6th annual

Cell Culture World Congress 2016

23-24 February 2016

Sofitel Munich Bayerpost, Munich

Enhancing and innovating your cell culture process

Created by terrapinn

use your brain

Part of total biopharma

Co-located with Downstream Processing World Congress 2016

Supported by BioM

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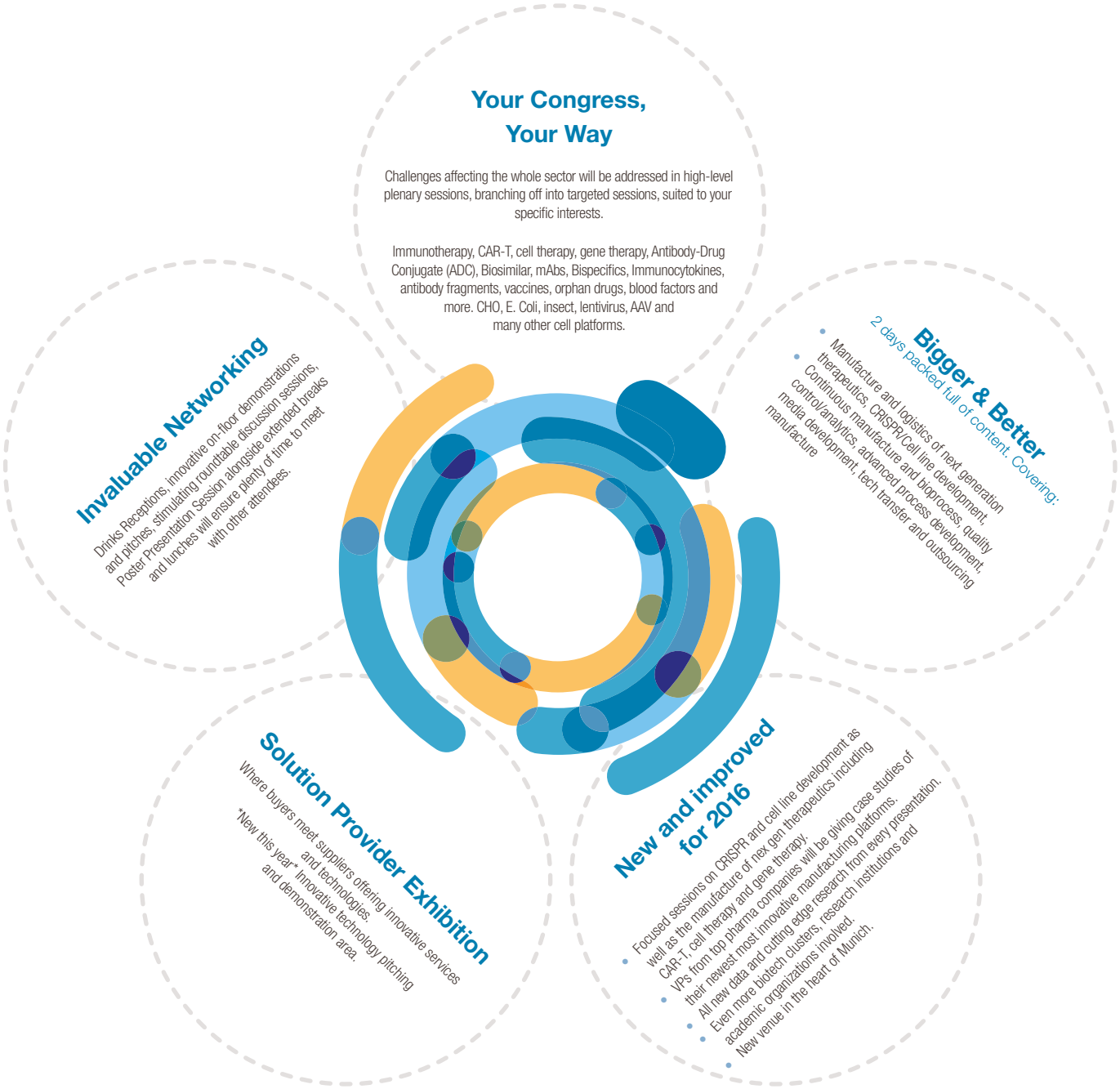
“THIS IS THE CELL CULTURE EVENT, WHERE YOU DISCUSS NOVELTIES, MEET THE MOST IMPORTANT PLAYERS, AND LEARN ABOUT THEIR OFFERS ON THE MARKET.”

Global Tech Transfer Manager | **Sandoz Biopharmaceuticals**

WHATS IN STORE FOR 2016?

The Cell Culture World Congress is where pharma, biotechs, researchers & innovative start-ups gather to develop new strategies and partnerships to advance biotherapeutic production, manufacture, and commercialisation. Join the largest cell culture event focused on producing new therapeutics and immunotherapies at a commercial scale and see where biologic manufacture is headed next.



For more information visit **terrapinn.com/CC2016** or to book visit:
terrapinn.com/RegisterCCWC16

10 REASONS TO ATTEND

1. Engage with 40+ high-level pharma and biotech speakers including Novartis, AstraZeneca, GSK, Genentech, Genzyme, Merck Serono, Sandoz, Bayer Pharma, UCB Pharma, GSK Vaccines and many more.
2. Learn from success stories in CAR-T, cell and gene therapy manufacture from Novartis, GSK, University of Pennsylvania, bluebird bio, Oxford Biomedica.
3. Explore the newest methods of CRISPR, genomics and gene editing with AstraZeneca, Horizon Discovery, Tokushima University, Dublin City University.
4. Top academic and research institutions will discuss the transfer of R&D into industry such as UCL, NC State University, BOKU, covering key issues in scale-up, quality control, novel methods for biomanufacture and PAT.
5. Examine how continuous manufacture and bioprocess has been physically implemented in case studies from key players, how they have laid out their business case as well as exploring best practices upscale and quality control from Genzyme Sanofi, Bayer Pharma and Sandoz.
6. Hear how industry leaders like Merck Serono, GSK & Oxford Biomedica are upgrading their process to include new modalities such as biosimilars and cellular therapies as well as making them cheaper and more cost effective.
7. See the newest methods in quality control and analytical technology from ETH Group, Institute of Thermal Process Engineering and Technology explore developmental updates and new emerging technologies.
8. Get updated on newest innovative technologies for optimising your manufacture at our first On-floor Innovation Showcase with Miltenyi Biotec, Purolite, Chemometec and Synentech already involved.
9. Collocated with the Downstream Processing World Congress featuring presentations from BioMaran, GSK, Janssen, Synthon, Oxford Biomedica, MayoClinic, IBET, UCL, TU Wein & Bamboo Therapeutics.
10. Network with 400 international, Cell Culture stakeholders over 2 days. Meet and do business with representatives from big pharma, biotech, investors, clinicians and researchers.

