Global Engage

3RD GLOBAL BIOPROCESSING, BIOANALYTICS & ATMP MANUFACTURING CONGRESS

DUBLIN, IRELAND

7-8 September 2020

#BioprocessingCongress

www.global-engage.com

Global Engage

The field of biologics continues to grow at an unprecedented rate, creating a need for novel manufacturing technologies and strategies to keep up with demanding market forces. Global Engage is therefore pleased to announce that the **3rd Global Bioprocessing, Bioanalytics and ATMP Manufacturing Congress** will be returning to Dublin, at the Castleknock Hotel, on 7-8 September 2020, to help you explore the latest research in bioprocessing and bioanalytics.

With the rise of continuous bioprocessing and single use technologies, process analytical technology (PAT) and digitalisation, this congress will provide numerous presentations on the next-generation technologies enabling the acceleration and optimisation of efficient biomanufacturing processes. An hour-long panel session will explore the definition of industry 4.0, as well as the challenges of implementing this in both new and existing systems. With the increased demands of regulatory agencies, the bioanalytics track will also focus upon data integrity, standards and regulation, QbD strategies, as well as characterisation and monitoring.

Not only will this event cover the production of well-established biologics, but we shall move beyond this to explore the complex manufacturing procedures of cell and gene therapies. Building upon the success of last year's meeting we shall once again delve into facility design and the need for flexible systems, the challenges of quality control and the production of vectors for drug delivery. Again, the regulatory demands for these novel therapies cannot be ignored, and so speakers will be encouraged to enlighten the audience with their experiences.

With a vibrant exhibition hall full of solution providers, showcasing their latest technologies and services, and a 40-strong speaker faculty comprising of individual presentations, roundtable sessions and senior-level panel discussions, this year's meeting will provide the opportunity to discuss current, and future, manufacturing and analytical strategies.

TRACK 1

Next-Generation Technologies & Novel Manufacturing Strategies

- Industry 4.0 and smart factories
- Single use technologies
- Integrated continuous biomanufacturing
- Technological developments
- Continuous vs. fed batch methods
- High-throughput methods
- Modular design possibilities
- Automation technologies and their applications
- Process modelling and analytics technologies
- Integrated analytics; PAT, real-time monitoring and sensors
- Improving purification and recovery methods: chromatography, centrifugation, filtration
- Process intensification and acceleration
- Novel cell lines and systems
- Moving beyond mAbs; manufacturing next-generation biologics
- The importance of collaborative projects

TRACK 2

Quality Control, Analytics & the Regulatory Landscape

- DOE and QbD Strategies
- Meeting GMP, PAT and CMC guidelines
- Protein characterisation and monitoring
- Bioassays and the determination of biological activity
- Data integrity, management and integration
- The rise of machine learning and predictive analytics
- The introduction of mass spec in the QC laboratory
- Outsourcing challenges
- Biosimilarity and comparability assessment
- Standards and regulation
- Change control and analytical method transfer

TRACK 2

Manufacturing Cell & Gene Therapies

- Regulatory challenges of ATMP manufacturing
- Assay development and the challenge of characterisation
- Analytical characterisation; process development, comparability assessments and stability testing
- AAV and lentiviral process development
- Quality control and CQA
- Scalability for autologous and allogenic products
- Facility design – flexible manufacturing methods
- The need for closed, automated systems; upstream and downstream challenges

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JUDY CHOU
President / CEO, AbGenomics

TONY D'AMORE
Vice President, Product R&D, Sanofi Pasteur

JONATHAN CARTOUX
EMEA Field Application Engineer, Entegris

CHRISTIAN WITZ
Head of the Computational Bioprocess Engineering Group, Institute for Process and Particle Engineering, Graz University of Technology

DAVID MURRAY
Pharmaceutical (Quality) Assessor – Biologics, HPRA

AMIR GOUDARZI
Head of Process Engineering, Biologics Pilot Plant, UCB

BAERBEL GROSSMAN
Associate Director, Global Regulatory Affairs CMC, Sanofi

PAUL KROLL
Business Development Manager Lucullus, Securecell AG

TAPAN DAS
Director, Analytical Development, Bristol-Myers Squibb

PAULINE RUDD
Visiting Investigator, Bioprocessing Technology Institute, A*Star Institute

CAITLIN O'MAHONY HARTNETT
R&D Scientist, BioTherapeutics Development Large Molecule, Janssen Sciences, Ireland

