

APC Ltd: Fresh approaches to manufacturing medicines

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SUMMARY

Being able to make medicines in a safe and reliable way is key to improving human health. Professor Brian Glennon and Professor Mark Barrett at UCD have developed approaches to optimise the processes involved in making those medicines.

The company they co-founded, APC Ltd. has gone from strength to strength, working with client companies to analyse and improve their manufacturing processes, particularly the steps involved in crystallising drug molecules to deliver them in tablets.

APC now employs over 100 people in Ireland. The company has worked with eight out of the top 10 pharmaceutical companies and five out of the top 10 biopharmaceutical companies in the world to safeguard the reliability and supply of more than 150 medicines for humans.

"We are seeing the global healthcare industry recognising Ireland as a location for this specialised and important research."

Safe medicines at scale

Around the world, human and animal health is improved and safeguarded by medicines that tackle symptoms or the root causes of disease. However, it is critical that companies can manufacture these medicines safely, reliably and in a timely manner.

One of the crucial factors in getting that medicine to you safely and when you need it is the manufacturing process. At UCD School of Chemical and Bioprocess Engineering, Professor Brian Glennon and Professor Mark Barrett have been on the case to make the 'making' of drugs more efficient, more environmentally friendly and more reliable, all the while ensuring that the medicine still does the job.

Their research has sparked the interest of pharmaceutical companies, who typically make what are called small-molecule drugs that are relatively simple chemicals, and the interest of biopharmaceutical companies, who develop more complex drug molecules, often made by micro-organisms such as bacteria.

"When such companies are testing potential new drugs, they often manufacture small amounts initially," explains Professor Glennon. "Then, if the drugs are approved for wider use, the companies need to scale up the manufacturing process. This is where our research at UCD has focused."

There was no particular Eureka moment: over the course of around two decades, Professor Glennon and Professor Barrett built deep expertise around the complex biology and chemistry of making medicines purely and efficiently, and how to analyse and optimise manufacturing processes using engineering.

"Working as part of the Science Foundation Ireland-funded SSPC, we particularly looked at the steps involved in forming crystal structures of the drug molecules," says Professor Glennon. "These crystals are then incorporated into the final form of the drug, such as a tablet that can be swallowed."

One of the standout aspects of the research is the **mix of computer-based and lab-based approaches** that the group uses to understand the individual manufacturing needs of a specific medicine, and through a spin-out company called APC the research has helped companies around the world to make medicines.



Making an impact on medicine

Through their research, Professor Glennon and Professor Barrett have helped to optimise the processes by which medicines are made.

Their work at UCD formed the basis of a **spin-out company**, **APC Ltd.**, which assesses and optimises manufacturing for individual client companies.

The UCD research group and spin-out company's work is increasing the awareness of how applying an engineering approach can fine-tune the drug manufacturing process, solve problems and increase the return or yield of medicine.

"Taking an engineering approach to optimising manufacturing means the company can support both pharmaceutical and biopharmaceutical companies even though the types of drugs they produce are quite distinct chemically," explains Professor Glennon.

APC has worked with eight out of the top 10 pharmaceutical companies and five out of the top 10 biopharmaceutical companies in the world to optimise manufacturing processes of more than 150 medicines for humans.

APC's work also configures drug manufacturing processes to make them more **environmentally friendly**, notes Professor Glennon. "It means that they use fewer organic solvents, that they recycle resources and that manufacturing facilities operate more leanly to conserve water and energy, as well as bringing operating costs down for companies," he says.

APC's Dublin operation in Cherrywood, Loughlinstown, currently **employs over 100 people,** most of whom have PhDs in chemistry or chemical engineering.

The UCD research group and APC provide an **environment** in Ireland for drug-manufacturing research that typically does not exist in other countries. Their work has attracted considerable international interest, with **more than 90% of APC's clients coming from outside Ireland.**

"For me this has been a really interesting and fulfilling aspect," says Professor Glennon. "We are seeing the **global** healthcare industry recognising Ireland as a location for this specialised and important research."

More generally, the UCD research group and APC's work has provided **new insights for the pharmaceutical and biopharmaceutical industries** about manufacturing processes.

Traditionally, drug manufacturers make batches of the medicine, but the UCD and APC are demonstrating the benefits of a more continuous process, as well as real-time

monitoring to test the purity and quality of the drugs.

APC's impact and successes have been recognised through **numerous awards**, including The 2016 Science Foundation Ireland Entrepreneurship Award and The 2014 Irish Times Innovation of the Year in Biosciences.

"Ultimately, the objective of the research and spin-out company is to accelerate the delivery of medicines to the people who need them in a safe and reliable manner," says Professor Glennon. "This will be the long-term impact and legacy."



Publications And Awards

G. Power, G. Hou, V.K. Kamaraju, G. Morris, Y. Zhao & B. Glennon, 'Design and optimization of a multistage continuous cooling mixed suspension, mixed product removal crystallizer', Chemical Engineering Science, 133, 125-139, 2015. DOI: 10.1021/cg101556s

S. Craven, J. Whelan & B. Glennon, 'Glucose concentration control of a fed-batch mammalian cell bioprocess using a nonlinear model predictive controller', Journal of Process Control, 24 (4), 344-357, 2014. DOI: 10.1016/j. jprocont.2014.02.007

J. Whelan, S. Craven & B. Glennon, 'In Situ Raman Spectroscopy for Simultaneous Monitoring of Multiple Process Parameters in Mammalian Cell Culture Bioreactors', Biotechnology Progress, 28 (5), 1355-1362, 2012. DOI: 10.1002/ btpr.1590

M. Barrett,, D. O'Grady, E. Casey & B. Glennon, 'The Role of Meso-mixing in Anti-solvent Crystallization Processes', Chemical Engineering Science, 66, 2523-2534, 2011. DOI: 10.1016/j.ces.2011.02.042

Awards

- The 2016 SFI Entrepreneurship Award
- The Fit Out Client of the Year 2016
- The 2016 Pharma Company of the Year SME
- The Irish Times Innovation of the Year Biosciences 2014
- The SME Pharma Company of the Year 2014
- The Pharma Innovation of the Year 2014
- The Start-up Lab of the Year 2013
- The Commercial Lab of the Year 2013