

CCID, the UL/SSPC Lilly Pfizer Partnership



A partnership alliance with Enterprise Ireland Innovation Partnership Project between global teams at Pfizer (Ringaskiddy, Cork, Ireland, Groton, Connecticut, US and Singapore), Eli Lilly (Kinsale, Cork, Ireland, and Indianapolis, US) and SSPC, the SFI Research Centre at the University of Limerick.

THE CHALLENGE

Continuous manufacturing is a novel concept to the Pharmaceutical Industry. There is currently no end-end continuous crystallization, isolation and drying pharmaceutical process in operation at a commercial scale. Pfizer, Ringaskiddy, Co. Cork, and Eli Lilly, Kinsale, Co. Cork, united with the common goal of identifying a solution to this problem. Therefore, the key objective is developing flexible platforms for Continuous Crystallization, Isolation and Drying (CCID) from existing off the shelf technology for real-world active pharmaceutical ingredients (APIs).

THE SOLUTION

The highlight of the CCID partnership was the development of a continuous crystallization process for a Pfizer API, using an Eli-Lilly lab scale 2-pot MSMR crystallization rig, and subsequent scale up of the crystallization to 2 20 L crystallizers and isolation on a high frequency filter (HFF) in the Pfizer KTL facility in Ringaskiddy, with a successful 95-hour continuous crystallization run.

THE IMPACT

The UL crystallisation process was successfully scaled up at the Kilo Technology Laboratory (KTL, Cork) in Pfizer by Pfizer technical staff following a technology handover. The UL researchers supported the demonstrations and Eli Lilly researchers were also in attendance, this in itself is a first for Irish academia and testament to the potential value realized in this work. The KTL also successfully demonstrated the continuous isolation of API by integrating the high frequency filter to the continuous crystalliser, generating 10kg of API per 24-hour period. CCID also leverages existing administration support structures within the SSPC, existing as an SSPC-associated project, and took advantage of existing SSPC procedures in relation to industrial interactions, Intellectual Property Management and Heads of Agreement.

The CCID partnership significantly enhanced the in-house expertise in continuous downstream processing in Pfizer and Eli-Lilly. The skill-set developed in continuous manufacturing within Pfizer and Eli Lilly will differentiate the Irish manufacturing base within the respective company parent networks. Since commencing this partnership project both Irish manufacturing bases have received significant investment from their US based parent company for continuous process development, and capital investment in continuous manufacturing. Lilly and Pfizer locally continue to consult with each other on new developments in this technology space. Continuous isolation and drying will continue to be investigated by SSPC through phase II of its funding period (2019 - 2025).

"For Pfizer, two results were achieved with this project, one been the successful running of the crystallisation and isolation for a full working week, and secondly the partnerships and relationships forged within Pfizer Cork, Singapore and US and also between Lilly Cork, Lilly US and UL, without them we wouldn't have achieved the milestones of the project."

Pat Sweeney, Pfizer KTL CCID Project Lead.