THOMAS MAISCHBERGER
Process Engineer & Project Development, ZETA GmbH

SHIRLEY O'DEA
Chief Scientific Officer, Avectas

SENIOR REPRESENTATIVE
Malema

CATHRINA HOULIHAN
Site Control Strategy Lead, New Product Industrialisation & Devices, Sanofi

RAHUL SINGHVI
Flagship Pioneering

STEVE LOCK
Marketing and Market Development Manager, SCIEX, CE EMEAI

SIMON WATSON
Scientific Investigator, GSK

MATTHEW CHEEKS
Director of Biopharmaceutical Development, AstraZeneca

VADIM KLYUSHNICHENKO
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MICHAEL BUTLER
Emeritus Professor and Principal Investigator in Cell Technology, NIBRT

MORITZ VON STOSCH
Senior Manager, Process Systems Biology & Engineering Center of Excellence, GSK Biologicals

SENIOR REPRESENTATIVE
TQS Integration

MIRIAM MCCARTHY
Head of Technical Services CMO EU, Takeda

ALEXANDRA HOFER
Business Development Manager Numera, Securecell AG

DOLORES CAHILL
Professor of Translational Science, University College Dublin, Ireland

MARIA GIANNELI
Field Application Specialist, Gyros Protein Technologies

HANI EL-SABBAHY
Life Science Application Engineer. Separation and Purification Sciences Division, 3M

ELMER MÉNDEZ ROSARIO
cGMP Specialist II, Office of Translational Production & Quality, Houston Methodist Research Institute

PHILLIP RAMSEY
Vice President, Technical Development, Sangamo Therapeutics

JAN TALTS
COO, Longboat Amniotics AB

08:00-08:50 Registration & Refreshments

08:50-09:00 **Global Engage Welcome Address & Morning Chair's Opening Remarks**

09:00-09:40

KEYNOTE ADDRESS:
JUDY CHOU
President / CEO, AbGenomics

The Biomanufacturing Strategies to Meet the Needs of Multiple Modalities in Biologics

09:40-10:20

TONY D'AMORE
Vice President, Product R&D, Sanofi Pasteur

Perspectives of Vaccine Development and Manufacture

This presentation will review the evolution of vaccine development and manufacture and the role of innovation and technology. As competition and cost increases, a number of strategies to leverage innovation and technology for rapid product development to shorten time to clinical trials and increasing productivity are discussed. Specific examples of accelerating process and analytical development will be provided. In addition, how we continue the evolution of vaccine development and manufacturing in the future.

10:20-10:50

JONATHAN CARTOUX
EMEA Field Application Engineer, Entegris

High Cell Concentration Banking for Seed Train Reduction on Fluoropolymer Single Use Bag

This presentation will demonstrate the best freeze and thaw protocol for the storage of high-density CHO cells in vapor liquid nitrogen. Monitoring and viability parameters will be compared to a 5 ml vial.

10:50-12:00 Morning Refreshments / One-to-One Meetings / Odd Numbered Posters

NEXT-GENERATION TECHNOLOGIES & NOVEL MANUFACTURING STRATEGIES

12:00-12:30

CHRISTIAN WITZ
Head of the Computational Bioprocess Engineering Group, Institute for Process and Particle Engineering, Graz University of Technology

Digital Design and Optimization of Bioprocessing Operations

Using the example of aerated stirred bioreactors, I will show how high-performance simulation algorithms can utilize current graphical processing units to achieve short simulation times without the need of costly mainframes. In combination with an easy and intuitive user interface an everyday tool for scientists and engineers is created.

12:30-13:00

AMIR GOUDARZI
Head of Process Engineering, Biologics Pilot Plant, UCB

Learnings & challenges in industrialization of biopharmaceuticals

- Bioprocesses are designed to run in the facility and not the other way around
- One approach in centrifuge performance characterization & its impact on separation performance
- Overcoming DSP challenges by integrated S/L separation design

13:00-13:30

PAUL KROLL
Business Development Manager Lucullus, Securecell AG

ALEXANDRA HOFER
Business Development Manager Numera, Securecell AG

Smart digital transformation of bioprocesses

Automation and digitization are becoming increasingly important in the modern environment of bioprocesses 4.0. Driven by the PAT initiative and the goal of a well-understood and optimally controlled process, the digital transformation of bioprocesses is inevitable. This transformation starts with digitization of your bioprocess, i.e. by generation of process data in an automated manner, and should result in digitalization. Hence, digital tools are needed that allow to use the generated data in a way to optimize your process and provide new value-producing opportunities. An example of how the transformation to a digital lab can be performed will be presented in that talk, using Numera, an automated sampling and sample processing system and Lucullus, a Process Information Management System.

