



BioProduction

2015

4x conferences, 1x forum, 1x exhibition

Benchmark technological developments
and explore best practices in biomanufacturing

14-15 October 2015

Citywest Hotel Conference & Event Centre | Dublin | Ireland

www.bio-production.com

1

Conference 1
**Continuous
Manufacturing**

3

Conference 3
**Manufacturing
Strategy &
Technology**

2

Conference 2
**Upstream Processing
– Production,
Development &
Analytics**

4

Conference 4
**Downstream
Processing**

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get one free***

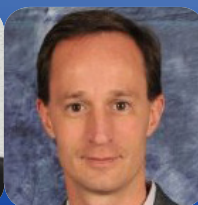
Academic price
£499*

SME/Industry start-ups
**50% off current
price tier!***

Global Panel of Senior Level Decision-Makers



Thilo Henckel
Vice President
Manufacturing
**Roche
Diagnostics
GmbH**



Trent Carrier
Vice President
Vaccine
Technology &
Engineering
Takeda Vaccines



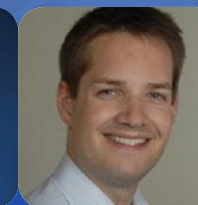
Roman Necina
Vice President
Process Science
& Technical
Operations
Baxalta



Paul McCormac
Director, Bio-
Manufacturing
Sciences Group
**Pfizer Global
Supply**



Sean McEwen
Vice President,
Biologics
Manufacturing,
AbbVie



Lars Dreesmann
Executive
Director,
Head of Clinical
Supply & Transfer,
**Boehringer
Ingelheim**



Joe Runner
Manufacturing
Technical
Specialist
Genentech



Weibing Ding
Principal
Scientist, Process
Development
Amgen Inc.

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Publication



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BioProduction and Ireland

The biopharmaceutical industry has made a capital investment of approximately \$8 billion in new facilities in Ireland. With most of this coming in the last 10 years, representing close to the biggest wave of investment in new biotech facilities anywhere in the world. Join us in Dublin this year for BioProduction!

Irish Biotech in Numbers



9 OF THE TOP 10

world's pharmaceutical companies



8TH LARGEST PRODUCER

of pharmaceuticals in the world



€55BN IN ANNUAL EXPORTS

world's pharmaceutical companies



120 PHARMACEUTICAL COMPANIES

operate in Ireland



33 FDA APPROVED

pharma & biopharma plants

Inspirational Speaker



Inspirational Speaker: Kevin Warwick

Kevin Warwick, Professor of Cybernetics carries out research in artificial intelligence, control, robotics and biomedical engineering.

Kevin's most recent research involves using intelligent computer methods to predict the onset of Parkinsonian tremors such that they can be stopped by means of a deep brain implant. This work was hailed in the Mail on Sunday as **"the most significant recent advance in biomedical engineering"**.

11+ Hours of Networking

BioProduction Networking Drinks Reception

Help celebrate the event by joining us for our networking drinks reception and evening entertainment. Catch up with your peers and discuss the latest development in the field in a more relaxed environment.



New Formats for 2015

BioProduction Interactive Hubs:

BioProduction Interactive Hubs will be expert-led and deliver case examples, interactive discussions, takeaway solutions and further action plans in focussed topic areas.



Join the Live Labs Tour and you will have insight into some of the most innovative equipment and services to hit today's biopharmaceutical market.



BioProduction Knowledge Exchange Roundtable Discussions:

Knowledge exchange roundtable discussions are highly interactive sessions where attendees can discuss and share solutions to common problems with other attendees in a less formal environment.



Present a Poster - €100 prize for top two plus exposure on BPI Online Poster Hall

Sponsored and judged by



To submit your poster and for additional details on deadlines, poster size and regulations, please visit:

www.bio-production.com



Live lab sessions were excellent and gave a great overview!

Chemist, Merck



Building on the success of last years' event we will be using the partneringOne networking tool at BioProduction. partneringOne is an industry recognised partnering system that allows you to:

- Arrange one-to-one meetings at the event
- Engage in pre-event discussions
- See a list of attendees

partneringONE® | a service of **EBD GROUP**

All meetings will be pre-arranged for you based on your availability, so maximise your time at BioProduction. All registered attendees are sent an email with the link to the BioProduction partneringOne site, along with their username and password. Please visit our event website **www.bio-production.com** for more details.

Agenda-at-a-Glance

PRE-CONFERENCE WORKSHOPS: 13 October 2015

Continuous Processing – Strategy, Technologies, Economics & Challenges

OR

The Challenge of Protein Aggregation and Sub Visible Particles in Biopharmaceuticals

CONFERENCE DAY ONE: 14 October 2015

Opening Plenary: Biomanufacturing and Facilities of the Future to Increase Productivity, Profitability and Product Quality

Morning Coffee and Start of **partneringONE®** | a service of **EBD GROUP**

1 CONTINUOUS MANUFACTURING	2 UPSTREAM PROCESSING – PRODUCTION, DEVELOPMENT & ANALYTICS	3 MANUFACTURING STRATEGY & TECHNOLOGY	4 DOWNSTREAM PROCESSING	5 OUTSOURCING, ALTERNATIVE EXPRESSION SYSTEMS AND E&L
Continuous Downstream Processing	High Throughput Tools & Scale Down Models	Flexible Facilities, Single Use and Facilities of the Future	Continuous Downstream Processing	Outsourcing Strategies, Quality Control and Supply Chain Management

Lunch and **LiveLab_s**

Knowledge Exchange Roundtable Discussions

Table 1: New Frontiers in Vaccine Manufacturing

Table 2: Facility Optimisation and Facility Utilisation Improvements to Maximise Capacity and Efficiency

Continuous Downstream Processing	Disposable Systems in Upstream Processing	Flexible Facilities, Single Use and Facilities of the Future	Continuous Downstream Processing	Alternative Expression Systems
	Novel Upstream Purification and Filtration Methods			

Afternoon Break

Continuous Downstream Processing	Process Analytics and Online Monitoring Methods	Manufacturing Strategies for Emerging Markets	Continuous Downstream Processing	Extractables & Leachables, Standardisation and Testing Strategies for Single Use Systems
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Closing Plenary - Inspirational Speaker: **Kevin Warwick**, *Professor of Cybernetics, The University of Reading, UK*

