

The background of the entire page is a nighttime aerial view of Berlin, Germany. The city lights are visible, including the TV Tower (Fernsehturm) in the distance. Overlaid on the top right of the image is a glowing blue and purple DNA double helix structure. The main title is centered over the image.

WORLD SMART BIOPROCESSING PHARMA 4.0 SUMMIT

27th - 29th September 2023 | Berlin, Germany

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EXHIBITORS



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BUSINESS DEVELOPMENT

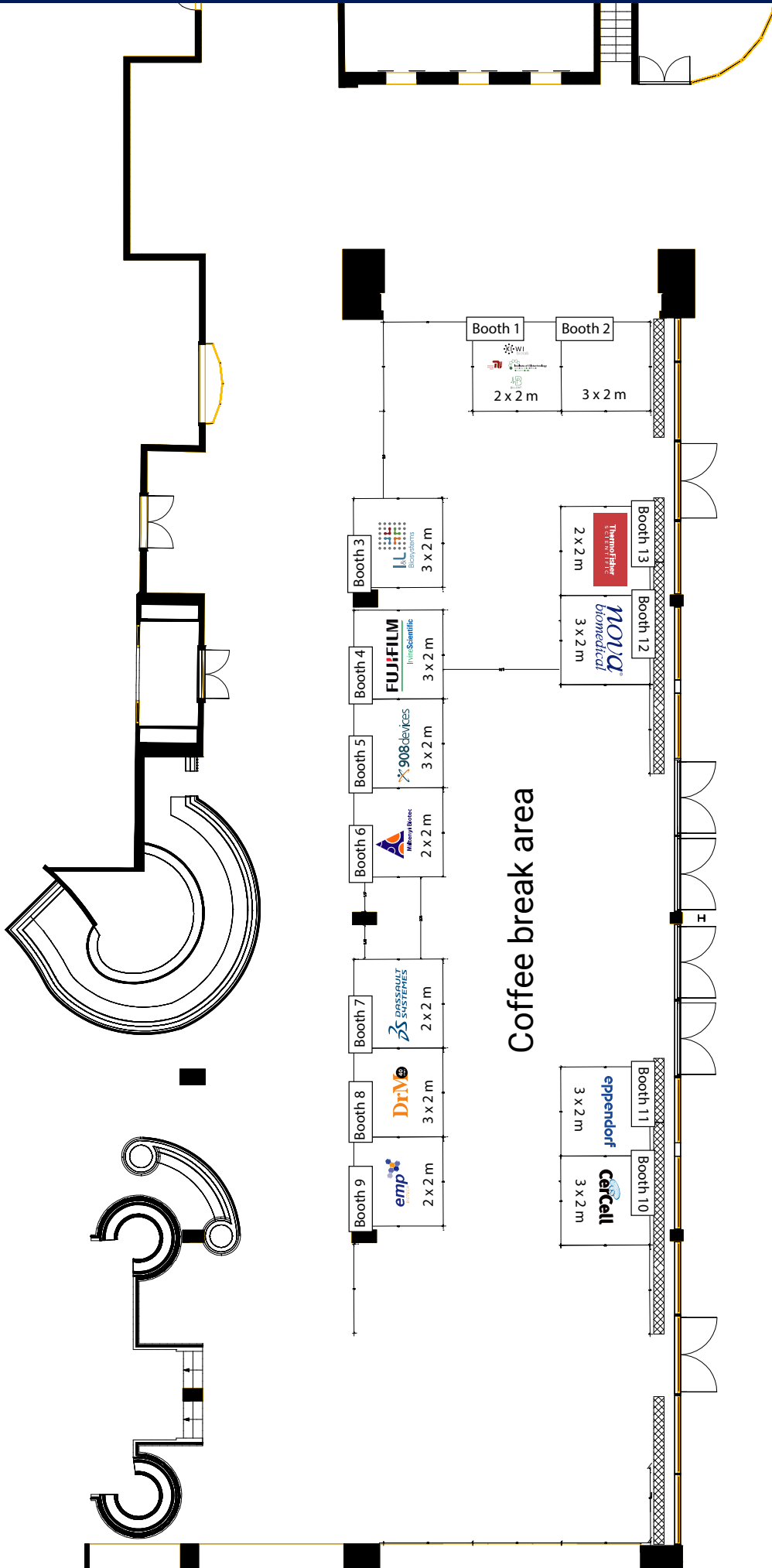


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08:20 REGISTRATION

DELEGATES WHO HAVE SIGNED UP FOR **THE TECHNISCHE UNIVERSITÄT BERLIN LAB OF THE FUTURE TOUR & BAYER FACTORY TOUR** SHOULD MEET AT THE HOTEL LOBBY AT **8:50AM** AFTER REGISTRATION AT THE FOYER AS THE COACH DEPARTS AT **9:00 AM**.

GROUP A: BAYER TOUR



09:00 AM - DEPART FOR PLANT TOUR
09:30 AM - ARRIVE AT PLANT
09:50 AM - INTRODUCTION TO THE TOUR
12:00 PM - TOUR ENDS & DEPART FOR HOTEL

GROUP B: TECHNISCHE UNIVERSITÄT BERLIN LAB



09:00 AM - DEPART FOR PLANT TOUR
09:30 AM - ARRIVE AT PLANT
09:50 AM - INTRODUCTION TO THE TOUR
12:00 PM - TOUR ENDS & DEPART FOR HOTEL

12:30 LUNCH BREAK

13:30 CHAIR'S OPENING ADDRESS

13:40 WORKSHOP 1

SMART MANUFACTURING WITH ARTIFICIAL INTELLIGENCE: A DIGITAL TWIN STRATEGY FOR ACCELERATED INNOVATION AND INDUSTRIAL SCALE-UP



M. Nicolas Cruz B.
Head of the KIWI-biolab
DataHow

14:20 EXPERT TALK

DEPLOYING APPROPRIATE SPENDING ON ANALYTICAL TESTING TO AVOID WASTING RESOURCES

Molecule and process understanding are the fundamental for defining a robust and lean commercial control strategy. Key for finding the right balance of a phase appropriate investment in analytical method development are the early understanding of the molecule's features and potentially critical quality attributes. Risk assessments, analytical quality by design and the definition of an analytical target profile can help to guide this process. Investments in analytical method development need to consider the current approval success rate for new therapies and the complexity and costs that are required to introduce changes post approval



Gerald Gellermann
Senior Fellow & Analytical Project Leader
Novartis

15:00 COFFEE BREAK & EXHIBITION

15:40 WORKSHOP 2

MODEL-BASED UPSTREAM PROCESS DEVELOPMENT

- How to use models for process development
- Hands-on experience with model-based process optimization
- How to get more from your data



Dr. Fabian Feidl
CTO and Co-Founder
DataHow

16:20 WORKSHOP 3

OUTSOURCING CMC DEVELOPMENT & MANUFACTURING FOR BIOLOGICS – A BIG PHARMA PERSPECTIVE

- The crucial make-or-buy question – what to outsource and what to do in-house?
- The benefits and challenges of outsourcing bioprocessing
- How to best select and manage your CDMO
- Contract making to prevent pitfalls and protecting your IP
- Establishing a productive partnership



