



BIOPROCESSING MATTERS

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Industrial Training Open Day

Interview with John More of BPL

Benefits of GSK
Industrial Secondment

£6M Industrial Doctorate
Training Centre win

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Editorial

Foreword by Professor Nigel Titchener-Hooker

Welcome to this second edition of *BioProcessing Matters*.

UCL and the Advanced Centre for Biochemical Engineering have always driven research excellence, and this newsletter provides a snapshot of some of the bioprocess leadership activities currently being undertaken with industrial partners.

The Department of Biochemical Engineering at UCL is unique both in terms of the broad philosophy for training and research it pursues, and also for the facilities and resources it deploys. Similarly, it has made a unique contribution to the international field of bioprocessing, seen from the perspective of process innovations and the skilled alumni who hold key positions in our industry worldwide.

In March of this year I reminisced upon these facts at a packed Team Briefing as a prelude to a vote of thanks for Mike Hoare, who has decided to step aside from leadership after over eleven years at the helm. During his tenure Mike has taken a department from its inception through to being acknowledged as the National Centre for Excellence in the UK. The Department has more than doubled its undergraduate intake over this period and matched this by a similar increase in academic staff, enabling new fields to be developed (most notably in regenerative medicine). Investment in our infrastructure has been similarly impressive and is enabling the introduction of new training modes and the exploration of new territories for research.

Thanks to the efforts of individuals such as Mike Hoare and very notably Peter Dunnill, who continues to provide strategic advice, we face the future with a degree of confidence, despite the level of international uncertainty. This issue of *Bioprocessing Matters* highlights some of our recent successes, such as the winning of an Industrial Doctoral Training Centre (IDTC), and showcases recent MBI[®] training developments. It also shows how we are helping to respond to the challenges faced by our graduates in the job market and how, with industry as our partner, we can continue to take forward an ambitious and relevant training and research agenda for the bioprocessing sector globally.



Nigel Titchener-Hooker

Departmental news

Renewal of Doctoral Funding

Since 1999, the department has hosted an Engineering and Physical Sciences Research Council (EPSRC) funded Engineering Doctorate (EngD) Training Centre involved in the enhanced doctoral level training of future industry leaders. We are delighted to announce that, on 5 December 2008, our funding was renewed for this vital activity as part of a £250 million Doctoral Training Centre Initiative launched by the Minister of State for Science and Innovation, Lord Drayson.

Lord Drayson said: *“Britain faces many challenges in the 21st century and needs scientists and engineers with the right skills to find answers to these challenges, build a strong economy and keep us globally competitive. EPSRC’s doctoral training centres will provide a new wave of engineers and scientists to do the job.”*

Professor Dave Delpy, Chief Executive of EPSRC, said: *“People are the heart of our future strategy. We want to drive a modern economy and meet the challenges of tomorrow by investing in talented people and inspiring the next generation of scientists and engineers.”*

The initiative is widely supported by business and industry. This approach to training has been extensively piloted by the EPSRC through a small number of thriving Centres (including our own, where more than 70 EngDs have been supported to date by 49 sponsors).

Our focus is serving UK-based companies in the fields of biopharmaceutical and chemo-enzymatic processes; we also address the area of regenerative medicine. Our EngDs focus on achieving the necessary speed in development to win, maintain and grow bioprocessing activity in this country and we have already worked with a wide range of established and start-up companies, including BioPharm Services, Biovex, BPL, Eli Lilly, Evotec, GE Healthcare, GSK, HEL, HPA, Ingenza, InterCell, Lonza Biologics, Moorfields Eye Hospital, Novo Nordisk, Onyvox, Pall Filtration, Plasticell, Pfizer, Protherics, Westfalia Separator and Wyeth Biopharma. The benefits to the companies who have collaborated so far by sponsoring a project are many, including high-quality knowledge transfer, access to a range of well-developed technology transfer mechanisms, long-term dedicated research into an area that could save much time and cost, and committed support of the world’s largest trainer of biochemical engineers for the bioprocess industries.

Their views are typified by that of the Chief Scientific Officer of Lonza Biologics, Professor John Birch: *“The attraction of the EngD programme to a company like Lonza is the prospect of solving a challenging technical problem cost-effectively, whilst gaining knowledge of the latest technologies in bioprocessing and access to top quality training programmes in the biotechnology field.”*

For further information see www.ucl.ac.uk/biochemeng/industry/engd or contact Prof. Gary Lye at g.lye@ucl.ac.uk.