End of Day One and BioProduction Networking Drinks Reception

CONFERENCE DAY TWO: 15 October 2015

Opening Plenary: Cost Effective Manufacturing Strategies for More Complex Molecules

Morning Coffee

1 CONTINUOUS MANUFACTURING	2 UPSTREAM PROCESSING – PRODUCTION, DEVELOPMENT & ANALYTICS	3 MANUFACTURING STRATEGY & TECHNOLOGY	4 DOWNSTREAM PROCESSING
Single Use Technology in Continuous Manufacturing	Data Driven Decisions and Knowledge Management	Process Improvements and Change Control in Commercial Manufacturing	Purification Technologies to Improved Separation and Meet Upstream Demand

Lunch and **LiveLab_s**

Technology Evaluation and Facility Setup for Coupling USP and DSP	Cell Culture Media Development	Monitoring and Quality Control Strategies	Innovative Purification Techniques for More Complex Proteins and Problematic Molecules
			Application of Single Use Technologies in DSP

Afternoon Tea and Poster Awards

Validation Using Real-Time In Process Analytics	Raw Material Quality Control	Process Portability and Technology Transfer	Alternatives to Protein A
Regulatory Standards for Continuous Manufacturing			Characterisation and Validation of HTPD, Modelling and Robotics

End of Day Two

POST-CONFERENCE SYMPOSIUMS: 16 October 2015

Cost Effective Manufacturing Strategies For Novel, More Complex Molecules

OR

Knowledge Management Across The Product and Process Lifecycle

This year's programme will address the need for keynote presentations, new formats, interactive debate and take home messages.



Knowledge Exchange Roundtable Discussion



Interactive Hub



Single Use Technologies



Panel Discussion

1. CONTINUOUS MANUFACTURING

CONFERENCE DAY ONE: WEDNESDAY 14 OCTOBER 2015

07:30 Registration and Morning Coffee

08.20 Chairperson's Opening Remarks

Barry Heavey, Head of Life Sciences, **IDA Ireland**



Opening Plenary: Biomanufacturing and Facilities of the Future to Increase Productivity, Profitability and Product Quality

08:30 **ISPE 2014 Facility of the Year Awards Category Winner for Operational Excellence**

Facility Design for Operational Excellence

Guy McDonnell, Director of Engineering & EHS, **Pfizer**, Ireland



09:00 **Regulatory Feedback: Expectations for Biomanufacturing and Facilities of the Future**

A Representative, **Health Products Regulatory Authority**, Ireland



09:30 **Biomanufacturing Strategies That Respond to Changing Industry Demands**

Rob Noel, Commercial Manager, Continuous Processing Unit, **Pall Life Sciences**, UK



10.00 **Thought Leaders Discussion Panel: Biomanufacturing and Facilities of the Future**

Trent Carrier, Vice President, Vaccine Technology & Engineering, **Takeda Vaccines**, USA

Roman Necina, Vice President Process Science & Technical Operations, **Baxalta**, Austria

Thilo Henckel, Vice President Manufacturing, **Roche Diagnostics GmbH**, Germany

Ciaran Brady, Director, Biotech Technical Services/ Manufacturing Sciences, **Eli Lilly**

and Company, Ireland

David Wolton, Consultant, **PM Group**, Ireland



10.30 Morning Coffee and Start of **partneringONE®** | a service of **EBD GROUP**

11.15 Chairperson's Opening Remarks

Implementation of Continuous Downstream Processing

11.20 **Addressing Future Production Challenges by Process Intensification**

Margit Holzer, Scientific Director, **Ulysse Consult**, France



11.50 **Implementation of a Continuous Downstream Process**

Xavier Le Saoût, Associate Manager – Biotech Technology and Innovation, **Merck Serono**, Switzerland



12.20 **Spotlight Presentation:**

A Representative, **GE Healthcare**



12.50 Lunch and **LiveLab's**

14.10 **Implementation of Continuous Downstream Processing for Viral Product**

Sebastien Carayol, CMC Coordinator, Purification & Formulation Processes - Bioprocess R&D, **Sanofi Pasteur**, France



14.40 **Integrated Continuous Processing for the Manufacture of Monoclonal Antibodies**

Massimo Morbidelli, Institute for Chemical and Bioengineering, Department of Chemistry and Applied Biosciences, **ETH Zürich**, Switzerland



15.10 **Spotlight Presentation**

Application of QbD Concepts to a Final Sterile Filtration

Nick Hutchinson, Global Market Development Manager, **Parker Domnick Hunter**, UK



15.40 Afternoon Break

16.10 **Continuous Chromatography: The Need For Speed**

Daniel G. Bracewell, Reader, Department of Biochemical Engineering, **University College London**, UK



16:40 **Continuous Purification of Virus and Virus-Like Particles Using Multi-Column Chromatography Towards Increased Productivity and Process Robustness**

Ricardo Silva, Postdoc Researcher, **iBET**, Portugal



Inspirational Speaker

17:15 **Inspirational Speaker: Advances in Biomedical Engineering**

Kevin Warwick, Professor of Cybernetics, **The University of Reading**, UK



18.00 Closing Remarks

18.05 **BioProduction Networking Drinks Reception**





The development and optimisation of a semi-continuous downstream process, including continuous protein A capture for a monoclonal antibody and the feasibility to implement this process at manufacturing scale

Xavier Le Saoût, **Merck Serono** (Speaking at 11:50, Day 1)



CONFERENCE DAY TWO: THURSDAY 15 OCTOBER 2015

08.55 Chairperson's Opening Remarks

Plenary: Cost Effective Manufacturing Strategies for More Complex Molecules

09:00 **Transforming Production Processes and Strategies for Novel, More Complex Products**

Sean McEwen, Vice President, Biologics Manufacturing, **AbbVie**, Ireland



abbvie

09.40 **Thought Leaders Discussion Panel: Developing and Adapting Manufacturing Processes for More Complex Products**

Lada Laenen, Senior Director, Allston Landing Manufacturing Science and Technologies Head, **Genzyme Corporation**, USA



