



**Dr. Gary Lye**  
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**Abstract**

**Accelerating Biopharmaceutical Process D**

Research led pharmaceutical companies are vital to the economy of most Western countries. The industry however faces significant new and global challenges. Regulatory demands on new chemical and biological pharmaceuticals are increasingly severe resulting in a high risk of failure. When such failures are taken into account the average cost of developing a successful new drug is around £0.5 billion. Companies are also increasingly challenged by generic products manufactured overseas, market segmentation and government pressures to ensure all new drugs are cost-effective.

In this situation expensive large scale pilot plant trials are delayed until the clinical efficacy of the new drug compound has been established. At this point bioprocess development is on the critical path to market and each day product launch is delayed is thought to represent an irretrievable loss of sales of around £1 million per day. Under these circumstances the bioprocesses developed are far from optimal making the manufacturing costs higher than they might otherwise be.

Research at UCL and elsewhere has begun to explore the use of automated microwell experimentation to explore key bioprocess issues at the earliest stages of product development. At UCL our goal is the creation of automated whole process sequences on the deck of a robotic platform that are predictive of ultimate large scale manufacturing performance. This presentation will describe some of the challenges of performing bioprocess experimentation at the microwell scale for key operations such as microbial and mammalian cell culture and bioproduct purification. Examples of their uptake by our industrial partners will also be given for products that are now entering early stage clinical trials.

**Biography**

Gary Lye is Professor of Biochemical Engineering within the Advanced Centre for Biochemical Engineering at University College London (UCL). He received his PhD in Biotechnology from the University of Reading in 1992. Between 1993 and 1996 he was successively a Research Fellow and then Lecturer in Chemical Engineering at Imperial College London and the University of Edinburgh. He joined UCL in 1996. He is currently Chair of the Biochemical Engineering Subject Group of the UK Institution of Chemical Engineers (IChemE). He has broad research interests on the application of microscale and automation techniques to rapid bioprocess design, optimisation and scale-up. He currently leads the multidisciplinary Bioconversion-Chemistry-Engineering Interface (BiCE) programme at UCL which is collaborative with 13 leading international companies.