In vitro testing for subcutaneous formulations under biorelevant conditions

Sirius Analytical is seeking partners to help further validate their Sirius Scissor platform which mimics the subcutaneous environment of the human body. The device enables the establishment of in vitro to in vivo correlations (IVIVC), formulation performance analysis and determination of formulation stability upon injection without using animals. This can support early identification of formulations with poor performance or stability upon injection so that they can be adapted before they progress to animal studies.

What could the Solution be used for?

Sirius Scissor mimics the subcutaneous space of the human body in vitro and can be used to evaluate and understand how a subcutaneous formulation performs after injection regarding its stability, diffusion of active pharmaceutical ingredients (API) and excipients from the injection site and uptake by the blood and lymphatic streams.

Scissor has been validated with antibody formulations and allows for an IVIVC of 90% regarding the formulations’ bioavailability. Additionally, we have worked with two different insulin formulations which also show a very high correlation between human data and that obtained using our novel technology.

Need for collaboration

We would like to generate more data to further validate the instrument with different types of formulations (e.g. peptides, coagulation factors). We are seeking partners with access to compound and formulation information (including existing preclinical/clinical data) that can be used in the instrument’s development.

3Rs impact assessment

Issues concerning the formulation of a potential new therapeutic can necessitate repetition of animal tests following optimisation of the formulation. Sirius Scissor recreates biorelevant study conditions in vitro; acting as an intermediate in the drug development process allowing many different formulations to be quickly tested and adapted according to need. This ensures that formulations with poor performance or stability upon injection will be identified early in development so that they do not progress to animal studies.

For more information or to contact the Solution provider: https://www.crackit.org.uk/vitro-testing-subcutaneous-formulations-under-biorelevant-conditions