

INDUSTRIAL BIOTECHNOLOGY

QUESTIONS TODAY FOR TOMORROW'S NEEDS

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INDUSTRIAL BIOTECHNOLOGY

QUESTIONS TODAY FOR TOMORROW'S NEEDS

February 14th and 15th, 2017

WELCOME

Dear Invited Speakers and Participants,

It is a great pleasure to welcome you to the Debate “Industrial Biotechnology. Questions Today for Tomorrow’s Needs“, co-organised by B-Debate, an initiative of Biocat and “La Caixa Foundation” and the Universitat Autònoma de Barcelona, with the contribution of the Red de Biotecnología Industrial Integrativa and the willingness of an outstanding group of invited speakers who accepted to participate and to whom we are profoundly thankful.

Industrial Biotechnology is the convergence of biological sciences and industrial process engineering to provide biocatalysts (enzymes, microorganisms, cell lines) and bioconversion-based manufacturing processes for the production of a wide variety of goods. Industrial Biotechnology has already contributed to the production of a great number of daily products: enzymes, amino acids, vitamins, organic acids, biopharmaceuticals, antibiotics, biopolymers, biofuels, among others.

We are in a transition from a fossil-fuel to a biobased economy. Such conversion is progressing step by step and involves the replacement of petrochemical processes and raw materials with more energy-efficient and renewable biological ones. Many aspects have an influence on this path: scientific, technical, industrial, environmental and societal components take a role in this multidisciplinary field. Industrial Biotechnology will be at the cornerstone of the bioeconomy delivering solutions to some of the grand challenges of the 21st century, a key enabling technology by which modern economies can be shifted toward a more competitive, low-carbon growth model. The objective of this B-debate is to discuss openly on Industrial Biotechnology and its future challenges from these different angles, providing a more comprehensive understanding of the field as well as the identification of key vectors for its development in the future.

The Debate is structured in four blocks. In each of them, three experts will introduce the topic presenting their own perspective on the topic, usually from different positions (science, industry, society) and then a debate will follow-up, with the rest of experts and the audience in general. Everybody is encouraged to participate actively.

The focus of this first block will set the scene of the B-Debate, exploring what are the main questions and what should be the main driving forces of Industrial Biotechnology in the future. This will be analysed from three different perspectives: science, technology and society. The second block will focus on the so-called white biotechnology, including the production of chemicals, materials and energy, the use of renewable resources, the dilemma of intensive agriculture for food or fuel, the impact of biotechnology on the chemical industry and the future of bioenergy. The third block will focus on the so-called red biotechnology, with emphasis on the production of biopharmaceuticals, the burdens in the development of new biopharmaceuticals, the emergence of biosimilars, the production of new vaccines and the access to health treatment. The fourth block focuses on responsible innovation as a main driver of Industrial Biotechnology in the future, the necessary balance between the company benefits and the society benefits, open science vs IP rights, the environmental impact of biotechnology and the intensive use of resources.

We do hope this will be a rewarding activity for all participants; we strongly encourage you to take active part in the debate and thank you for joining us!

Yours sincerely,

Francesc Gòdia and Pau Ferrer (Scientific Leaders) and B-Debate

PROGRAM

Tuesday, February 14th, 2017

9:00 **Welcome**

Ignasi López Verdeguer, Director, Science and Grants Department, la Caixa Foundation

Albert Barberà, CEO, Biocat

Francesc Gòdia, Universitat Autònoma de Barcelona (UAB), Barcelona, Spain

9:30 **SESSION 1: INDUSTRIAL BIOTECHNOLOGY: SCIENCE, TECHNOLOGY AND SUSTAINABILITY**

Chair: **Pierre Monsan**, Toulouse White Biotechnology, Toulouse, France

Metabolic Engineering and Synthetic Biology for improved biotechnological production: promises and realities

