Researched and produced by
WORLD TRADE GROUP

7th annual biological production forum

2-4 June ✻ Arabella Sheraton Grand Hotel Munich, Germany

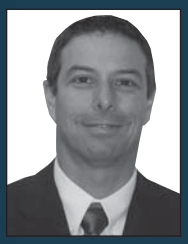
Europe's only event dedicated to biomanufacturing excellence

Featuring Bio Innovation Day including a tour of GE Healthcare's Munich Facility

Dr. Christian Eckermann
Associate Director,
Downstream Development,
Boehringer Ingelheim,
Germany

Dr. Jerry Kinsel
Director Optimisation &
Material Supply,
Eli Lilly,
USA

Dr. Gerard Brummelhuis
Director,
Biotech Operations,
Centocor,
Germany



Michael Cicio
VP Operations and Site Head,
Lonza Biologics,
USA

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PROGRAMME

7th annual biological production forum

2-4 June ✲ Arabella Sheraton Grand Hotel, Munich, Germany

Join the leading biological manufacturing, production and cGMP specialist at this year's conference featuring case studies and interactive sessions on the latest industry developments.

Attending Biological Production will enable you to:

- **Benchmark** your company's best practices
- **Discover** the latest good manufacturing practises
- **Network** in an interactive environment
- **Debate** today's challenges effecting your industry
- **Develop** new relationships with your peers
- **Learn** the latest strategies adopted by your industry leaders
- **Understand** the rigorous regulatory strategies
- **Increase** production efficiencies & processes

Featuring Bio Innovation Day • 2nd June 2008

in association with GE Healthcare

GE Healthcare

Take an exclusive behind the scenes look at GE Healthcare's manufacturing facility at their European Global Research Centre, and learn first hand how one of the world's leading companies has adopted cutting-edge best practices and new technologies to increase efficiency.

This is an exclusive agreement with GE healthcare giving our delegate members unprecedented access to their research laboratories for a behind the scenes look at some of the innovative projects that they are working on to make the highly anticipated boom in biopharmaceutical products a production reality.

Delegates will:

- Participate in interactive workshops exploring the potential of GE Healthcare's latest offerings
- Take an exclusive tour of their leading manufacturing facilities, including their Ready To Process platform, Axichrome columns and ÄKTA platforms.
- Hear about the new technology you can expect from GE in the next 18 months

Featuring pre-arranged one-to-one meetings

This is a dedicated session which allows you to take up to seven pre-arranged business meetings with fellow delegates and leading solution providers.
You will meet with people who you have chosen and who have expressed a strong interest in meeting with you. Pre-arranged meetings ensure your networking time is spent productively - maximising your chance of doing real business at the event.

08:00 **Morning coffee**

08:30 **Chairman's opening remarks**

Dr. Mark Bustard, *Technical Manager*, **bioProcessUK** UK

08:35 **CREATING THE ALL INCLUSIVE MANUFACTURING PLATFORM**

Case study: Standardised manufacturing platforms - seamlessly integrating discovery through to manufacturing and increasing time to market

- Creating a standardised generic manufacturing platform - one size to fit all molecules
- Integrating manufacturing steps from discovery through to manufacturing and modifying molecules to fit platforms
- Successful tools and techniques: Bags and disposables - eliminating down time and turn around
- The flexible facility of the future - managing capacity demands and variability in capacity demands
- Implementing successful tech transfer techniques

Dr. Jerry Kinzel, *Executive Director of Bioproduct Research and Development*, **Eli Lilly** USA

09:10 **SUCCESSFUL CAPACITY PLANNING AND UTILISATION - BUILDING THE FLEXIBLE FACILITY OF THE FUTURE**

Effectively building flexibility throughout manufacturing operations - responding to global multi-product demand

- High capacity facility design concepts and development
- Transferring current operational excellence know-how into new facility design concepts
- Increased throughput through effective equipment utilisation, new hardware capital investment, online dilution and increasing media capacity
- Implementing new factors to accommodate higher titer demands and impacts on facility design
- Increasing flexibility through disposables: Filters, buffer containers, solution bags, connectors and columns

