HOW TO ENGAGE WITH SSPC

SSPC researchers working in partnership with the international pharma and biopharma sector to solve key industrial challenges enabling novel and efficient methods of manufacturing safer, cheaper and more effective medicines for the future.

SSPC has a proven track record in delivering excellent research that is critically informed by the needs of the pharmaceutical sector. SSPC can support your research and development activities with particular emphasis on:

- **Reducing Time to Market in Drug Development**
- **Advancing Manufacturing Process and Technologies**
- **Improving Efficacy of Drug Products**
- **Addressing the Needs of New, More Complex Active Ingredients**

BECOME AN INDUSTRY MEMBER TO:

- Access to a €12M research programme with world leading academic experts
- Initiate a research project aligned with your research priorities
- Access a talent pipeline comprising over 100 PhD graduates and post-doctorate researchers
- Co-supervise, inform and host PhD students in an area relevant to your organisation
- Upskill your workforce through our industry based PhD and Master's programme
- Benefit from high caliber training sessions
- Be part of an international community of practice for pharmaceutical research, innovation and training

DEVELOP A RESEARCH PROJECT

Industry projects can be supported in a number of ways in SSPC.

Companies have the option to initiate industry specific research projects and own all project IP thanks to a flexible Irish IP protocol that facilitates industry led project collaborations with Irish research performing organisations.

Companies can also avail of SSPC Co-Funding (max. 50%), providing organisations with the opportunity to licence back any IP arising.

For more information on how we can work with you please contact our Industry Engagement Manager Aisling.Arthur@sspc.ie

SSPC

The SFI Research Centre for Pharmaceuticals

What We Do

SSPC manages a €12M research portfolio comprising 68 projects across 5 thematic research areas and the bio-pharma space. The Centre brings together renowned researchers across Ireland and collaborates on many industry-led projects. Currently SSPC works with 16 industry members and on multiple non-member projects.

An example of some of our industry member projects:

This project addressed the limit of detection and quantification of polymorphs of drug substances (DS) in a fixed-dose combination(FDC) drug-product (DP) on Panalytical Empyrean Series 3. The project extended over a period of 4 months with the post-doctoral researcher working between the Alkermes site in Athlone and the University of Limerick, Ireland. This project also facilitated knowledge sharing and exchange of best practice approaches between the SSPC researcher and Alkermes staff located in both the Irish and US sites.

Mechanistic Modelling of a biologics development process APC and SSPC conducted a feasibility study to assess the optimal parameters for the Cation Exchange Chromatography step by Chromatography Mechanistic Modelling, using the GoSilico ChromX® software package. The integration of modelling tools into process development of biologics is an important part of the quality by design approach. Mechanistic modelling ensures time and cost-efficient process optimization by minimizing experimental work. Consequently, the adoption of modelling tools has increased to support process development, process optimization, process characterization and scale-up phases across the pharmaceutical sector.

This 12 month post-doctoral project addresses commercial challenges for Fill Finish Manufacturing of Lyophilised Biopharmaceuticals by the development of an in situ analytical method compliant with the orange guide requirements for ID. Many products have a frozen intermediate step for DS prior to Fill Finish Manufacturing, often DS is shipped in multiple containers from the DS site to the DP site and as per the orange guide for parenteral biopharmaceuticals, each container is required to be identified. This usually requires liquid state sampling and testing by HPLC or Dot Blot for example. Opportunities to ID the frozen bulk provides a significant improvement to the manufacturing process.

The aim of this project is to determine if mesoporous silica can have a protective effect on Amorphous Solid Dispersions (ASD), and so enhance the physical stability and dissolution performance of such formulations. ASDs are highly useful but physically unstable drug-delivery platforms. Maintaining physical stability over the shelf-life of the product is especially challenging for high drug loaded ASDs and for ASDs containing APIs that are prone to rapid crystallization. Mesoporous silica may be a useful formulation additive for de-risking the ASD platform. Silica materials can preferentially adsorb water and thus may promote physical stability of the ASD, stabilizing it by avoiding plasticization of the ASD.

Zinc Ionophoric activity: Zinc has emerged as a potentially important factor in the treatment of COVID-19; it appears that increasing intracellular zinc with ionophores can inhibit the replication of the virus within in vitro models. The overall goal for the study is to investigate how the putative zinc ionophores counterparts compare. The study focuses on ionophoric mechanisms of transport, cellular growth, cell death mechanisms, zinc uptake and expression of key proteins associated with cellular zinc physiology. The study will form the basis for more advanced in-depth studies focusing on particular mechanisms and pathways identified during these initial experiments and to establish a set of 'design rules' for effective Zn2+ ionophoric activity.

Machine Learning applied to Centrifuge process: This project will develop a predictive model of the Centrifugation process using machine learning algorithms to process data in order to study the effects of centrifugation and drying on the particle size of the API product. The process will be modelled using a combination of auto-encoder and neuro-fuzzy or deep learning approaches.