Ulrich Rümenapp
Head of Launch Preparation
Bayer AG

17:00 CHAIR'S CLOSING REMARKS

17:10 END OF WORKSHOP



08:20 REGISTRATION & WELCOME COFFEE

08:50 OPENING REMARKS FROM THE CHAIR

09:00 OPENING KEYNOTE

IN-LINE MONITORING OF BIOPROCESS PARAMETERS FOR THE 21ST CENTURY

- Current solutions for in-line upstream bioprocess analytics
- Strengths and limitations of in-line multivariate bioprocess analysis
- A new solution that overcomes the major hurdles of implementing optical sensing technology



Dr. Stephen Driscoll
Senior Scientist, Algorithms
908 Devices

09:30 CASE STUDY

THE BIOMANUFACTURING STRATEGIES TO MEET THE NEEDS OF MULTIPLE MODALITIES IN BIOLOGICS

Some of the most difficult biological drug development challenges occur during process and analytical development of novel molecular biologic formats. How some of these key challenges can be addressed will be discussed during this presentation with example case studies. Considerations for end-to-end integrated drug substance and drug product CMC strategies to accelerate the path of biological molecules to IND will be highlighted.



Alice Harrison
Global Technical Director
Lonza

10:00 EXPERT TALK

BEYOND DIGITAL TWINS: COMBINING VIRTUAL MODELING AND REAL DATA TO DRIVE BIOPROCESS UNDERSTANDING AND OPTIMIZATION

During the presentation you will learn how Dassault Systemes helps Biotech and Pharma to achieve significantly faster time to markets at scale and cost without compromising quality. We will discuss how you can leverage the following capabilities to achieve your goals for quality by design:

- Utilizing virtual models and multi-physics simulations to define, optimize and validate the behavior of complex process systems
- Support your continuous improvement activities around process development by performing virtual systems analysis and tests
- Validate process changes or the integration of a new process before it even exists
- Utilizing virtual simulations to understand and analyze air flows through a best-in-class solution for the simulation of virtual buildings
- Predict the flow field and transport path of droplets, air flows, chemical emanation considering different building and layout configurations
- Support decision making about layout changes earlier in the project phase, staff protection against toxic emanation, epidemic crises and environmental impact
- Utilizing real data for Batch Process Analytics to understand and monitor your process to improve quality, increase yield and avoid failures
- Identify Process Parameters (CPPs) and Critical Quality Attributes (CQAs) and therefore the process design space
- Monitor production to react to process trends before "failure occurs"



Dr. Barbara Holtz
Life Science and Healthcare Industry Business Consultant Expert
Dassault Systèmes

10:30 COFFEE BREAK & EXHIBITION

11:10 CASE STUDY

FUNDALOOP: SINGLE-USE MULTICYCLE FILTERS FOR PROCESS INTENSIFICATION





- Single-Use
- Cake Filtration
- Multi-Cycle Filtration
- Process intensification
- Cell harvesting



Davide Stucchi
Product and Sales Manager – Single Use Technologies
DrM, Dr. Mueller AG

5 MINS RELOCATION TO BREAKOUT ROOMS





11:55 BREAKOUTS

CELL & GENE THERAPY	UPSTREAM PROCESSING	CONTINUOUS & INTEGRATED PROCESSING	PHARMA 4.0/SMART MANUFACTURING
<p>DEVELOPMENT OF AUTOMATED CELL AND GENE THERAPY WITH COMMERCIAL READINESS IN MIND</p> <ul style="list-style-type: none"> • Automation • Process Development • Analytical Development • Tech Transfer to Clinical Manufacturing • Integration/Digitalization 	<p>INCREASING UPSTREAM BIOPROCESSING EFFICIENCY THROUGH PROCESS ANALYTICAL TECHNOLOGY</p> <ul style="list-style-type: none"> • Get to know, how inline process analytics can improve bioprocess efficiency • Learn, which bioreactor software features are needed to integrate analyzers and to implement automated feedback control loops • Benefit from hands-on experience in integrating analyzers to automate culture feeding 	<p>PUSHING THE ENVELOPE IN BIOPROCESS DEVELOPMENT – FROM DISPOSABLES, CONTINUOUS MANUFACTURING TO BIOPROCESSING IN A CONTAINER</p> <ul style="list-style-type: none"> • What sorts of big ideas have been enabled by these new technologies, beyond the obvious applications? • What problems are likely to remain, which will require additional disruptive innovations to solve? • How can a company balance vision with risk when making bold steps forward? 	<p>MANUFACTURING A CURE: ADVANCING CELLULAR THERAPIES TOWARDS COMMERCIALIZATION</p> <ul style="list-style-type: none"> • How should our industry build upon current cell therapy advances to create even more advanced and complex biopharmaceutical treatments • Understanding how facility and process validation considerations change and become even more important when dealing with cell therapies • Illustrating how investing in the relevant science directly informs product knowledge • Demonstrating that this hard-won internal expertise can be harnessed into developing a successful new modality for cell therapies • How to manage and maximize internal and external capacity to overcome product supply challenges
<p>Silvio Weber Scientific Director of the Industrial Workflow Development Miltényi Biotec</p> 	<p>Dr. Daniel Wünsch Bioprocess Sales Specialist eppendorf</p> 	<p>Renaud JACQUEMART, PhD, MBA Chief Technology Officer Mannin Research</p> 	<p>Ben Weil Director of Manufacturing INmune Bio</p> 

5 MINS RELOCATION TO BREAKOUT ROOMS

12:40 LUNCH BREAK


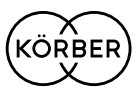


13:40 BREAKOUTS

CELL & GENE THERAPY	UPSTREAM PROCESSING	CONTINUOUS & INTEGRATED PROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0
<p>METABOLIC MODULATION IN MSC MANUFACTURING TO IMPROVE MSC THERAPEUTIC POTENTIAL FOR ARTICULAR CARTILAGE REPAIR</p> <ul style="list-style-type: none"> • Need for a MSC manufacturing protocol to overcome cellular heterogeneity and reproducibly generate MSC populations that are functionally equivalent. • Control MSC fate during manufacturing via metabolic modulation. • Ascorbic acid can act as a metabolic modulator to shift MSC metabolic profile, improve cell yield, MSC function and cellular heterogeneity. • Culture monitoring using process controls including micro-magnetic resonance relaxometry (uMRR) can improve the robustness of MSCs. 	<p>STRATEGIES AND TECHNOLOGIES FOR DETECTION, ANALYSIS AND CONTROL</p> <ul style="list-style-type: none"> • Control Strategies • Emerging Characterization Methods • High-Risk Host Cell Proteins • Adapting analytical platforms to new modalities 	<p>REDUCED CARBON FOOTPRINT AND DRUG PRODUCT COST WITH THE HELP OF AI IN HEALTHCARE ENSURING SUSTAINABLE PRODUCTION</p>	<p>BIOMANUFACTURING 4.0 APPLIED TO MICROBIAL FERMENTATION BIOPROCESSES: IMPLEMENTATION OF PHYSIOLOGICAL CONTROL STRATEGIES USING A CONTROL LOOP ON THE CLOUD</p>
<p>Ching Ann Tee Postdoctoral Associate Singapore-MIT Alliance for Research & Technology Centre</p> 	<p>Dr. Mohamad Toutounji ATMP/Biologicals CMC Developer ADQC Specialist Molgenium</p> 	<p>Sonia Sahukar Process Responsible Upstream Novo Nordisk</p> 	<p>Chetan Srinivas Senior Manager DSP Process Engineering Biogen</p> 