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10.20 Morning Break

11.00 Chairperson's Opening Remarks

Application of Single Use Technology

11.05 **High Cell Density, High Productivity, Long-Term Continuous Bioprocessing with Single-Use Bioreactors**

Neha Shah, Staff Scientist I; **Genzyme, A Sanofi Company**, USA



genzyme
A SANOFI COMPANY

11.35 **Evaluation of Single-Use Materials for Up- and Downstream Processing of Virus-Like Particles**

Ricardo Silva, Postdoc Researcher, **iBET**, Portugal



iBET

12.05 **In the Buffer Zone: Streamlining Downstream Operations to Improve Process Productivity and Throughput**

Jonathan Haigh, Head of R&D Downstream Processing Operations, **FUJIFILM Diosynth Biotechnologies**, UK



FUJIFILM
Diosynth
biotechnologies

12.35 Lunch and **LiveLab**

13:00 **Knowledge Exchange Roundtable Discussions**

Table 1: **New Frontiers in Vaccine Manufacturing**

Table 2: **Facility Optimisation and Facility Utilisation Improvements to Maximise Capacity and Efficiency**

Technology Evaluation and Facility Setup for Coupling USP and DSP

14.00 **Knowledge Exchange Roundtable Discussion:**

Technology and Process Evaluation for Coupling Upstream and Downstream to Improve Manufacturing Efficiency and Product Quality

Neha Shah, Staff Scientist I; **Genzyme, A Sanofi Company**, USA

Massimo Morbidelli, Institute for Chemical and Bioengineering, Department of Chemistry and Applied Biosciences, **ETH Zürich**, Switzerland



15.00 **Filling the Void; The Key Element of Continuous Processing**

Marc Bisschops, Principle Scientist, **Pall Life Sciences**, The Netherlands



PALL Life Sciences

15.30 Afternoon Tea and Poster Awards

Validation Using Real-Time In Process Analytics

16.00 **Spectroscopic Monitoring of Continuous Bioprocessing for Knowledge Based Process Control**

Dörte Solle, Research Assistant, Institute of Technical Chemistry, **Leibniz Universität Hannover**, Germany



16:30 **A Development Strategy for Continuous Processing Using Concomitant Impurity Monitoring**

Christoph Herwig, Head Biochemical Engineering, **Vienna University of Technology**, Austria



TU WIEN
TECHNISCHE UNIVERSITÄT WIEN
Vienna University of Technology

Regulatory Standards for Continuous Manufacturing

17:00 **Regulatory Expectations and Standards for Continuous Manufacturing**

A Representative, **FDA Center for Drug Evaluation and Research (CDER)**, USA
(awaiting final confirmation)

17:30 Chairperson's Closing Remarks and End of Day Two

Media partners



2. UPSTREAM PROCESSING – PRODUCTION, DEVELOPMENT

CONFERENCE DAY ONE: WEDNESDAY 14 OCTOBER 2015

- 07:30 Registration and Morning Coffee
- 08:20 Chairperson's Opening Remarks
Barry Heavey, Head of Life Sciences, **IDA Ireland**



IDA Ireland

Opening Plenary: Biomanufacturing and Facilities of the Future to Increase Productivity, Profitability and Product Quality

- 08:30 **ISPE 2014 Facility of the Year Awards Category Winner for Operational Excellence**
Facility Design for Operational Excellence
Guy McDonnell, Director of Engineering & EHS, **Pfizer**, Ireland



- 09:00 **Regulatory Feedback: Expectations for Biomanufacturing and Facilities of the Future**
A Representative, **Health Products Regulatory Authority**, Ireland



- 09:30 **Biomanufacturing Strategies That Respond to Changing Industry Demands**
Rob Noel, Commercial Manager, Continuous Processing Unit, **Pall Life Sciences**, UK



- 10:00 **Thought Leaders Discussion Panel: Biomanufacturing and Facilities of the Future**
Trent Carrier, Vice President, Vaccine Technology & Engineering, **Takeda Vaccines**, USA
Roman Necina, Vice President Process Science & Technical Operations, **Baxalta**, Austria
Thilo Henckel, Vice President Manufacturing, **Roche Diagnostics GmbH**, Germany
Ciaran Brady, Director, Biotech Technical Services/ Manufacturing Sciences, **Eli Lilly and Company**, Ireland
David Wolton, Consultant, **PM Group**, Ireland



- 10:30 Morning Coffee and Start of **partneringONE** | a service of **EBD GROUP**

- 11:15 Chairperson's Opening Remarks

Application of High Throughput Tools & Scale Down Models

- 11:20 **Transforming Fermentation Process Development with a High-Throughput Automated Bioreactor System**
Bob Kuczynski, Engineer II, **Genentech**, USA



Genentech
A Member of the Roche Group

- 11:50 **Case Studies for Utilisation of Conventional and CFD Approaches for Successful Scale Up and Scale Down of Bioreactor Processes for Monoclonal Antibodies**
Michelle LaFond, Director, Bioreactor Scale-Up and Development; **Regeneron Pharmaceuticals**, USA



- 12:20 **Spotlight Presentation: Virus Removal in Cell Culture Media with Planova Nanofiltration**
Bixente Martirene, MSc Chem Eng, Senior Product Manager Europe, **Asahi Kasei Bioprocess Europe**, France



Asahi Kasei
BIOPROCESS

- 12:50 Lunch and **LiveLab**

- 14:10 **Engineering Challenges in the Validation of CHO Processes in Scale Down Models**
Detlef Eisenkraetzer, Director Fermentation Development, Pharma Technical Development Biologics Europe, **Roche Diagnostics GmbH**, Germany



Application of Disposable Systems in Upstream Processing

- 14:40 **Development and Implementation of New Cellbag™ Film Suitable for Commercial Biopharmaceutical Production through Collaboration between End User and Supplier**
Weibing Ding, Principal Scientist, Process Development, **Amgen Inc.**, USA
Sara Ullsten, **GE Healthcare**, Sweden



- 15:10 **Novel Upstream Purification and Filtration Methods to Improve Yield and Reduce Manufacturing Steps**
Alexei M. Voloshin, Global Scientific Services Leader, Life Science Process Technologies, 3M Purification, **3M**, USA



