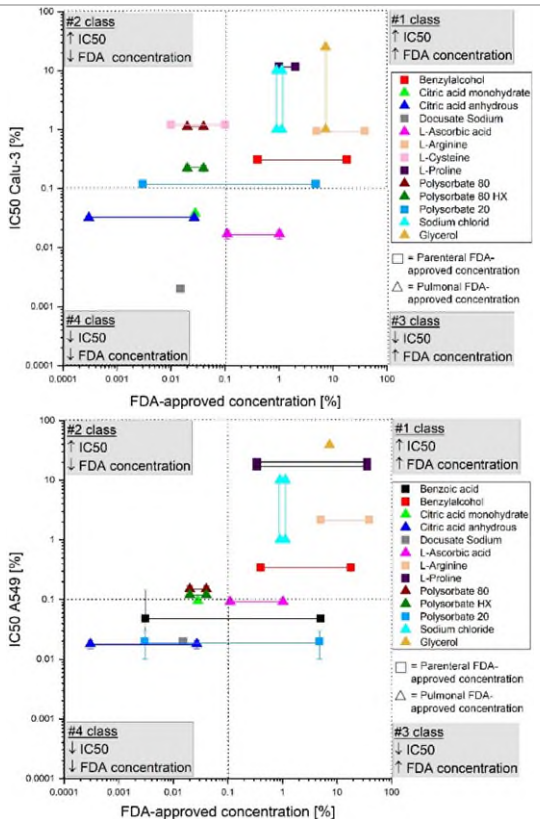
Safety evaluation of pulmonary formulations

Method name	Safety evaluation of pulmonary formulations
Organ system	Lungs
Subject area	Drug development
Area of application	Formulation development
Relation of the method to the 3Rs	Replacement & Reduction, Safety evaluation of pulmonary formulations
Figure	 *The figure shows the plot of IC50 values of various excipients against FDA regulatory data (upper figure: Calu-3, lower figure: A549). Figures from Metz et al. 2020*
Brief description	The method is based on cell viability assays and assumes cytotoxicity (A549, Calu-3) associated with regulatory data (FDA) and toxicity assessments from known animal studies. Using this method, a preclinical formulation is optimized to the point, in which toxicity problems in acute toxicity testing in animals should not occur. This relatively simple approach should be used in addition to other techniques (e.g. aerosol properties) even before a formulation candidate enters the animal study. The method can be applied to single excipients or combinations of excipients and active ingredients.
Theme-based funding	BMBF project AeroSafe (031L0128C)
Publications	Metz, Julia. 2020. “Safety Assessment of Excipients (SAFE) for Orally Inhaled Drug Products.” *ALTEX*. https://www.altex.org/index.php/altex/article/view/1474.

PharmBioTec gGmbH
Dr. Marius Hittinger
Am Nußkopf 39
66578 Schiffweiler
m.hittinger@pharmbiotec.de

PharmBioTec
in vitro research & development