5 MINS RELOCATION TO BREAKOUT ROOMS



14:25 BREAKOUTS

CELL & GENE THERAPY	UPSTREAM PROCESSING	CONTINUOUS & INTEGRATED PROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0
<p>OPTIMIZATION OF RAAV6 AND RAAV8 TITERS USING BALANCD HEK293 VIRAL FEED PANEL</p> <ul style="list-style-type: none"> • BalanCD HEK 293 media effectively supports high-titer rAAV production in HEK 293 cells with possibility of transfection at high cell density • For the two serotypes, Design of Experiment was efficiently used to determine: <ul style="list-style-type: none"> - Optimal plasmid and Fecto-Vir concentrations - Optimal feed addition protocol • Different feed formulations and protocol additions increase rAAV titer in a serotype depending manner 	<p>DIGITALIZATION PLATFORM AND SUPERVISORY CONTROL FOR INTEGRATED CONTINUOUS BIOMANUFACTURING</p> <ul style="list-style-type: none"> • Need for an efficient process data collection and real time architecture • Monitoring and control concepts for robust continuous upstream processing and to operate at maximum productivity • Strategies to react to varying input material quality • End to end digital twin for real time release 	<p>SMART BIOPROCESS DEVELOPMENT WITH AN END-TO-END MINDSET: HIGH THROUGHPUT SYSTEMS, DIGITAL TWINS, PAT</p> <ul style="list-style-type: none"> • Optimization of high throughput systems- Utilization of Digital Twins in early stage and late stage development- Online process control with PAT Knowledge bridging from process development to commercial 	<p>PROCUREMENT ENABLED SMART SELECTION AND RELATIONSHIP MANAGEMENT OF CDMOS</p> <p>Pharma companies often require or rely on external suppliers for the development and clinical manufacturing of its New Molecular Entities. The capability, available capacity, quality adherence and agility of suppliers are crucial to adhere to the Key Event Map of the CMC process. The selection of suppliers must be done in a smart way to maximize the success later on. As of when the supplier is selected, it will be key to follow up performance and have a mechanism in place to develop the relationship. The relationship management is key to bring the relationship to the next level and allow suppliers to develop into partners.</p>
<p>Laia Bosch Molist PhD student at the Universitat Autònoma de Barcelona UAB, Barcelona, Spain</p> 	<p>Prof. Dr. Christoph Herwig Senior Scientific Advisor Körber Pharma Austria GmbH</p> 	<p>Raena Morley Scientist - Pharma Technical Development Europe Roche Diagnostics GmbH</p> 	<p>Ward Mennes, M. Sc. Chem. Eng. & MBA Director, Procurement CMC & Devices Johnson & Johnson</p> 

15:05 COFFEE BREAK & EXHIBITION



15:35 BREAKOUTS

CELL & GENE THERAPY	UPSTREAM PROCESSING	CONTINUOUS & INTEGRATED PROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0
<p>AAV DOWNSTREAM INNOVATION TRENDS</p> <p>This presentation aimed to provide a general overview of the current USP and DSP AAV processes, their bottlenecks, and the innovation trends to tackle those challenges. The differences between CHO-cell biologics bioprocess were also highlighted to explain the unique challenges in AAV process development. Technologies specific to unit operations and the AAV-specific process challenge were presented.</p>	<p>NOVEL PAT APPLICATIONS FOR LVV UPSTREAM PROCESS DEVELOPMENT</p> <p>Using ML-assisted data analytics and modelling together with genome-scale metabolic modelling to gain processlevel understanding on the performance of a novel PAT tool used for real time monitoring of the metabolic activity during lentiviral vector manufacturing</p>	<p>CSL112 PROCESS CHARACTERIZATION: A MODERN PROCESS DEVELOPMENT APPROACH IMPLEMENTING QBD PRINCIPLES</p> <ul style="list-style-type: none"> Implementing QbD principles for a plasma-derived biotherapeutic product Applying a risk- and science based approach leading to the identification of process parameters potentially impacting quality and performance attributes Sequential DoE approach for process characterization: Pre-screening DoE followed by high resolution DoE Process performance analysis followed by statistical model building and Monte Carlo simulation to predict and minimize defect rate Outcome of process characterization leading to final classification of process parameters Thorough process understanding leading to a robust process control strategy 	<p>ADVANCED PROCESS CONTROL AND PROCESS ANALYTICAL TECHNOLOGY FOR CONTINUOUS BIOPROCESSING</p> <ul style="list-style-type: none"> Advantages of continuous bioprocessing include smaller footprint, faster turnaround and increased flexibility compared to batch. However, continuous requires more stringent process control and understanding The CPI UK Continuous 2 project aims to build a flexible control system that can detect changes and automatically adapt the process, reducing necessary intervention, improving product consistency and maximizing output. To achieve these goals, we employ advanced process control (APC) and process analytical technology (PAT) on top of a conventional control system This project will serve as test bed for various types of PAT and APC for bioprocess control
<p>Elise Huang Former Group lead, Gene therapy downstream process development UCB</p> 	<p>Duygu Dikicioglu Associate Professor UCL</p> 	<p>Islem Younes, PhD Principal Scientist - Head of Strategic Office Bioprocess Development CSL Behring</p> 	<p>Dr. Sean Ruane Senior Scientist II – Data Science CPI</p> 

5 MINS RELOCATION TO MAIN HALL

16:20 CASE STUDY

SMART BIOPROCESSING GRAND CHALLENGE

- Development of bioprocesses often occurs under pressure for time to market and cost constraints, not leaving room for thorough optimization and resulting in sub optimal processes going into manufacture
- Learning is difficult to transfer from process to process
- This project aims to bring together industry partners to create an analytical platform resulting in in-silico end-to-end process development
- Platform measurements will be transferrable between a wide range of products
- Envisioned benefits are drastically reduced need for experiments, faster development turnaround and better optimization results



Lukas Kürten
Principal Scientist - Data Analytics
CPI

17:00 CHAIR'S CLOSING MARKS

17:10 END OF CONFERENCE DAY 2

08:20 REGISTRATION & WELCOME COFFEE

08:50 OPENING REMARKS FROM THE CHAIR

09:00 KEYNOTE

BIOPROCESS MODELS IN THE DIGITAL AGE – HOW TO MAKE VALUE OUT OF DATA

- How to implement modelling and AI strategies into early bioprocess development
- The digital twin of cells and processes
- Making use of fully automated intelligent laboratories
- Early implementation of scale down and scale up strategies



