

2nd Annual Modern Challenges in Therapeutic Protein Production Event

The Penridge Suite, 470 Bowes Road, London N11 1NL: Friday, 10 June 2011

The purpose of this 2nd Annual Therapeutic Protein Production meeting is to look at the challenges facing therapeutic protein production and demystify some of the novel approaches and new technologies currently being developed.

This event has CPD accreditation and will have a troubleshooting panel session.

On registration you will be able to submit your questions to the panel that will be asked by the chair on the day of the event

Meeting chair - *Dr Brendan Fish*, NPI-PT Director at GSK Barnard Castle

Meeting web site: www.regonline.co.uk/protein2011

- 9:00 – 9:30 **Registration**
- 9:30 – 9:40 **Morning Session - Introduction by the Chair:** *Dr Brendan Fish*, NPI-PT Director at GSK Barnard Castle
- 9:40 – 10:05 **Scale down approaches to CHO clone selection and process development facilitating high-level mAb expression**
Dr Gareth Lewis, Medimmune Cambridge, UK
- 10:05 – 10:30 **Bioprocess Characterisation using Quality by Design Principles**
Philip Mellors, Eden Biodesign, UK
This presentation will introduce the concept of Quality by Design and show how its principles were implemented to provide a greater understanding and control of a process to manufacture a biological product. The case study will focus on a mammalian fermentation process and walk through the activities required to determine the criticality of process parameters and then map the Design Space using a combination of risk assessments and DoE.
- 10:30 - 10:55 **Disposable Technologies**
Dr Tony Hitchcock, RecipharmCobra Biologics, UK
- 10:55 – 11:00 **Speakers photo**
- 11:00 – 11:30 **Mid-morning break, posters and trade show**
- 11:30 – 11:55 **Magnetic Bioseparation**
Professor Owen Thomas, The University of Birmingham
- 11:55 – 12:10 **Using a novel HPCE approach in all stages of the bioprocess**
Dr Stuart Hassard, DeltaDOT Ltd, London, UK
This presentation will describe how a new instrument is able to assist at all stages of the bioprocess from molecular biology to final QA/QC. This unique patented High Performance Capillary Electrophoresis system eliminates the need for labels, thereby reducing the cost of analysis and avoiding label-induced bias. This highly innovative fully automated approach significantly improves sensitivity, resolution and repeatability – all of which are integral to the QA/QC process. *Dr Stuart Hassard*, CSO of deltaDOT, will explain how this one instrument could potentially address most of your analytical needs whilst also saving you both time and money.
- 12:10 – 12:35 **Rapid Screening of Proteins for Manufacturability**
Dr Paul Dalby, University College London, UK
Microscale and microfluidic platforms enable small quantities of proteins to be rapidly analysed under pre-formulation, stress and bioprocess conditions, to assess their manufacturability. Automatable high-throughput methods for measuring protein stability, tolerance to freeze-drying, solubility, aggregation and precipitation will be introduced. A recently established rapid and accurate microfluidics-based biophysical analysis of protein stability and ligand interactions will also be discussed.

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- 12:35 – 13:00 **New proteins, new problems: Analytical clues to the stability of therapeutic proteins outside the lab**
Simon Webster, Avacta, UK
 Early prediction of how a candidate therapeutic protein will behave during manufacture and storage over extended periods has always been highly desirable to help identify optimum candidates and reduce development risks. As the biopharmaceutical industry begins to move beyond relatively well understood protein formats like mAbs this is becoming increasingly critical as many of the exciting new formats are proving 'troublesome' or at the very least less predictable. This presentation will review some of the analytical 'clues' to a protein's suitability for subsequent manufacture and long term storage. This will include some commonly used stability indicators and some more speculative ideas.
- 13:00 - 13:45 **Lunch, Poster Viewing and Trade Show**
- 13:45 – 14:30 **Discussion panel session**
 Please submit questions to Euroscicon staff during the event. These questions will be asked to the panel of speakers at this panel session. Plus you are free to ask additional questions during the session
- 14:30 – 14:55 **Characterisation of Protein Aggregation: Why it is Important and how NanoSight can help**
Dr Patrick Hole, Nanosight, UK
 It is widely recognised that there is a potential risk from protein aggregation but that current technologies are limited to a late indication where aggregation has reached the micron size. This talk will describe how NanoSight is uniquely able to detect and measure protein aggregates down to 30nm. The measurement directly supplies a size distribution of aggregates along with an absolute concentration measurement. NanoSight. The NanoSight technique is rapid gives high resolution data and the systems (of which there are >300 installed worldwide) are inexpensive and easy to use.
- 14:55 – 15:25 **Afternoon Tea/Coffee, Poster Viewing and Trade Show**
- 15:25 - 15:50 **Using light scattering to predict protein formulation stability and detect the early onset of aggregation**
Dr.Hanna Jankevics, Malvern Instruments, UK
- 15:50 – 16:15 **Therapeutic Protein Production - a Regulatory Update**
Dr Stephen Thompson, S-cubed Ltd, Oxfordshire, UK
- 16:15 – 16:40 **Reducing the Cost of Therapeutic Protein Production Through Economic Modelling**
Dr Andrew Brown, BioPharm Services UK
 The success of monoclonal biologics is reflected in the large investments seen in manufacturing where capacity has grown significantly through capital intensive facilities. We have many examples of facilities that end up manufacturing something completely different from that for which they were initially designed, and in reality we see that biotech product forecast are in the majority inaccurate beyond 3 years. Economic modelling can be used throughout the biopharmaceutical development cycle to assess the manufacturing costs and the sensitivity of financial returns to changes in the projected market demand. This presentation will present a modelling approach that is used extensively within the industry.
- 16:40 **Chairman's summing up**

