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Biopharmaceutical evaluation of a parenterally injected formulation

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Abstract

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.

Biography:

Dr. Patricia Hegger has completed her PhD on "Hyaluronan Based ECM-Mimetics with Tunable Charge Densities – Physico-Chemical Properties and Biological Implications" from Max-Planck-Institute for medical research in 2017. Before starting her career in industry she took over an interim-groupleader position at the Max-Planck-Institute for medical research continuing her studies on hyaluronic acid. She is now a lab head in the biopharmacy group of the TIDES Drug Product department of Sanofi-Aventis Deutschland GmbH, a global pharmaceutical company.

Speaker Publications:

1. Charge-Controlled Synthetic Hyaluronan-Based Cell Matrices; Molecules/Volume 23/Issue 4
2. Hyaluronan Based ECM-Mimetics with Tunable Charge Densities - Physico-Chemical Properties and Biological Implications
3. Charge Matters: Modulating Secondary Interactions in Hyaluronan Hydrogels; ChemistrySelect/Volume 2/Issue 25
4. Charged Triazole Cross-Linkers for Hyaluronan-Based Hybrid Hydrogels; Materials /Volume9/Issue 10

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