Europe's #1 Disposable Solutions event just got

BIGGER and BETTER...

8th Annual

DISPOSABLE solutions for Biomanufacturing

- Improving the interconnectivity and functionality between different suppliers and systems
- Maximising capabilities and improving product cycle times
- Minimising the harmful effects of extractables and leachables

Conference + Extractables and Leachables Focus Day
29th February – 2nd March, 2016 | Munich, Germany

Increase Output and Decrease Timelines: Seize the Opportunity

Ken Wong
Deputy Director
Sanofi Pasteur

Michael Schneider
Head of Manufacturing Science and Technology
Roche

Xavier Derouck
Senior Sourcing Group Manager of Bioprocessing
GlaxoSmithKline Biological

Torben Frandsen
Operational Manager of Process Development
CMC Biologics

Markus Ganzlin
Project Leader Upstream Process Development
Lonza

Maria de Jesus
Co-founder and COO
ExcellGene

Ashley Wigley
Albumin Process & Validation Manager
Novozymes Biopharma

Seán Coomey
Senior Project Engineer
Janssen Biologics

Francis Verhoeye
Director Biological Development Europe
Zoetis

No other European event comes close in **SCOPE, BREADTH** and **DEPTH**

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NEW FOR 2016

Every year we work harder to offer you the very best case studies, insights and advice from across the biopharma industry. In 2016 delegates can look forward to first-hand case studies and in-depth presentations on critical topics such as:

- **Developing Strategies to Move Toward Operating a 100% Disposable Site** – **Zoetis** *share their first-hand experience*
- **Ensuring Integrity by Evaluating the Polymers and Resins Used in Your Disposable Solutions** – *with advice from* **Bio Products Laboratory**
- **Overcoming the Lack of Standardisation Between Vendors** – **Sanofi** *give you insight into how they're dealing with this challenge*
- **Implementing Continuous Processing Technologies to Increase Production Capacity** – **Novozymes Biopharma** *share their experiences and successes*
- **Implementing a Risk-Based Strategy for Using Disposables in a Commercial Manufacturing Process** – **GlaxoSmithKline** *talk you through their most successful strategies*
- **Applying Best Practice for Extractables and Leachables Testing** – **BPOG** *share their best practice guide*
- **Employing Disposable Solutions for Optimized Downstream Processing** – **Lonza** *divulge how they overcame the downstream bottleneck constrictions with innovative disposable solutions*
- **Achieving Operational Excellence with Disposable Systems** – **CMC Biologics** *explain the multiple activities that are needed to converge a fully integrated disposable solutions system*
- **Maximising Your Site's Potential With an Effective Change Management Programme** – **Roche** *share how to implement a successful change management policy to prevent disruptions to manufacturing processes*

Get the most out of your experience with plenty of opportunities to get involved!

Choose from 5 different round table discussions led by a leading industry figure.

Tailor your agenda by taking part in either the upstream or downstream interactive trouble shooting sessions and ask relevant experts your most pressing questions.

Join in with the technology demo drive and get face time with different vendors and their latest products.

Come along to the networking drinks reception and try your luck at our interactive games.

Attend the extractables and leachables intensive workshops to push the boundaries of your knowledge. Leave feeling inspired and informed.

Engage with topic champions as well as solution providers in one of the many catered networking break out sessions

Take advantage of our targeted Q+As and learn as much as possible from leading industry experts.

INTRODUCING YOUR 2016 EXPERT SPEAKER PANEL

Ken Wong
Deputy Director, **Sanofi Pasteur**

Michael Schneider
Head of Manufacturing Science and Technology, **Roche**

Xavier Derouck
Senior Sourcing Group Manager of Bioprocessing, **GlaxoSmithKline Biological**

Torben Frandsen
Operational Manager of Process Development, **CMC Biologics**

Markus Ganzlin
Project Leader Upstream Process Development, **Lonza**

Maria de Jesus
Co-founder and COO, **ExcellGene**

Nigel Beaumont
Principal Process Engineer, **Fujifilm Diosynth Biotechnologies**

Alain Pralong
VP New Product Introduction and Technical Life Cycle Management, **GlaxoSmithKline Vaccines**