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“VERY GOOD AND DIVERSE PROGRAM. EXCELLENT ORGANIZATION”

Chief Scientist & Head of Cell Culture | **Bayer Pharma Germany**

SPOTLIGHT ON SPEAKERS

Specialists in CRISPR, cell line development and next gen therapeutics

Dr Stefan Wildt, VP, Global Head Technical Research and Development, Cell- and Gene Therapies, **Novartis**

In support of Novartis' growing cell- and gene therapy portfolio Stefan and his team are responsible for setting the integrated process development strategy and its execution. Stefan joined Novartis as Global Head of Integrated Biologics Profiling, a unit focused on the early development of the Biologics portfolio at Novartis.

Stefan will be making a keynote presentation on 'Manufacturing immunotherapy: new manufacturing paradigm for biomanufacture' and will discuss producing redirected T-cells on an industrial scale from start to finish, developing a process for a complex product and tackling variability and controlling quality.

Dr Lorenz Mayr, VP Reagents & Assay Development, **AstraZeneca**

Lorenz Mayr's role includes generation of proteins and cell lines for hit finding, hit-to-lead and lead optimisation activities including structure & biophysics activities across all therapeutic areas, the generation of tool antibodies, transgenic animals, stem cells and primary cells as tools for target validation studies and lead optimisation programmes.

Lorenz will be making a keynote presentation on using CRISPR for cell line development for preclinical drug discovery, transcriptomics to analyse the effect of reagents on cells and phenotypic screening of recombinant iPSC cell lines.

Bo Kara, Head Process Development, Advanced Therapy Delivery, **GSK**

Bo Kara has over 25 years' experience in designing research and development programmes to develop scaleable and validatable manufacturing processes for recombinant protein products. He has published widely and is primary inventor on a range of process/expression patents. He has developed a keen understanding of the technical, regulatory and commercial issues faced at each stage of the development of manufacturing processes for biopharmaceuticals.

Bo Kara will be discussing manufacturing ex-vivo cell & gene therapy for rare disease and oncology applications, expression and manufacturing platforms for lentivirus production and CAR-T, upscaling to improve patient access and attempting to answer the question: 'what does the future hold for this area of manufacturing?'

Dr Helene Faustrup Kildegaard, Co-Principal Investigator, The Novo Nordisk Foundation Center for Biosustainability, **Technical University of Denmark**

Helene Faustrup Kildegaard's current research focuses on applying 'omics data and developing efficient genome editing tools to engineer CHO cell factories for increased production and improved quality of therapeutic proteins.

Helene will present the application of omics data, screening and genome editing to improve CHO cell factories. She will cover. an update on strategies to engineer improved CHO cell factories, predictive host cell line engineering with target integration and increasing the efficiency of precise gene editing to improve product yield and quality.

Mark D. Angelino, SVP, Pharmaceutical Sciences, **bluebird bio**

Mark Angelino manages the development, analytical development/QC, and clinical manufacturing functions for both bluebird's lentiviral vector materials and autologous drug products. He has worked on small-molecule, peptide, biologic, bioconjugate, oligonucleotide, and complex mixture development programs through various companies including Momenta Pharmaceuticals, Millennium Pharmaceuticals, and Bristol-Myers Squibb..

Mark will be discussing CMC considerations for manufacturing gene and CAR-T cell therapies. He will cover robust, scalable, and controlled processes for product commercialization. Advancements in process robustness, analytics, and work flows will also be discussed. Automation, scalability and cost, as well as appropriate tracking of products will be considered.

SPOTLIGHT ON SPEAKERS

Experts in cell and gene therapy

Sam Wadsworth, CSO, **Dimension Therapeutics**

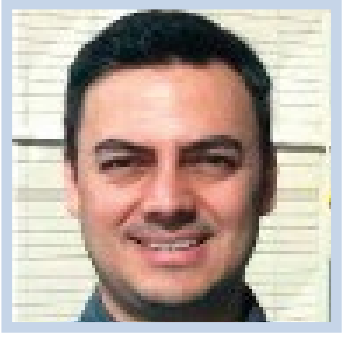
Dr. Wadsworth brings extensive drug discovery and development experience in the gene therapy and rare disease area. In his more than 20 years of industry experience at Genzyme and later Sanofi, he oversaw the discovery and translational research on multiple rare disease and gene therapy programs, including Genzyme's only clinical stage gene therapy program./ Close –

Most recently before joining Dimension, he served as the head of gene therapy research and early development at Sanofi Genzyme. Previously, he served as group vice president for translational research at Genzyme.

James Miskin, Chief Technical Officer, **Oxford BioMedica**

James Miskin has significant experience in GxP assay development, routine testing, manufacturing, manufacturing development and analytical development. In his current role as Chief Technical Officer (CTO), he is a member of the company's senior executive team (SET) with overall leadership responsibility for two teams within the Company: Manufacturing and Manufacturing Development. The Manufacturing team is responsible for routine GMP production, supply chain and oversight of technical programmes with strategic partners, including Novartis and Sanofi.

James will speak on GMP production strategies for lentiviral vector, process design, development and scale up. As well as improving quality and purity while decreasing cost and tackling the challenges of commercialization.



Dr Felipe Bedoya, Director of the Product Development Laboratory, Translational Research Program, **University of Pennsylvania**

Dr. Bedoya joined the Translational Research Program at the University of Pennsylvania as part of the Process Development team. In January 2014, Dr. Bedoya transitioned into the role of Director of the Product Development Laboratory. Dr. Bedoya has been recipient of several research training grants and has co-authored original research articles in the areas of immunology and leukemia.

His presentation will cover GMP considerations for autologous CAR-T cell therapy, isolation, optimisation and improving the timescale of cellular therapy. He will consider the major challenges in upscaling a T-Cell trials and future considerations and automation of immunotherapy manufacture, as well as what actions need to be taken.

Josh Grieger, Co-founder and Vice President of Manufacturing, **Bamboo Therapeutics**

Josh Grieger has dedicated his career to gene therapy with much of his research focused on the basic biology of Adeno-associated virus (AAV) and development of processes for large scale manufacturing of rAAV vectors for human gene therapy clinical trials. Prior to co-founding Bamboo Therapeutics, Dr Grieger was the Director of the Gene Therapy Center Vector Core Facility and Research Assistant Professor in the Ophthalmology Department at the University of North Carolina at Chapel Hill. Dr. Grieger has direct oversight of GMP, GLP and research grade AAV viral vector manufacturing, process development, technical training and technical writing.