Department tackles the credit crunch following HEFCE Economic Challenge Innovation Fund (ECIF) bid

UCL has unveiled a radical package of activity designed to prepare UCL students for entry into an unprecedentedly difficult employment market, and to support businesses during the economic downturn.



In April 2009 UCL received £500,000 from Higher Education Funding Council for England's 'Economic Challenge Investment Fund', which will be boosted with a further £2 million from a combination of UCL's own income and contributions from Capital Enterprise, biotechnology and pharmaceutical companies and other sources. The total £2.5 million represents the largest financial commitment on the part of all universities receiving funding from the ECIF to this kind of activity.

Our Department's activity revolves around providing support to graduates to access skills training in a wide range of biotechnology and pharmaceutical companies. Graduate recruits to our ECIF scheme will work with companies for between ten and 50 weeks, accessing our high-quality MBI® post-experience modules and acquiring relevant bioprocessing and business skills at their host company.

If you would be interested in taking on a new graduate for a training placement under this scheme please contact Dr Karen Smith at karen.smith@ucl.ac.uk.

Launch of new e-bulletins

In order to ensure that companies are kept up to date with developments we have launched e-bulletins for both the Innovative Manufacturing Research Centre (IMRC) and Industrial Doctoral Training Centre (IDCC), *Pathways* and *Cutting Edge* respectively. The first issues of both have already been sent out and we plan a quarterly schedule. If you have not received the bulletins but would like to, please email mbi-training@ucl.ac.uk.

New Staff

Dr Ivan Wall joined the department in April 2009 as a lecturer in regenerative medicine bioprocessing. He completed his PhD at Cardiff University in 2005, then moved to the Eastman Dental Institute at UCL to study regenerative processes in the oral mucosa and adult mesenchymal stem cells. In 2007 he moved to the world-renowned UCL Institute of Ophthalmology to research angiogenic regulation of neural stem cells during development. He maintains



a strong interest in both adult and embryonic stem cells and their therapeutic potential for treating age-related degenerative disorders. Please feel free to contact him on 0207 679 3918 or email him at i.wall@ucl.ac.uk.

We are also in the process of recruiting a new staff member in the area of Synthetic and Molecular Biology. The intention is to strengthen the capacity of the Department to manipulate genetically microbial and mammalian cells so as to improve the performance of the bioprocess in which they are utilised. Examples would include the application of synthetic biology principles to synthesise chiral chemicals and pharmaceuticals from cheap and renewable feedstocks using heavily engineered bacteria or the use of genetic means to enhance the level of potential therapeutic proteins in mammalian cells and to facilitate the process by which they are purified. As with all the Department's research the objective is that the new member works closely with the rest of the staff team helping to underpin the future bioprocesses by which new medicines will be made.

First Industrial Training Open Day

We held our first Industrial Training Open Day on 12 March 2009 and are pleased to report that it was a great success. We were joined by 20 industrialists including representatives from Applikon, Biopharm, BPL, eXmoor Pharma Concepts, GE, Genzyme, GSK, Infors, Merck, Novasep, Pall, Sartorius and Xenova.

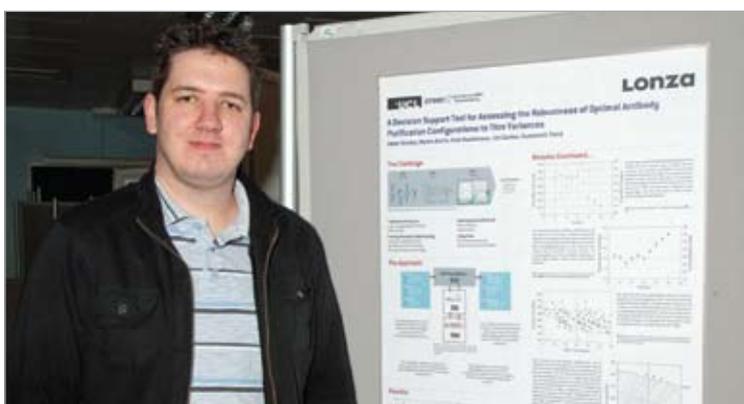
In the morning Advisory Board session delegates heard presentations from Prof. Gary Lye (the use of disposables in training); Prof Nigel Titchener-Hooker (Engineering Doctorates) and Dr Karen Smith and Dr Eli Keshavarz-Moore (MBI® training and the development of a programme for senior executives). These presentations stimulated much discussion and were extremely valuable to all involved.