Eleftherios Papoutsakis, University of Delaware, Delaware, USA

Industrial Biotechnology and Circular BioEconomy: opportunities and challenges

Javier Velasco-Alvarez, Neol Bio, Granada, Spain

10:30 **Coffee Break**

11:00 **Innovation & Sustainability in the Bio-based Industry**

Ulrich Kettling, Clariant, Planegg, Germany

11:30 **Biotechnology in the light of the future of the industrial system**

Suren Erkman, Université Lausanne, Lausanne, Switzerland

12:00 **Open debate**

13:00 **Networking lunch**

14:30 **SESSION 2: SUSTAINABLE PRODUCTION OF CHEMICALS, MATERIALS AND ENERGY**

Chair: **Pau Ferrer**, UAB, Barcelona, Spain

Tools for a revolution in biotechnology production platforms

José Luis García, CIB-CSIC, Madrid, Spain

Industrial Biotechnology and Circular BioEconomy: opportunities and challenges

Christine Lang, Organobalance-Novozymes, Berlin, Germany

Sustainable bio-production, a summary for policy makers

James Philp, Organisation for Economic Co-operation and Development (OECD), Paris, France

16:00 **Open debate**

17:00 **Wrap-up of the day**

Wednesday, February 15th, 2017

9:00 SESSION 3: BIOPHARMACEUTICALS PRODUCTION

Chair: **Francesc Gòdia**, UAB, Barcelona, Spain

Precision Medicine and the Human Protein Atlas

Mathias Uhlen, Royal Institute of Technology (KTH), Stockholm, Sweden

Development of innovative biologics – obstacles and opportunities

Ralf Schumacher, Boehringer Ingelheim, Biberach, Germany

Title to be confirmed

Josep Torrent, UAB, Barcelona, Spain

10:30 Open debate

11:00 Coffee break

11:30 SESSION 4: RESPONSIBLE INNOVATION IN INDUSTRIAL BIOTECHNOLOGY

Chair: **Ignasi López Verdeguer**, La Caixa Foundation, Barcelona, Spain

Innovation and corporate social responsibility in health care

Boerge Diderichsen, Novo Nordisk, Copenhagen, Denmark

TWB: An original public/private consortium for Industrial Biotechnology

Pierre Monsan, Toulouse White Biotechnology, Toulouse, France

The role of spin-off companies in responsible innovation ecosystems

Jordi Naval, Aelix Therapeutics, Barcelona, Spain

13:30 Open debate

14:00 Closing remarks

14:15 Networking lunch

SCIENTIFIC COMMITTEE



Pau Ferrer, Associate Professor at **Universitat Autònoma de Barcelona (UAB)**, Barcelona, Spain.

Pau Ferrer is Associate Professor of Biological Engineering at the Universitat Autònoma de Barcelona (UAB). He received his BSc Degree in Biology from the University of Barcelona (1988), MSc degree in Biotechnology from the UAB (1991) and his PhD Degree from The University of Reading, UK (1995). He joined, after a postdoctoral stay at the Universidad de Chile (1995-1996), the Department of Chemical, Biological and Environmental Engineering of the UAB, where he was appointed Associate Professor in 2008. He is in charge of the Systems Biology Laboratory of the Bioprocess Engineering and Applied Biocatalysis Group of this Department. Pau Ferrer's current research is focused on rational engineering of microorganisms (metabolic engineering) for production of useful products from renewable resources, with emphasis on recombinant proteins such as industrial enzymes. P. Ferrer's laboratory has adopted many of the latest analytical and biocomputational tools for quantitative physiology studies of industrial yeasts. He has published over 70 scientific publications and supervised 15 PhD Thesis. He is also co-founder of the company Bioingenium, UAB representative at the ACIB (Austrian Centre of Industrial Biotechnology) Strategy Board since 2015, member of the steering committee of the Microbial Physiology Section of the European Federation of Biotechnology since 2004. Serving as editorial board member for several journals and referee for national and international funding agencies.



Francesc Gòdia, Full Professor at **Universitat Autònoma de Barcelona (UAB)**, Barcelona, Spain.

