From old assays to new margins with the Equivalence Margin Development document

Next Trainings
May 18-20, 2020 | Boston, MA, USA

June 15-17, 2020 | Frankfurt am Main, Germany

October 05-07, 2020 | San Francisco, CA, USA

Meet us at
2020 US Bioassay Conference | March 25-27, 2020 | Seattle, WA, USA

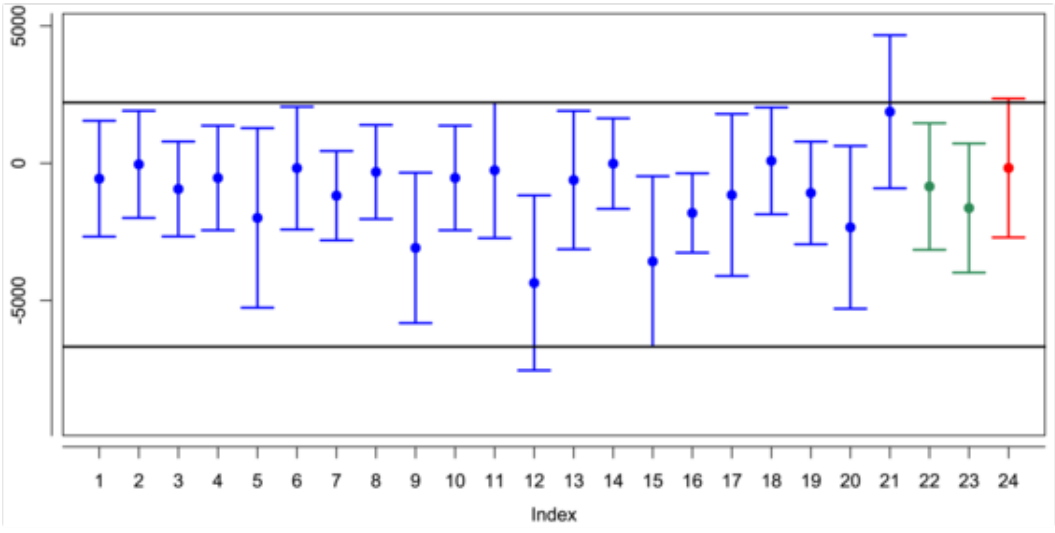
April 26-28, 2020 | CASSS Bioassays 2020 | Gaithersburg, MD, USA

Latest Release
PLA 3.0 - Biological Assay Package 26 SR1 (build 1043) | May 2019

PLA 2.1 (build 605 SR1) | Sep 2019

Dear Max,

In the last few years, classical hypothesis testing for determination of assay and sample suitability in biological assays has been the target of much criticism. Due to advancements in measurement techniques and assay preparation workflows, most modern assays are capable of obtaining replicate observations with very low variability. It is well known that for such assays the hypothesis tests, or F-tests, on significance of regression, non-parallelism and non-linearity will become overly sensitive. Using these tests not only risks discarding perfectly fine assays and causing costly and cumbersome re-runs, but they also create a misleading incentive where imprecise work yields improved test results. Luckily, hypothesis testing isn't the only approach for determining the suitability of your samples or your whole assay.



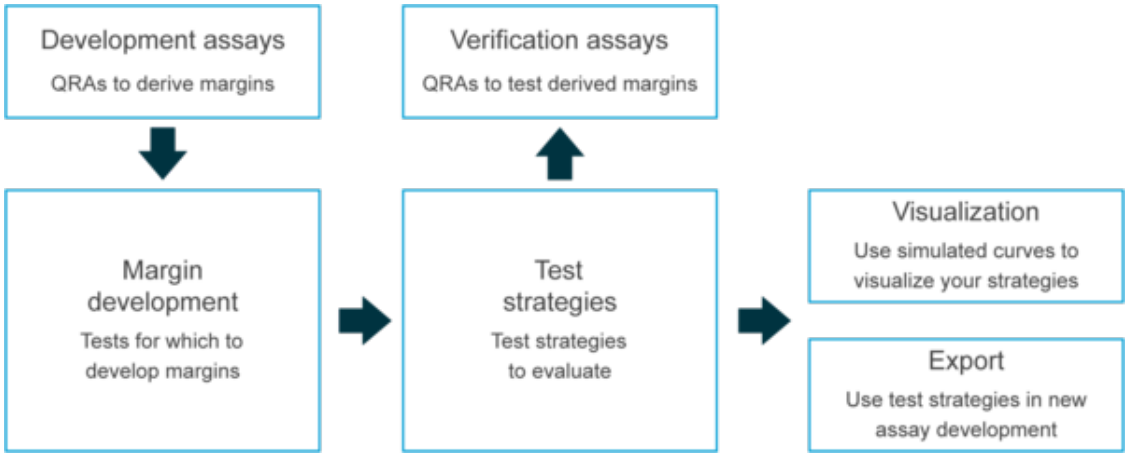
Visualization of margin development including positive and negative verification data