QUALITY CONTROL, BIOANALYTICS & THE REGULATORY LANDSCAPE

12:00-12:30

DAVID MURRAY
Pharmaceutical (Quality) Assessor – Biologics, HPRA

Biologics & Regulation: The Next Generation

This talk will focus on the regulatory expectations and challenges for the next generation of biological medicinal products and their manufacturing processes.

12:30-13:00

BAERBEL GROSSMAN
Associate Director, Global Regulatory Affairs CMC, Sanofi

Regulatory challenges of ATMP manufacturing

- ATMP – regulatory landscape
- Regulatory challenges of manufacture
- Future perspective – need of harmonization

13:00-13:30

MARIA GIANNELI
Field Application Specialist, Gyros Protein Technologies

Biopharmaceuticals and ATMP therapies: bioprocess applications and benefits using an automated immunoassay platform

Utilization of innovative bioanalytical platforms in biopharmaceuticals and ATMP therapeutics remains critical for increased analytical throughput and generation of high-quality data. We will give an overview on how the Gyrolab automated platform can improve productivity by boosting workflows, data quality and greatly reducing the consumption of precious samples in a wide range of applications including IgG titer, immunogenicity, viral vector titer and HCP impurities analysis.

13:30-14:30 Lunch

14:30-15:00

MICHAEL BUTLER

Emeritus Professor and Principal Investigator in Cell Technology, NIBRT

Real-time monitoring of cell viability during a bioprocess

- Although cell viability by dye exclusion has been used for 100 years it has many limitations
- Dielectric spectroscopy and high resolution optical methods are alternatives.
- Early detection of the loss of cell viability can be used to extend the longevity of cultures

14:30-15:00

TAPAN DAS

Director, Analytical Development, Bristol-Myers Squibb

Attribute-Focused Methods for Building Robust Control Strategy

Quality of biologics drug substance and drug product depends critically on performance of the analytical methods. The analytical methods intended for measuring purity and residual impurity, or separating product related variants must be sensitive to many factors that can impact quality. In practice, however, it is quite challenging to ensure that the methods can detect a wide variety of degradation products and modifications that are known for biologics. Therefore, method development requires not only a robust qualification of the operating parameters but also an in-depth understanding of the protein degradation and modifications. This session will highlight progress with our attribute-focused method development strategy, evolution of methods in a phase-appropriate manner, and partnering across many functional lines for knowledge exchange.

15:30-16:00

CAITLIN O'MAHONY HARTNETT

R&D Scientist, BioTherapeutics Development Large Molecule, Janssen Sciences, Ireland

Monitoring and Controlling Critical Components in Cell Culture Process using Advanced Process Control Ensure process robustness and productivity in scale up operations using advanced process control

- Case studies demonstrate the application of Raman chemometric models can increase the likelihood of early event detection
- Proof of concept studies demonstrate process gains by increasing process control by automating media feeds
- Application of PAT can facilitate real time control of the cell culture production process and product quality

15:00-15:30

PAULINE RUDD

Visiting Investigator, Bioprocessing Technology Institute, A*Star Institute

An Integrated Multi-Omics (BTI-Biomodel) Platform Includes New Software for Automated Detailed Glycan Analysis to Aid QBD and Process Control

- We optimised a suite of coupled instruments (LC/MS/MS/CCS) (with Waters Corporation) for 96 well-plate robotics and glycan and glycopeptide analysis.
- We built automated software tools for data interpretation (open access to academia) (i) GlycoStore DB for released glycans (with Macquarie University, 2014) (ii) Glycoanalyser for exoglycosidase digestions (with New England Biolabs, 2016) (iii) GlycopeptideGraphMS (2019) for rapid and comprehensive data base semi-independent analysis of glycopeptides (iv) MAGmap (2019) data base semi-independent, combines multidimensional glycan data and other -omics data and features.
- BTI-BIOMODEL (2019-) incorporates these programmes, enabling us to build a design space to simulate bioreactor conditions. From these we can identify physiochemical features that associate with product quality outcomes (QBD, basis of Digital Twin). It can predict CQAs (including glycan abundance, titre and VCD).

