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IMRC 6th Annual Briefing

Vaccines MBI® module launch and Biopharmaceutical Development & Manufacture module

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Editorial

Foreword by Professor Nigel Titchener-Hooker

Welcome to this sixth edition of *BioProcessing Matters*.

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

2011 will be a busy year without a doubt! We ended 2010 on a high note with an 'across-the-board' endorsement from the Institution of Chemical Engineers (IChemE) for all of our taught degree programmes. This came on the back of a slew of awards in 2010 that really underline both the quality and enthusiasm of o



awards in 2010 that really underline both the quality and enthusiasm of our students and the relevance and excellence of our research. Our students and staff alike are setting the bar high for others to follow – which I'm sure they will!

Our knowledge exchange and outreach activities have always been a hallmark of the department. 2011 will see VISION, our new offering for Senior Executives, move into a second year, building on the success of the first. I have been delighted to see how well this offering has been taken up and by the enthusiasm for the programme of exceptional technical and business briefings offered. Similarly, we launched our latest MBI® offering in 2010, *Vaccine Bioprocessing*, which achieved a capacity delegates list. Perhaps a sign of the times – and certainly a clear vote for the relevance of this module.

The UK research and training agenda is moving fast. As I write, staff are busy grappling with the concept of Technology Innovation Centres (TICs). We wait to see what happens on this front; all of the signs are that the Government sees clearly that the biotechnology-based industries are a UK success story but that they require investment. UCL Biochemical Engineering will be working hard to play its full role in that future. This issue of *Bioprocessing Matters* serves to underline just how broad our activities are but, as always, we are keen to hear your news and views. Our Linked In sites have been enormously successful so please do use them to keep in touch and to help 2011 to be a highly successful year!

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Prof. Nigel Titchener-Hooker

Head of Department and Director of the Advanced Centre for

Biochemical Engineering

Departmental news

Providing access to our research outputs through refereed publications

The Department's research underpins cutting-edge bioprocessing discoveries in several of the most important areas of advanced medicines and industrial biotechnology:

- · Bioconversion Bioprocessing
- Fermentation/Cell Culture
- Faster Creation of Bioconversion, Fermentation and Cell Culture Bioprocesses
- Primary Recovery
- Purification and Formulation
- Faster Creation of Primary Recovery, Purification and Formulation Bioprocesses
- Regenerative Medicine Bioprocessing
- Decisional Tools to Capture the Bioprocess-Business Interface.

All academic staff in the department collaborate across each of the above fields which share common themes such as micro biochemical engineering, including ultra scale-down, microfluidics and automation, cell and protein engineering and synthetic biology, bioconversions, fermentation and cell culture, downstream processing and formulation.

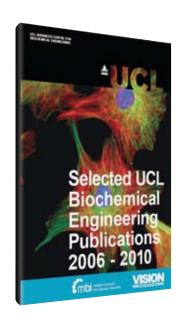
Studies in each of these areas are underpinned by work on intelligent design of experiments and are integrated via whole bioprocess modelling and decisional tools.

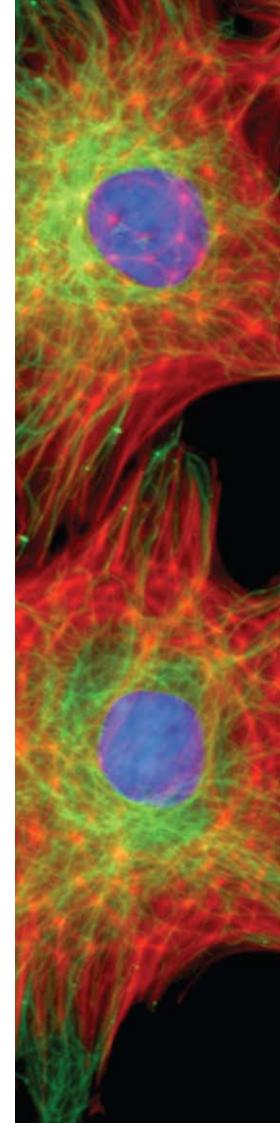
This document highlights some of our best publications in these areas for the period 2006–2010. For further information contact Dr Karen Smith (karen.smith@ucl.ac.uk). Also see our website for more extensive listings and earlier publications which are still providing the fundamental insights for new ways forward in the sector.

