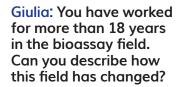
# **EXPERT**



# Challenges of quality control potency bioassays

Dr Giulia Mancini interviews Dr Alexander Knorre regarding changes and challenges in the field of potency bioassays, which are used to determine the biological activity of biopharmaceuticals.



Alexander: Various major modifications have occurred, partly driven by the fact that new types of molecule with different modes of action require different potency assays. To name a few, novel readouts are used, some assays are semi- or even fully automated and the assay endpoint is much earlier in the signal transduction cascade. This means that three-day assays have been replaced by one-day assays, which are also supported by the availability of frozen ready-to-use cells.

From a statistical point of view, Parallel Line Analysis has been replaced by Four Parameter Logistic (4PL) or 5PL curves and equivalence testing can be used now instead of F-tests, which was introduced by the USP <1032-1034> series. Moreover, Design of Experiments is applied for assay development/optimisation and for evaluation of assay robustness.

Giulia: You mentioned guidelines for assay development, can these be easily followed?

**Alex:** A lot of experience is needed to develop a robust potency assay for use in the quality

control environment in a reasonable time. Guidelines like USP <1032> or the new draft ICHQ14 guideline can be used, but they cannot provide a recipe of how to develop an assay. We have been developing potency assays for more than 15 years and this experience is also used for troubleshooting of QC assays in case there is an issue during QC release and stability testing.

#### Giulia: In which ways can Eurofins support assay transfers of qualified or validated potency assays?

Alex: We have a harmonised network of bioassay labs at different sites in Europe and in the US, working closely together. The capacity of these have heavily increased in the last couple of years. In Europe we started with one bioassay lab in Munich, Germany and now there are labs in Ireland, the Netherlands, Italy and a second lab in Germany.



**Dr Giulia Mancini**Lab Manager of bioassay testing,
Eurofins BioPharma Product Testing Italy



**Dr Alexander Knorre**Senior Scientific Director Biologics & Bioassays
Europe, Eurofins BioPharma Product Testing
Munich/Head of Quality Control



www.eurofins.com





# **BioPharma Product Testing**

## If Bioassay testing is what you're in need of, don't worry we won't let you sink.

Here at Eurofins Biopharma Product Testing we offer a wide range of potency bioassay services such as: assay development, validation, method transfer and GMP batch release and stability testing. We provide a dedicated turnkey service for all your bioassay needs so you won't miss anything important.

## Why Choose Eurofins BioPharma Product Testing?

- Both bioassay development and performance are complex to perform. Our team of experts are ready to help.
- Our scientists and analysts have a wealth of experience performing a variety of binding and cell-based potency assays with various readouts (including flow cytometry, SPR, BLI and ddPCR)

### **Our Experience**

Monoclonal Therapeutic Antibodies Bispecific Therapeutic Antibodies Antibody Drug Conjugates (ADC) Complex Antibody-like constructs Proteins/Peptides

Vaccines

MRINA

Gene and Cell Therapeutics

#### Contact us:

BPTEU\_marketing@eurofins.com

www.eurofins.com/bpt