Josh's presentation will be on process development for upstream AAV manufacture. He will detail Adeno-associated virus (AAV) vector design and scalable AAV manufacturing for Gene Therapy, new data on commercial scale manufacture of gene therapy and achieving a higher cell density.

Dr Arie van Oorschot, Senior Bioprocess Lead - Process Development, **uniQure N.V.**

As Sr Bioprocess Lead, he has an expert function throughout the different phases of development of manufacturing processes for gene-therapy products. Within uniQure, gene-therapy products are manufactured for commercial use (Glybera) and to supply products for different phases of clinical testing (phase I/II and III).

Arie will be talking through setting up a market scale vector manufacturing platform from scratch, proof of concept to GMP manufacturing, process development of market scale gene therapy. He will also touch upon improving robustness and quality and tackling the challenges of tech transfer & information flow.

SPOTLIGHT ON SPEAKERS

Leaders in the bioprocess industry

Dr Herve Broly, VP of Biotech Process Science, **Merck Serono**

Herve Broly's current research focus relates to the improvement of the Merck Serono technology platform for the manufacture of McAbs and Fc-fusion recombinant proteins, to applying Quality by Design approach for the manufacture of bulk drug substance, and to the development of novel approaches for downstream processing.

Herve's presentation will be on process development to control the quality in the continuous production of biosimilars. He will go into detail on creating a toolbox in order to adjust key quality attributes. He will be discussing developing process maintain viability and system of expression. Also analyzing critical care attributes to ensure maximum load.

Dr Yang Yang, Staff Scientist, Late Stage Process Development, **Genzyme Sanofi**

Yang Yang has been in the cell culture process development group for the past six years, where she has worked on projects such as high throughput model development, raw material investigation, and manufacturing support.

Yang will be giving one half of a two part case study for business case and implementation of continuous biomanufacture on behalf of Genzyme Sanofi. Yang will be examining the business drivers for an integrated and continuous biomanufacturing platform, the critical roles that cell culture medium and medium cost play in making such a platform financially viable and developing a cell culture medium to support very high cell densities and high productivities while maintaining low perfusion rates.

Dr Berthold Bödecker, Chief Scientist, Global Drug Discovery - Global Biologics Biotech Development, **Bayer Pharma AG**

Berthold Boedeker is responsible for the technical development and clinical material production of microbial and mammalian proteins. During his almost 30 years within the Bayer group he held several positions in research, development and production of proteins from mammalian cell culture, the last head of Cell Culture and Pilot Plants. In addition he is head lecturer for biotechnology at the Medical University of Essen, Germany.

Berthold will be giving an update on ballroom concept facilities for continuous manufacturing. He will also cover scale down model considerations for upstream, and future considerations for biomanufacturing: Process validation and characterization.

Dr Michael Pohlscheidt, Site Director External Manufacturing, Head of Asia Pacific Region, **Genentech Inc**

Michael Pohlscheidt leadership of senior professionals and cross functional management teams (including. Quality, Regulatory, Technology, Site Managers, Supply Chain, etc.) to ensure OTIF delivery, strategic site development as part of the external manufacturing network, development of strategic business plans, continuous improvement, BPM, relationship management, management of TMSA, etc. (virtual plant model).

Michael will be discussing outsourcing manufacture to the Asia-Pacific region. He will cover accelerated technology transfer and strategic CMO management, strategically managing benefit during collaboration and improving quality systems and working to a timescale in a still developing region.

Dr Alain Bernard, Vice-President, Biopharmaceutical Process Sciences, **UCB Pharma**

Alain Bernard is currently overseeing process developments for new chemical and new biological entities as well as for life-cycle management of marketed products. He joined UCB in 2006, from Serono where he was Director of Process Development. He has authored or co-authored many publications in biotechnology.

Alain will discuss process characterization using scale down, how to qualify and validate processes to quickly manufacture products as well as optimizing timelines and accelerating product to the clinic and using QbD ensure rapid development towards commercialization.

DAY 1 – TUESDAY 23RD FEBRUARY, 2016

CRISPR, Cell Line Development & Manufacturing New Formats

08:00	Registration opens
08:55	Chair's opening remarks

Opening Keynotes: New developments for cell culture in 2016

09:00

Manufacturing immunotherapy: new manufacturing paradigm for biomanufacture

- From start to finish, producing redirected T-cells on an industrial scale
- Developing a process for a complex product
- Tackling variability and controlling quality

Dr Stefan Wildt, VP, Global Head Technical Research and Development, Cell- and Gene Therapies, **Novartis**

09:25

A commercially viable novel CMC approach to bioprocessing AAV for rare diseases

- Creating a continuum for both upstream and downstream
- Viewing large scale manufacture from the very beginning: important considerations
- What are the main challenges associated with cost and scale-up and how are we tackling them?

Sam Wadsworth, CSO, **Dimension Therapeutics**

09:50

Manufacturing ex-vivo cell & gene therapy for rare disease and oncology applications

- Expression and manufacturing platforms for lentivirus production and CAR-T
- Upscaling to improve patient access
- What does the future hold for this area of manufacturing?

Bo Kara, Head Process Development, Advanced Therapy Delivery, **GSK**

10:15

Reserved for Platinum Partner
If you are interested in hosting this session call Toby Lomax on +44 207 092 1249

10:40 Networking refreshment break

11:40

Plenary Roundtable Discussion Session
8 senior level tables hosted by thought leaders on key challenges and opportunities in the manufacture of biologics. Participants are invited to join in the small-group discussions on a topic of primary importance to them. – if you are interested in hosting one of these sessions call **Toby Lomax** on **+44 207 092 1249**

Media Development **Reserved: Irvine Scientific**	Resolving the Complexity versus Time Conundrum in Process Development **Dr Sam Watts,** Commercial Technology Officer, **Stratophase**	Adapting the CHO host to express next generation therapeutics **Jamie Freeman, Product Manager, Horizon Discovery**	Continuous Manufacture/ Perfusion
Developing and Optimising your Chromatography Process	Manufacturing strategy	Purification of novel biologic formats	Analytical, Formulation and Quality

12:30

Speed Networking
A fun, exciting and effective way to make a lot of initial connections (in a very different environment from the standard business networking meetings).