*This meeting was **organised by Euroscicon** (www.euroscicon.com), a team of dedicated professionals working for the continuous improvement of technical knowledge transfer to all scientists. Euroscicon believe that they can make a positive difference to the quality of science by providing cutting edge information on new technological advancements to the scientific community.*

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About the chair

Brendan Fish is Director of New Product Introduction and Process Technology for GSK at Barnard Castle. With a career spanning over 20 years, he was Director of Bioprocess Sciences at MedImmune Cambridge where he was responsible for all aspects of the development of purification methodologies, product characterisation, QC, formulation and delivery for MedImmune products in relation to their use in commercial pharmaceutical processes. This included initial design and optimisation, scale-up, process cost modelling, process integration and technology transfer to GMP Production for clinical trial supply. Brendan was also at Delta Biotechnology Limited as a Consulting Scientist. He played a key role in the development of their biotechnology-based products providing expert opinion and strategies for QA, QC, Production, Marketing, Operations, Regulatory Affairs and Engineering on all aspects of Process Development. Early in his career, he was a Post-doctoral fellowship at University of Toronto in Canada working in the School of Nutritional Sciences, studying the anti-nutritional effects of lectins in the diet.

About the speakers

Philip Mellors is responsible for Eden Biodesign's in house upstream development programs and management of its outsourcing requirements. The upstream development group has capabilities in molecular biology, cell line construction (microbial and mammalian), fermentation development, scale up and transfer into Eden's GMP facilities. The group is also responsible for upstream bioprocess characterisation and validation. Prior to joining Eden, Phil led the bioprocess development team at Renovo PLC and has held positions at Lonza Biologics, CellTech-Medeva. Phil graduated with an Applied Biology degree from the University of Coventry in 1997.

Dr Gareth Lewis has over 11 years of experience of bioreactor process development. After completing his PhD at the University of Birmingham/AstraZenca in 2003, he joined MedImmune, formally known as Cambridge Antibody Technology, as a cell culture process development scientist. In his current role at MedImmune he leads a team of scientists working on manufacturing cell line selection and preclinical process development. Alongside his core responsibilities for process development, technology transfer and CMC, Gareth has developed a keen interest in scale-down cell culture systems to aid improved process development and cell line selection strategies.

Paul Dalby is a Reader in Biochemical Engineering and Biotechnology at UCL. His research addresses protein engineering and biophysics challenges associated with bioprocess development, protein engineering and biopharmaceutical formulation. He graduated from the University of Cambridge with a degree and PhD in protein folding and engineering with Sir Prof Alan Fersht, then worked at the University of Pennsylvania with Prof William DeGrado.

He is currently Chairman of the RSC Biotechnology Group. Awards include the 2008 Evonik European Science-to-Business Award, the 2010 IChemE Innovation and Excellence Award in Bioprocessing, and the 2010 RSC Rita and John Cornforth Award for teamwork.

Patrick Hole is currently Head of Development at NanoSight and has been with the company five years. Previously he has completed a PhD in optoelectronics at the University of Southampton and a Masters Engineering degree at Oxford University. He has focussed on developing both the hardware and software involved in the Nanoparticle Tracking Analysis (NTA) technique, invented eight years ago, to be an easy to use, accurate and robust system.

Simon Webster is CSO and co-founder of Avacta Group plc. Simon's scientific career has focused on the practical application of a wide range of analytical techniques to a wide range of tasks including pharmaceutical analysis and the study of biological systems, in both academic and commercial environments. Since 2004 the scientific focus has been on biophysical analysis of biopharmaceuticals, understanding protein physical stability and the development of innovative analytical instrumentation for biopharmaceutical developers. Simon's current role involves providing scientific and technical support to Avacta's existing contract analytical service and instrumentation business and leading the development of new, innovative products and services aimed at meeting the needs of the biopharmaceutical sector.

Andrew Brown is a Bioprocess Consultant Engineer at BioPharm Services, UK. He works primarily on the development and product management support of BioSolve, a scalable process and economic modelling tool. In addition to these activities he has worked on a wide range of client projects to assess the economic impact upon bioprocesses of new technologies, process scenarios and strategies. Previously he was an EngD researcher at UCL within the Department of Biochemical Engineering, where he worked upon the development of Ultra Scale-down methods for the rapid prediction of the performance of large-scale membrane filtration operations, work that led to the publication of several research papers.

Stephen Thompson has over twelve years' regulatory affairs experience in the pharmaceutical industry as a consultant, joining Origin Pharmaceutical Services (which then became Constella Group), before moving to S-cubed Ltd as Director of Regulatory Affairs in March 2009. Stephen has provided regulatory support to many pharmaceutical and biotechnology companies in both Europe and the USA, and has worked with European regulatory agencies and the US FDA. His experience includes the preparation, submission and approval of clinical trial applications for clinical studies in the EU and USA, as well as marketing authorisation applications and subsequent maintenance, for both small molecules and biologicals.

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