Dr. Peter Neubauer
Professor for Bioprocess Engineering
Technische Universität Berlin

09:30 CASE STUDY

DIGITAL DISTRUPTION IN CHATGPT

- Consequences and opportunities for employees and employers
- Usage of AI to predict life cycle of components in a manufacturing plant
- How to organize digital and data science resource to manage innovation



Massimo Buonaiuto
Principal Scientist
DSM

10:00 EXPERT TALK

CMC FRAMEWORK AT CEPI – DEVELOPMENT STAGE APPROPRIATE CMC MILESTONES

CEPI recommends generating a robust CMC strategy for vaccine development and lifecycle management. To support this CEPI's Manufacturing and Supply Chain division has developed a CMC Framework in collaboration with the Global Regulatory Affairs Department and Clinical Development Department, listing stage appropriate deliverables. With CEPI's mission to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need, the CMC Framework was established with vaccine development in mind, though it can be applicable to any biologics drug development with some adaptations. These phase-appropriate CMC deliverables would be supportive in establishing comparability between a. development stages, e.g., between Phase I -> II -> III lots, and b. tech transfer, e.g., geo-diversification of vaccine manufacturing sites. This resonates well with the CEPI 2.0 objectives which include late-stage development, product licensure and tech transfer to create a geo-diversified manufacturing network. The intent of the CEPI CMC Framework is to provide guidance to developers and integrate relevant quality elements throughout development, from pre-clinical stage to launch, ensuring commercial manufacturing line in sight is embedded in the projects.



Vishal Mukund Sonje
Commercial Manufacturing Lead
CEPI

10:30 COFFEE BREAK & EXHIBITION

11:10 PANEL DISCUSSION

HOW IS AI IMPACTING BIOPHARMA AND PROCESS DEVELOPMENT?

- What is the future of AI in biopharma
- How can we take advantage of AI in bioprocessing?

MODERATOR

Graziella Piras, Ph.D
Bioprocessing
Segment Director
908Devices

Dr. Barbara Holtz
Life Science and
Healthcare Industry
Business Consultant
Expert
Dassault Systèmes

Dr. Peter Neubauer
Professor for
Bioprocess
Engineering
**Technische
Universität Berlin**

Dr. Sean Ruane
Senior Scientist II –
Data Science
CPI

Dr. Xavier Garcia Ortega
Project Leader
Researcher and
Assistant Professor
**Universitat Autònoma
de Barcelona**







5 MINS RELOCATION TO BREAKOUT ROOMS

11:55 BREAKOUTS

CELL CULTURE AND BIOPRODUCTION	ANALYTICAL PROCEDURES	CONTINUOUS & INTEGRATED PROCESSING	PHARMA 4.0/ SMART MANUFACTURING AND TECHNOLOGY
<p>TOWARDS IMPROVED EFFICIENCY BY CELL-LINE ENGINEERING</p> <p>In an effort to improve the performance of a manufacturing clone expressing a complex therapeutic protein, we have used genome scale based cell-line engineering, to generate a large panel of cell lines with improved features resulting in a more predictable bioprocess, and protein quality.</p>	<p>ANALYTICAL REQUIREMENTS FOR IND AND BLA SUBMISSION</p> <ul style="list-style-type: none"> • IND and BLA • Regulations and Agency Meetings • Example 	<p>DEFINING SPECIFICATIONS IN A RISKBASED CONTROL SYSTEM</p> <p>Defining global harmonized limits for attributes analyzed with different analytical methods is a central element of a control strategy. Traditional approaches usually focus on ensuring process consistency, while in more advanced approaches the understanding of structural function relationships are utilized to define patient centric limits for a critical attributes. This enables definition of limits that may extend outside those determined by product specific clinical experience and process consistency monitoring. Where indicated, this is required to incorporate more worst case assessments to predict future manufacturing variability as the basis to mitigate risks to patients and supply</p>	<p>TOWARDS SMART BIOMANUFACTURING 4.0 IMPLEMENTING ADVANCED AI-BASED MODELS FOR THE CONTROL OF MICROBIAL FERMENTATION BIOPROCESSES</p> <ul style="list-style-type: none"> • Cloud systems, the internet of things, and artificial intelligence (AI), considered key technologies in Industry 4.0 to provide the expected horizon for the adaptive vision in Continued Process Verification in microbial fermentation-bases bioprocesses • Pichia pastoris is currently considered the second preferred microbial host for recombinant proteins, since numerous products biomanufactured with this cell factory are FDA approved for therapeutics and food applications. • An innovative physiological control has been implemented based on an AI approach. • Opening a window for data-driven technologies to be applied in microbial fermentation bioprocesses including both Pharma and Biotech industries.
<p>Bjørn Voldborg Head of The National Biologics Facility DTU Bioengineering</p>	<p>Baerbel Grossmann Associate Director Global Regulatory Affairs CMC Biologics Sanofi</p>	<p>Gerald Gellermann Senior Fellow & Analytical Project Leader Novartis</p>	<p>Xavier Garcia Ortega Project Leader Researcher and Assistant Professor Universitat Autònoma de Barcelona</p>

12:35 LUNCH BREAK

13:35 BREAKOUTS

CELL CULTURE AND BIOPRODUCTION	ANALYTICAL PROCEDURES	CONTINUOUS & INTEGRATED PROCESSING	PHARMA 4.0/ SMART MANUFACTURING AND TECHNOLOGY
<p>DEVELOPMENT OF A STABLE CELL LINE FOR CONTINUOUS MANUFACTURING PROC</p> <ul style="list-style-type: none"> • Overview of the importance of lentiviral vectors for cell and gene therapy • Orchard's stable cell line development platform • Steps for an optimised CLD workflow • GMP Requirements for LVV Manufacturing with Stable Cell lines 	<p>THE EVER-EXPANDING HYPHENATION OF SEPARATION TECHNIQUES TO MS IN BIOPHARMACEUTICAL DEVELOPMENT – LESSONS LEARNED AND CASE STUDIES</p> <ul style="list-style-type: none"> • Dealing with increased MS data generation, storage, and processing demands in biopharmaceutical development • The impact of combining orthogonal separation techniques with mass spectrometry for biopharmaceutical characterization • Streamlining MS-based characterization workflows • Case studies from pre-clinical and clinical biopharmaceutical development 	<p>ONE-STEP CLARIFICATION, CAPTURE AND RECOVERY PROCESS FOR BIOLOGICAL MODALITIES BASED ON MAGNETIC SEPARATION</p> <ul style="list-style-type: none"> - DSP application for monoclonal antibody manufacturing • Integration of clarification and capture step • Elimination of centrifugation and filtration steps • Overcome very high concentration of cells and particles in viscous cell suspension • Industrial scale model show • Gentle technology - Technology also suitable for cell therapy DSP • Usable for the targeted isolation of cell subpopulations • High isolation efficiency and consistent isolation performance • High biocompatibility • High robustness against mechanical stress and minimal unspecific binding 	<p>IMPROVING PROTEIN PURIFICATION: APPLICATION OF EXCIPIENTS IN DOWNSTREAM PROCESSING</p> <p>The low pH elution during Protein A chromatography, as well as during virus inactivation in downstream processing of antibodies and Fc-fusion proteins may induce aggregation. Excipients have shown that they can minimize aggregation levels in the final product formulation. For this reason, we have investigated the benefits of adding excipients during downstream processing on protein stability, chromatographic performance and viral inactivation</p>
<p>Chrysanthi Sitmalidou Scientist II Orchard Therapeutics</p> 	<p>Dan Bach Kristensen Principal Scientist Symphogen</p> 	<p>Nils Brechmann, Ph.D. Application and Product manager MAGic BioProcessing</p> 	<p>Supriyadi Hafiz Senior Scientist Formulation Merck KGaA, Darmstadt, Germany</p> 

