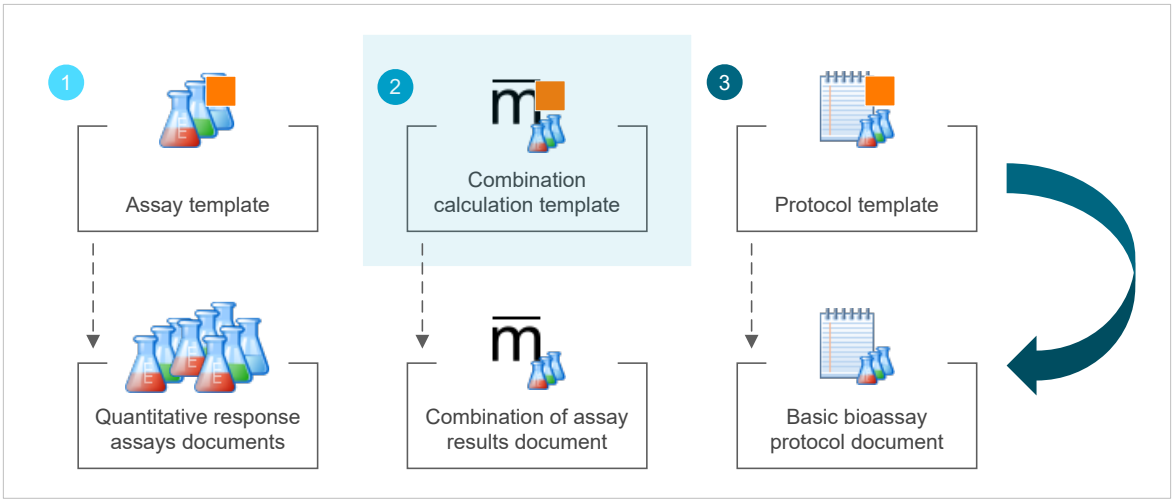


**Figure 1-1** From plate to process step 2: Setting up a combination calculation template

This topic belongs to a three-part series that guides you through the complete setup process in PLA 3.0. Each part focuses on one stage of this process. This topic forms the second part.

The series is based on the '40 Basic Bioassay Protocol' demonstration data included in version 27 of the Biological Assay Package. You will learn how to set up the data and understand the purpose behind each setup step.

### What the setup looks like

In this use case, you combine the results of three assay runs. You set up PLA 3.0 to calculate the relative and the absolute potency, with the confidence interval accounting for variation within each assay run.

**Note:** The assays you work in this use case have one test sample only. You therefore do not use combination groups.

### What you do step by step

The following table shows the tasks you need to perform to set up a Combination of assay results document for this use case:

| Step | | Description | Task |
|---|---|---|---|
| 1 | **Document creation** | Create a new Combination of assay results template. | Create the combination template |
| 2 | **Combination logic setup** | Select the parameters that determine how PLA 3.0 should combine assay results. | Select how to combine assay results |

## 1.1 Create the combination template

Combination documents hold the logic according to which PLA 3.0 combines potency estimates. Create the Combination of assay results template required for this use case.

### About this task

**Tip:** Instead of creating a template from the finished document like you did for the Quantitative response assay document type, you use the 'create as template' feature to create a template from the start.

### Procedure

To create the document:

1. In the **Navigator**, select the folder in which you want to create the document.
2. From the context menu, select **New**.
3. In the **Create a new document** dialog, on the **Available document types** tab, go to **Biological Assay Package** > **Combination of assay results**.
4. You can create combination templates from scratch or using another template. For this use case, you create a template from scratch. Select 'New Combination of assay results.'
5. At the bottom of the dialog, select the **Create as template** option.

6. To confirm your selection and create the document, select **Create**.

   **Result:** The **Content** editor opens, displaying your new template.

7. As the template name, enter `Combination Calculation for Product X`.
8. Save the template.

### What to do next

Select how to combine assay results.

## 1.2 Select how to combine assay results

PLA 3.0 provides a variety of combination calculation methods for combining assay results. Select the method, compendial guidance, and the potency type required for this use case.

### Before you begin

You have created the combination template.

### About this task

Combination calculation methods determine how PLA 3.0 combines the results of independent assay runs into a single reportable value.

The method you select defines whether all assays contribute equally or whether more precise runs have greater influence on the final result. You also select the applicable compendial guidance, which specifies the statistical rules and conventions used for the calculation. In addition, you define the potency type to be calculated.

For this use case, you use the weighted method with the confidence interval accounting for variation within each assay run, in accordance to the European Pharmacopoeia 4th to 9th edition. You select both relative and absolute potency.

**Note:** Combination of assay results documents use the natural logarithm (base e) by default.

### Procedure

To select how PLA 3.0 combines assay results:

1. In the **Content** editor, expand **Analysis**.
2. For the **Combination type** list, switch the value to **Weighted: CI based on intra-assay variation**.
3. As value for **Compendial guidance**, select **European Pharmacopoeia, 4th - 9th edition, chapter 5.3**.
4. As value for **Potency type**, select **Relative and absolute potency**.
5. Save the template.