Michael Cicio, *VP Operations and Site Head*, **Lonza Biologics,** USA

09:45 **BUILDING NEW CAPACITY VS. ADVANCED PROCESS IMPROVEMENT STRATEGIES**

Case study: Avoiding investment into large bioreactor capacity through continuous process improvement

- Focus on secure supply while continuously reducing both capital investment and operating expenses simultaneously
- Increase manufacturing output of existing operations by strengthening the continuous improvement process
- Mitigate the investment risk of building up bioreactor capacity by increasing process stability
- Achieve operational excellence in capacity management with best practice sharing and lean six sigma
- What is the impact on demand for bioreactor capacity caused by efficiency gains and the advent of bio-similars and targeted therapies?

Patrick Carl, *Head of Capacity Management Technical Operations*, **Merck Serono** Germany

10:20 **Morning coffee**

10:40

Conf room 1 NEXT GENERATION DISPOSABLE TECHNOLOGIES

Disposable technologies of the future - outlook from the Parenteral Drug Association (PDA) Disposables Task Force

- How will current and future regulatory initiatives like QbD drive the introduction of new disposable technologies and systems?
- Disposable technology assessments - opportunities and threats of new tech implementation
- Novel technologies beyond filtration and storage - membrane chromatography, tangential flow systems, disposable bioreactors
- Creating more efficient manufacturing practices with disposables
- Determining range, scalability and impacts on product licensing
- Expanding the use of disposable technology throughout operations

Robert Repetto, *Director, Global New Technology and Innovation, Manufacturing Sciences & Technology*, **Wyeth Biotech** USA

Conf room 2 DEVELOPING THE SMART REACTORS OF THE FUTURE

Bigger is not always better: How optimisation is replacing maximisation in biologics production

- Pros and cons of maximise vs. optimise
- Understanding the overall strategic superiority of optimisation
- Becoming a nimble production facility capable of meeting variations in customer demand
- Practical optimisation examples and solutions
- What does the future hold in biologics production?

Dr. Fadel Hamed, *Head of Operational Excellence*, **Genentech Product Operations** USA

Conf room 3 FORMULATION TECHNOLOGIES AVAILABLE FOR BIOLOGIC UNIT OPERATIONS

Implementing in-line systems to monitor lyophilised biologics

- Overview of available technologies for biologic unit operations from incoming raw materials, blending in formulation tank, sterile filling, lyophilisation, capping and inspection
- Implementing in-line vacuum detection technology for a lyophilised biologic
- Understanding the business

Dr. Ranjit Sarpal, *Associate Director Manufacturing Technology*, **Bristol Myers Squibb** USA

11:15 **IMPLEMENTING NEXT GENERATION DOWNSTREAM METHODOLOGIES**

Dr. Uwe Gottschalk, *Head of Purification Technologies*, **Sartorius** Germany

11:50

ADAPTING AND MODIFYING EXISTING DOWNSTREAM PROCESSES TO ACCOMMODATE HIGH TITERS

- Adapting existing processes - dealing with very high productivities and higher product demand
- Fully exploiting existing technologies – pushing technologies to the edge and understanding the potential and limits
- Short term vs. long term solutions – knowing when and how to invest in new technologies
- Evaluating and understanding long term future technology requirements

Dr. Christian Eckermann, *Associate Director, Downstream Development*, **Boehringer Ingelheim** Germany

NEW MEDIUM DESIGN METHODS FOR MAMMALIAN CELL CULTURE

Wyeth case study: Cell culture process development for current and future manufacturing processes

- Process changes - determining the effect on manufacturing performance
- Continuous process improvements to achieve higher yielding processes
- Successfully addressing and controlling processs changes
- Achieving a high productivity cell culture processes and determining the effect on manufacturing strategies

