



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.



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

Giulia: You have worked for more than 18 years in the bioassay field. Can you describe how this field has changed?

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 This means that three-day assays have been replaced by one-day assays, which are also supported by the availability of frozen ready-to-use cells.

From a statistical point of view, Parallel Line Analysis has been replaced by Four Parameter Logistic (4PL) or 5PL curves and equivalence testing can be used now instead of F-tests, which was introduced by the USP 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 Alexander Knorre
Senior Scientific Director Biologics & Bioassays
Europe, Eurofins BioPharma Product Testing
Munich/Head of Quality Control



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