15:30-16:00

THOMAS MAISCHBERGER

Process Engineer & Project Development, ZETA GmbH

Opening the "Black Box": An Innovative kLa Measurement Procedure for Bioreactor Characterization & Optimization.

In line with the evolution of bioprocessing techniques, satisfying the concepts of Pharma 4.0, there is a heavy emphasis on expression system improvement. Currently, the demands on bioreactors have become ever more exacting, requiring paradigm shifts in manufacturing efficiencies to provide continuous optimization, design improvements and detailed characterization. The kLa-value and the mixing time are the key performance indicators for bioreactors. Few publications, reporting on large scale bioreactor characterization studies, are available because calculation and modelling of the kLa-value and mixing time is extremely. This presentation, incorporating QbD techniques and validated CFD simulations, will give new insights on novel and innovative hydrodynamic modelling and how a comprehensive understanding of process parameters can be implemented to boost productivity and make it easier to meet regulatory requirements.

15:30-16:00

HANI EL-SABBAHY

Life Science Application Engineer. Separation and Purification Sciences Division, 3M

Polisher ST – A novel salt tolerant flowthrough chromatography technology to improve your downstream process

- High product loading capacity leading to smaller unit operation footprint, hold up volumes and buffer requirements
- Good HCP removal even at low pH and high conductivity
- Robust viral clearance using 4 main models over a wide range of pH and conductivity
- And >95% product recovery

16:00-16:50 Afternoon Refreshments / One-to-One Meetings / Even Numbered Posters

16:50-17:20

SENIOR REPRESENTATIVE

TQS Integration

16:50-17:20

SENIOR REPRESENTATIVE

Malema

17:20-18:20

PANEL DISCUSSION:

Industry 4.0: Challenges and Implementation

Invitations out to Senior Representatives

17:20-18:20

ROUNDTABLE DISCUSSIONS:

Roundtables are informal, small-group interactive discussion on key topics in the field. Discussion leaders will introduce sub-topics/questions for discussion and roundtable attendees are encouraged to participate actively in the session.

Table 1: Control Strategy

CATHRINA HOULIHAN

Site Control Strategy Lead, New Product Industrialisation & Devices, Sanofi

Table 2: Reimbursement strategies & health economics

DOLORES CAHILL

Professor of Translational Science, University College Dublin, Ireland

Table 3: Introducing Quality to Translational Research

ELMER MÉNDEZ ROSARIO

cGMP Specialist II, Office of Translational Production & Quality, Houston Methodist Research Institute, USA

- What are the challenges faced by newly discovered therapies and translational research organizations?
- Strategies to introduce quality into translational projects at pre-clinical stages.
- Organizational structure, support, and collaboration strategies.

18:20	Chair's Closing Remarks / End of Day 1
18:20-19:20	Networking Drinks Reception

08:00-08:55 Refreshments

08:55-09:00 **Chair's opening remarks**

09:00-09:40

RAHUL SINGHVI

Flagship Pioneering

Topic: Transformational Companies in Gene Therapy

09:40-10:10

STEVE LOCK

Marketing and Market Development Manager, SCIEX, CE EMEAI

Recent Developments in the use of Capillary Electrophoresis in Gene Therapy Research and Development

In this presentation find out about recent developments in using Capillary Electrophoresis (CE) in gene therapy. In this presentation, learn:

- How CE is being used to study viral particles e.g. Viral Protein profiling
- The advantages of DNA and RNA purity analysis by CE
- Where CE is being used in Quality control in Plasmid production
- About the future of CE in full gene therapy product testing e.g. empty vs full analysis

NEXT-GENERATION TECHNOLOGIES & NOVEL MANUFACTURING STRATEGIES

Chair:

10:10-10:40

MATTHEW CHEEKS

R&D Director, Biopharmaceutical Development, AstraZeneca

Towards Continuous Processing In Biopharmaceutical Manufacturing: Approach and Considerations

- Perspective into AZ's current situation
- Today's opportunities & challenges
- Remaining competitive in the mid/long term

MANUFACTURING CELL & GENE THERAPIES

Chair: Jan Talts, COO, Longboat Amniotics AB

10:10-10:40

SIMON WATSON

Scientific Investigator, GSK

Lentiviral Vector Manufacturing and analytics - Opportunities, Challenges and Ways Forward

- Viral vectors are the most common gene delivery system for cell therapies. There is an increased demand for LentiViral Vector to treat more prevalent diseases such as cancer.
- Manufacturing viral vectors of the desired quality on a commercial level presents many challenges.
- In this presentation, the authors will demonstrate how new analytical technologies could be used to develop, monitor and potential control viral vector production.