12:45 Networking lunch

DAY 1 – TUESDAY 23RD FEBRUARY, 2016

CRISPR, Cell Line Development & Manufacturing New Formats

14:10

Keynote: Using CRISPR for cell line development for preclinical drug discovery

- Genome editing of isogenic cell lines for target validation and identifying the function of the genome
- Applications in target finding, hit & lead discovery, efficacy & safety models
- Transcriptomics to analyse the effect of reagents on cells
- Phenotypic screening of recombinant iPSC cell lines

Dr Lorenz Mayr, VP Reagents & Assay Development, **AstraZeneca**

14:35

CRISPR/Cell line development

Application of omics data, screening and genome editing to improve CHO cell factories

- An update on strategies to engineer improved CHO cell factories
- Predictive host cell line engineering with target integration
- Increasing the efficiency of precise gene editing to improve product yield and quality.

Dr Helene Faustrup Kildegaard, Co-Principal investigator, The Novo Nordisk Foundation Center for Biosustainability, **Technical University of Denmark**

Manufacture and logistics of next generation therapeutics

Immunotherapy, Cell Therapy & CAR-T production

GMP considerations for autologous CAR-T cell therapy

- Isolation, optimisation and improving the timescale of cellular therapy
- What are the major challenges in upscaling a T-Cell trial?
- Future considerations: automation of immunotherapy manufacture what actions need to be taken

Dr Felipe Bedoya, Director of the Product Development Laboratory, Translational Research Program, **University of Pennsylvania**

14:55

Genetically ensuring stability of CHO cell line

- Using RMCE recombinance mediated cells to produce targeted antibodies
- Digital PCR methods for analysing cell lines
- Selection, cultivation and cloning of favourable cells

Dr Hansjörg Hauser, Head of Department Gene Regulation and Differentiation, **Helmholtz Centre for Infection Research**

CMC considerations for manufacturing gene and CAR-T cell therapies

- Robust, scalable, and controlled processes for product commercialization
- Advancements in process robustness, analytics, and work flows
- Considerations of automation, scalability and cost, as well as appropriate tracking of products

Mark D. Angelino, SVP, Pharmaceutical Sciences, **bluebird bio**

15:15

The potential of CRISPR to engineer an improved CHO cell platform

- The pros and cons of different engineering technologies to improve CHO cell performance
- Using a hypothesis driven approach to engineer the next generation CHO platform
- Using an sgRNA screen to improve expression of “difficult to express” products

Jamie Freeman, Product Manager, **Horizon Discovery**

GMP production strategies for lentiviral vectors

- Process design, development and scale up
- Improving quality and purity while decreasing cost
- Tackling the challenges of commercialisation

James Miskin, Chief Technical Officer, **Oxford BioMedica**

15:50 Networking refreshment break

Save money and book early @ **terrapinn.com/CC2016**

DAY 1 – TUESDAY 23RD FEBRUARY, 2016

CRISPR, Cell Line Development & Manufacturing New Formats

16:35

Chromosome identification and stability in Chinese Hamster Ovary cells

- Stability difference of individual chromosomes
- The effect of chromosome number to antibody production
- Induction of chromosomal instability by cell fusion

Dr Noriko Yamano, Project-based Assistant Professor, Institute of Technology and Science, **Tokushima University**

Process development for upstream AAV manufacture

- Adeno-associated virus (AAV) vector design and scalable AAV manufacturing for Gene Therapy
- New data on commercial scale manufacture of gene therapy
- Achieving a higher cell density

Josh Grieger, Co-founder and Vice President of Manufacturing, **Bamboo Therapeutics**

16:55

The future of cell line development – regulatory, logistic and financial considerations

DNA Sequencing of cell lines to increase yield, quality & time for production of biologics

- Upregulating expression of anti-death genes in cells, to maintain viability increasing production
- Engineering cells to grow faster, increase cell densities & decreases time production of recombinant protein
- Decreasing operating costs

Reserved for supporting partner call Toby Lomax on +44 207 092 1249

Gene Therapy and Vaccine Production

Tackling the challenges of scale-up, quality and cost in gene therapy production

- Innovation in viral vector development, generation, and production;
- Intensification of rAAV manufacturing
- Improved optimisation and quality of baculovirus

Dr Otto-Wilhelm Merten, Head of the Applied Vectorology and Innovation Group, **Généthon**

17:15

Building a 'tool box' of various genetic and process related tools to fine tune cell line to your product

- Improving cell line stability through genetic manipulation
- Tackling the production bottlenecks of newer molecules
- Advanced bioinformatics, posttranslational modification and ensuring correct glycosylation

Dr Niall Barron, Programme Leader, Mammalian Cell Line Engineering, **Dublin City University**

Setting up a market scale vector manufacturing platform from scratch

- Proof of concept to GMP manufacturing
- Process development of market scale gene therapy
- Improving robustness and quality
- Tackling the challenges of tech transfer & information flow

Dr Arie van Oorschot, Senior Bioprocess Lead - Process Development, **uniQure N.V.**

17:35

Host cell proteins in biotechnology-derived products: A risk assessment framework: Host cell protein risk assessment

Dr Christina de Zafra, Senior Scientist, **Genentech (invited)**

Ensuring optimal processes for vaccines and producing new vaccine related formats

- Developing an efficient process for RSV pre-fusion F vaccine
- Tackling the challenges of manufacturing new RNA vaccines involving in vitro transcription
- Process development to ensure cost effective processes – focus on robustness and efficiency

Dr Mark Wilson, Head of US Drug Substance Technical Development, **GSK Vaccines**

17.55 Chairperson's closing remarks

18.00 Networking drinks reception

Save money and book early @ **terrapinn.com/CC2016**

DAY 2 – WEDNESDAY 24TH FEBRUARY, 2016

Continuous Bioprocess, Control and Design

08.00	Registration Opens, Morning Refreshments
09.00	Chairman's opening remarks

Continuous manufacture and bioprocessing

09.05

KEYNOTE: Genzyme: A two part case study for business case and implementation

1. UPSTREAM - Media development toward high cell density, high productivity and low perfusion rates for continuous biomanufacturing platforms

- Examining the business drivers for an integrated and continuous biomanufacturing platform
- The critical roles that cell culture medium and medium cost play in making such a platform financially viable
- Developing a cell culture medium to support very high cell densities and high productivities while maintaining low perfusion rates

Dr Yang Yang, Staff Scientist, Late Stage Process Development, **Genzyme Sanofi**

2. DOWNSTREAM - Rethinking downstream process monitoring for implementation of continuous bioprocessing

- Ensuring robust process performance using process monitoring and control
- Tackling the main challenges in monitoring of continuous downstream process such as large number of cycles,
- large amount of data and need for real time analysis
- Addressing these challenges using automated, real time data analysis, allowing real time decisions