Full Professor of Chemical Engineering at Universitat Autònoma de Barcelona. Overall Manager of the MELiSSA Pilot Plant (European Space Agency). Research activity in Animal Cell Technology and Life Support in Space. Teaching activity in Biotechnology and Chemical Engineering. Author of more than 85 papers, 5 patents, and advisor of 28 PhD thesis. Coordinator of the Courses on Animal Cell Technology and Cell culture-based Viral Vaccines of ESACT (European Society of Animal Cell technology). Committee Member of several Congresses. Chair of the European Congress of Biotechnology in 2009 and ESACT Meeting in 2013 and 2015. Member of the Executive Board of the European Federation of Biotechnology. President of Fundació Parc Taulí (Hospital de Sabadell, Barcelona). Member of the BOD of the Blood and Tissue Bank of Barcelona. Member of the Bureau of the Working Party Biotechnology, Nanotechnology and Converging Technologies of the OECD.

DETAILED PROGRAM AND INVITED SPEAKERS

Tuesday, February 14th, 2017

Session 1: Industrial Biotechnology: Science, Technology and Sustainability



Pierre Monsan, Founding Director of the **Toulouse White Biotechnology (TWB)**, Toulouse, France.

Pierre Monsan (68) is Professor Emeritus at the National Institute for Applied Sciences (INSA) of the University of Toulouse, and Professor at Mines ParisTech (Department of Biotechnology). He was elected member of the French University Institute (IUF) in 2003 and re-elected in 2008. He is Founding Director of the pre-industrial demonstrator “Toulouse White Biotechnology (TWB)”, which was granted M€ 20 within the frame of the French National Program “Investissement d’avenir” in March 2011 (www.toulouse-white-biotechnology.com). He has been active for 44 years in the field of enzyme catalysis (enzyme production, purification, immobilization and application, screening, structural characterization and molecular design). He authored more than 238 scientific publications, 3 books and 65 patents. His H-factor is 41. He was involved in the founding of several start-up companies: BioEurope (1984), BioTrade (1996), Genibio (1998) and in the move of LibraGen from Lyon to Toulouse (2004). He is member of the Scientific Advisory Board of several companies, founding member of the French Academy of Technology, member of several Scientific Societies and member of the College of Fellows of the American Institute for Medical and Biological Engineering (AIMBE). He is Chairman of the French Federation of Biotechnology (FFBiotech), member of the Executive Board of the European Federation of Biotechnology (EFB).

Chair of **SESSION 1**



Eleftherios Papoutsakis, Eugene DuPont Endowed Chair Professor, **University of Delaware & Delaware Biotechnology Institute**, Newark, Delaware (DE), USA.

Since 2007, E. Terry Papoutsakis is Eugene DuPont Professor of Chemical & Biomolecular Engineering at the University of Delaware. He received his undergraduate education at the Nat. Technical Univ. of Athens, Greece, and his MS & PhD from Purdue University. He started his academic career at Rice University before moving to Northwestern University where he was appointed as Walter P. Murphy Professor. His group has made important contributions in the areas of clostridia genetics and metabolic engineering; animal-cell biotechnology; & stem-cell bioengineering. He is widely recognized as a leader in metabolic engineering and synthetic biology of industrial clostridia. His lab is interested in developing strains of industrial importance in the biorenewables arena. His group was one of the first to recognize the importance of and study the fundamental mechanisms, both fluid-mechanical and biological, underlying cell injury and death due to mixing and aeration in animal-cell bioreactors. He pioneered several bioprocessing issues in stem-cell biotechnologies. Most recently, he is working on developing cell and gene-therapy technologies based on extracellular vesicles, and separately on biotechnologies to convert natural gas to liquid fuel. He has trained 66 PhD, 27 MS, & 32 postdoctoral students. His research has been funded by \$35+ millions of federal grants. He has published over 250 papers (receiving 15500 citations with a 73 h-factor), and has 17+ issued or pending patents.