Equivalence Testing: The modern approach to testing your assay

Since the disadvantages of hypothesis testing are well known, Chapter <1032> of the US Pharmacopoeia recommends to use equivalence testing for determining your sample similarity. However, overall adaption of equivalence testing is still relatively low. Partially, this might be explained by the fact that this method isn't as ready-to-use as hypothesis testing. Hypothesis testing only requires choosing an adequate confidence level. In contrast, to perform effective equivalence testing it is not only necessary to determine suitable measures of similarity but also to determine the margins against which these measures are tested. The USP states:

"The challenge in implementing equivalence testing is setting appropriate equivalence bounds for the nonsimilarity measures"

Usually, these measures of similarity and their margins are developed from historical data, but manually collecting and processing all the relevant parameters is cumbersome and prone to errors. PLA 3.0 already stores your historical data in the documents on your database. With PLA 3.0 you can start developing your margins right away.



An example workflow for developing margins with Equivalence Margin Development documents

Using your assay archive for margin development

The Equivalence Margin Development document of the Biological Assay package in PLA 3.0 is capable of extracting and processing the relevant information from the Quantitative Response Assays already stored in your database. With a few clicks, you can select your development assays, develop margins, and define, verify and visualize different testing strategies. You can also export your new margins as a test system definition to include in your future QRAs. So there's no need for manual transfer from Equivalence Margin Development to assay either.

Stay tuned for next week's newsletter, where we will give a short overview of the five principal components of the Equivalence Margin Development document, how to use them and how they work together during margin development.

Best regards
Mathias von Gellhorn
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Meet us at

- 2020 US Bioassay Conference,
March 25-27, 2020 | Seattle, WA, USA
- CASSS Bioassays 2020,
April 26-28, 2020 | Gaithersburg, MD, USA
- 2020 EUR Bioassay Conference,
September 23-25, 2020 | Rome, Italy
- Well Characterized Biologics & Biological Assays,
October 27-29, 2020 | Hyattsville, MD, USA

If you wish to meet one of our representatives, please contact: Tanja Farrenkopf, Sales Manager, by mail.

Trainings Calender

- May 18-20, 2020, Boston, MA, USA - Booking open - Early bird available until April 03, 2020
  - May 18-19: PLA 3.0 Super User Training
  - May 20: PLA 3.0 Advanced Analysis Workshop
- June 15-17, 2020, Frankfurt, Germany – Booking open - Early bird available until May 01, 2020
  - June 15-16: PLA 3.0 Super User Training
  - June 17: PLA 3.0 Advanced Analysis Workshop
- October 05-07, 2020, San Francisco, CA, USA - Booking open - Early bird available until June 30, 2020
  - October 05-06: PLA 3.0 Super User Training
  - October 07: PLA 3.0 Advanced Analysis Workshop

Corporate Training

Are you interested in a corporate in-house training? Please contact us via mail or visit or website.

Latest Releases

PLA 3.0.4 SR6 (build 762)
Released: 2018/09/28
PLA 3.0.4 includes Biological Assay Package 23

Biological Assay Package 26 SR1 (build 1043)
Released: 2019/05/17

PLA 2.1 (build 605 SR1)
Released: 2019/09/30

Download

Add-ons for PLA 3.0

PLA is an extensible platform. The user has several options to customize this platform and extend its functionality with add-ons. Go to Add-Ons Overview.

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