Biopharmaceutical Emerging Best Practices Association

Steps for Developing a Potency Assay

BEBPA Technical Note

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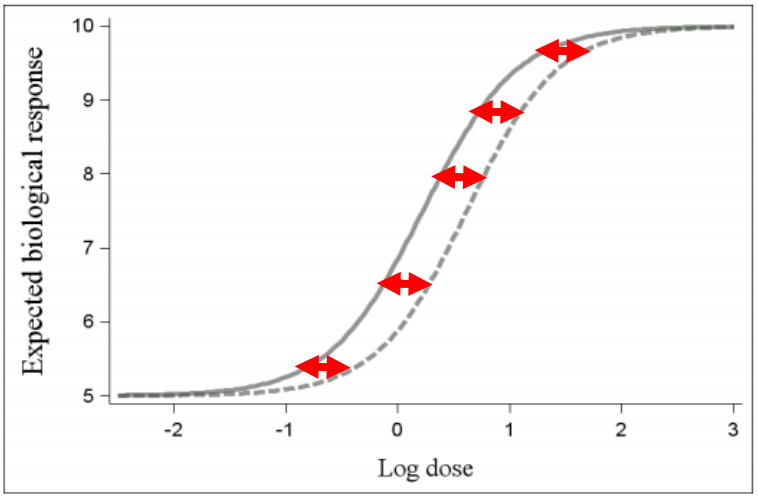
One of the hallmarks of potency assays is that they are based upon the mechanism of action (MOA). Since each biotherapeutic has a specific and different MOA, it means that each potency assay has a very different biological system as part of the analytical method. However, despite this difference there are some "usual" characteristics which unite potency assays and make it possible for us to discuss these assays.

Typically, potency assays, whether they be ligand binding, cell-based or animal assays, are relative assays, meaning that unknown test samples are compared to reference material. Furthermore, this comparison is typically the comparison of a full curve of reference to a full curve of the test material. As discussed in a prior email technical note: it is critical that these two dose-response curves are similar. Once this is determined – we typically fit a consensus curve to the two sets of data. Then the potency of the test material is defined by the right or left shift of the response curves. (See the graph below – red arrows highlight the shift resulting from the differing potency



Therefore, when we get ready to develop a potency assay, we need to do the following:

1. Optimize the biological components – so we have consistent responses across time.
2. Select appropriate drug dilutions to create a dose-response curve which can be modelled for quantitative.
3. Determine that the reference vs. test dose-response curves is similar.
4. Calculate the shift and relate it to potency.
5. Once this is done, depending on the necessary precision required to support the product specification, we need to determine the number of replicate assays required and combine the various assay runs in an appropriate fashion.