- 15:40 Afternoon Break

Implementation of Process Analytics and Online Monitoring Methods

- 16:10 **Implementation of Raman Spectroscopy as a PAT Technology in Cell Culture Processes**
Bart Royens, Operational Director & Technical Support, **Genzyme Flanders**, Belgium
- 16:40 **How Analytics are used in the Processing/Release of Biologics**
Jette Wypych, Senior Scientist, **Amgen**, USA

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Inspirational Speaker

- 17:15 **Inspirational Speaker: Advances in Biomedical Engineering**
Kevin Warwick, Professor of Cybernetics, **The University of Reading**, UK



The University of Reading

- 18:00 Closing Remarks



- 18:05 **BioProduction Networking Drinks Reception**



CONFERENCE DAY TWO: THURSDAY 15 OCTOBER 2015

08.55 Chairperson's Opening Remarks

Plenary: Cost Effective Manufacturing Strategies for More Complex Molecules

09:00 **Transforming Production Processes and Strategies for Novel, More Complex Products****Sean McEwen**, Vice President, Biologics Manufacturing, **AbbVie**, Ireland

abbvie

09.40 **Thought Leaders Discussion Panel: Developing and Adapting Manufacturing Processes for More Complex Products****Lada Laenen**, Senior Director; Allston Landing Manufacturing Science and Technologies Head, **Genzyme Corporation**, USAgenzyme
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10.20 Morning Break

11.00 Chairperson's Opening Remarks

Data Driven Decisions and Knowledge Management

11.05 **Interactive Hub:****Information Knowledge Management & Data Storage Systems to Improve Decision Making in Biomanufacturing***This interactive hub will be expert-led and deliver short case study examples followed by interactive discussions and takeaway solutions.*

- Application of information management systems for centralised data storage and to improve decision making in biomanufacturing
- Methods and tools for faster data processing and knowledge management
- High Throughput Systems: Translation from data to knowledge outcomes
- Continuous Manufacturing
- Management and translation of knowledge outcomes from large amounts of continuous data using validated data sources
- How to use data to manage consistent performance and stable production in continuous systems

Robert Heckathorn, Associate Director, **MedImmune, LLC**, USAA Representative, **IDBS**12.05 **Spotlight Presentation**A Representative, **IDBS**12.35 Lunch and **LiveLab_s**13:00 **Knowledge Exchange Roundtable Discussions**Table 1: **New Frontiers in Vaccine Manufacturing**Table 2: **Facility Optimisation and Facility Utilisation Improvements to Maximise Capacity and Efficiency**

Cell Culture Media Development

14.00 **Computational Fluid Dynamics (CFD) as Tool to Improve Scale Up/Scale Down of Cell Culture Media Preparation****Martina Berger**, Associate Director Cell Culture Development, **Boehringer Ingelheim Pharma GmbH & Co. KG**, GermanyBoehringer
Ingelheim14:40 **Comparison of Clone Screening in Liter Scale Bioreactors, a Miniaturised Bioreactor System and Shake Flasks****Benjamin Neunstoecklin**, Post Doc, **Novartis**, Switzerland

NOVARTIS

15.00 **Spotlight Presentation**A Representative **GE Healthcare**

15.30 Afternoon Tea and Poster Awards

16:00 **Feedback from Baxter BioScience****Philippe Baumgartner**, Head of Technical Operations, **Baxter BioScience**, SwitzerlandBaxter
BioScience

Raw Material Quality Control

16.30 **Understanding Raw Material Variability in Manufacturing using a Lab Scale Model****Geraldine Kelly**, Technical Services/Manufacturing Science (TS/MS) Cell Culture Scientist, **Eli Lilly**, Ireland

Lilly

17:00 **Understanding the Effects on Colour Formation of a Glycoprotein in Cell Culture****Eimear O'Donovan**, Principal Scientist / Manager Proteins Development, MSAT, **Pfizer Biotech**, Ireland

Pfizer Biotech

17:30 Chairperson's Closing Remarks and End of Day Two

3. MANUFACTURING STRATEGY & TECHNOLOGY: FLEXIBLE

CONFERENCE DAY ONE: WEDNESDAY 14 OCTOBER 2015

07:30 Registration and Morning Coffee

08:20 Chairperson's Opening Remarks

Barry Heavey, Head of Life Sciences, **IDA Ireland**



Opening Plenary: Biomanufacturing and Facilities of the Future to Increase Productivity, Profitability and Product Quality

08:30 **ISPE 2014 Facility of the Year Awards Category Winner for Operational Excellence**

Facility Design for Operational Excellence

Guy McDonnell, Director of Engineering & EHS, **Pfizer**, Ireland



09:00 **Regulatory Feedback: Expectations for Biomanufacturing and Facilities of the Future**

A Representative, **Health Products Regulatory Authority**, Ireland



09:30 **Biomanufacturing Strategies That Respond to Changing Industry Demands**

Rob Noel, Commercial Manager, Continuous Processing Unit, **Pall Life Sciences**, UK



10:00 **Thought Leaders Discussion Panel: Biomanufacturing and Facilities of the Future**

Trent Carrier, Vice President, Vaccine Technology & Engineering, **Takeda Vaccines**, USA

Roman Necina, Vice President Process Science & Technical Operations, **Baxalta**, Austria

Thilo Henckel, Vice President Manufacturing, **Roche Diagnostics GmbH**, Germany

Ciaran Brady, Director, Biotech Technical Services/ Manufacturing Sciences, **Eli Lilly and Company**, Ireland

David Wolton, Consultant, **PM Group**, Ireland



10:30 Morning Coffee and Start of **partneringONE**® a service of **EBD GROUP**



11:15 Chairperson's Opening Remarks

Flexible Facilities, Single Use and Facilities of the Future

11:20 **Coping with Complexity in a Multi-Product Facility by Systematic Continuous Improvement**

Thomas Oppolzer, Executive Director Downstream Manufacturing H84 & BioMES, **Boehringer Ingelheim**, Germany



11:50 **Transfer and Implementation of a New Process, Combining Single-Use and Stainless Steel: A Successful Case Study**

Lars Dreesmann, Executive Director, Head of Clinical Supply & Transfer, Biopharma Bioprocess & Pharmaceutical Development, **Boehringer Ingelheim**, Germany