Dr Yogesh Waghmare, Staff Scientist, Late Stage Process Development, **Genzyme Sanofi**

09.55

Future considerations for biomanufacturing: Process validation and characterisaion

- Scale down model considerations for upstream
- Lifecycle management guidelines: post-approval cell line changes requirements risks and benefits
- An update on 'ballroom' concept for continuous manufacture

Dr Berthold Bödecker, Chief Scientist, Global Drug Discovery - Global Biologics Biotech Development, **Bayer Pharma AG**

10.15

Designing the biomanufacturing of the future

- Steps from fed batch stainless steel to continuous single use concept
- Increasing the manufacturing capacities in the shortest possible time
- Challenges on that way and how to overcome them

Dr Sasa Stojkovic, Global Tech Transfer Manager, **Sandoz Biopharmaceuticals (invited)**

10.35	Networking refreshment break

Media and Accelerated Process Development

11.30

Using process development to control the quality of biopharmaceuticals

- Identification of critical quality attributes
- Creating a toolbox in order to adjust key quality attributes
- Experimental designs
- Analytical tools

Dr Herve Broly, VP of Biotech Process Science, **Merck Serono**

11.50

Process characterisation using scale down

- How to qualify and validate processes to quickly manufacture products
- Optimising timelines and accelerating product to the clinic
- Using QbD ensure rapid development towards commercialisation

Dr Alain Bernard, Vice-President, Biopharmaceutical Process Sciences, **UCB Pharma**

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DAY 2 – WEDNESDAY 24TH FEBRUARY, 2016

Continuous Bioprocess, Control and Design

12.10	**Process development of perfusion systems for CHO and stem cell systems** • How to tackle the challenges in quality control when adopting a perfusion system • Control strategies for continuous bio manufacture and glycosylation • An update on processes using established recombinant cell lines and human stem cell bioprocessing **Dr Véronique Chotteau,** Principal Investigator, Cell Technology Group, School of Biotechnology - Div. of Bioproduction, **KTH - Royal Institute of Technology**
12.45	**New paradigms in bioproduction culture media development** *If you are interested in hosting this session call Toby Lomax on +44 207 092 1249*
13.00	Networking Lunch
14.30	**Exploring the effects of cell culture media on therapeutic protein quality: an update** *If you are interested in hosting this session call Toby Lomax on +44 207 092 1249*
	Quality Control/Analytics
14.50	**In-depth characterisation analytics in continuous biomanufacturing** • Producing vaccines and virus like particles using perfusion • Improving understanding on a molecular level to achieve consistent product using perfusion • Process control and analytics during continuous processing **Prof Alois Jungbauer,** Head of Bioprocess Engineering, **BOKU**
15.10	**Advanced multivariate analysis for the production of biosimilars** • Hybrid statistical methods for increased quality and decreased cost of production • Decreasing the risk of selecting a cell, medium or nutrition • Qualification and validation of development of biosimilars **Dr Alessandro butte,** Senior Researcher, **ETH Group**
15.30	**Process development: ensuring the highest/sustainable level of product quality** • Developing faster & more accurate analytics • Ensuring product control, which parameters are more sensitive than others • Important considerations when moving from batch to continuous **Prof Dr Jochen Strube,** Professor, **Institute of Thermal Process Engineering and Technology**
15.50	**Automation tools and logistics: solutions for quality control** *If you are interested in hosting this session call Toby Lomax on +44 207 092 1249*
16.10	Afternoon Refreshments
	Tech Transfer and Outsourcing Manufacture
16.50	**Outsourcing manufacture to the Asia-Pacific region** • Accelerated technology transfer and strategic CMO management • Strategically managing benefit during collaboration • Improving quality systems and working to a timescale in a still developing region **Dr Michael Pohlscheidt, Site Director External Manufacturing, Head of Asia Pacific Region, Genentech Inc**
17.15	**Manufacturing a viral vector for gene therapy at the 2000L scale** • A virtual company's path to the largest manufacturing scale of an AAV vector to date • Viral safety for a virus-based process • Manufacturing at large scale with single-use systems – lessons learned **Barbara Thorne,** Previously Executive. Director Process/Product Development, **Celladon**
17.40	Closing remarks and thank you from Terrapinn
17.45	Close of Day Two

BIG TOPICS

Key themes for 2016

MANUFACTURE AND LOGISTICS OF NEXT GENERATION THERAPEUTICS

From cell and gene therapies to biosimilars, ADCs, antibody fragments, vaccines and much more we will be exploring the challenges in manufacture and logistics for these exciting new formats and applying them in case studies from the very best in the industry.

CRISPR/CELL LINE DEVELOPMENT

Learn how genome editing technology can affect different cell lines using multiplex genome engineering, CRISPR design and TAL design as we compare various technologies for specific applications, and managing off target effects.

CONTINUOUS MANUFACTURE AND BIOPROCESS

Many of the current blockbusters will be "running out of patent" during the next few years and there will be less, or even no blockbusters due to a shift towards stratified medicine. The trend towards stratified therapeutics will support a change in plant design aiming for highly flexible multi-purpose facilities for small production volumes.

QUALITY CONTROL/ANALYTICS

In the past decade, the FDA's process analytical technology (PAT) and Quality-by-Design (QbD) initiatives have been major drivers for developing well-understood, robust processes for assuring reproducible pharmaceutical product safety and efficacy. Industry trends are moving toward the implementation of automated PAT strategies that are designed to bring analytics closer to the operation, eliminate gaps in real-time process monitoring, and develop a more rapid, deeper understanding of the bioprocess

ACCELERATED PROCESS DEVELOPMENT

One of the major limitations of cell culture manufacture is speed. We will explore some of the innovations that are currently in development to improve the CHO cell platform, from cell line specific technologies to overarching technologies that are designed to improve the overall workflow of bioprocess development

TECH TRANSFER AND OUTSOURCING MANUFACTURE

Biopharmaceutical outsourcing has been growing steadily at 12–18%, along with the overall biopharma industry over the past five years. But recently their clients are allocating a greater percentage of their budgets for contracting out activities previously considered core business. We explore best practices in working with CMOs and cost efficiency in outsourcing and partnering in order to best get your cell culture product to market.

INNOVATIVE TECHNOLOGY SHOWCASE

Scientists around the world make use of cell culture techniques on a daily basis. They all face many of the same problems: slow growth, spontaneous differentiation, evaporation, contamination and a host of other issues that require troubleshooting. Recent advances in cell culture consumable technology have endeavored to solve many of these problems experienced by those at the bench and in industry and we will be showcasing them.