BiCE team wins 2010 IChemE Innovation and Excellence award

Staff within the Department's multidisciplinary BiCE programme (Biocatalysis-Chemistry-Engineering interface programme) won the Institute of Chemical Engineers (IChemE) Innovation and Excellence Award for Bioprocessing at the end of 2010.

The BiCE team, who focus on novel biocatalytic manufacturing routes to speciality chemicals and pharmaceuticals, also received the Royal Society of Chemistry's 2010 Rita and John Cornforth Award in June 2010 for studies at the

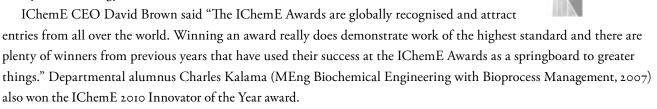






Prof. Gary Lye (third from left) receiving the Innovation & Excellence Award for Bioprocessing.

Chemistry-Biology interface. The leaders of BiCE span three UCL Faculties and include Gary Lye, Paul Dalby, Frank Baganz (Biochemical Engineering), Helen Hailes (Chemistry) and John Ward (Structural and Molecular Biology). Recent staff additions to the team bring in expertise in bioreactor engineering and automation (Martina Micheletti), microfluidics (Nicolas Szita) and synthetic biology (Darren Nesbeth).



for innovation and excellence

10 Winner

For further information please contact Prof. Gary Lye at g.lye@ucl.ac.uk.

iGEM Team wins Gold Medal

iGEM is an annual synthetic biology design competition for undergraduates which UCL entered for the first time in 2009. This year 128 teams entered worldwide from internationally leading universities.

UCL Biochemical Engineering sponsored a truly multidisciplinary team comprising Biochemical Engineering students Ali Ali-Albazergan, Arif Abed, Carolina Moujaes, Elena Pallari and Omar El Saidi and also James Brown, Mariam Awlia and Xiang Chen from the Research Department of Structural & Molecular Biology, Veronika Raszler from the Department of Science and Technology Studies and external student David Bennett from Central Saint Martins College of Art and Design.

The team worked throughout the summer, making full use of the industrial biomanufacturing facilities at the Advanced Centre for Biochemical Engineering (ACBE), before the final iGEM jamboree event at MIT in November. Building on the silver medal success of UCL's iGEM 2009 team was a major goal for 2010, and this year the team walked away with gold. Team member Omar El Saidi said: "We are all delighted at our success, and really enjoyed the opportunity to work on a truly multidisciplinary project that has real-world relevance. I personally really enjoyed building the team's website."

At the conclusion of iGEM 2010 Carolina Moujaes has started the final year of a Biochemical Engineering MEng. She reflected: "iGEM 2010 provided a great opportunity to develop real hands-on practical fermentation

skills. Collaborating with students and advisors from art, design and social sciences backgrounds was also a real eye-opener and has made me aware of the different perspectives people have on synthetic biology, engineering and science in general. I also found the Jamboree at MIT very fascinating, with over 2000 international students from different countries bringing in

novel ideas and making people

aware of the new science of synthetic biology."



found the Jamboree at MIT The 2010 iGEM gold-medal-winning team, including very fascinating, with over 2000 their departmental tutors Prof Eli Keshervarz-Moore international students from (fourth from left) and Dr Darren Nesbeth (third different countries bringing in from right).

The UCL team – called 'Project Hypoxon' – set out to reduce the financial and environmental cost of manufacturing medicines by genetically re-programming the *E. coli* cells in which many modern medicines are made. Currently these cells are controlled by addition of chemicals to trigger drug production. By constructing a synthetic gene network in the cell Project Hypoxon hoped to allow the cells to be triggered by simple changes in their environment, such as low oxygen or a change in temperature, without the need to add chemicals. The technology could ultimately be deployed in commercial *E. coli* strains commonly used in drug manufacturing, in

Each iGEM team is supported by staff instructors and student advisors who guide the students through the experience. Project Hypoxon was supported by Dr Darren N. Nesbeth and Professor Eli Keshavarz-Moore from UCL Biochemical Engineering, Professor John Ward of the Research Department of Structural & Molecular Biology and Dr Jane Gregory from the Department of Science and Technology Studies. Additional advice and creative input was also provided by the artist Giulia Ricci, a recent alumnus of the Slade School of Fine Art.

order to boost productivity and reduce the cost of drug production.