5 MINS RELOCATION TO MAIN HALL



14:20 CASE STUDY

INTEGRATED CONTINUOUS PROCESSING – A SUSTAINABLE WAY

- Establishing end-to-end processing skid
- Membrane based purification of proteins
- Process development challenges



Bernhard Sissolak
Head of Innovation Management/Pharma
Bilfinger Life Science

14:50 CHAIR'S CLOSING MARKS

15:00 END OF CONFERENCE

NEXT EDITION:

**WORLD BIOPROCESSING SUMMIT
PHARMA 4.0**

September 2024 | Berlin, Germany

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Lonza**Alice Harrison**Global Technical Director
Lonza

Alice Harrison is currently Director, Global Technical & CMC, Analytics providing scientific and technical leadership to benefit customer programs. Alice studied chemistry at Queen Mary College (University of London - UK) and earned her DPhil in molecular immunology from University of Oxford in the UK. She has over 20 years' experience in large molecule analysis within industry and founded and led businesses supporting the development of antibody and complex protein therapeutics. Alice has an in-depth understanding of the bioanalytical challenges of complex molecule programs.

sanofi**Baerbel Grossmann**Associate Director Global Regulatory Affairs CMC Biologics
Sanofi

Dr. Baerbel Grossmann studied Biology at the Ruprecht-Karls University in Heidelberg, Germany, followed by 4 years of post doc position as a head of laboratory in the Institute of Human Genetics in Mainz with emphasis on reproductive genetics, polar body diagnosis, and chromosome evolution. Baerbel joined Sanofi in 2006 as QA for Toxicology and changed to Regulatory CMC in 2011 in different positions. The focus of her work as associate director GRA CMC & Devices is to develop and coordinate strategies for the worldwide submission of variations for Biologics (life cycle management) in collaboration with internal and external partners and to provide support to ensure regulatory compliance. She is also responsible for Regulatory CMC in development projects for Biologics.

**DASSAULT
SYSTEMES****Dr. Barbara Holtz**Life Science and Healthcare Industry Business Consultant Expert
Dassault Systèmes

Barbara Holtz, Life Science and Healthcare Industry Business Consultant Expert. Barbara has over 20 years of experience working in the Life Sciences, mostly in customer facing roles. She has been working for a range of IT and Software companies, most recently as a Value Expert at Dassault Systèmes, helping to improve the way scientists and engineers in the Life Science Industry work with digital, data, modeling and simulation. She has a background in Physics, having completed in PhD in Molecular Simulations and is currently focusing to apply her analytical skills and deep industry knowledge to understand virtual twins and the benefits they can deliver across the entire pharma, medical device and biotech value chain.

INmuneBio
INNATE IMMUNITY**Ben Weil**Director of Manufacturing
INmune Bio

Ben is a Bioprocess Engineer with a PhD in Biochemical Engineering from UCL, and completing an MBA in Businesses Management & Leadership from the Open University. He currently holds positions as:

- Director of Manufacturing at INmune Bio: Leading a multidisciplinary translational GMP bioprocessing team to design & manufacture Advanced Therapies/ATMPs for oncology and immunotherapy trials in the UK, US, and Europe.
- Head of GMP Engineering and Senior Manager at the Centre for Cell, Gene and Tissue Therapeutics (CCGTT): Established and leading the GMP Engineering group at the Royal Free Hospital to drive development of cost-effective Advanced Therapy Medicinal Products (ATMP) provision through increased scale, automation, and "closing" processes to minimise costs of goods and maximise accessibility for patients and the NHS.
- Honorary Lecturer at UCL: supporting UCL early clinical trial design and GMP manufacture.
- Director of WEIL CONSULTING Ltd: providing advice and support to accelerate the translation of Process Development through clinical trials. 8 years experience in the rapid translation and scale-up of ATMP manufacture, biochemical engineering, MHRA/FDA/EMA clinical trial applications, commercial scale manufacture of genetically modified cell/gene therapy, and bioprocess design to enable a diverse skillset to be shared with clients.

BILFINGER**Bernhard Sissolak**Head of Innovation Management/Pharma
Bilfinger Life Science

Experienced in bioprocess engineering and leading R&D project teams. PhD Thesis focused on implementing QbD&PAT in a mammalian cell culture processes. Now leading innovation management at Bilfinger Life Science with a focus on three core topics digitalization, sustainability, and efficiency. Supporter of early career scientists.



Bjørn Voldborg

Head of The National Biologics Facility
DTU Bioengineering



Bjørn Voldborg is Head of the National Biologics Facility and Director of the Cell Line and Protein Production Facility at DTU and has more than 20 years of experience working with recombinant protein production from both academic and industrial settings. Bjørn was team leader in the biotech company Pharmexa A/S, responsible for molecular cloning and expression of protein-based drug candidates. From this, he went to the NNF Center for Protein Research at the University of Copenhagen as Head of the Protein Production Unit, and, since 2012, Bjørn has been heading the CHO Cell Line Engineering project dedicated to the engineering of improved protein production cell factories, and since 2021 he has been heading the Cell Line and Protein Production Facility and the National Biologics Facility at the Technical University of Denmark.

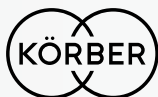


Ching Ann Tee

Postdoctoral Associate
Singapore-MIT Alliance for Research & Technology Centre



Ching Ann TEE, Ph.D., joined Critical Analytics for Manufacturing Personalized Medicine (CAMP) interdisciplinary research group under Singapore-MIT Alliance for Research and Technology (SMART) in May 2021. She works under Professor Laurie A. Boyer as a Postdoctoral Associate. She obtained her Bachelor of Bioengineering in 2016 from Nanyang Technological University and her Ph.D. in 2021 from National University of Singapore. Her Ph.D. research focused on developing a zonal chondrocyte production protocol integrating inertial spiral micro-channel cell separation and dynamic microcarrier culture to generate a clinically relevant number of zonal chondrocytes with high zonal functionality for stratified articular cartilage repair. Her current research focuses on metabolic modulation of mesenchymal stromal cells (MSCs) phenotypic commitment. The goal is to develop a MSC manufacturing pipeline with feedback control to generate a homogenous population of MSCs with predictable phenotypic commitment, by varying culture media composition as metabolic modulators and incorporating process analytical tools targeting MSC metabolism.