In Vitro In Vivo evaluation of toxicity and efficacy of CBD formulation

This study investigated the impact of CBD formulations with respect to toxicity and bioavailability. The project was a collaboration between Dublin City University and Maynooth University and benefited from the combined expertise and infrastructure to support both in-vitro testing on skin and intestinal cell models and in-vivo testing on larvae to measure the toxicity of compounds and in vivo efficacy. The use of in-vitro cell line allows the study of various molecular pathways.

This study uses the established cell lines, Caco-2 and HT-29, as models of the intestinal epithelia. In Vivo testing was conducted using Larvae (caterpillars) of Galleria mellonella. The insect immune response is very similar to the innate immune response of mammals and so insects may be used in place of mammals for a wide range of applications and yield results equivalent to those from mammalian testing. Larvae can also be used to study the metabolism of compounds and show similar metabolic process as occur in mammals.

Alternate Catalyst Project: This project has a high commercial potential for Lily. The goal of the project is to determine if an alternate catalyst and/or ligand will lead to an increase in the yield of an isolated product.

Meso- and Micro-Mixing in a Static Mixer: This international project team brings together expertise from Merck US, MSD Ballydine, Ireland and SSPC.
The project uses Lattice Boltzmann techniques to study the effect of mixing on yield and selectivity. The goal of this project is to computationally simulate meso-mixing and micro-mixing in a static mixer reactor – where multiple related reactions take place with different reaction rates.

Conversion of Chord Length Distribution to Particle Size Distribution
This project aims to develop systematic methodology to convert Chord Length Distribution data to Particle Size Distribution for enhancing the prediction of oral absorption of weakly basic drugs. The computational models used in this project will assist in the interpretation of data being collected.

Continuous Anti-solvent Cavi-crystallization: This project aims to develop a PhD candidate Continuous Anti-solvent Cavi-crystallisation in partnership with Pfizer and two Irish based SFI research Centres namely: SSPC and CONFIRM.
The goal of the research is to develop a systematic methodology for design, optimisation and scale-up of continuous crystallisers working in combination with hydrodynamic cavitation for realising better control on particle size distribution. The developed insights and computational models will be useful to critically evaluate applications to industrially relevant crystallisations.

Scale-up Systems initiated a CFD study of the mixing properties of some Mettler-Toledo lab-scale reactor systems under standard operating conditions. Predictions of mixing using traditional chemical engineering relationships become increasingly unreliable as the scale of operation decreases, especially in lab-scale equipment typically used in early-stage process development. This project has developed a number of simulations in OpenFoam and provided users of the Scale-up Dynochem software with more accurate predictions of the scalability of processes in early-stage development.

SSPC BIO CAPABILITIES

Gene & Cell Therapy

- Proteomic profiling
- Cell models
- Gene and Protein expression patterns
- Engineering Nanotherapeutics for macromolecule delivery, including peptides, proteins and nucleic acids such as siRNA

Protein Engineering

- Crystallisation
- Characterisation (aggregation, structure, binding, activity, stability)
- Structure-function elucidation
- Rational computational design
- Site directed mutagenesis
- Sequence alignment

Drug Hybrid Conjugates

- Chemical
- ligation methods for accessing therapeutic proteins and protein conjugates
- Protein Glycosylation and PEGylation
- Protein oligomerisation
- Labelling of biomolecules

Protein Production

- Bacterial and mammalian fermentation
- Optimisation of bioprocess
- Purification Characterisation(aggregation, structure, binding, activity, stability)
- Formulation
- Lyophilisation

Modelling

- Molecular simulations
- Computational Fluid Dynamics for bioreactors, tubing and pumps
- Mathematical first -principles modelling

A selection of our biopharmaceutical project topics:

- Bacterial and Mammalian Cell Fermentation and Analysis
- Calixarene-controlled Protein Crystallization
- The stability of proteins and their chemically modified derivatives
- New expression systems for the production of immunomodulatory enzymes as therapeutics
- Real-time control of mAb glycosylation
- Optimisation of Transport and Hybrid Processes in (Bio)pharmaceutical Manufacturing
- Multiscale modelling of membrane separation operations, development of a multipurpose digital twin for pharmaceutically relevant membrane separation operations (nanofiltration/ultrafiltration)
- Accelerated Microfluidic Chemical Ligation for Synthesis of Peptide and Protein Therapeutics
- Enzyme Activated Peptides (EAPs): Application of EAPs as disease specific biological probes and targeted drug delivery vectors
- Peptide Synthesis
- Utilise Proteomic techniques to assess mode of action of antimicrobial agents
- Development of targeted ‘click chemistry’ strategies for the characterisation of drug uptake and localisation in cellular environments
- Bacterial and Fungal antibiotic resistance; mechanism discovery and screening systems
- In vitro mimetic scaffolds of intestinal, blood brain barrier, skin and cardiovascular mimetic system
- In vitro Cell Culture Models and Toxicity Testing
- Advanced therapies, including gene and cell-based products
- Excipient variability in a Biopharmaceutical Manufacturing
- Atomistic scale modelling to design coatings compatible with ALD for modulation of porosity in target polymers
- CFD Modelling and Scale Up
- Modelling self-assembly of peptides for next-generation pharmaceuticals
- Mathematical modelling of physicochemical processes