Alexander KROK

Technology Centre: Pharmaceutical Manufacturing Technology Centre (PMTC), CIT
Academic Mentor: Dr. Sandra Lenihan
Commercial Partner: Pfizer Newbridge
Commercial Mentor: Kieran Coffey

Alexander graduated with a BSc degree in Organic Chemistry and an MSc degree in Chemical Engineering at the Faculty of Chemical and Food Technology. He completed a PhD at Faculty of Mechanical Engineering in Slovak University of Technology in 2011. From 2014 to 2016, Alexander spent two years at University of Surrey as a Marie Curie Fellow in Prof. Wu's research group and between 2016-2017 he worked at RCPE as a Senior Scientist. He was also Research Fellow at Cork Institute of Technology between 2017-2019 to support market focused applied research at PMTC.

Pharmaceutical Manufacturing Technology Centre (PMTC)

The Pharmaceutical Manufacturing Technology Centre (PMTC) is a leading industry-informed research centre focused on developing advanced technology solutions for all stages of pharmaceutical manufacturing. The market-focused research delivers solutions to contemporary issues currently facing the pharmaceutical industry. The PMTC is hosted at the University of Limerick with core funding from the Irish Government, supplemented with co-funding from industry and leveraging further research funding. Company engagement allows the PMTC to execute world-leading, industry relevant research in advanced technology solutions to address contemporary manufacturing issues across the pharmaceutical sector.

Dr. Sandra Lenihan

Dr. Sandra Lenihan has significant pharmaceutical processing experience to date (Eli Lilly, Astellas, ALTANA Pharma and Gilead Sciences) and has experience of industrial and academic collaborations. She has published papers and conference proceedings within the pharma space and has mentored several Postdoctoral researchers to date. Sandra completed her BSc Industrial Chemistry and PhD in Physical Chemistry in the University of Limerick. She has significant experience of technology transfer of new solid dosage products from sites in Germany and USA to Cork. Since 2009, Sandra lectures in Chemical and Biopharmaceutical Engineering (Level 8) in Cork Institute of Technology (CIT) and is proactive researcher.

Kieran Coffey

Kieran has over 15 years in the field of solid oral dose pharmaceutical manufacture. He has been involved in over ten successful technical transfers of products, development of numerous new products, and has successfully managed projects from the small to the large international scale. He was heavily involved as an equipment owner in the design and delivery of a state of the art development centre with capability from 5 kg to 50 kg scale manufacture. Mr. Coffey was also the technical lead for a new active coated product as it went through the filing and pre-approval inspection process. He has worked at two pharmaceutical companies in Ireland in technical roles and has spent a year at the global manufacturing headquarters of Pfizer Inc. in the United States.

Pfizer Ireland Pharmaceuticals

Pfizer Ireland Pharmaceuticals (PFIZER) in Newbridge Ireland is one of the leading sites in the Pfizer global network. It has a twenty-five-year history of supplying products to global markets including the EU, US and Japan. It also has a license for the manufacture of material for clinical supply and for the manufacture of active pharmaceutical ingredients. PFIZER was selected as a host due to their significant experience and a pilot scale facility for the manufacture of tablets, including capacity for blending, roll compaction, milling and compression. The site has a technical services department consisting of highly experienced scientists and pharmacists with many educated to PhD level.

Alexander's project

"The development of robust computational models for the dry granulation processing of bilayer solid dosages"

Bi-layer tablets are novel drug delivery systems where a combination of two or more drugs in a single unit having different release profiles which improves patient compliance, prolongs the drug action. The lower cost and the ability to mask objectionable odours and bitter tastes are a few examples of the aspects in which bilayer tablets are superior compared to all other oral dosage forms.

Drugs with poor wetting and slow dissolution properties may be difficult to formulate or manufacture as a tablet that will still provide adequate drug bioavailability. Dry granulation means that no moisture is involved in the process; it is therefore an ideal way to process compounds that are physically or chemically unstable when exposed to moisture. The development of high added-value products is a costly and time-consuming process.

It takes 6~12 years and costs more than £500 million on average to develop a new drug product in the pharmaceutical industry, among which about 20% of the total cost is associated with failure in process engineering and product development. The development of predictive models based upon a thorough understanding of the fundamental mechanisms would dramatically reduce the time and cost in developing particulate products; consequently the price of these products will be reduced, and they will become more affordable to EU citizens. For instance, cheaper medicines will enable European healthcare services to be more sustainable.

Over the duration of this project, a multidisciplinary approach will be applied to develop robust computational process models. This approach will allow to predict the final properties of bilayer tablets producing by a dry granulation process based on the properties of individual particles of powders.