Prof. Dr. Christoph Herwig

Senior Scientific Advisor
Körber Pharma Austria GmbH



Christoph Herwig, bioprocess engineer from RWTH Aachen, worked in industry in the design and commissioning of large chemical facilities prior to enter his interdisciplinary PhD studies at EPFL, Switzerland in bioprocess identification. Subsequently he positioned himself at the interface between bioprocess development and facility design in biopharmaceutical industry. Since 2008, he is full professor for biochemical engineering at the Vienna University of Technology. The research area focuses on the development of data science methods for integrated and efficient bioprocess development along PAT and QbD principles for biopharmaceuticals. In 2013 he founded the company Exputec, which is now part of Körber Pharma, pioneering data science software solutions for the biopharma life cycle.



Chrysanthi Sitmalidou

Scientist II
Orchard Therapeutics



Chrysanthi is a Scientist II in Vector Process Development team within Cell & Gene Therapy Technologies Department and joined Orchard Therapeutics in September 2020. She is working on the development and optimization of lentiviral vector (LVVs) USP platforms and involved in LVV analytical assay development. She was also responsible for the development of stable cell lines for LVVs and optimisation and establishment of a stable cell line platform. Chrysanthi's background is in retro and lentiviral vectors. With wide experience in the process development field, she is skilled in Cell Line Development, Viral vector upstream Process Development and Molecular & Cellular Biology. Prior to Orchard Chrysanthi was a viral vector Senior Research Associate in Autolus, working on stable cell line development and optimization of CLD platform and vector analytical assays for CART cell therapies. Chrysanthi holds a MSc in Molecular Medicine and Cancer Research from Brunel University London and BSc in Molecular Biology and Genetics.



Dan Bach Kristensen

Principal Scientist
Symphogen



Dan Bach Kristensen holds a Ph.D. in biology and B.Sc. degree in chemistry. Dan is specialized in protein chemistry and mass spectrometry, which he initially applied in the field of proteome research in Japan and later in Denmark. For the last 17 years Dan has been working with analytical development in the biopharmaceutical industry, on projects ranging from early discovery to product registration. Clinical indications include bleeding disorders, neutropenia, autoimmune diseases and oncology. Dan currently works as a Principal Scientist at Symphogen, a part of Servier, which specializes in the development of antibodies, antibody formats and antibody mixtures for the treatment of cancer.



Dr. Daniel Wünsch

Bioprocess Sales Specialist
eppendorf



Daniel Wuensch has a classical bioprocess background with studies in biotechnology and pharmaceutical biotechnology at the University of Applied Sciences in Hamburg. Here, the focus was on process development and optimization to produce biopharmaceuticals with GMOs. This included automated, process-controlled cultivation and screening in bioreactors (1-50 L) as well as automated purification of target compounds. During the PhD and PostDoc period at the Carl von Ossietzky University Oldenburg, the emphasis was on the investigation of growth physiological and energetic characteristics of environmental bacteria. In addition, process-controlled cultivations were used to generate high-quality samples for downstream multi-OMICs analyses. This enabled the integration of growth physiology data with OMICs data to develop metabolic models of the organisms. Since September 2023, Daniel Wuensch is part of the Bioprocess Sales Team at Eppendorf and supports the European team in Germany, Spain and Portugal.



Davide Stucchi

Product and Sales Manager – Single Use Technologies
DrM, Dr. Mueller AG



Davide Stucchi

Product and Sales Manager – Single Use Technologies

Davide Stucchi studied chemical and process engineering at Politecnico di Milano, Italy, and then at ETH Zurich, Switzerland. After his studies, he worked as a project manager at a Swiss university, where he managed projects covering many fields of process engineering (catalysis, industrial chemistry, materials science). As of April 2022, he is Product and Sales Manager at DrM, Dr. Müller AG where he is in charge of Single Use product sales.



Duygu Dikicioglu

Associate Professor
UCL



Duygu Dikicioglu is an Associate Professor in Digital Bioprocess Engineering at the UCL Department of Biochemical Engineering. Her research focuses on the adaptation of digital technologies to solve problems at the cellular level and at the process level to improve manufacturing and development pipelines. She integrates systems biology and systems engineering approaches to handle complexity in biotechnological applications. She is an Associate Member of the Institution of Chemical Engineers, a Member of the Society for Biological Engineering, and of the International Metabolic Engineering Society.



Elise Huang

Group lead, Gene therapy downstream process development
UCB



Elise leads the gene therapy process science downstream team at UCB Pharmaceuticals (Brussels, Belgium). At UCB, she strategizes development activities on an accelerated timelines, sets up a bench- and pilot-scale laboratory, provides inputs on manufacturing equipment selection, and recruits talents to construct her team. She is interested in connecting with curious minds of different technical and cultural backgrounds to tackle downstream challenges. Prior to joining UCB, she worked at Apogenix (Germany), Takeda, Bristol-Myers Squibb and more companies in the USA. Elise obtained her PhD in chemical engineering from University of Wisconsin-Madison, USA, and BS in chemical engineering and BA in molecular cell biology from University of California-Berkeley, USA.



Gerald Gellermann

Senior Fellow & Analytical Project Leader
Novartis



Gerald currently works as Scientific Officer at Novartis TRD biologics. He is member of the Novartis ICHQ12 implementation team and leads the TRD biologics QbD and Control Strategy initiative. Prior to joining Novartis, he gained professional experience in CMC and analytical development during his time at Roche from 2008 to 2015 and before that at Abbott. Gerald currently represents Novartis in industry consortia including workstreams supporting Analytical Quality by Design and ICH Q14 establishment.



Laia Bosch Molist

PhD student at the Universitat Autònoma de Barcelona
UAB, Barcelona, Spain



Laia Bosch is a Biotechnologist from Universitat Autònoma de Barcelona (UAB, Barcelona, Spain). After graduating she did her Master thesis on the topic "Stable HEK 293 cell line generation for the production of GageGFP VLPs using CRISPR/Cas9 technology" in Cell Engineering and Bioprocess group at UAB. Then she enrolled a PhD in Biotechnology on Strategies for improving rAAV production for gene therapy applications using HEK 293 cells. Her current research activities focus on uncovering mechanisms associated with cell production of adeno-associated viral vectors and the use of metabolic engineering and analytical technologies to achieve high-yield productions of viral vectors for gene delivery.



Lukas Kürten

Principal Scientist - Data Analytics
CPI



Lukas is a Principal Data Scientist at the Biopharmaceuticals division of the Centre for Process Innovation (CPI), where he helps to transform CPI into a digital and data-driven enterprise. His responsibilities include both the analysis of data from biological systems and processes and the implementation of automation and advanced process control in the laboratory. One of his main current projects focuses on Smart Bioprocessing, aiming to deliver a step-change in the use of digital tools in bioprocess development. Lukas' background is in solid state physics, which he studied both during his PhD at the Max-Planck institute in Stuttgart and a postdoc at ETH Zurich.