Ashley Wigley
Albumin Process & Validation Manager, **Novozymes Biopharma**

Adriana Lopes
Head of Manufacturing, **Cobra Biologics**

Florian Wurm
CEO and Founder, **ExcellGene**

Seán Coomey
Senior Project Engineer, **Janssen Biologics**

Aidan Sexton
Facilitator, **BioPhorum Operations Group**

Francis Verhoeye
Director Biological Development Europe, **Zoetis**

Richard Chester
Senior Bioprocessing Scientist, **Bio Products Laboratory**

Angela Waugh
Manufacturing Manager, **BioReliance**

Alan Kelly
Process Engineer Manufactoring, **Genzyme**

Tony Hitchcock
Technichal Director, **Cobra Biologics**

Constance Perrot
EASE Project Director, **University of Strasbourg**

Jackie Richards
Process and Analytical Support Specialist, **Porton Biopharma**

www.disposablebiomanufacturing.com

DAY ONE

Monday, 29th February 2016

DISPOSABLE solutions

08:00 **Registration and Coffee**

08:40 **Pharma-IQ Welcome**

08:45 **Chairman's Opening Remarks**
The chair will set the mission statement for the two days ahead, introduce the key themes and highlight the outline of the day. Take this opportunity to get to know your peers and discuss your priorities for the next two days.

Overcoming Risks and Challenges to Capitalise on the Benefits of Disposable Technology

09:00 **KEYNOTE ADDRESS: Applying a Risk-Based Strategy for Implementing Disposables in a Commercial Manufacturing Process**

- Implement a risk-based strategy to your manufacturing process to capitalise of the potential of single-use technology
- Examine the latest trends in risk-management and decide which strategies could work best for your site
- Identify individual risks to your manufacturing process and cultivate smart guidelines for mitigating their effects
- Learn how to ensure that your suppliers maintain strong quality oversight to support their product from a control process and ensure regulatory compliance

Xavier Derouck, *Senior Sourcing Group Manager of Bioprocessing,* **GlaxoSmithKline Biological**

09:40 **CASE STUDY: Overcoming the Challenges of Operating a 100% Disposable Site**

- Our reasons for choosing to go 100% disposable
- Evaluating the regulatory constraints involved in transitioning to a 100% disposable site and how to these requirements
- The challenges and hurdles we faced along the way and practical solutions

Francis Verhoeye, *Director Biological Development Europe,* **Zoetis**

10:20 **Networking Coffee Break**

Optimising Vendor Relations and Simplifying the Purchase of Disposable Solutions

10:50 **Technology Demo Drive: The Most Innovative Service Providers from Across the Single Use Space Will Be Showcasing Their Newest Products**

Split into groups and rotate around an exhibition that showcases all the latest technological innovations from various leading companies

11:30 **Ensuring Integrity: Evaluating the Polymers and Resins Used in Your Disposable Solutions**

- Develop methods for evaluating the materials the suppliers are using in their disposable systems
- Improve your ability to prove compliance to regulators by knowing exactly what is in your disposable systems
- Learn how to make informed decisions on materials
- Take home strategies to help reduce time and cost in product development

Richard Chester, *Senior Bioprocessing Scientist,* **Bio Products Laboratory**

12:10 **Translating Regulations and Customer Expectations to Simplify the Regulation Validation Process**

- Overcome the confusion surrounding exactly what documentation is needed from single-use system providers to demonstrate regulatory compliance
- Improve your process efficiency and save time by requesting only what information is actually needed from vendors
- Qualify this information with your current processes to ensure you are minimising effort and maximising results in regulation compliance

Helen Pora, *Single Use Systems Vice President,* **Pall**

13:00 **Networking Lunch**

14:00 **Overcoming the Lack of Standardisation for Single-Use Components: BPOG Present Their Long Anticipated White Paper**

- BPOG will address the biggest challenges associated with the lack of industry standardisation
- Capitalise of years of industry discussion and debate by hearing BPOG's solutions for overcoming these challenges
- Avoid wasting resources by learning the best way to identifying the right system for your particular product

Aidan Sexton, *Facilitator,* **BioPhorum Operations Group**

14:40 **INTERACTIVE ROUNDTABLE DISCUSSIONS:**

Choose from five different round table discussions to participate in, each moderated by a leading industry figure.