For more information visit **terrapinn.com/CC2016** or to book visit:
terrapinn.com/RegisterCCWC16

CO-LOCATED WITH

Downstream Processing World Congress 2016

The Downstream Processing World Congress 2016 will introduce new and exciting content focusing on innovation and development. With an emphasis on next gen therapeutics, new biologic modalities, novel separation and purification methods, continuous bioprocess, USP and DSP linker steps and much more you can't afford to miss it!

Discussion Topics Include:

- Purification approaches and platforms for next generation therapeutics: Cell and gene therapies with presentations from Bamboo Therapeutics and IBET.
- The newest methods, technologies and approaches for PAT, Process Modelling, Monitoring and Control from Oxford Biomedica, GSK and TU Wein.
- New approaches and platforms of purification of novel modalities: Orphan drugs, ADCs, blood factors and vaccines from NC State University and many more.
- Assessing whether continuous bioprocess really is cost efficient from the key players who are already implementing perfusion and continuous purification. Presentations from Genzyme Sanofi, Bayer Pharma, Sandoz and more.
- What the best options are for linking USP and DSP and the latest on primary recovery steps from UCL and Genentech.
- How far are we from commercialising novel and column free purification methods?

From process optimisation to commercial expansion and partnering, the Downstream Processing World Congress proudly welcomes 400 members of the bioprocess community to meet and do business in 2016.

Companies already involved:

Industry:

Genzyme Sanofi
Genentech
GSK
Johnson & Johnson
Oxford Biomedica
Bayer Pharma
Sandoz

Research & Academia:

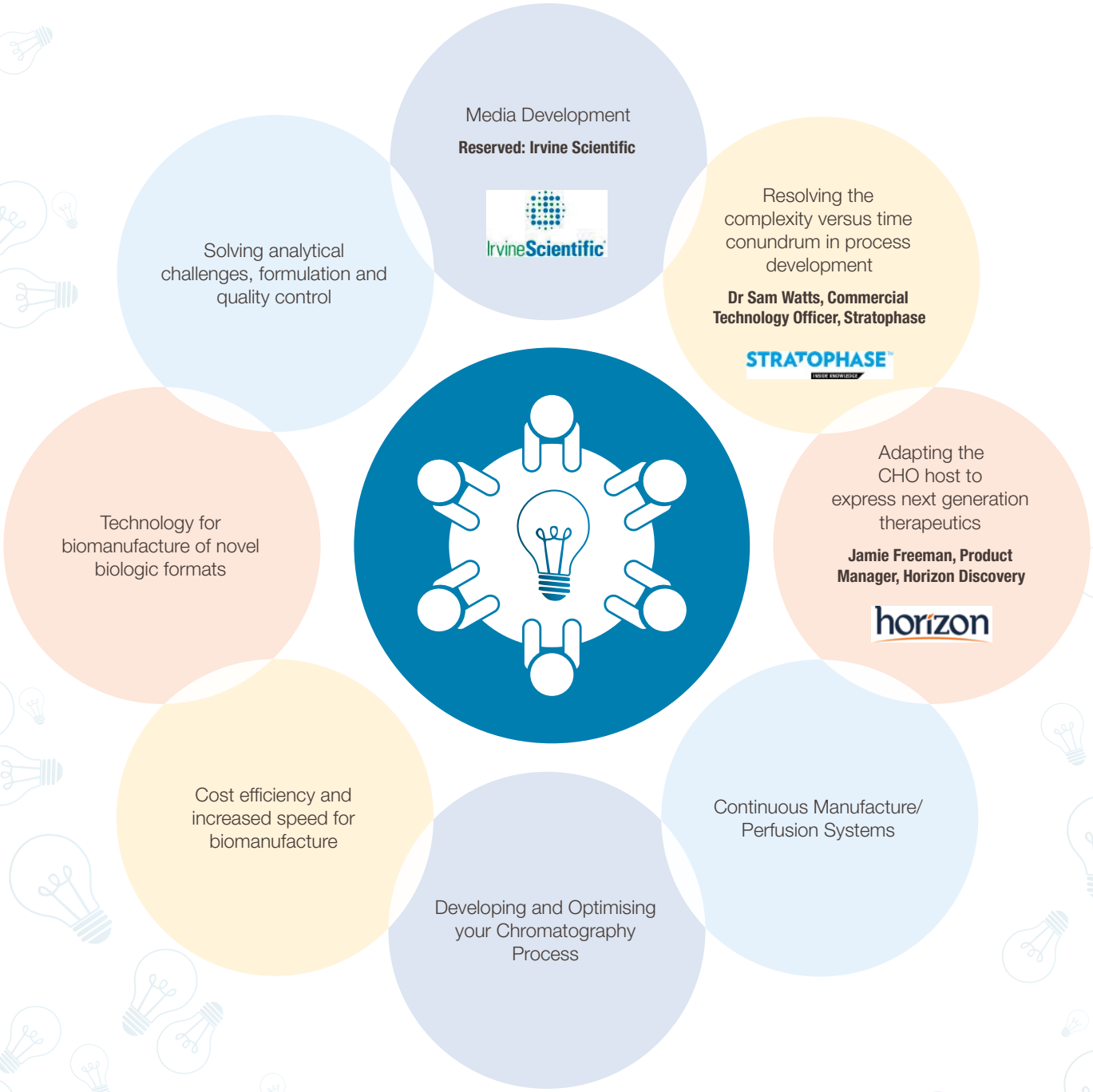
IBET
BOKU
ETH
NC State University
TU Wein
UCL
UNC Vector Core

Partnered with: BioM

More information is available @ **terrapinn.com/Downstream16**

ROUNDTABLES

As there is so much competition in the biomanfacturing sector it is now more important than ever that you keep up to date with the latest developments and what competitors are working on. The Cell Culture World Congress roundtable discussions do just this, they provide inside information that you can't get anywhere else.
Take time to hear from leading providers and authorities in the manufacturing space and exchange knowledge and ideas with your peers in these facilitated discussion sessions. Confirmed roundtable discussions include:



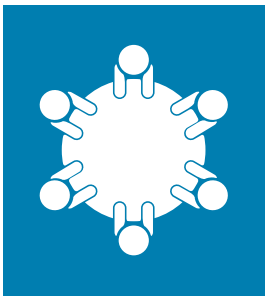
To host a roundtable, speak to **Jessica** e/ **jessica.robinson@terrapinn.com**

"VERY MUCH LIKED THE INTERACTIVE MEETING FORMAT WITH ROUNDTABLES & CLINICS. GOOD DISCUSSIONS AND MEETINGS."

