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Biopharmaceutical evaluation of a parenterally injected formulation

Patricia Sibylle Hegger
Sanofi Aventis Deutschland GmbH, Germany

The uptake of subcutaneous (s.c.) administered formulations into the systemic circulation is a function of numerous quite diverse processes like active pharmaceutical ingredient (API) dissolution from the formulation and disintegration to monomers ("liberation"), local metabolism and the permeation through the interstitium and endothelium into the blood vessels ("absorption"). The determination of these parameters prior to launch of the drug is the field of biopharmacy, with its three pillars: in silico, *in vitro* and *in vivo* assessment combined with *in vivo* - *in vitro* correlation. For s.c. administered formulations however there is only a limited number of systematically applied biopharmaceutical *in vitro* - in silico tools for characterization of those processes. For example the first *in vitro* methods for biopharmaceutical evaluation was published in 2015, whereas comparable methods for orally administered small molecules are established since the 1960s. Taken into account, that around 70% of the marketed drugs today are s.c. applied, this is a highly evolving field with the potential of improvement for (I) molecule selection, (II) formulation selection and optimization and (III) understanding as well as prediction of *in vivo* findings in animals and humans.