Table 1 Implementing Disposable Solutions for Optimized Downstream Processing	**Table 2** Implementing Disposable Solutions for Optimized Upstream Processing	**Table 3** Innovation in Product Development: Technologies, Strategies, Cutting Costs, Utilizing Creativity and Lessons Learned
Table 4 Achieving Operational Excellence in Single Use Systems	**Table 5** Dealing with Vendors and Optimizing the Supply Chain	

15:20 **Networking Coffee Break**

The Latest Innovations in Disposable Solutions

15:50 **The Benefits of Using Single-Use Technology for Microbial Fermentation**

- Capitalise on recent advances in single-use technology the production of microbial systems
- Circumvent the most common engineering challenges involved with bioreactors being utilised in microbial fermentation
- Access methods for ensuing fermentors can handle the high metabolic rates and oxygen demands of microbial cultures
- Maximise your understanding of how by applying general bioengineering principles and designs, high oxygen transfer rates can be achieved also in disposable fermenters

Adriana Lopes, *Principal Scientist,* **Cobra Biologics**

16:30 **Implementing Continuous Processing Technologies to Increase Production Capacity**

- Discover why continuous bioprocessing is being called "the biomanufacturing model of the future"
- Investigate how continuous processing methodologies can be used to increase productivity, reduce cost of goods, resolve facility capacity challenges and reduce capital expenditure
- Maximise production capacity while improving process robustness and maintaining consistently high quality by implementing continuous bioprocessing
- Gain practical insights into the implementation of continuous manufacturing techniques from real-life experiences from marketed biopharmaceutical products

Ashley Wigley, *Albumin Process & Validation Manager,* **Novozymes Biopharma**

17:10 **How to Control Your Bioprocess with Single-Use Automation**

- Ensure airtight compliance with the FDA's guidance document on "Process Validation, General Principles and Practices"
- Gain an understanding of the sources of variation in your bioprocess, detect the presence and degree of variation, understand the impacts on product attributes and implement appropriate control measures
- Capitalise on the potential of single-use automation to control variation in your bioprocess to achieve reproducible product quality for increased drug efficacy and safety

Markus Ganzlin, *Project Leader Upstream Process Development,* **Lonza**

17:50 **Chairman's Summary of Day One**

18:00 **Networking Drinks Reception**

DAY TWO

Tuesday, 1st March 2016

DISPOSABLE solutions

08:15 Registration and Welcome Coffee

08:45 Chairman's Recap of Day One

09:00 KEYNOTE ADDRESS: **The Past, Present and Future: A 30 Year Journey of Manufacturing Proteins with CHO Cells in Stirred Bioreactors of Steel, Glass and Plastic**

- Advance your discoveries by understanding the origins of the protein based pharmaceutical industry and how large scale manufacturing with animal cells has benefited from research and development efforts that resulted in 10 and 100 folding of volumetric yields - a key driver for the reduction of cost
- Discover why these yields mean that the manufacturing scale for many new protein entities will require smaller volumes than in the 80s and 90s, with impacts in upfront and maintenance investments
- Utilise new processes of finding faster and cheaper solutions to protein manufacturing
- Investigate which issues have to be considered when determining the economic advantages of disposable systems - especially when considering operations beyond the several hundred litre scale

Florian Wurm, *CEO and Founder,* **ExcellGene**

Perfecting Implementation of and Transition to Disposable Solutions

09:40 CASE STUDY: **Successful Implementation of Disposable Development and Manufacturing Technologies**

- Get it right from the beginning – discover how to successfully implement disposable solutions to your site
- Overcome worries about change control, quality performance and unforeseen supply-chain costs
- Investigate about the multiple activities that are needed to converge a fully integrated disposable solutions system
- Hear a case study on implementation of "6Pack" — 6x2000L single-use cell culture line

Torben Frandsen, *Operational Manager of Process Development,* **CMC Biologics**

10:20 **Change Management from a Single-Use Perspective**

- Maximise your site's potential by understanding why efficient change control processes are a critical part of overall system quality and efficiency
- Implement a successful change management policy to prevent disruptions to manufacturing processes
- Avoid costly supply chain interruptions by integrating an efficient but flexible change control strategy

Michael Schneider, *Head of Manufacturing Science and Technology,* **Roche**

10:50 **Networking Coffee Break**

11:20 **Achieving a Seamless Transition to Disposable Technology: A Project Manager's Guide**