This session was followed by a lunchtime poster presentation of the work of 20 of our senior EngD and PhD students. These students and our industrial guests were joined by our academic staff and post-docs, giving the event a real buzz. The Bio Products Laboratory kindly sponsored the £200 poster prize, awarded to Adam Stonier (pictured) for his poster entitled *A decision support tool for assessing the robustness of optimal antibody purification configurations to titre variances*.

A company networking and information session followed in parallel with interviews for the prestigious Sir Derek Roberts Scholarships. These scholarships are awarded to students who demonstrate their enthusiasm for Biochemical Engineering and their understanding of its value to society, have a clear vision of what they want to achieve from the degree course, and have an idea of the career they intend to follow. Each award is worth £1,500; this year's winners were Lisa Mears, Omar El Saidi, Natasha Davie, David Brindley, Sofia Labbouz and Alma-Mona Antemie.

The day ended with a briefing that brought together all Departmental staff and students along with our industrial guests to hear the Department's latest news. It was a particularly special evening as we heard how, under the leadership of Prof. Mike Hoare, the Department had grown to its current world-leading status. Prof. Hoare will be enjoying a short sabbatical before returning to the Department to lead on several new and exciting initiatives; Prof Nigel Titchener-Hooker assumes the role of Head of Department.

We are planning our second Open Day for March 2010. It representing a wonderful opportunity for you to see some of the latest research and training being undertaken here and to meet our students and staff – why not join us?





Angela Osbourne, eXmoor Pharma Concepts, and Prof. Nigel Titchener-Hooker discussing the latest in bioprocess technologies.



Peter Levinson, Pall (Europe) and Paul Beckett (EngD) during the networking session. Paul won a hotly contested Graduate School Bursary to attend the Cheltenham Science Festival (3-7 June 2009)



Students and post-docs enjoying the poster session.

New MBI® module: *Quality by Design for Effective Bioprocess Characterisation and Validation*

Cost-effective process characterisation that fulfils evolving regulatory requirements is a challenge faced by all process development scientists and engineers. UCL's MBI® Programme has developed a new module to meet the increasing expectations by regulatory authorities to incorporate Quality by Design (QbD) in product registration submissions.

This module, *Quality by Design for Effective Bioprocess Characterisation and Validation*, has been developed with industry experts* to equip delegates with the skills to understand how best to implement QbD concepts into process characterisation and validation studies.

The module draws on the expertise of industrial and regulatory experts and places special emphasis on integration of QbD, DoE and PAT concepts into a knowledge-driven lifecycle approach to process characterisation. It also provides an opportunity for delegates to become familiar with these concepts and to debate developments with the expert speakers during workshop and case study sessions. Lectures will focus on how effective characterisation and validation can help the sector realise the desired shift in paradigm from compliance to enhanced process understanding. Case studies will be provided to illustrate how the ICH guidelines encouraging a more science- and risk-based assurance of quality can be applied to help manage critical sources of variability and move towards a more flexible and agile sector. Delegates will:

- Learn about the latest FDA and EMEA regulations with regards to QbD, PAT, process characterisation and validation studies
- Understand how to adopt a lifecycle approach to process characterisation and validation to obtain deeper process understanding
- Understand current and future perspectives of the impact of QbD and PAT on the effort required for process characterisation
- Learn how to perform Risk Assessments and Risk Management to select Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs)
- Review examples of how to leverage historical knowledge and combine it with Design of Experiments and Design Space data to determine process limits and minimise change applications
- Understand the principles behind the characterisation and validation of unit operations involved in bulk manufacture, such as fermentation, filtration and chromatography, through to formulation and cold-chain transportation
- Learn how to integrate the use of scale-down models into process qualification studies
- Put their new-found skills to the test on real, complex characterisation problems to recommend strategies and solutions.

During the module delegates will experience stimulating interactive lectures and workshops guided by experts in this field and brainstormed in teams on a range of industrially-relevant scenarios to determine how best to approach process characterisation and validation. There will be ample opportunity for debate on current and future perspectives relating to how best to implement QbD and PAT principles in a timely and cost-effective manner. As in all MBI® modules, we look forward to engaging discussions with enthusiastic participants!