Head Biotech Process Optimisation | **Insilico Biotechnology**

IT'S A NETWORKING EVENT

The Cell Culture World Congress recognizes the importance of networking and offers an experience which allows you to do just that.

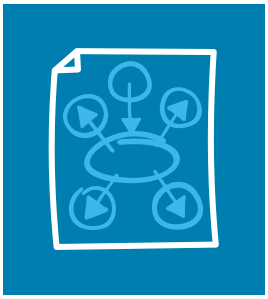


ROUNDTABLE DISCUSSIONS

With moderators to lead discussions on key topics, you will take your engagement and learnings to a new level in this interactive and results-driven setting.

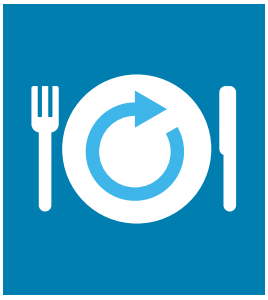
NETWORKING RECEPTION

It's not always about the conference sessions. Our themed evening networking drinks receptions both at the conference venue and off-site on days one and two will allow you to unwind with your peers and continue conversations in good company.



SCIENTIFIC POSTERS

Share research with leaders in the biomanufacturing sector. Posters allow for pharma, biotech and academia to present previously unpublished work. It will be possible for poster contributors to answer questions and gain feedback, during networking breaks.
Please see terrapinn.com/CC2016 for further details.



NETWORKING LUNCHES

Our extended lunch periods will provide you with ample time to network between sessions. These lunch formats allow for more opportunities for casual conversations and introductions, without compromising your time attending the conference sessions..

For more information visit **terrapinn.com/CC2016** or to book visit:
terrapinn.com/RegisterCCWC16

ON-FLOOR INNOVATION SHOWCASE

Seeking partnership, investment, licencing or looking to sell your technology? Want to hear about the latest innovative platforms? Looking to invest?

A new targeted session exploring the most innovative new platform technologies being developed towards biomanufacture and process development will take place. Attendees will have the chance to see innovative pitches of new technologies that could help them get their facility to the next level.

- Do you have a platform technology? You could be one of the 13 companies who will have the chance to pitch to a pharma and biotech audience.
- Hear about the latest pioneering platform technologies: Sit in on the pitching session to what is out there and see if you could take your antibody development process to the next level.
- Audience Participation: Give feedback, ask questions, make connections with innovators and perhaps form a new partnership.

How to get involved to get your technology in front of the right people.

Do you have a platform technology that you want to promote or sell? Are you looking for partnership, investment and licencing from big pharma and biotech companies?
As part of the inaugural On-floor Innovation Showcase, we are offering you the opportunity to apply for one of the 10 minute pitching slots available. To apply, speak to **Toby** on t/ **+44 207 092 1249** or email e/ **toby.lomax@terrapinn.com**

Companies already involved

chemometec

MACS Miltenyi Biotec

Purolite Life Sciences

SynenTec

DAY 1

Lunch	
13.00 - 13.10	**Available**
13.15 - 13.25	**Available**
13.45 - 13.55	**Synentec**
14.00 - 14.10	**Chemometec**
Afternoon break	
15.50 - 16.00	**Miltenyi Biotec**
16.05 - 16.15	**Available**

DAY 2

Morning break	
10.55 - 11.05	**Purolite**
11.10 - 11.20	**RESERVED**
Lunch break	
13.10 - 13.20	**Available**
13.25 - 13.35	**Available**
13.55 - 14.05	**Available**
14.10 - 14.20	**Available**

For more information speak to **Toby Lomax** on t/ **44 207 092 1249** or e/ **toby.lomax@terrapinn.com**

THE EXHIBITION

WHO SHOULD SPONSOR & EXHIBIT?

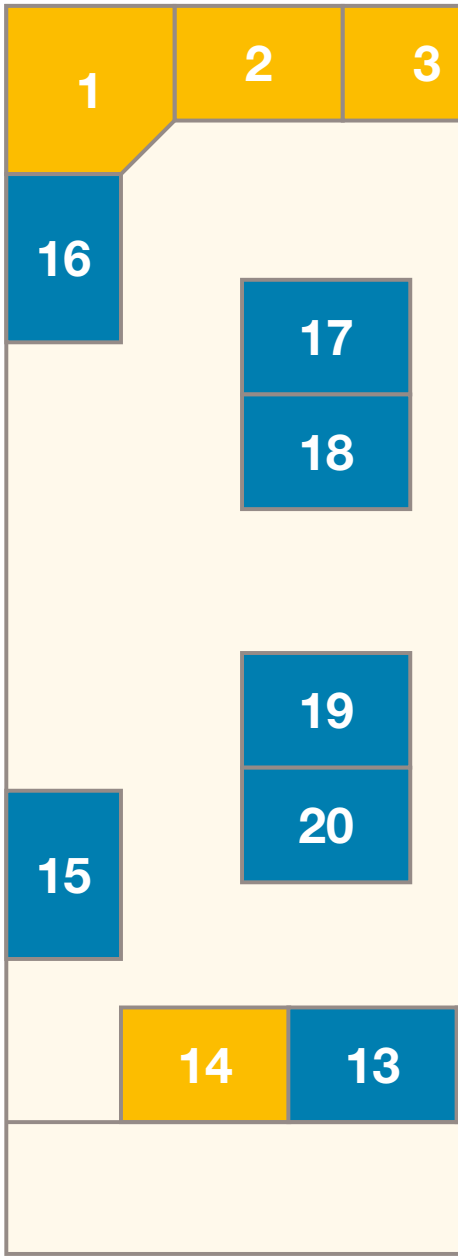
- Equipment providers
- CROs
- CMOs
- Media suppliers
- Cell line developers
- Platform Technology providers
- Bio-informatics and computational biology

WHY SPONSOR & EXHIBIT?