- Implement a roadmap that enables your company to transition to disposable solutions in a way that demonstrates efficiency, cost-savings and ingenuity
- Increase your competitive edge by improving your site's performance and applying a systematic and scientific approach to the transition process
- Improve your risk assessment: when your completed strategy is in place potential risks will be easy to spot and address before you start working on project completion
- Improve growth and development within your team and inspire your team to continue to look for ways to perform more efficiently by achieving increasingly positive results

Seán Coomey, *Senior Project Engineer,* **Janssen Biologics**

12:00 CASE STUDY: **Constructing a Disposable Solutions Site From the Ground Up**

- The University of Strasbourg believes that they key to success in disposable Biomanufacturing is training for the best gestures. That is why they have set up EASE – the European Aseptic & Sterile Environment Training Centre, in conjunction with several local pharmaceutical companies, to train people on jobs that take place in white-rooms.
- In this case study you will investigate how to begin implementing disposable solutions into your lab by hearing how the EASE I project was constructed
- Acquire take home strategies to help you perfect the basics of single-use system integration

Constance Perrot, *EASE Project Director,* **University of Strasbourg Upstream and Downstream Processing with Disposable Solutions**

12:40 **The Benefits of Single-Use Technology in Downstream Processing**

- Discover how single-use technology can benefit all relevant downstream processing steps including chromatography systems, filtration systems and mixing systems
- Learn about the key considerations when making the switch to single-use systems in downstream processing
- Discover how to overcome complexities caused by selecting technologies with a high degree of exchangeable components
- Discover how to best consider the actual cost factors and greater dependency on the supply chain
- Gain insight to help you decide between adopting a new facility or using an existing facility

Parker Hannifin Representative

13:00 **Networking Lunch**

14:00 **Upstream and Downstream Interactive Troubleshooting Sessions**

One of the best aspects of a conference is the knowledge of its delegates. Is there a particular challenge you are facing that another delegate might already have a solution for? Have you recently overcome a challenge are willing to share you achievement? This session allows you to write down you post pressing question, and see who in the room already has the answer. Tailor this session to your needs by choosing from up or downstream processing tracks

Downstream Trouble Shooting Track
Angela Waugh, *Manufacturing Manager,* **BioReliance**

Upstream Trouble Shooting Track
Markus Ganzlin, *Project Leader Upstream Process Development,* **Lonza**

Looking to the Future – Maximising the Capabilities of Disposable Solutions

14:40 INNOVATION SESSION: **What are the Latest Innovative Initiatives in the Single-Use Space?**

Hear three small but innovative solution providers describe their latest products and solutions to the most pressing challenges in disposable solutions

15:20 **Networking Coffee Break**

16:00 **Implementing Closed-System Processing for Increased Manufacturing Efficiency**

- Capitalise on closed, single-use systems to protect against both biological and cross-contamination, saving valuable research time and money
- Evaluate if this new method can work at your site
- Better understand the debate about whether closed systems can be established with a sufficient degree of confidence that classified environmental controls around bioprocesses can be removed
- Asses the different ways that closed systems are defined and referenced within the body of regulatory guidance documents and how companies differ in their implementation of a "closed manufacturing" concept

Tony Hitchcock, *Technical Director,* **Cobra Biologics**

16:00 CASE STUDY: **5 mL to 2500 L: Predictable, High-Yield Culture of CHO Cells in Impeller-Free Disposable Bioreactors**

- Capitalise on the results of 15 years of research, including unpublished case studies with CHO cells and their performance
- Discover why impeller-free mixing of a liquid is in fact possible
- Investigate the necessary technical parameters of the shaking processes, including: vessel geometry, direction and frequency of vessel displacement, gas transfer, power input, shear stress impac

Dr Maria De Jesus, *Co-Founder and COO,* **ExcellGene**

17:20 **Chairman's Closing Summary and End of Conference**

DAY TWO

Extractables and Leachables Workshop Day
Wednesday, 2 March 2016

DISPOSABLE solutions

Take your knowledge further with dedicated interactive sessions to get to grips with the most challenging extractables and leachables issues. These tailored workshops are targeted to really push the boundaries of knowledge and leave our delegation inspired and informed.