Who should attend: Scientists and engineers working in the biotech sector that are involved or liaise with people in Process Development, Process Characterisation, Validation, Manufacturing, Quality and Regulatory activities.

Industrial expert course leaders and speakers: *Tim Hughes, CSL Ltd (ex-Genentech); *Michael Beatrice (ex-FDA), *Ron Wheeler, Abbot Laboratories; Ingrid Maes, PricewaterhouseCoopers; Suzanne Aldington, Lonza Biologics; Richard Francis, BTG plc; Paul Bird & Angus Thompson, Avecia Biologics; Mark Ayles, Pall Life Sciences; Graham McCartney, Lilly UK

This module will run 1–4 March 2010 and complements other MBI modules, in particular *Design of Experiments for Bioprocess Optimisation*. Please feel free to contact Dr Suzanne Farid (s.farid@ucl.ac.uk) if you have any queries.



Interview with John More, Bio Products Laboratory

John More, Product Development Manager from BPL, recently attended the Industrial Training Open Day on 12 March, which was a great opportunity to feed into the ‘thought process’ for potential future innovation in bioprocessing, as well as to hear the views of other companies and to meet talented students from UCL’s Department of Biochemical Engineering. He was delighted to present an award for the best poster presentation on behalf of BPL. John spoke to Karen Smith (Director of Bioprocess Leadership, UCL Department of Biochemical Engineering), discussing the role of the MBI® modular scheme in achieving BPL’s strategic training objectives.

“BPL is a public sector organisation operating within the NHS, with a unique role as a manufacturer of a wide range of therapeutic human plasma proteins. These are used both within the NHS and (increasingly nowadays) in overseas markets, with sales in over 30 countries. Effective training of staff has been a central tenet to the BPL philosophy in achieving our business goals.

UCL has been a key training provider for BPL for many years through the MBI® Bioprocessing courses. The modular programme has met our needs very well, due to the relevance of the courses and the ability to ‘cherry-pick’ modules to meet the specific training needs of our staff. We have also encouraged staff participating in the MBI® training programme to go on to achieve Certificate and Diploma qualifications; several have now been awarded the full MSc in Bioprocessing.

Iain Badbury (BPL Training Manager) and Karen Smith (UCL MBI® Director) have recently introduced a new way of utilizing the MBI® modular scheme through an innovative system of training vouchers. Running over three years, the scheme builds on the good working relationship BPL have with UCL. It also has the advantage of securing more cost-effective development opportunities for BPL staff, and makes it easier to define training budgets. The voucher scheme has become a central part of our Continuing Professional Development (CPD) programme and has enabled a wide range of staff, both technical and management, to benefit from the MBI® modules. As well as bringing new skills to BPL, it has also impacted positively on the careers of many BPL staff.”



John More, BPL

Novasep contributes to Chromatography module

A fundamental strength of the MBI® modules is the involvement of industry expert speakers in their delivery. We make a constant effort to ensure that delegates hear about the latest real world developments and their industry applications and have the opportunity to ask plenty of questions.

In 2010 we will welcome Laurent Davies from Novasep as an expert speaker on our Chromatography module. Laurent will be joining a distinguished group of experts from BioRad, Xendo, Atoll, ProMetic Life Sciences, ABD Life Sciences, GE Healthcare, Millipore and BIA Separations.

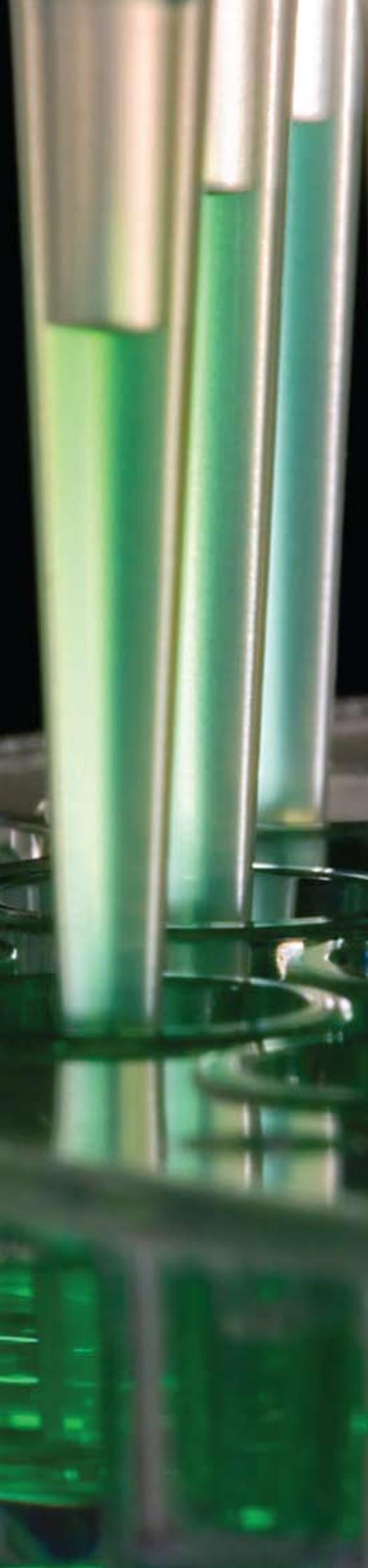
Laurent will focus on Sequential Multi-Column Chromatography (SMCC), a continuous approach in relieving capacity bottlenecks and for raising downstream processing efficiency.