12:20 **Expression and Disposable Technologies for Accelerated Development of Biopharmaceuticals**

Torben Frandsen, Vice President, Process Development, **CMC Biologics**, Denmark



12:50 Lunch and **LiveLab**



14:10 **Biopharmaceuticals of the Future: Adapting Facilities for Smaller Volume & Specialised Products**

Oliver Fay, Project Engineer, **Janssen Biologics**, Ireland



14:40 **Facility of the Future**

Alain Pralong, VP NPI & TLM, **GSK Vaccines**, Belgium



15:10 **Spotlight Presentation: Key Considerations in Stability Studies for Biopharmaceuticals**

Stella Chotou, Team Leader, Stability Services, **SGS Life Science Services**, UK



15:40 Afternoon Break

Manufacturing Strategies for Emerging Markets

16:10 **Key Success Factors for Manufacturing in Emerging Markets**

Roman Necina, Vice President Process Science & Technical Operations, **Baxalta**, Austria



16:40 **Knowledge Exchange Roundtable Discussion:**

Strategies for Manufacturing, Evaluating and Entering Emerging Markets

Trent Carrier, Vice President, Vaccine Technology & Engineering, **Takeda Vaccines**, USA



Inspirational Speaker

17:15 **Inspirational Speaker: Advances in Biomedical Engineering**

Kevin Warwick, Professor of Cybernetics, **The University of Reading**, UK



18:00 Closing Remarks

18:05 **BioProduction Networking Drinks Reception**



FACILITIES, SINGLE USE, CHANGE AND QUALITY CONTROL

CONFERENCE DAY TWO: THURSDAY 15 OCTOBER 2015

08.55 Chairperson's Opening Remarks

Plenary: Cost Effective Manufacturing Strategies for More Complex Molecules

09:00 **Transforming Production Processes and Strategies for Novel, More Complex Products**

Sean McEwen, Vice President, Biologics Manufacturing, **AbbVie**, Ireland



abbvie

09.40 **Thought Leaders Discussion Panel: Developing and Adapting Manufacturing Processes for More Complex Products**

Lada Laenen, Senior Director, Allston Landing Manufacturing Science and Technologies Head, **Genzyme Corporation**, USA



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10.20 Morning Break

11.00 Chairperson's Opening Remarks

Process Improvements and Change Control in Commercial Manufacturing

11.05 **Case Study: Developing and Improving Manufacturing Processes within GMP Environments**

Priscilla Verjans, Managing Scientist, Department Head MSAT Purification, **Genzyme**, Belgium



genzyme
A SANOFI COMPANY

11.35 **Case Study: Implementing a Major Process Change, Demonstrating Comparability, and Regulatory Interactions**

Chun Zhang, Head of BioProcess Development, **Shire Pharmaceuticals**, USA



Shire

12.05 **Biopharmaceutical Factory of the Future**

Richard Alldread, Head of Innovation, **CPI**, UK



cpi

12.35 Lunch and **LiveLab**

13:00 **Knowledge Exchange Roundtable Discussions**

Table 1: **New Frontiers in Vaccine Manufacturing**

Table 2: **Facility Optimisation and Facility Utilisation Improvements to Maximise Capacity and Efficiency**

Monitoring and Quality Control Strategies

14.00 **Design of a Process Qualification and Continuous Process Verification Program within an Enhanced Development Framework**

Ciaran Brady, Director, Biotech Technical Services/ Manufacturing Sciences, **Eli Lilly and Company**, Ireland



Lilly

14.30 **Toward Adaptive Control Strategy for Raw Material Variability**

Nina Terp Mønster, Scientist II, **Biogen, Manufacturing Sciences**, Denmark

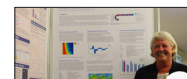
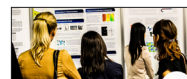


Biogen

15.00 **Spotlight Presentation**

This slot is reserved for technology and service providers; please contact james.miguel@informa.com for more info.

15.30 Afternoon Tea and Poster Awards



16:00 **Introduction of Continued Process Verification for Legacy Products as an Opportunity for an Integrated Informatics Approach**

Paul McCormac, Director Bio-Manufacturing Sciences Group, **Pfizer Global Supply**, USA



Pfizer

Process Portability and Technology Transfer

16:30 **Interactive Hub:**

Technology Transfer- Best Practices for Transferring Processing from Clinical to Commercial Manufacturing

A Risk Based Approach to Rapid Technical Transfers

Joe Runner, Manufacturing Technical Specialist, **Genentech**, USA



17.30 Chairperson's Closing Remarks and End of Day Two

4. DOWNSTREAM PROCESSING

CONFERENCE DAY ONE: WEDNESDAY 14 OCTOBER 2015

07:30 Registration and Morning Coffee

08.20 Chairperson's Opening Remarks

Barry Heavey, Head of Life Sciences, **IDA Ireland**



Opening Plenary: Biomanufacturing and Facilities of the Future to Increase Productivity, Profitability and Product Quality

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A Representative, **Health Products Regulatory Authority**, Ireland



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10.00 **Thought Leaders Discussion Panel: Biomanufacturing and Facilities of the Future**

Trent Carrier, Vice President, Vaccine Technology & Engineering, **Takeda Vaccines**, USA

Roman Necina, Vice President Process Science & Technical Operations, **Baxalta**, Austria

Thilo Henckel, Vice President Manufacturing, **Roche Diagnostics GmbH**, Germany

Ciaran Brady, Director, Biotech Technical Services/ Manufacturing Sciences, **Eli Lilly and Company**, Ireland

David Wolton, Consultant, **PM Group**, Ireland



10.30 Morning Coffee and Start of **partneringONE®** | a service of **EBD GROUP**

11.15 Chairperson's Opening Remarks

Implementation of Continuous Downstream Processing

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Margit Holzer, Scientific Director, **Ulysse Consult**, France



11.50 **Implementation of a Continuous Downstream Process**

Xavier Le Saoût, Associate Manager – Biotech Technology and Innovation, **Merck Serono**, Switzerland



12.20 **Spotlight Presentation:**

A Representative, **GE Healthcare**



12.50 Lunch and **LiveLab's**

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Sebastien Carayol, CMC Coordinator, Purification & Formulation Processes - Bioprocess R&D, **Sanofi Pasteur**, France