09:00-11:00 WORKSHOP A:

Designing Studies to Identify Extractables and Leachables

The demand for increasingly extensive methodologies for designing studies to identify extractables and leachables in pharmaceutical products by regulators is growing, as data from these assessments identifies potential contaminants that migrate from containers, closure systems, tubing, and other materials, potentially rendering drug products unsafe.

Attend this session in order to:

- Develop a comprehensive approach to identifying compounds extracting from materials under elevated temperatures, extended contact time, or solvent exposure with help from an Extractable and Leachables expert

Karen Pieters, Toxikon

11:30-13:30 WORKSHOP B:

Successfully Apply a Risk-Based Approach to Extractables and Leachables

The introduction of leachables into a pharmaceutical product stream can alter its stability and potency, interfere with an assay that is crucial to measuring an important property of the product, and can even pose a health risk to the consumer. Unfortunately, extractables and leachables issues often are not addressed up front and ultimately can cause regulatory delays for the drug manufacturer. A risk-based approach to leachables and extractables testing is imperative to ensure the safety of all biopharmaceutical products and efficiency in product time cycles.

Attend this session in order to:

- Understand the impact of process parameters
- Hear novel and innovative approaches to risk assessment
- Discover analytical techniques used to quantify and measure extractables and leachables

14:00-16:30 WORKSHOP C:

BPOG's Best Practice Guide for Extractables and Leachables Testing

This presentation will cover BPOG's standard extractables and leachables testing protocol and address common flexibilities, myths and misconceptions. Delegates can benefit from a presentation of data from the completed 'proof of concept' case study data using bags and O-rings to demonstrate the viability of the study design. You will be introduced to BPOG's new Best Practice Guide for extractables and leachables testing, covering: risk assessment; leachable study design for SUS components; leachable test methods. The workshop will close with an end user perspective on how a member company can implement BPOG's recommendations.

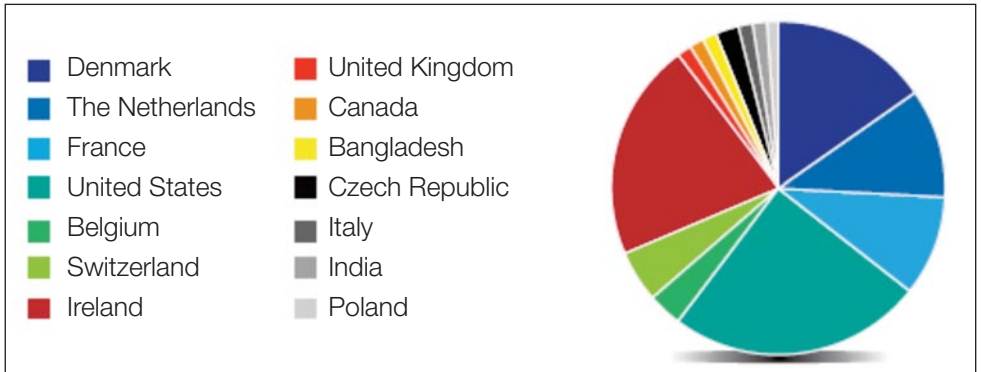
Attend this session in order to:

- Discover best practice and analytical considerations of leachables testing methods
- Learn about leachable study design for Single-Use components
- Hear about risk assessment using a standard RA model approach

Ken Wong, *Deputy Director,* **Sanofi Pasteur**

Who will attend Disposables Solutions for Biomanufacturing Europe?

- Head of Manufacturing
- Head of Bioprocessing
- Head Process Development
- Director Upstream Processing
- Director Downstream Processing
- CTO
- Technical Director
- Process Engineer
- Process Scientist



DAY TWO

Extractables and Leachables Workshop Day
Wednesday, 2 March 2016

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Conference + Extractables and Leachables Focus Day
29th February – 2nd March, 2016
Munich, Germany

DISPOSABLE solutions for Biomanufacturing

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Access to Focus Day (2nd March)	✓	x
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Please photocopy for each additional delegate

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Please note: If you have not received an acknowledgement before the conference, please call us to confirm your booking.

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Venu: Munich, Germany

Accommodation:
Travel and accommodation is not included in the registration fee. For updates on the venue and accommodation information, please visit: www.disposablebiomanufacturing.com

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