The module will next run on 30 November 2010. For further information, please contact Dr Dan Bracewell at d.bracewell@ucl.ac.uk, or call 0207 679 2374.



Laurent Davies, Novasep





Secondment collaboration between GSK and UCL

UCL and Global Manufacturing & Supply (GMS) (a business division within GSK) have initiated a collaboration through a 6–9 month part-time secondment. Lucy Wakeford, a chartered process engineer from a central technology group within GMS, will spend 1–2 days per week in the Department of Biochemical Engineering, identifying and supporting activities of mutual benefit for collaboration and knowledge sharing.



Lucy Wakeford, GSK

Biopharmaceuticals is a key growth area for GSK. However, the majority of the existing manufacturing network in GSK is based around traditional small-molecule discovery, formulation and production. GMS needs to prepare for a growing portfolio of biopharm products, both in terms of manufacturing technologies and people with the right skills and knowledge to support this area.

At the same time, as with the rest of the industry, there is increasing pressure on both finances and resources. This drives an increasing need to collaborate externally, in particular with academia, to access expertise to support specific projects and training activities.

Through this collaboration GSK will gain a greater understanding both of research activities at UCL and where expertise and technology developments align with business requirements. It is also possible to provide more active support for GSK-funded projects, such as a recently initiated two-year post-doc project on fill-finish operations.

UCL will gain greater visibility of GSK's focus areas for improvement, including training programmes. For example, it was recently possible at short notice to gain GSK support for a successful funding proposal to the HEFCE Economic Challenge Investment Fund for provision of training modules to industry. There is also the opportunity for students to have more informal contact and learn more about GSK.

Lucy will be based in the department on most Fridays until September 2009.