Dr. Yen-Tung Luan, *Principal Engineer II Bioreactor Process Development/Drug Substance Development* , **Wyeth Biotech** USA

APPLYING NEAR INFRA RED SPECTROSCOPY IN FORMULATION

Applying Near Infrared Spectroscopy in the development of lyophilised formulations

Dr. Mikael Brülls, *Team Head, Product Development*, **AstraZeneca R&D Mölndal** Sweden

12:25 **Hosted luncheon**

13:25

DEPLOYING A DOWNSTREAM COST REDUCTION STRATEGY - CREATING TANGIBLE RESULTS

Medarex case study: Effectively analysing multiple processes to achieve real cost reduction and increased facility throughput

- Evaluating various processes to understand cost reduction opportunities
- Understanding and exploiting the enormous true cost reduction opportunities in downstream
- Implementing single columns
- Reducing filtration steps
- Replacing flow through with membrane steps
- Implementing a realistic change programme to reduce costs by 75%

Dr. Alajari Arunakumari, *Senior Director, Process Development*, **Medarex** USA

CREATING A HIGH INTENSITY mAb MANUFACTURING PROCESS WITH DISPOSABLE TECHNOLGY

Integrating a lean approach with disposable systems

- Streamlining mAb production for high throughput
- Implementing disposables as a process change
- Lean six-sigma in a regulated environment

Dr. James S. Wilson, *Technical Director*, **Millipore** UK

CLINICAL DELIVERY OF HUMAN EMBRYONIC STEM CELLS

On the road to the clinical delivery of human embryonic stem cell therapies

- Manufacturing considerations for human embryonic stem cell therapies
- Regulatory concerns

Dr. Paul De Sousa, *Chief Scientific Officer*, **Roslin Cells** United Kingdom

14:00 **Pre-arranged one-to-one meetings**

17:00

Conf room 1 Interactive workshop

Clearing trace HCP, DNA and viruses in the manufacture of biologics – Introducing a novel single use anion exchange membrane adsorber

- Review of current methodologies and limitations in the anion exchange chromatography polishing step
- Introducing ChromaSorb™ - a chromatographic disposable solution combining a porous membrane and a proprietary anionic gel
- How ChromaSorb™ can reduce buffer consumption to free up production facilities tank capacity constraints
- How disposable technology provides manufacturing facilities ease of use, smaller plant footprint and cost savings in validation and buffer costs

Conrad Maher, *Product Manager*, **Millipore**

Conf room 2 Interactive workshop

Cell culture optimisation

- Responding to increased demands on media and supplements in platform production systems
- Single-use bioreactor optimisation: Cell platforms, process parameters, mixing and sparging options, monitoring and control options and scaling up
- Economic modeling of single-use systems: Key areas of concern, direct and indirect benefits, systems for modeling of a whole manufacturing flow, case studies

Frank Wolpers, *Industrial Sales Director Europe*, **ThermoFisher Scientific** Germany **Brandon L. Pence**, *BioProduction Market Manager HyClone*, **ThermoFisher Scientific** Germany

Conf room 3 Interactive workshop

Progress in fast and efficient monoclonal antibody production

- Get more productive in R&D to improve pipeline success rates
- Know more about your processes to increase yield
- Create flexibility in manufacturing to increase facility output

Dr. Günter Jagschies, , **GE Healthcare Bio-Sciences AB, R&D** Sweden

18:00 **Chairman's closing remarks and drinks reception**

08:30 **Morning coffee**

09:00 **Chairman's opening remarks and recap of first day**

09:10 **INVESTING IN INNOVATION TO CREATE A STEP CHANGE IN BIOPROCESSING**

Dr. Mark Bustard, *Technical Manager*, **bioProcessUK** UK

09:45 **SECURING TOMMORROW'S BIOPRODUCTION WORKFORCE**

Case study Abbott: Creating a long term workforce development strategy

- Creating a high tech apprentice programme with hands on specific training
- Working with institutions to secure the right staff
- Partnering with schools to offer career development and classes
- Providing a technically adept workforce for the future to satisfy high demand for products