As well as research, iGEM teams are encouraged to explore the possible societal impacts of synthetic biology. Media skills and public engagement are also an essential for success. Dr Nesbeth commented: "iGEM is a great opportunity for UCL to encourage students from different departments and faculties to come together and work on a project. By focusing on today's biochemical engineering challenges we also enable UCL iGEM teams to take their projects out into the wider world of the general public. Recruitment for iGEM 2011 is already under way and we will finalise a roster by the end of November."

Financial support for UCL's iGEM 2010 team was provided by Eli Lilly, Lonza Biologics and the Health Protection Agency (all partners in the Innovative Manufacturing Research Centre programme within UCL Biochemical Engineering), and King Abdullah University of Science and Technology. For more information about iGEM contact Dr Darren N. Nesbeth at d.nesbeth@ucl.ac.uk.



AIChE award

Congratulations to Dr Frank Baganz on receiving the 2010 2010 Pharmaceuticals Division Plenary Award (Pharmaceuticals Division) for his contributions to rapid bioprocess development using microwell and miniature bioreactor technologies. In particular, his scaling work based on the thorough engineering characterisation of mixing and oxygen transfer in shaken and stirred miniaturised bioreactor systems was recognised by the (largely industrial) selection panel. They commented that this work is of great interest in the biopharmaceutical industry, especially the potential to utilise micro reactors to explore a wide range of conditions, clone selection, manufacturability, and even Quality by Design.

For further information please contact Dr Frank Baganz at f.baganz@ucl.ac.uk.

Visiting Professorship in Stem Cell Biology

Dr Ivan Wall, Lecturer in Regenerative Medicine Bioprocessing in the Department, has recently been appointed Visiting Professor in Stem Cell Biology at Dankook University, Cheonan, South Korea.

The appointment builds on existing collaborative research into biomaterials and tissue engineering between Korea and UCL academic Professor Jonathan Knowles, of the UCL Eastman Dental Institute. The post is funded as part of the Korean government's World Class Universities Program in Nanobiomedicine, which aims to develop collaborative links with world class universities to strengthen Korea's growing research profile in regenerative medicine and tissue engineering.

Ivan spends time in Korea where he teaches translational stem cell biology to Masters students and has established a research team of three PhD students working on scaffold-based approaches for skeletal tissue regeneration.

For further information please contact Dr Ivan Wall at i.wall@ucl.ac.uk.

Ashok Kumar Fellowship

Congratulations to student Iwan Roberts on winning the IChemE Ashok Kumar Fellowship. The three-month internship for EngD/PhDs is based at the Parliamentary Office of Science and Technology. Iwan will undertake a project or prepare a research paper related to chemical engineering; he is particularly looking forward to learning how to present complex science viewpoints to policy makers in order to help them make decisions.

Iwan's research focuses on exploring engineering solutions to take stem cell processes from the lab into the commercial world. He says "I believe that it is vital that the chemical engineering community not only actively engages in the debate to argue against any cuts to the sector and to science as a whole, but that it should also actively lobby for further investment and policies amenable to an industry that represents a key driver for the economy."

Undergraduate design project poster presentations

On 17 December 2010 a panel of industrial experts from biotech/pharmaceutical companies and design consultancies assessed the Design Project Posters presented by 3rd year Biochemical Engineers tackling global healthcare issues. Dr Suzy Farid, Co-ordinator of the Undergraduate Design Project, noted that the introduction of the poster session with industrialists over the past few years has been extremely successful in conveying invaluable industrial insight to the students and assessing the industrial relevance of their work. In the reception following the poster session it was clear that the students really enjoyed the session and valued the opportunity to discuss their work with experts and learn from them.

The 3rd year Design Project this year is on biopharmaceuticals for neglected diseases in the developing world. Nine teams, each looking at a different expression system (CHO, *P. pastoris*, *E.coli*) and target indication (TB, malaria, and HIV) explored innovative flowsheet designs in an attempt to increase overall yields and drive down the costs. The industrial experts quizzed the students on issues relating to the processing challenges posed by each of their expression systems, the implications of their yields and equipment sizes, the impact of their facility location in Asia/Africa on their economics analysis, and the regulatory hurdles they may face with innovative technologies.

The Industrial Panel who attended the 2010 poster session included Lee Allen (Lonza Biologics), George Blewitt (Jacobs Engineering), Barry Buckland (BiologicB Consulting), Richard Hill (Whitewater Limited), Chris Illidge (UCB Pharma), Phil Milburn (MSD), and Vaughan Thomas (Tillingbourne Consulting).

