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## A novel in vitro method to analyse the performance of subcutaneous formulations

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**Statement of the Problem:** Subcutaneously administered biopharmaceutical formulations undergo significant changes when transitioning from the formulation buffer to the subcutaneous (SC) environment. That transition happens with regards to several parameters: pH, temperature, and pressure. Furthermore, the molecules in the subcutaneous space (i.e. collagen, hyaluronic acid) will also interact with the formulation. Scissor is a novel instrument capable of analysing *in vitro* the fate of SC formulations when in contact with a mimicked subcutaneous environment. It allows for the identification of any instability that may hinder drug diffusion from the injection site, facilitating a more rational formulation design as well as providing a better understanding of how a drug behaves upon entering the subcutaneous space.

**Methodology & Theoretical Orientation:** A sample is injected into a cartridge containing an extracellular matrix (ECM), where light transmission and pH are monitored. The formulation components then diffuse out through a customised dialysis membrane to an outer chamber containing a bio-relevant buffer (under sink conditions) that represents the blood stream from which aliquots can be collected for further analysis.

**Findings:** It was possible to distinguish between two different insulin formulations (rapid and basal). The amount of protein released vs time showed that both the onset time and release profile were like the values presented in the literature. When analysing monoclonal antibodies (previously tested in humans) it was possible to establish an *in vivo*, *in vitro* correlation (IVIVC) of 90%. This represents a marked increase from data obtained from animal studies which has on average 60-70% IVIVC.

**Conclusion & Significance:** Scissor allows for an *in vitro* determination of the behaviour of subcutaneously administered formulations. This can be particularly useful in expediting formulation development. Moreover, Scissor can help to reduce the number of laboratory animals used for testing biopharmaceutical formulations and gather information in a cost-effective and timely manner.

## Biography

Nuno Madeira do O is currently the Head of Biopharmaceutical Development at Sirius Analytical, a Pion company. His background is in the formulation of biopharmaceuticals, having previously worked at Novaliq (R&D Department) and Medimmune (Biopharmaceutical Development – Formulation Sciences), where he carried out work focused on the formulation of peptides and peptide-antibody conjugates. He has completed his PhD in the Drug Delivery department of the University of Nottingham. Currently, at Sirius Analytical/Pion, he is focused on understanding the behaviour and stability of drugs once injected in the subcutaneous space as well as other administration routes (intra-ocular and intra-articular).

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