14.40 **Integrated Continuous Processing for the Manufacture of Monoclonal Antibodies**

Massimo Morbidelli, Institute for Chemical and Bioengineering, Department of Chemistry and Applied Biosciences, **ETH Zürich**, Switzerland



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Nick Hutchinson, Global Market Development Manager, **Parker Domnick Hunter**, UK



15.40 Afternoon Break

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Daniel G. Bracewell, Reader, Department of Biochemical Engineering, **University College London**, UK



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Ricardo Silva, Postdoc Researcher, **iBET**, Portugal



Inspirational Speaker

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Kevin Warwick, Professor of Cybernetics, **The University of Reading**, UK



18.00 Closing Remarks

18.05 **BioProduction Networking Drinks Reception**





CONFERENCE DAY TWO: THURSDAY 15 OCTOBER 2015

08.55 Chairperson's Opening Remarks

Plenary: Cost Effective Manufacturing Strategies for More Complex Molecules

09:00 **Transforming Production Processes and Strategies for Novel, More Complex Products**

Sean McEwen, Vice President, Biologics Manufacturing, **AbbVie**, Ireland



abbvie

09.40 **Thought Leaders Discussion Panel: Developing and Adapting Manufacturing Processes for More Complex Products**



Lada Laenen, Senior Director; Allston Landing Manufacturing Science and Technologies Head, **Genzyme Corporation**, USA



genzyme
A SANOFI COMPANY

10.20 Morning Break

11.00 **Chairperson's Opening Remarks**

Carsten Voß, Application Specialist, Process Chromatography, **Bio-Rad Laboratories GmbH**, Germany



BIO-RAD

Advances in Purification Technologies to Improve Separation and Meet Upstream Demand

11.05 **A Toolbox for Industrial Refolding of Therapeutic Proteins**

Matthias Berkemeyer, Head of Downstream Development, Biopharma Process Science, **Boehringer Ingelheim RCV GmbH & Co KG**, Austria



Boehringer Ingelheim

11.35 **Application of Straight Through Processing to Reduce Cycle Time for Downstream Manufacturing Processes**

Barbara Burgoyne, Senior Associate Scientist, PDMS Pharmaceutical Development & Manufacturing Sciences, **Janssen Biologics**, Ireland

janssen

12.05 **Leveraging Selectivity and Resolution: Purification Development and Applications for Challenging Separations**

Carsten Voß, Application Specialist, Process Chromatography, **Bio-Rad Laboratories GmbH**, Germany



BIO-RAD

12.35 Lunch and **LiveLab**

13:00 **Knowledge Exchange Roundtable Discussions**

Innovative Purification Techniques for More Complex Proteins and Problematic Molecules

14.00 **BEAT® Bispecific Antibody: Development of a Process with a Platform Approach**

Sonia Letestu, Process Engineer, Downstream Processing Unit, **Glenmark Pharmaceuticals S.A.** Switzerland



glenmark
A new way for a new world

14.15 **Purification of Recombinant Viral Glycoprotein for Subunit Vaccine Development**

Yingxia Wen, Lead of Protein Biochemistry, **Novartis Influenza Vaccines, Novartis**, USA

NOVARTIS
VACCINES

Application of Single Use Technologies in DSP

14.30 **Knowledge Exchange Roundtable Discussion:**



Practical Strategies for the Implementation of Single Use Platforms in Downstream Processing

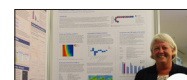
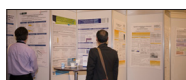
- Strategies to implement single use systems in DSP
- Overcoming challenges when transferring processes to a single-use DSP system: What are the steps needed for a smooth transfer?
- Comparison of results compared to traditional methodologies



15.00 **Spotlight Presentation**

This slot is reserved for technology and service providers; please contact james.miguel@informa.com for more info.

15.30 Afternoon Tea and Poster Awards



Evaluating the Latest Developments and Alternatives to Protein A for Large Scale Commercial Manufacturing

16.00 **How to Throughput Affinity Step**

Camille Gay, Bioprocesses - Head of Purification Development, **SANOFI**, France



SANOFI

Characterisation and Validation of HTPD, Modelling and Robotics

16.30 **Comprehensive Process Validation Powered by High-Throughput Chromatography**

Julia Heymann, Associate Scientist and Scientific Writer, **Merck Serono SA**, Switzerland



MerckSerono

17.00 **Assessment and Implementation of HTPD Chromatography for Process Characterisation Studies**

Jean Aucamp, Lab Head in Protein Processing, **Novartis Pharma AG**, Switzerland



NOVARTIS

17.30 Chairperson's Closing Remarks and End of Day Two

5. INTERACTIVE HUBS: OUTSOURCING STRATEGIES, ALTERNATIVE EXPRESSION SYSTEMS & EXTRACTABLES & LEACHABLES

CONFERENCE DAY ONE: WEDNESDAY 14 OCTOBER 2015

07:30 Registration and Morning Coffee
 08.20 Chairperson's Opening Remarks
Barry Heavey, Head of Life Sciences, **IDA Ireland**



Opening Plenary: Biomanufacturing and Facilities of the Future to Increase Productivity, Profitability and Product Quality

08:30 **ISPE 2014 Facility of the Year Awards Category Winner for Operational Excellence Facility Design for Operational Excellence**

Guy McDonnell, Director of Engineering & EHS, **Pfizer**, Ireland



09.00 **Regulatory Feedback: Expectations for Biomanufacturing and Facilities of the Future**
 A Representative, **Health Products Regulatory Authority**, Ireland



09:30 **Biomanufacturing Strategies That Respond to Changing Industry Demands**
Rob Noel, Commercial Manager, Continuous Processing Unit, **Pall Life Sciences**, UK



10.00 **Thought Leaders Discussion Panel: Biomanufacturing and Facilities of the Future**
Trent Carrier, Vice President, Vaccine Technology & Engineering, **Takeda Vaccines**, USA
Roman Necina, Vice President Process Science & Technical Operations, **Baxalta**, Austria
Thilo Henckel, Vice President Manufacturing, **Roche Diagnostics GmbH**, Germany
Ciaran Brady, Director, Biotech Technical Services/ Manufacturing Sciences, **Eli Lilly and Company**, Ireland
David Wolton, Consultant, **PM Group**, Ireland