Chris Illidge from UCB Pharma (pictured below talking to students) commented: "the range and depth of information that the posters convey is impressive and is a testament to the quality of the course and standard of teaching at UCL."

This term, the students are continuing the facility designs and delving into more detailed design considerations, to satisfy regulations. This will take students from the stage of reconciling SHE and GMP considerations with facility layouts through to specification of equipment (mechanical design, P&IDs, HAZOP). Close involvement with industrial experts continues this term with works visits to Jacobs Engineering and Genzyme, as well as expert talks from Stephen Flanagan (Eli Lilly), Vaughan Thomas (Tillingbourne Consulting), Richard Hill (Whitewater Limited) and Rolf Clayton (Crowther Clayton Associates). The Design Project Prize is sponsored by Jacobs Engineering.

For more information about the Design Project Industrial Panel, please contact Dr Suzy Farid at s.farid@ucl.ac.uk.





VISION

Our VISION programme for senior executives in the bio-industies continues to go from strength to strength, with a full programme of business and technical briefings under way. On the evening of 16 September 2010, Professor Steve Arlington of PwC gave the first VISION Business Briefing, entitled *De-risking Development*. The theatre was filled by 40 industrial delegates from companies such as GSK, Lonza, Merck, Novasep, Pfizer and UCB.

Professor Arlington, always controversial and thought-provoking, predicted that the future success of the industry will hinge on a better understanding of the patients' needs and demands – in other words, a closer relationship between the providers of the therapies and the final recipients. (For further information see PwC's Pharma 2020 Series.)

This was followed by our second Business Briefing on 13 January 2011, when Dr Mark Richardson spoke about *Biosimilars: A Regulatory Perspective*. There were 20 delegates in attendance from a wide range of companies including BioMarin, Boehringer Ingelheim, GE, MedImmune, Tillingbourne Consultancy and Ten Alps Creative and Taylor Wessing.

"The Briefing was ideal for my purposes as a legal adviser in this sector. Dr Richardson provided an excellent overview of the regulatory landscape together with illuminating comments on the practical and business implications of this emerging field." Stephen Whitfield, Competition, EU and Trade, Taylor Wessing

If you are interested in attending the next core course or one of the future Executive Briefings, or believe that there is a senior executive within your organisation who would benefit from attendance, please contact Dr Karen Smith, Director of Bioprocess Leadership, at karen.smith@ucl.ac.uk or telephone (0)20 7679 4411.

The year ahead

- 10 March 2011: Technical Briefing
 Disposable Technology a technobuisness perspective for bio-industries
 (Miriam Monge, Biopharm Services, and Prof. Gary Lye, UCL)
- 18–20 May 2011: Core Course

 At the heart of VISION is an intensive three day core course comprising lectures,

 case studies, problem-solving exercises and networking dinners.
- 30 June 2011: Business Briefing
 The Role of Entrepreneurial Thinking in Large and Small Business Concerns

 (Dr Edward Arcuri, Auxilium Pharmaceuticals, Inc.)
- 15 September 2011: Business Briefing

 Does QbD make business sense? What new approaches to technology can make it
 a viable proposition?

 (Peter De Phillips, Merck (tbc))

6th annual IMRC Bioprocess Briefing

Our Annual IMRC Briefing was held on 16 September 2010 in the Christopher Ingold (Chemistry) Building where the large lecture theatre was filled to capacity to hear a range of excellent talks from members of the Department, including Engineering High-Throughput Formulation Development (An EngD with NIBSC) by Yitzchak Grant, Paul Dalby (UCL), Paul Matejtschuk (NIBSC); Interfacial effects during the manufacturing and supply of biologics: A knowledge transfer secondment (A KTS project) by Alex Berrill, Gaik Sui Kee (GSK) and Dan Bracewell (UCL); Embryonic stem cell bioprocessing (An overview of an emerging area with strong KT potential) by Farlan Veraitch (UCL); Evaluating mAb downstream processing options at the bioprocess-business interface (A TSB Collaboration) by Sofia Simaria, Suzanne Farid (UCL), Ying Gao (MedImmune) and Richard Turner (MedImmune) and Integration of a bioprocess modelling tool into teaching and research at UCL (A KTS project) by James Savery, (formerly BioPharm Services Ltd), Andrew Sinclair (BioPharm Services Ltd) and Mike Hoare (UCL). The range of posters displayed by students (listed below) reflects the breadth of research undertaken in the Department. For more information about IMRC activities please contact Dr Karen Smith, Director of Bioprocess Leadership at karen.smith@ucl.ac.uk or telephone (0)20 7679 4411.

