

Biopharmaceuticals: Meeting the challenge of change

The need

As the medical profession searches for new ways to fight disease and illness, the American Food and Drug Administration has led an initiative to get better biopharmaceutical products onto the market quicker. PAT – Process Analytical Technologies – applies existing technology systems in a novel, cutting edge way in the production process of new biopharmaceuticals. It reduces development time and produces a product of significantly higher quality, benefiting both the industry and the consumer.

It's likely that, in the future, no regulatory bodies will license new biopharmaceuticals which do not incorporate these technologies.

And to put this into a financial context: the world-wide market for one biopharmaceutical, IgG, is expected to reach \$26bn by 2010. The global pharmaceuticals market is poised to grow at a CAGR of 11.6% from \$64.5bn in 2007 to \$135bn by 2014 (Frost & Sullivan, 2007).

Incorporating a refined version of an existing technology into the development of new biopharmaceuticals will enable UK companies to compete effectively in a multi-billion dollar global market.

The results

The £2.5m three-year project introduces Near Infra-Red Spectroscopy - a technology previously used for assessing the quality of raw materials and finished products - into the early stages of developing a new biopharmaceutical. It's at the development stages many products fail – only one in 12 will make it to market, and of that number, one in three will show a profit for the company.

Previous monitoring of bioprocesses has relied on more traditional methods of analysing samples which might

take hours or even up to a day, by which time the process has moved on. Using biosensors and Near Infra-Red Spectroscopy, it's now possible to get a real-time evaluation of what is happening in the bioreactor. Control and monitoring of the process is much closer and more effective, and multivariate analysis of the data enables predictive modelling.

The advantages

- more efficient control of the process means that products that won't make it to market can be identified earlier, saving production time and costs
- deviations in the process can be spotted and corrective adjustments made
- there have been some severe allergic responses from individuals to biopharmaceuticals; improved processes will mean purer, better products.

What's next

The knowledge gained in this project will be disseminated throughout the industry in the UK - a Knowledge Transfer Partnership programme has already been set up within the National Biomanufacturing Centre (Eden Biodesign) - and super-data banks will be established, providing small biotech companies with secure, confidential data storage facilities.



'Technology Strategy Board has provided support from the onset. Help is available to develop the grant application, ensure the programme is running to schedule, minimise risks and spur the academics on to exploit the results of the programme.'

DR LINDA M HARVEY, UNIVERSITY OF STRATHCLYDE



Technology Strategy Board Driving Innovation

Collaborative research and development projects are one of the tools that the Technology Strategy Board uses to drive innovation in the UK. The Technology Strategy Board is a business-led executive non-departmental public

body, established by the Government. Its role is to promote and support research into, and development and exploitation of, technology and innovation for the benefit of UK business, in order to increase economic growth and improve the quality of life. It is sponsored by the Department for Business, Innovation and Skills (BIS).

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Project partners

GlaxoSmithKline
University of Liverpool
University of Newcastle
University of Strathclyde

Technology Strategy Board investment £1.3m

Total project investment £2.7m

Project contact details

Dr Linda M Harvey
Strathclyde Fermentation Centre
Strathclyde Institute of Pharmacy and Biomedical Sciences (Royal College)
University of Strathclyde
204 George Street
Glasgow G1 1XW

T 00 44 141 548 2056

F 00 44 141 553 4124

E L.M.Harvey@strath.ac.uk