10.30 Morning Coffee and Start of **partneringONE** | a service of **EBD GROUP**

11.15 Chairperson's Opening Remarks

Outsourcing Strategies, Quality Control and Supply Chain Management

11.20 **Interactive Hub: Outsourcing Strategies, Relationship and Quality Control Management**



- Key partner criteria and success factors to establish partnerships
- Evaluating hybrid solutions for flexible manufacturing
- Single source: Advantages and disadvantages of single source suppliers
- Relationship management and interaction with suppliers to ensure product quality
- Single use systems: How to disconnect processes from vendors
- Supplier perspective: How to get validated as a second or third supplier for a site?
- Managing quality in the supply chain: Developing quality control portfolios
- Case study examples on good and bad relationships

Balazs Kiss, Head of Bioproduction Department, **Gedeon Richter Plc**, Hungary

12:20 **Spotlight Presentation: Innovations in Hollow Fibre Perfusion**
David Serway, Vice President of Business Development, **Spectrum Laboratories**, Inc. USA



12.35 **Spotlight Presentation:**
 This slot is reserved for technology and service providers; please contact james.miguel@informa.com for more info.

12.50 Lunch and **LiveLab**s

Alternative Expression Systems

14.10 **Interactive Hub: Evaluation and Application of Alternative Expression Systems**



- Critical review of advantages, applications and limitations of the variant to CHO
- Novel routes to make expression systems: Antibody tools applied to non-antibody products
- Challenges and change over strategies from CHO to alternative systems
- Increasing productivity and product quality
- Suitability for use in manufacturing
- Regulatory feedback on acceptance of use of alternative expression systems
- Microbial expression:
 - Manufacturing expression vectors for use in ecoli
 - Technologies to increase solubility of protein production in ecoli

Regis Sodoyer, Technology/ Innovation Expert, **IRT Bioaster**, France

15.10 **Spotlight Presentation:**
 A Representative, **GE Healthcare**



15.40 Afternoon Break

Extractables & Leachables, Standardisation and Testing Strategies for Single Use Systems

16.10 **Interactive Hub: Extractables and Leachables, Standardisation and Testing Strategies for Single Use Systems**



- Extractables testing: User requirements for biopharmaceutical single use systems
- A best practice guide to leachables testing of SUS
- Extractable and leachable studies as risk-assessment and qualification tools for single-use technologies used in the manufacture of biologics
- Standardisation for single use technologies implementation and installation
- Integrating testing strategies for single use technologies to ensure quality and security of supply

Aidan Sexton, Senior Validation Engineer, **Janssen Biologics**, Ireland • **David Wolton**, Consultant, **PM Group**, Ireland
Deirdre Buckley, TS/MS Bioprocess Chemist, **Eli Lilly**, Ireland • **Weibing Ding**, Principal Scientist, Process Development, **Amgen Inc.**, USA



Inspirational Speaker

17:15 **Inspirational Speaker: Advances in Biomedical Engineering**
Kevin Warwick, Professor of Cybernetics, **The University of Reading**, UK



18.00 Closing Remarks

18.05 **BioProduction Networking Drinks Reception**



WORKSHOPS AND SYMPOSIUMS

Pre-Conference Workshops: Tuesday 13 October 2015

Pre-Conference Workshop (W) Continuous Processing – Challenges, Technologies, Processes, Economics & Strategy

Registration 08.30 • Start 09.00 • End 14.30 followed by NIBRT Site Visit

Workshop Leaders:



Margit Holzer
Scientific Director chez **Ulysse**
Consult, France



Roger-Marc Nicoud
Consultant

Technologies & Processes

- Motivations for continuous bioprocessing
- Definitions
- Process designs of a typical mAb production process
- Landscape of continuous processing technologies
- In-line dilution
- Perfusion cultures
- Continuous chromatography
- Continuous TFF
- Continuous centrifugation, reactions; etc.
- Process integration

Economical evaluations

- Existing facilities
- Design of new facilities
- Example of cost studies of a mAb process

From batch to continuous ... Is it the right question? The unit operation perspective

- A few trivial considerations on reactions and chromatography in batch or continuous mode
- Basic chemical engineering lessons for reactors, liquid-liquid extraction and chromatography
- Further insights on chromatography
- From unit operations to complete processes
- **Day-to-day challenges during implementation of continuous processes**
- Batch definition
- Process control strategy - PAT
- Cleaning strategy
- Process validation

Pre-Conference Workshop (X) The Challenge of Protein Aggregation and Sub Visible Particles in Biopharmaceuticals

Registration 08.30 • Start 09.00 • End 14.30 followed by NIBRT Site Visit

Workshop Leader:



Tudor Arvinte, Chairman, **School of Pharmacy Geneva-Lausanne**, Switzerland and Chairman, CEO, **Therapeomic Inc.** Switzerland

- Different aggregation mechanisms will focus on peptide and protein examples
- Available techniques for detection of aggregation and impurities (leachables) and how these methods can be applied
- Combining analytical methods to ensure detection of aggregates across a range of particle sizes.
- New technologies for characterisation of aggregates will be presented
- Strategies for developing stable peptide drug formulations. High-throughput analysis (HTA) and high-throughput formulation (HTF) platforms will be addressed
- Aggregation of biopharmaceuticals in human plasma depends on formulation: a new development and research field
- Regulatory aspects and concerns

Both Pre-Conference Workshops include Optional Site Visit to NIBRT



NIBRT Site Visit:

The National Institute for Bioprocessing Research and Training (NIBRT) is a global centre of excellence for training and research in bioprocessing. It is located in a new, world class facility in Dublin, Ireland. This facility is purpose built to closely replicate a modern bioprocessing plant with state of the art equipment. These facilities are all operated in a realistic GMP simulated, operational manufacturing environment. In 2012 NIBRT was awarded a Special Recognition Award for Novel Collaboration in the Facility of the Year Awards (FOYA) from ISPE.