Dr. Jim Fraser, *Associate Director Biologics Manufacturing*, **Abbott** USA

10:20 **IMPLEMENTING A LEAN INITIATIVE – MAXIMISING OPERATIONAL EFFICIENCY**

Case study: Centocor, Leiden's lean initiative

- Planning boards vs. computer systems – reducing costs and maximising throughput
- Transferring tools from the automotives industry to biologics
- Lean tools - utilising official schedules and planning boards in biological production

Gerard Brummelhuis, MSc, MBA, *Director Biotech Operations*, **Centocor** The Netherlands

10:55 **Morning coffee**

11:30 **NEW METHODOLOGIES FOR CHARACTERISING COMPLEX BIOLOGICAL MOLECULES**

New product characterisation technologies and methodologies for complex biological molecules

- Implementing increasingly sophisticated techniques in biomanufacturing
- Mass spectroscopy - applying small molecule technology to complex biologicals
- Is the technology sophisticated enough and what are the future expectations?

Dr. Andy Pickett, *Senior Director Biologicals Science and Technology*, **Ipsen Biopharm Ltd.** UK

12:05

Conf room 1: OPERATIONAL EXCELLENCE IN VACCINE MANUFACTURING

Enhancing efficiency of a commercial viral vaccine production platform through process intensification

- Developing successful lean concepts and models - reducing costs of goods
- Moving from 10000 litre to 1000 litre bioreactors - achieving real results
- Achieving a ten-fold cost of goods reduction

Dr. Emile Van Corven, *Director Process Development*, **Crucell** The Netherlands

Conf room 2 DOWNSTREAM PROCESS DEVELOPMENT STRATEGIES - ALLEVIATING THE CAPACITY CRUNCH

Process development methodologies to alleviate the downstream capacity crunch

- Addressing the productivity challenge

Dr. Hari Pujar, *Head of Bioprocess R & D Outsourcing*, **Merck & Co** USA

Conf room 3 RESPONDING TO BIOSIMILAR AND BIOGENERIC REGULATION

Correctly defining similarity and achieving it

- Guidelines – claiming similarity is in the eye of the beholder - addressing the gap in what each party believes to be similar
- Claiming similarity from a quality and clinical perspective
- How will pricing models for reimbursement for biogenerics be different to normal generics? US and European markets - determining
- lucrative opportunities and different regulatory environments

Dr. Keith Chidwick, *Pharmaceutical Assessor*, **Medicines and Healthcare Products Regulatory Agency**

12:40 **Themed luncheon discussions**

14:00

Conf room 1 Interactive workshop

BIO-RAD

UNOsphere S and RS: TAILORED CATION EXCHANGE RESINS

- Studying two cation exchangers with different properties
- Separating proteins with almost identical isoelectric points
- Running a pH gradient without having to mix buffers

Dr. Mark A. Snyder, *Manager, Process R&D Applications Group*, **Bio-Rad Laboratories** USA

Conf room 2 Interactive workshop

invitrogen

THE USE OF HIGH THROUGHPUT TECHNOLOGIES IN PROCESS DEVELOPMENT: MYTHS AND REALITIES

- Understanding high throughput technologies - do they fit your requirements?
- Overview of upstream and downstream workflows enabling process optimisation
- Accessing larger experimental spaces for improved results

Dr Jonathan Dempsey, *Process Science Fellow*, **Invitrogen Limited**

Conf room 3 Interactive workshop

aegis

ACHIEVING MANUFACTURING EXCELLENCE ACROSS THE GLOBAL MANUFACTURING NETWORK USING AN ON-DEMAND PROCESS DATA ACCESS AND ANALYTICS PLATFORM

- Competitive and regulatory drivers for an on-demand data access platform
- Benefits of immediate data access in the same environment with analytics
- Technology aspects of on-demand aggregation of on-line and off-line data
- Leveraging process data in multiple existing manufacturing systems
- The new IT paradigm for multi-site global manufacturing networks
- Making the business case for an on-demand data access platform and change management for user retooling and realisation of benefits