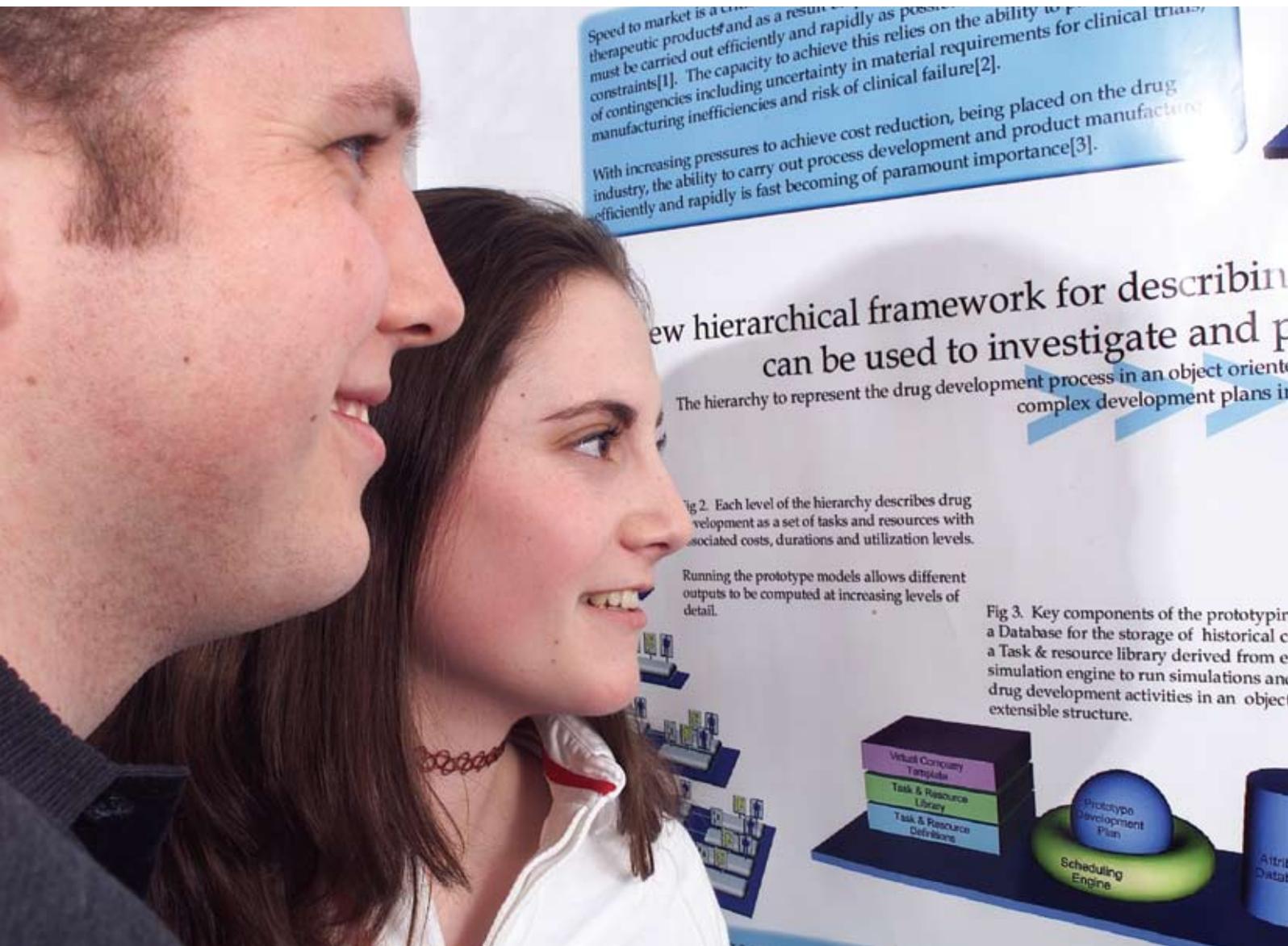
MBI[®] module: *Effective Biopharmaceutical Development*

This module addresses the major issues in taking products from research through to manufacture with special emphasis on speed to manufacture for both clinical trials and commercial production. The module focuses on how to deal with the internal and external factors governing the efficient and successful translation of research into products.

These include:

- Radical approaches to efficient process development.
- Development of R&D plans.
- Technology transfer.
- Production of materials for clinical applications.
- Regulatory considerations.
- Aspects of quality systems management.
- Outsourcing options.

The module will next run on 10 May 2010. For further information, please contact Dr Eli Keshavarz-Moore at e.keshavarz-moore@ucl.ac.uk, or telephone 0207 679 2961.



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MBI® course dates 2009–10

Principles of Fermentation Processes: 5 – 7 Oct 2009

Rapid Fermentation Process Design: From Development to Manufacture:
19 – 21 October 2009

Challenges & Opportunities in Industrial Biotechnology Biocatalysis and
Synthetic Biology: 2 – 4 November 2009

Downstream Processing: Primary Recovery: 16 – 19 Nov 2009

Downstream Processing: Chromatography: 30 November – 3 December 2009

Mammalian Cell Processes: 1 – 3 February 2010

Stem Cell and Regenerative Medicine Bioprocessing: 22 – 24 Feb 2010

Quality by Design for Effective Bioprocess Characterisation and Validation:
1 – 4 March 2010

Design of Experiments for Bioprocess Optimisation: 15 – 17 March 2010

Effective Biopharmaceutical Development & Manufacture: 10 – 12 May 2010

Bioprocess Design & Economic Evaluation: 7 – 10 June 2010

Bioprocess Facility Design: 21 – 24 June 2010

For more information, email mbi-training@ucl.ac.uk



Work with us

The UCL Advanced Centre for Biochemical Engineering actively encourages and fosters long-term research partnerships between its academics and sponsors for mutual benefit. We facilitate interaction in a range of ways, such as sponsor visits, industrial advisory boards, Bioprocess Briefings, industrial placements for graduate students and the MBI® Programme. Over 60 industrial and academic experts contribute to our MBI® activities. If you would like further information, please contact the appropriate member of staff listed to the left.