- Razwan Hanif: Methods to Establish Scaleable Operations for Contaminant Removal Prior to Packed Bed Steps
- Candy Ng: High performance affinity chromatography to optimise purification via protein A capture
- Qiang Li: ultra scale down of large scale homogenistation of E. coli cells expressing a fragment antibody
- Mike Delahaye: Human Cells for Prostate Cancer Vaccine Therapy The impact of centrifugation upon key product quality attributes
- Juan Pablo Acosta: Ultra-scale down studies of human cell bioprocessing for a prostate cancer vaccine therapy - The impact of capillary shear
- Jun Zhang: Data & Knowledge Engineering for Intelligent Bioprocess Design
- Yu Ji: Modelling and model-based experimental design
- Ana Sofia Simaria: Process Intensification of Antibody Purification Processes: A Comparison of MILP versus Evolutionary Algorithms
- Affaro Affandy: Hydrodynamic profiles inside sterile filtration membranes and it impact to supercoiled plasmid DNA.
- Mike Hughson: Inactivation studies on Japanese Encephalitis Virus Vaccine using Design of Experiments
- Alex Chatel: An ultra scale-down approach to discovery of new opportunities when
 processing protein domains
- Edward Close: Process modelling approaches to biological complexity in the production of therapeutic proteins
- Kristina Kovacs-Schreiner: Measurement of protein self association behaviour as a determinant of aggregation in bioprocessing
- John Betts: Incorporation of Developability into cell line selection
- Maria Velez Suberbie: The Impact of Bioreactor Aeration and Mixing on Chinese Hamster Ovary Cell Physiology and Structure during Antibody Production
- Richard Tarrant: Development and Implementation of Downstream Processing Methods to Investigate Host Cell Protein Contaminants
- Andrea Rayat: Application of a Novel Microscale Crossflow Filtration Device to Study the Impact of DNA Hydrolysis in the Recovery of Antibody Fragments from an Industrial E. coli Strain
- Heather Guy: Microscale characterisation of a manufacturing route for lentiviral vectors
- Balasundaram Bangaru: Evaluation of the effect of dual-salt precipitation as a primary recovery step on the chromatographic purification of Fab' antibody fragments
- Roumteen Tavakoli-Keshe: Investigation of antibody aggregate formation in bioprocess; a study of the location and mechanism of aggregation
- Shaukat Ali: Design, characterisation and feasibility of a miniaturised bioreactor to perform high cell density fermentations
- Sally Hassan: Strategy for the consistent preparation of sufficient non-viral large vectors for biopharmaceutical applications
- Gemma Ordidge: A generic automated microscale platform for evaluating inclusion body refolding
- Jasmin Baboo: Automated evaluation of microscale linked process sequences for generation of scaleable bioprocess design data
- Chuanjie Du: Bioconversion of Lignin Degradation Products To Higher Value Chemicals Using Transaminase
- Leonardo Rios: A hight throughput toolbox for the transketolase-transaminase synthesis of chiral amino-alcohols

- Raha Jahromi: Evolutionary and mutagenesis analyses of Transketolase to guide further protein engineering
- Nihal Bayir: De-novo pathway engineering for pharmaceutical synthesis: understanding and optimization of pathway interactions with host cell metabolism
- Yvonne Pang: Functional Isolation of Dental Stem Cells
- Tristan Pritchard-Meaker: A scalable technology to produce stem cells for clinical use
- Jennifer Badger: The effect of hypoxia on the culture of stem cells for the treatment of Parkinson's disease
- Sion Lewis: Activation of intracellular signalling pathways during mouse embryonic stem cell division
- Nathalie Moens: Controlled studies of stem cell culture and differentiation in parallel microwell cultures
- Iwan Roberts: Potential Separation Solutions in a hESC Bioprocess to Treat Blindness
- Owen Bain: Improving autologous bone marrow stem cell therapy for cardiac repair
- Patrick Radone: Cell engineering and processing of recombinant Pichia pastoris strains capable of high specific yield production





The MBI Training
Programme is run by
the Department and
comprises a series of
UCL-accredited short
courses in bioprocessing,
designed specifically
for industrialists. They
can be taken as standalone modules or can be
combined for certificate,
diploma or Masters
qualifications. To date
1,000 modules have
been taught to over 700
international delegates, and
more than 200 companies
have participated.

