SIGMOID PHARMA

INDUSTRY PROBLEM STATEMENT

Sigmoid Pharma Limited is a specialty pharma product development company headquartered in Dublin, Ireland. The company leverages its proprietary SmPill® oral drug delivery platform to facilitate reduced-risk, innovative, patentable product development. Sigmoid's goal is to identify and create novel therapeutic opportunities that address unmet clinical needs. By applying SmPill® technology to existing therapeutics, Sigmoid works to improve the safety and/or efficacy of such therapeutics for existing or new uses in a range of diseases, focusing on gastrointestinal disease. SmPill® technology has demonstrated potential in the oral delivery of vaccines and peptides. Sigmoid's lead product, CyCol®, has completed a Phase II study in ulcerative colitis.

To enable the development of stable, reproducible and scalable products, Sigmoid needs a range of characterisation methods to gain a greater understanding of their novel manufacturing processes.

CRANN VALUE ADD

The expertise of CRANN's dedicated technical staff in combination with access to CRANN's Advanced Microscopy Laboratory and extensive material characterisation suite resulted in the development of a range of methods to characterise the SmPill® core, the surface and coating layers.

CRANN's Focused Ion Beam (FIB) microscope was used to prepare cross sections of the SmPill® bead. The cross sections were analysed by SEM (Scanning electron microscope) and the interfaces and interactions occurring within the different coating layers were investigated. Energy Dispersive X-ray (EDX) analysis provided detailed qualitative and quantitative compositional information for each layer. A range of beads with various drug/coating permutations were analysed to provide precise specific surface area evaluation.

The methods developed with CRANN supported Sigmoid in the development of improvements to their manufacturing process.

CRITICAL CRANN ENABLERS

- Proven expertise in advanced microscopy techniques and soft materials characterisation.
- Access to the Focused Ion Beam microscope and highly trained technical staff.
- Access to the Scanning Electron Microscope and Energy Dispersive X-ray analyser.
- Polymeric material analysis and Spectroscopy.

TYPE OF ENGAGEMENT

This project was co-funded by Enterprise Ireland under a 50/50 innovation voucher. The 50/50 innovation voucher scheme provides industry with funding of up to 50% (€5k) towards the costs of contract research projects employing an academic partner. Innovation vouchers are accessible to any SME, and SME consortia on the island of Ireland for engagements with an academic institute in order to answer a specific well defined knowledge question. [Contact colm.faulkner@tcd.ie for further details about EI voucher scheme].

"Understanding the interaction between the coating and the underlying SmPill® technology was critical to the development and knowledge of the SmPill® technology and supported Sigmoid in identifying process improvements for consistent manufacturing and scale up"

Dr. Ivan Coulter, CEO, Sigmoid Pharma

ENTERPRISE IRELAND