10:40-11:50 Morning Refreshments / One-to-One Meetings / All Poster Presentations

11:50-12:20

VADIM KLYUSHNICHENKO

Vice President, Pharmaceutical Development and Quality, Calibr, Scripps Institute

Development and manufacturing of immuno-oncology products through global CDMOs

- Calibr business model and product portfolio
- The complexity of the process and product development for immuno-oncology products
- CMO selection process and criteria for successful project implementation

11:50-12:20

FRANZ SCHNETZINGER

Director Quality Control & CMC Analytical Development, Gyroscope Therapeutics

Capillary electrophoresis and liquid chromatography for characterisation of AAV vectors

A CE-SDS method replacing SDS-PAGE for purity determination of AAV vector material and the implementation of affinity, ion-exchange, and size-exclusion chromatography as rapid tools in-process monitoring of vector quality.

12:20-12:50

MIRIAM MCCARTHY

Head of Technical Services CMO EU, Takeda

External Manufacturing, Getting the best out of Contract Manufacturing

The financial benefits of using a contract manufacturer for production of early phase moieties are well know but when it comes to commercial supply how best can you work with CMOs? What responsibilities do you have as the product owner and how can you ensure a secure supply?

12:20-12:50

BEATA ADAMIAK

Senior Manager, Process Sciences, Allergan

Optimisation of Upstream Processes for Viral Vector Delivery

While developing scalable robust manufacturing process for viral therapeutics, they may be several challenges encountered. Through optimisation of process parameters for viral vector production, using high throughput small scale reactor systems and scaling to representative bioreactor systems, we have not only driven yields but have also focused on viral vector quality. During this presentation we will share how we have overcome some of the challenges to create a scalable upstream production solution to deliver ground-breaking medicines to patients.

12:50-13:20

SENIOR REPRESENTATIVE

Labware Ltd

How the Internet of Lab things (IoLT) is changing the Lab World

More and more devices are including connectivity technology, allowing them to be part of a persistent network. This includes laboratory instruments such as balances. These instruments can become a seamless part of a laboratory's Internet of Things (IoT) environment, allowing quick interfacing and simple usage. During this session, we will discuss the practical ways of creating an Internet of Lab Things (IoLT) environment, and the technical and regulatory challenges to be expected. Actual devices such as wirelessly-connected instruments, printers and mobile phones will be used to illustrate how IoLT can work in the real world.

12:50-13:20

SHIRLEY O'DEA

Chief Scientific Officer, Avectas

Solupore®- Next-Generation Non-Viral Cell Engineering

CAR-T product approvals are driving the development of next-generation immune cell therapies and complex engineering will be required for these products. Non-viral engineering platforms that are closed, automated and can integrate into manufacturing processes are required. The Avectas Solupore non-viral cell engineering platform is being developed to meet the manufacturing and clinical needs of the cell therapy sector.

13:20-14:20 Lunch

14:20-14:50

MORITZ VON STOSCH

Senior Manager, Process Systems Biology & Engineering Center of Excellence, GSK Biologicals

Interfacing machine learning and process science for next level process development

- A collection of possibilities and examples of machine learning and hybrid modeling application for bioprocess development.
- Beyond data-centric knowledge management
- A collection of possibilities and examples of AI application for bioprocess development.

14:20-14:50

FRANCESCA BELLINTANI

Downstream Process Development Manager, Molmed

A practical look at Analytical methods across all stages of ATMPs

- Analytical methods strategy troughs clinical phases
- Continuous optimization to increase reproducibility
- Continuous optimization to increase throughput: automation

14:50-15:20

MATHIEU DELANNOY

Biotech Process Sciences Development Manager, Merck Group

Case study

14:50-15:20

AOIFE DUFFY

Cell and Gene Therapy Operations Manager, Hitech-Health, Ireland

15:20-15:50

PHILLIP RAMSEY

Vice President, Technical Development, Sangamo Therapeutics

Gene therapy process and analytics - AAV - TBC

15:20-15:50

ISAAC ERICKSON

Director of Bioprocess Engineering & Global Market Development, DiscGenics

Delivering a Globally Compliant Allogeneic Cell Therapy for Low Back Pain

Strategy employed to produce an allogeneic cell therapy for US and JP markets on accelerated pace. Scale-up technology selection and process development. Implementing serialization for global requirements.