M. Nicolas Cruz B.

Head of the KIWI-biolab
DataHow



Dr. M. Nicolas Cruz B. is heading of the KIWI-biolab as well as Bioprocess Modelling and Automation Expert at DataHow AG. He works intensively in the fields of bioprocess digitalization, model-based tools for biotechnology and biopharma, High Throughput Bioprocess Development, and autonomous biolabs. In the recent years his research has pushed the integration of model-based methods and High Throughput experiments to accelerate bioprocess development. The most relevant results include the first adaptive algorithms for online optimal redesign of parallel experiments and novel hybrid (Machine Learning and dynamical modelling) tools for bioprocess engineering. The driving force of his research is the conviction that robotic systems need proper digital tools, models, and algorithms to fully exploit its capabilities in bioprocess development and biomanufacturing.



Massimo Buonaiuto

Principal Scientist
DSM



Results-driven professional with 20 years of experience at international level in data science for R&D. Experienced leader in complex business environments and with multinational teams. International experience with top-tier Corporations and Organizations like United Nations, Fair Trade, Nespresso Nestlé, DSM in multiple fields like Data Science, Artificial Intelligence, Data Analytics, Data governance, Project Management, Agile, product management, R&D, Innovation management, Lab automation, Global Manufacturing, Change Management, eCommerce, Digital Marketing. Member of Artificial Intelligence Suisse Group – Zurich.



Michael Sokolov

Co-founder & COO
DataHow



Dr. Michael Sokolov is co-founder and COO of DataHow AG, a spin-off company from ETH Zurich specialized on process data analytics and modeling with a particular focus on the biopharmaceutical and chemical domains. He also holds a lecturer position for statistics for chemical engineers at ETH. Dr. Sokolov holds a PhD degree in bioengineering from ETH Zurich and obtained his MSc in chemical engineering from TU Munich.



Dr. Mohamad Toutounji

ATMP/Biologicals CMC Developer | ADQC Specialist
Molgenium



Mohamad Toutounji has an extensive experience in the biopharmaceutical industry working in Bioprocessing, Bioanalysis of biologics and ATMPs. In his current role at Molgenium, he focuses on providing CMC regulatory and strategy in biologics and cell and gene therapy areas. His role includes developing the Bioprocessing and the Bioanalysis aspects of the product and helping the clients in FDA/EMA meeting preparation (INTERACT, pre-IND), authoring quality control process, preparation of information request (IR) responses and authoring of biologics and ATMP master files.



Nils A. Brechmann

Application and Product Manager
MAGicBioProcessing



Dr. Nils Brechmann is an Application and Product Manager at MAGic Bioprocessing (former Lab-on-a-Bead AB) with 7 years of experience in magnetic separation helping biologic manufacturers streamlining the downstream process. Specializing in magnetic separation for biomolecules, such as monoclonal antibodies, and negative selection of cell subpopulations Nils uses that experience to elevate manufacturing of monoclonal antibodies within the process intensification and to enable large scale allogenic production in the future based on micro-scale magnetic beads.



Dr. Peter Neubauer

Professor for Bioprocess Engineering
Technische Universität Berlin



Prof. Dr. Peter Neubauer has been Professor of Bioprocess Engineering at the TU Berlin since 2008. He received his PhD from the University of Greifswald, Germany, worked as a postdoctoral fellow at KTH Stockholm, Sweden, and Halle, Germany, before becoming Professor of Bioprocess Engineering in Oulu, Finland. He worked with a variety of difficult-to-express proteins and (co-)developed technologies such as EnBase®, CELL-tainer® and FastScan®. He has over 250 publications. Currently, his laboratory focuses on the efficient development of bioprocesses for recombinant proteins and engineered cells and the scale-up/scale-down of bioprocesses. In the KIWI Future Lab strategies for future autonomous bioprocess development are developed. For this purpose, state-of-the-art technologies of PAT, robotics for cell cultivation and analysis, digitalization, modelling and AI are integrated.



Raena Morley

Scientist - Pharma Technical Development Europe
Roche Diagnostics GmbH



Raena Morley has been part of the Purification Technical Development group at Roche in Penzberg, Germany, for two years. In this time, she has contributed to various large molecule projects during late stage development and process validation with a focus on internal reports and regulatory filings. She is also involved in automation and data initiatives, and is a member of the DSP Modeling Team. Before starting at Roche, Raena completed her PhD at the Technical University of Munich on the topic of model-based design of preparative liquid-liquid chromatography processes. She holds a master's degree from the University of Erlangen-Nuremberg in Advanced Materials & Processes and obtained her bachelor's degree in Chemical Engineering from the University of Rhode Island.



Renaud Jacquemart, PhD, MBA

Chief Technology Officer
Mannin Research



Renaud Jacquemart is the CEO of Omnium Global, a boutique consulting firm launched in 2017. Renaud is a purpose-driven, strategic, global business executive with over 20 years of experience in process technology and leadership in the Biologics industry, including roles at Sanofi Pasteur, Merck KGaA and Batavia BioSciences. He has been instrumental to several commercial successes, including delivering a process that obtained a 10-fold reduction in the cost of manufacturing of MosquiRix™ (GSK), being awarded a Grand Challenge by the Bill & Melinda Gates Foundation for his work on making the next generation Polio vaccine affordable, or completing the sale of Matrix Separations to MilliporeSigma. He has designed multiple Biologics facilities for Biotechs and CDMOs, structured and led CDMO commercial operations and closed commercial agreements for over \$750M USD for Omnium clients. Renaud holds several C-level roles in companies that he co-founded or is advising, including Chief Technology Officer at Mannin Research. He is adjunct professor at McMaster University (Hamilton) and instructor at the Solvay Business School (Brussels). Best characterized by a holistic vision combined with a pragmatic and hands-on approach, he is familiar with all areas of biomanufacturing organizations where he and his team advise on the coordination of processes and operations across functions, from corporate strategy to CMC. To achieve his personal goal of supplying high quality, affordable biologics to create a sustainable impact on global health, Renaud has worked, consulted or partnered with clients in 30 countries across the world. His educational background includes a PhD in pharmaceutical engineering from University of Grenoble, a Post-Doc in chemical engineering from Polytechnique Montreal and an MBA from University of Toronto's Rotman School Of Management.



Silvio Weber

Scientific Director of the Industrial Workflow Development
Miltenyi Biotec



Silvio is the Scientific Director of the Industrial Workflow Development Team at Miltenyi Biotec being responsible to provide automated Cell and Gene Therapy procedures on the CliniMACS Prodigy for industrial customers. Silvio has more than 15 years of R&D experience in various fields of cell biology, including Immunology, Regenerative Medicine and Pharmacology. After joining Miltenyi Silvio has been coordinating custom-tailored development of automated processes for T-cell mediated Immunotherapy, Stem Cell Engineering and other innovative Cell and Gene Therapy approaches using the Miltenyi Biotec CliniMACS Prodigy platform. Silvio holds a Diploma degree in Biochemistry from the University of Bielefeld and a Doctoral degree in Biochemistry from the University of Kiel.



