

## The equations for both the OEL and ADE seem pretty simple. Can't I do the literature searches and calculations myself?

While both the OEL and ADE equations may look straightforward, the selection of the appropriate point of departure (PoD), adjustment factors, and pharmacokinetic (PK) factors can be quite complex, requiring advanced knowledge in toxicology and pharmacology. In addition, the EMA's "Guideline on setting HBELs for use in risk identification in the manufacture of different medicinal products in shared facilities" states that an "expert review" is required. Unless you have an advanced degree (M.Sc. or Ph.D.) in a toxicology-related field, approximately 10+ years of professional toxicology experience, and have published peer-reviewed journal articles in toxicology-related publications, it's fairly risky to defend yourself as an "expert" in the field (3).

### Reference:

Affyility OEL Guidance Document, v9, Jun2022

(3) EMA (2014) Guideline on Setting HBELs for use in Risk Identification in the Manufacture of Different Medicinal Products in Shared Facilities. 30 Churchill Place, Canary Wharf, London, UK.