15:50 Conference Close

Castleknock Hotel - 4 Star Hotel Dublin

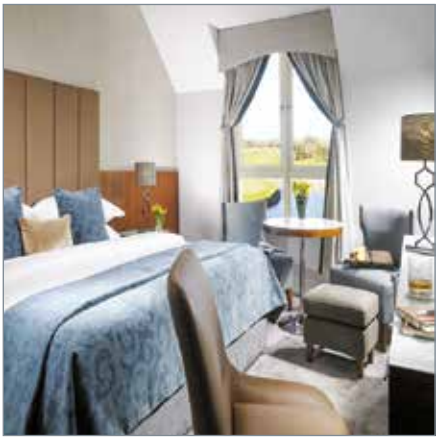
Porterstown Road, Castleknock, Dublin D15 WNR7
www.castleknockhotel.com

Castleknock Hotel is a 4 star country hotel located about 2 kilometres from Castleknock Village between The Phoenix Park and Blanchardstown.

Awarded 'Best Place to Stay' in the 2019 Fingal Chamber Awards, Castleknock Hotel has 190 bedrooms. Each room includes a safe, flat screen TV, ironing board, trouser press, tea/coffee making facilities, bathroom with underfloor heating and separate shower & bath and complimentary 500mb fibre optic uncontested Wi-Fi.

At Castleknock Hotel, we have a range of beverage and dining options to cater for all tastes, all of which have been recently refurbished. The hotel has been awarded 'Best Place to Eat' for two consecutive years at the Fingal Dublin Business Excellence Awards. There are two restaurants, Earth & Vine, our signature restaurant and 22 Bar & Restaurant, our casual dining experience. The Lobby is the hotel patisserie while the Lime Tree Bar is our main bar.

The Spa at Castleknock Hotel, a luxury spa in Dublin. Working with luxury spa brand, Elemis and secondary brand Voya, the spa offers a range of treatments including massage, facials, nails, makeup and tanning.



POSTER PRESENTATIONS

MAKING A POSTER PRESENTATION

Poster presentation sessions will take place in breaks and alongside the other breakout sessions of the conference. Your presentation will be displayed in a dedicated area, with the other accepted posters from industry and academic presenters. We also issue a poster eBook to all attendees with your full abstract in and can share your poster as a PDF after the meeting if you desire (optional). Whether looking for funding, employment opportunities or simply wanting to share your work with a like-minded and focused group, these are an excellent way to join the heart of this Congress. In order to present a poster at the forum you need to be registered as a delegate. Please note that there is limited space available and poster space is assigned on a first come first served basis (subject to checks and successful registration).

POSTER SUBMISSION – CLOSING DATE: 21st August 2020

SUBMISSION INSTRUCTIONS

We will require the form (downloadable below) to be submitted by the 1st May 2020. To simply have your poster at the meeting, submissions must be made no later than 1st May 2020. This is the formal deadline however space is another limiting factor so early application is recommended. Therefore please contact us with any questions you have as soon as possible.

DON'T DELAY, BOOK YOUR PLACE TODAY!

Places are limited and are based on a first come, first served basis so to avoid disappointment contact us today to reserve your place at Global Engage's 3rd Global Bioprocessing, Bioanalytics and ATMP Manufacturing Congress on the 7th-8th September 2020, Dublin, Ireland.

PHONE BOOKING

+44 (0) 1865 849841

Our conference team will make all the necessary arrangements.

ONLINE BOOKING

Visit the website to book your place

www.global-engage.com/event/bioprocessing-bioanalytics

THE CONGRESS PACKAGE INCLUDES:

All Conference Sessions
Lunches and Refreshments
Access to Exhibition Room
Networking Drinks Reception
Conference Workbook
E-Document Pack

HOTEL ACCOMMODATION

Hotel accommodation will be available at a group rate.

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www.global-engage.com/event/bioprocessing-bioanalytics

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tony@globalengage.co.uk or call **+44 (0) 1865 849841**

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www.global-engage.com

Global Engage Ltd., The Kidlington Centre, Kidlington, Oxford, OX5 2DL, United Kingdom

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