Dr. Stephen Driscoll

Senior Scientist, Algorithms
908 Devices



Dr. Stephen Driscoll is a senior scientist at 908 Devices, specializing in the development and application of multivariate algorithms. He obtained his Ph.D. from Dalhousie University, where he studied under the guidance of Professor Peter Wentzell. During his doctoral research, Dr. Driscoll focused on the advancement of algorithms and evaluation techniques for multivariate chemical subspace estimation. Additionally, he made significant contributions to the mathematical understanding and modeling of long-range correlated error structures in analytical measurements. With a strong foundation in mathematical modeling and algorithm development, Dr. Driscoll now applies his expertise at 908 devices. He continues to push the boundaries of multivariate analysis by further refining existing algorithms and spearheading the development of novel approaches.



Supriyadi Hafiz

Senior Scientist Formulation
Merck KGaA, Darmstadt, Germany



Supriyadi hafiz is currently a senior scientist in Process and Formulation Materials R&D at Merck Life Science. In his current role, he is mainly responsible for the development of excipients for downstream processing and final formulations of biotherapeutics. He holds a Master's Degree in Biosystem Technology from Darmstadt University of Applied Sciences.



Ulrich Rümenapp

Head of Launch Preparation
Bayer AG



Dr. Rümenapp is based in Wuppertal, Germany and working within the Bayer Pharma Product Supply Biotech organization, where he is responsible for late-stage development and launch preparations of Bayer's biotech assets, e.g., antibodies or antibody-drug-conjugates, including the transfer to external manufacturing partners, as well as strategic projects. Prior to that, Dr. Rümenapp worked in Bayer Biologics Development and was Head of Projects in Biotech Contract Manufacturing, where he was responsible for contract manufacturing partnerships to ensure market supply. Before it was acquired by Bayer, Dr. Rümenapp held a similar position at Schering AG, and he started his career in the Production & Logistics department of Schering, being responsible for production aspects of licensing deals, due diligences, and product acquisitions of small molecule products and biologics. Dr. Rümenapp studied chemistry and holds a Ph.D. in biosciences. He worked several years in academic biosciences research and as an assistant teacher in general pharmacology.



Vishal Mukund Sonje

Commercial Manufacturing Lead
CEPI



Mr. Vishal Sonje is an experienced CMC professional in the vaccines field, currently working as a Commercial Manufacturing Lead at CEPI (Coalition for Epidemic Preparedness and Innovations), based in London. Prior to joining CEPI, he worked at Sanofi Pasteur, as a CMC lead for pediatric hexavalent combo new vaccine development. He was in Sanofi for 07 years. Before that, he started his career in industry with the future leaders program (02 years) at GSK Vaccines, after completing the program he took the role of site projects lead and operational excellence champion. Within 05 years at GSK, he worked at various GSK vaccines sites located in Belgium and India, with areas focused mainly in tech transfer, productivity improvement, new product introduction etc. In addition to his primary job function, he has actively contributed in quality remediation programs, CAPEX projects for manufacturing building / tech transfer, projects in supply chain, financial modelling for CoGS and CAPEX investment. He holds a Masters in Pharm. Tech. (Formulations) from NIPER, Mohali and is a qualified Project Management Professional (PMP).



Dr. Xavier Garcia Ortega

Project Leader Researcher and Assistant Professor
Universitat Autònoma de Barcelona



Dr Xavier Garcia Ortega did his PhD and Postdoc in the Bioprocess Engineering Group of the Universitat Autònoma de Barcelona (UAB). This group has been working on developing bioprocesses with the yeast *Pichia pastoris* for 20+ years now. During these periods he worked combining strain and bioprocess engineering to optimize the performance of methanol-free bioprocesses towards its implementation in large-scale production processes. Currently, he's the Project Leader and coordinator at UAB of numerous International Academic and Industrial projects at the same time that he's supervising numerous PhD and MSc students.



Ward Mennes, M. Sc. Chem. Eng. & MBA

Director, Procurement CMC & Devices
Johnson & Johnson



Ward Mennes is the Director, Procurement CMC and Devices for the Pharma sector at Johnson & Johnson. At Johnson & Johnson he held other roles within Janssen Supply Chain Global Procurement and Janssen Supply Chain Planning. Prior to joining Johnson & Johnson, he held various roles at Borealis, where he gained valuable experience in chemical engineering, manufacturing, sourcing and supply chain management. He holds a Master of Science degree in Chemical Engineering from Katholieke Universiteit Leuven and an MBA from Katholieke Hogeschool Limburg.



Graziella Piras, Ph.D

Bioprocessing Segment Director
908Devices



Graziella Piras, Ph.D. Senior Director of Strategic Marketing, Life Science at 908 devices.

Graziella has over 15 years of experience in developing applications and solutions for upstream bioprocessing. Before joining 908 Devices, she held various positions in marketing and R&D at Thermo Fisher Scientific, leading projects to support the Cell Culture and Cell Therapy business. Graziella obtained her Ph.D. in Biochemistry & Molecular Biology from the University of Liège in Belgium. She did her postdoc studying the role of epigenetic regulation on cancer and development at the National Cancer Institutes in Maryland.



Dr. Fabian Feidl

CTO and Co-Founder
DataHow



Dr. Fabian Feidl studied Molecular Biotechnology at the Technical University of Munich (Germany). After his Master's thesis he collaborated within a research project at the University College London (UK), before he began his PhD in the Morbidelli-Group at the ETH Zurich (Switzerland). Fabian Feidl got scholarships from Roche, Hans-Rudolf foundation, Karl-Schlecht foundation and was elected to join the Bayerische EliteAkademie. In 2017 he co-founded DataHow AG and has since held the position of Chief Technology Officer. Presently, he is pursuing an international executive MBA at the University of St. Gallen (Switzerland).



Dr. Sean Ruane

Senior Scientist II – Data Science
CPI



Dr. Sean Ruane is a Senior Data Scientist at CPI's National Biologics Manufacturing Centre in Darlington, UK. Sean's current focus is leading projects in process modelling and digitalisation, leading CPI's Smart Bioprocessing project which aims to build transferrable, cross-process predictive models. Sean also works in Process Intensification and Process Control, including setting up CPI's continuous processing lab, and in novel techniques for RNA and mAb production and purification.



Islem Younes, PhD

Principal Scientist - Head of Strategic Office Bioprocess Development
CSL Behring



Islem Younes, PhD engineer in Bioengineering, is a principal scientist and head of the strategic office of Bioprocess Development within CSL Behring Bern. During her 3- year tenure, she gained experience in the development and optimization of novel manufacturing processes for plasma derived therapeutic agents leading to robust and scalable purification processes for new and commercialized drugs. Prior to joining CSL, Islem has experience in academic setting in the field of pharmaceutical sciences, having worked for over 2 years as post-doctoral research associate at the university of Geneva and for 3 years as assistant professor at the university of Tunis.