Dr. Justin O. Neway, *Chief Science Officer*, **Aegis Analytical Corporation** USA **Randall A. Tatlock**, *Associate Information Consultant*, **Eli Lilly & Company** USA

15:00

Conf room 1 Interactive workshop

WHOLE CELL BIOPROCESSING FOR REGENERATIVE MEDICAL THERAPIES

- Bioprocessing considerations
- Manufacturing steps: Isolation, culture, expansion, manufacture and clinical delivery
- Growing cells in conditions that maintain cell functionality to preserve therapeutic effects
- Maximising potential development opportunities

Dr. Paul Kemp, *Chief Scientific Officer*, **Intercytex** UK

conf room 2 Interactive workshop

ALTERNATIVE ENABLING TECHNOLOGIES TO OVERCOME LIMITS IN PACKED- BED CHROMATOGRAPHY

- Determining alternatives to oversized stainless steel columns and buffer requirements
- Reducing column chromatography - implementing membrane based flow through chromatography
- 2-3 column steps, very robust resins, high affinity capture steps, robust chromatography
- disposable technology, transferring to stainless steel
- Disposable chromatography focus - alternative downstream purification techniques - column vs. precipitation and crystallisation - determining the future
- Reducing validation requirements for contaminant removal and achieving scalability

Conf room 3 Interactive workshop

DESIGN SPACE FROM A MULTIVARIATE BIOPHARM PROCESS

- Multivariate technology in practice
- Practical ideas from performed projects
- Design space visualisation and continuous improvement.

Dr. Ing-Marie Olsson, *Application Specialist*, **Umetrics AB** Sweden

16:00 **SUCCESSFULLY ACHIEVING LEAN PROTEIN DEVELOPMENT**

- Streamlining bioproduction R&D - cutting down development steps to speed proteins to market
- Bringing together internal and worldwide stakeholders to modify and improve existing processes
- Tightening up and cutting down on labour intensive processes
- Achieving successful tech transfer

Dr. Berthold Bödeker, *Head, Cell Culture & Pilot Facilities*, **Bayer Healthcare AG** Germany

16:35 **Chairman's closing remarks and close of conference**

DELEGATE REGISTRATION FORM

7th annual biological production forum

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A 8% service charge will be levied to cover all administration services completed per delegate prior to the event

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VENUE DETAILS

Arabella Sheraton Grand Hotel,
Arabellastrasse 6
Munich 81925, Germany
Telephone: +49 89 92640

Fee £1,895 (+VAT @ 19%)

DELEGATE PARTICIPATION PACKAGE

Fee includes:
– One to one meetings
– Conference sessions
– Lunches and refreshments
– Networking drinks reception
– Themed luncheon discussions
Hotel accommodation is not included in the registration fee. Information on suitable hotels will be sent out on receipt of the registration form

PRE-ARRANGED ONE-TO-ONE MEETINGS

World Trade Group reserve the right to refuse a delegate participation in the one-to-one meeting sessions if entry criteria is not met. Contact us for more details.

VIRTUAL CONFERENCE PACKAGE

There's no substitute for being there, but if you cannot attend, purchase the virtual conference package
– Interactive CD with slides and audio
– Dispatch costs

Fee: £495 + VAT @ 17.5%

☐ I am unable to attend please send ____ copies of the virtual conference package at £495 + VAT. (Payment must be received before dispatch)

TERMS AND CONDITIONS

Participation at event
The organiser will prepare a schedule of meetings and individual delegates will attend the business meeting appointments as detailed on the final itinerary presented to them at the venue

Cancellation policy
Delegate bookings are transferable but cannot be cancelled. World Trade Group reserve the right to reject delegate applications

Payment terms
14 days from date of invoice

Please sign and fax back to +44 (0)20 7202 7600 to confirm your attendance