Post-Conference Symposiums: Friday 16 October 2015

Post-Conference Symposium (S) Cost Effective Manufacturing Strategies for Novel, More Complex Molecules

Registration 08.30 • Start 09.00 • End 15.00

Case study examples will address overcoming the upstream, downstream and facility design challenges to develop cost effective manufacturing strategies for novel and more advanced products including ADCs, bispecifics, fragments and other non-mAb products.

Overcoming Challenges and Enhancing Production of Antibodies for Site-Specific Antibody-drug Conjugates



Wolfgang Noe
Vice President Technical
Operations
Agensys, USA

Discovery, Development, and Production of Homogeneous ADC and Bispecific Molecules Using Xpress CF™ Cell-Free Expression Technology



Heidi Hoffmann
Senior Director, Manufacturing
Sutro Biopharma, USA

Developing Multi-Specific DARPin® Therapies



Alexander Zuercher
Vice President Operations
Molecular Partners AG,
Switzerland

Double Digit-Titers and High Product Quality of Therapeutic Nanobodies® Produced in the Yeast *Pichia Pastoris*



Manu de Groeve
Scientist Upstream Process
Development
Ablynx nv, Belgium

Interactive Roundtable Breakout Discussions:

- Manufacturing processes for cost effective manufacturing of novel products
- Overcoming upstream challenges
- Innovative purification strategies:
- Evaluating cost vs. yield
- Protein A purification or alternative strategies
- Adapting single use technologies
- Application of high-throughput development technologies

Post-Conference Symposium (T) Knowledge Management Across the Product and Process Lifecycle

Registration 08.30 • Start 09.00 • End 15.00

Symposium Leaders to Include:



Jose Menezes
Professor, Institute for
Biotechnology &
Bioengineering, **Technical
University of Lisbon**, Portugal



Nuala Calnan
DIT
**Dublin Institute of
Technology**, Ireland

- Methods and tools for Knowledge Management
- What are the gaps, roadblocks and challenges in capturing, managing and effectively using Knowledge Management?
- How can Knowledge Management efforts support more sustainable business models for biopharma?
- Can investigations be triggered simply because Knowledge Management provided us additional detection capabilities?
- Knowledge Management applications in biopharma development and manufacturing
- Knowledge Management and its role in:
 - Operational excellence
 - Supply chain / raw materials
- Knowledge Management, continued process verification and continuous improvement
- Knowledge Management: Nice-to-have or really a must-have coming of age?

BioProduction by Numbers

“ We got a good number of new contacts ”

BIO-RAD



235 attendees



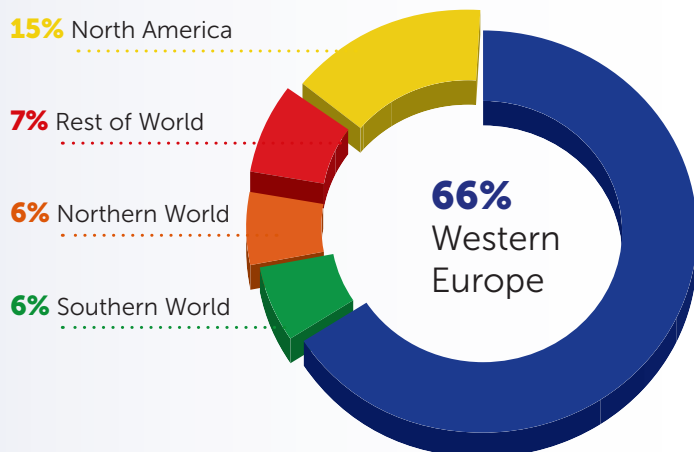
112 companies



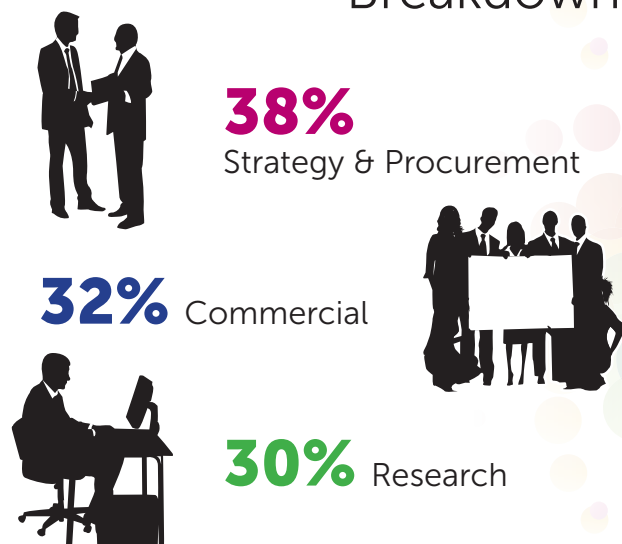
300 pre arranged onsite meetings

For more information please contact: James.Miguel@informa.com Tel: +44 (0) 207 017 5011

Attendee Geographical Breakdown



Job Responsibility Breakdown



Who attends BioProduction

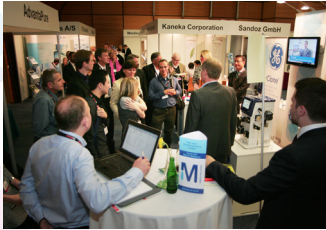
- Project Manager
- Product Manager
- USP Directors
- Chief Scientists
- Researchers
- Senior Scientists
- CMC Coordinator
- Process Specialists
- Global Engineer
- VP's
- CEO's
- DSP Technician
- Head of Department
- Site Director
- Process Developer
- Purification Technician
- Operations Director
- VP Project Management
- Strategic Projects Mgr
- Pilot Manager
- Facility Design Engineer
- Head of Procurement
- CSO
- Lab Specialist
- USP Scientists
- Mgr of Industrial Development
- Laboratory Process Developer
- Dir of Vaccine Innovation
- TD Analytical Specialist
- Head of New Technologies
- Head of QA
- Dir of Purification & Formulation
- GMP Specialists

“ attendees from 2014 BioProduction gave their networking experience a rating of 4.2 out of 5 ”

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OR

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☐ **FOLLOWED BY FREE SITE VISIT TO NIBRT** (tick if you wish to attend. You must be registered to attend a Pre-Conference Workshop)

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Strategies for Novel, More Complex Molecules

OR

☐ Post-Conference Symposium (T): Knowledge Management
Across the Product and Process Lifecycle

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