MBI® Vaccine Bioprocess Development and Commercialisation module launch

This was a new MBI° course that attracted 40 delegates in total. Apart from the usual opening night nerves, matters were further complicated by student protests against the Governments' tuition fee increase and occupation of several campus buildings. However, unabated, we continued with our course.

Many commented very positively on the quality of the lectures, with most lectures scoring between four and five out of five. Favourite lectures were that by Debbie Drane (CSL Ltd) on Modern Adjuvants, Martin Wisher (BioReliance) on Analytics and Assay Development and Mark Proctor's (MedImmune) influenza case study.

In total 15 speakers lectured on the course and, though there was a heavy industrial presence, an academic feel was maintained – with many lively discussions between delegates and speakers. This course covered a broad range of topics from cell engineering and expression systems to development, formulation, IP and analytics.

We hope to vary the material so that should delegates have attended one course, they might attend the course the following year. Vaccines are a very broad area and, while we did our best this year to cover in-vogue topics, there is still plenty more out there, such as conjugate and bacterial vaccines, and better focus on some of the process challenges relating to production and purification of vaccines.

The student occupation ended peacefully at 5pm on Friday 10 December. Armed with a court order, the Provost offered amnesty from all costs if the students left peacefully. Thankfully they obliged. We plan to run the course again in December 2011 with a few improvements taking into account the comments and feedback received – but this time without the student protests!

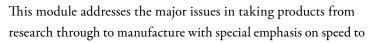
If you would like further details please contact Liz Barrett at mbi-training@ucl.ac.uk.

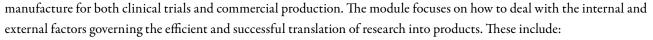


MBI® Effective Biopharmaceutical Development & Manufacture module

9-11 May 2011

Learn how to deal with the internal and external factors governing the fast, efficient and successful translation of research into products.





- 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
- Application of single use technology
- Modelling for strategy development

This course is suitable for a wide range of delegates interested in obtaining an overview of the interaction between drivers of biopharmaceutical development/manufacture and business development.

- Monday 9 May: Management of Research and Development; Efficient translation of process development strategies into manufacturing; R&D Management & Regulation; Case study: Managing multiple simultaneous projects
- Tuesday 10 May: Management and Control of Quality; Impact of clinical trials on the development process; The Quality organisations; Regulatory requirements; Present and Future Challenges in R&D and Manufacture; Case Study: Risks and Benefits of outsourcing
- Wednesday II May: Radical Approaches for Speed to Manufacture; Accelerating bioprocess development;
 Cell engineering to speed up development; Process-Business interface; Case study: Cost modelling tools to support business strategy development
- Module Leaders: Eli Keshavarz-Moore, UCL, Andrew Sinclair, BioPharm Services Ltd
- Industrial Speakers: Susan Dexter, Biopharm Services Ltd; Sharon Grimster, Antisoma PLC; Claire Hill, Biopharm Services Ltd; Lynne Hill, L H Consultancy; Miriam Monge, Biopharm Services Ltd; Ian Nicholson, Chroma Therapeutics Ltd; Mark Richardson, Richardson Associates.

A networking dinner will be held on the first evening. The module costs £1300. Please contact mbi-training@ucl.ac.uk for further information.



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MBI® course dates 2011

Principles of Fermentation Processes: 4 – 6 October 2010

Rapid Fermentation Process Design: From Development to Manufacture: 18 – 20 October 2010

Challenges & Opportunities in Industrial Biotechnology: Biocatalysis and Synthetic Biology: 1 – 3 November 2010

Primary Recovery: 15 – 18 November 2010

Chromatography: 29 November – 2 December 2010

Vaccines Bioprocessing Development: 8 – 10 December 2010 Mammalian Cell Processes: 31 January – 2 February 2011

Stem Cell and Regenerative Medicine Bioprocessing: 21 – 23 February 2011

Quality by Design: 28 February - 3 March 2011

Design of Experiments for Bioprocess Optimisation: 14 - 16 March 2011 Effective Biopharmaceutical Development & Manufacture: 9 - 11 May 2011

Bioprocess Design & Economic Evaluation: 6 – 9 June 2011

Bioprocess Facility Design: 20 - 23 June 2011

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 70 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.