- Generate new business leads
- Position your organisation as genuine thought leaders and technical experts
- Build brand presence and awareness
- Forge strategic partnerships and joint ventures
- Showcase latest products
- Promote new services to prequalified buyers and decision makers

GET INVOLVED

- Book a stand
- Join our digital marketing campaign
- Help shape the event plans
- Invite your clients
- Book on-site meetings

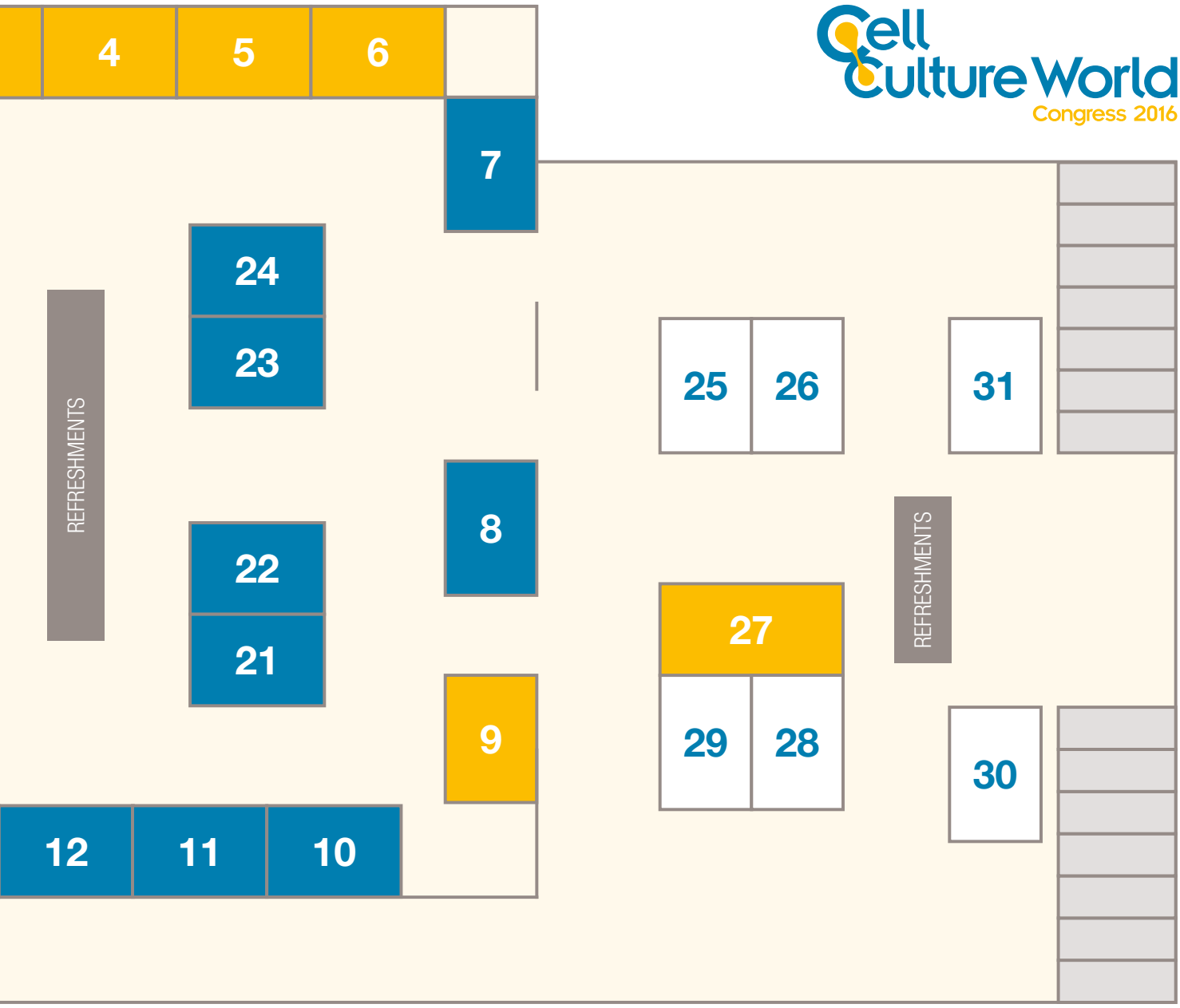


Contact **Toby Lomax** directly to tailor-make your package on **+44 207 092 1249** or email **toby.lomax@terrapinn.com**

CONFIRMED EXHIBITO

STAND NO.	COMPANY	STAND NO.
1	Reserved	6
2	–	7
3	–	8
4	–	9
5	–	10

Cell Culture World Congress 2016



** Last updated 21 September 2015*

SOLD RESERVED AVAILABLE

RS

COMPANY	STAND NO.	COMPANY	STAND NO.	COMPANY	STAND NO.	COMPANY	STAND NO.	COMPANY
—	11	JSR Life Sciences	16	Tosoh	21	Eppendorf	26	—
Irvine Scientific	12	Eurogentec/Kaneka	17	Stratophase	22	CerCell	27	—
KBI Biopharma	13	Alfa Wassermann	18	Labor Dr. Spranger	23	Chemometec	28	—
—	14	Reserved	19	Synentec	24	Purolite	29	—
Evonik	15	Novo Nordisk Pharmatech	20	Miltenyi Biotec	25	—	30	—

SPONSORSHIP AND EXHIBITION PACKAGES

BENEFITS	PLATINUM	GOLD	SILVER	EXHIBITOR	PLATFORM TECHNOLOGY PACKAGE
Keynote Plenary Presentation or Interview	1				
Track Presentation	1	1			
Roundtable Host	2	1	1		
Access to Networking Manager	Up to 12 meetings	Up to 8 meetings	Up to 5 meetings		
Delegate passes	6	3	2		
Exhibition booth	6sqm	6sqm	6sqm	6sqm	
On-Floor Innovation Showcase					1

Can't find a package that's right for you? Contact **Toby Lomax** on **+44 207 092 1249** or email **toby.lomax@terrapinn.com**

REGISTER YOUR PLACE TODAY

The earlier you book the more you'll save.

For the latest price see
terrapinn.com/CC2016

Delegate Booking

Package	Before 9 October	Before 13 November	Before 4 December	Before 15 January	Before 5 February	Final Price
Standard Package	£1280 **SAVE £480**	£1440 **SAVE £320**	£1520 **SAVE £240**	£1600 **SAVE £160**	£1680 **SAVE £80**	£1,760
Academic & Regulatory Package	£640 **SAVE £240**	£720 **SAVE £160**	£760 **SAVE £120**	£800 **SAVE £80**	£840 **SAVE £40**	£880
Display a Scientific Poster	£50					

BOOK NOW

Register at
terrapinn.com/CC2016
Or call **+44 (0) 207 092 1210**

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EVONIK INDUSTRIES

JSR Life Sciences MATERIALS INNOVATION

kaneka

KBI BIOPHARMA

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Purolite® Life Sciences

Spranger Laboratories

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TECHNOLOGY NETWORKS

For sponsorship and exhibition opportunities,
please contact **Toby Lomax** t/ **+44 (0) 207 092 1294** e/ **toby.lomax@terrapinn.com**
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