Metabolic Engineering and Synthetic Biology for improved biotechnological production: promises and realities

Metabolic engineering (ME) emerged as an autonomous research activity in the late 1980s, at the point where genetic manipulation of cellular pathways became possible. Both experimental and computational tools were developed over the next 20 years to the point that one could confidently undertake the development of an engineered organism to produce a novel chemical or improve the production of a native metabolite. Industrial processes slowly emerged, and the field achieved increased recognition and respect. ME should not be confused with the development of genetically modified animal cells to produce therapeutic or diagnostic proteins, an activity that developed in parallel with ME, but led to the

enormous, in impact and value, biopharmaceuticals industry. Some 15-20 years later, in the early 2000s, Synthetic Biology (SB) emerged as another enterprise based on the ability to modify (the new word now was “edit”) DNA. In the beginning, there was a marked confusion: was SB different from ME, and if so, how and why? As the field moved forward, a combination of “political” and scientific advances gave SB a distinct character, but yet with large overlap with ME. SB became more sophisticated on engineering complex traits based on engineered regulatory components and focusing largely in non-pathway dependent traits, but also on generating precise DNA editing tools. I will discuss what is the present reality in terms of practical applications, aiming to separate hype from reality.



Javier Velasco-Álvarez, Managing Director of Neol Bio, Granada, Spain.

Chief Executive Officer of Neol Bio holds a PhD in Industrial Biotechnology (Universidad de León) and MD in Food Sciences and Technology (Universidad de León) and a Master in Innovation Management (Universidad Politécnica de Madrid). Managing Director of Neuron Bio (2005-2012), contributing to its incorporation to the MAB (Spanish Alternative Stock Exchange). Previously, Mr. Velasco led the Biotechnology Department of Puleva Biotech, S.A. and was researcher in GlaxoSmithKline and Antibioticos, S.A. He is an expert in technologies valuation and biotechnological Companies, as well as in the management of intellectual property portfolios. He is Member of the Board of the Spanish Technology Platform for Sustainable Chemistry (SUSCHEM-ES) coordinating the working group on “Industrial Biotech & Biorefineries”. He is also Member of the Board of Directors of the Spanish Association of BioIndustries (ASEBIO) where he has been named Chairman of the Industrial Biotechnology working group and coordinating the BioEconomy Group. He is also Member of the Board of the Spanish Association of Scientific Entrepreneurs. He is co-author of more than 30 scientific publications and 17 patent families related to Industrial Biotechnology.

Industrial Biotechnology and Circular BioEconomy: opportunities and challenges

Industrial biotechnology is a key enabler of the circular bioeconomy and a smarter, more sustainable industrial production of goods. This technology enables renewable, bio-based products to be developed in sectors as diverse as chemicals, materials, pharmaceuticals, plastics, food and feed ingredients, detergents, pulp and paper, textiles and bioenergy. Analysts predict a rapid expansion of renewable chemical production in the near future based on planned capacity expansion or new construction. However, the principal barrier to fully exploiting the industrial biotechnology opportunities relates to product cost-competitiveness, both compared to fossil alternatives and to equivalent products from elsewhere in the world. Cost-competitiveness is affected by many factors including the cost of feedstock, technology readiness level and the level of market support for biobased products. The competitiveness issue is compounded by difficulties in accessing finance for large-scale projects, and often low end-user awareness of IB-derived products and by a lack of skills and operational relationships to drive the sector forward. All this issues will be addressed during the debate.



Ulrich Kettling, Head of Market Segment Industrial Enzymes, Clariant, Planegg, Germany.

Dr. Ulrich Kettling is Head of Market Segment Industrial Enzymes at Clariant Group Biotechnology, Group Technology and Innovation based in Planegg, Germany. Before, Dr.Kettling was Head of R&D, Group Biotechnology at Clariant Biotechnology Center, Munich; Global Director Biotechnology and Biorefineries at Süd-Chemie AG, Munich; Chief Scientific Officer at Direvo Biotech AG, Cologne. He graduated in Biotechnology at the Technical University Carolo-Wilhemina, Braunschweig, and obtained a PhD in Biophysical Chemistry under the supervision of Nobel Laureate Manfred Eigen at the Max Planck Institute, Göttingen.

Innovation & Sustainability in the Bio-based Industry

Clariant is a globally leading specialty chemicals company, based in Muttenz near Basel/Switzerland. On December 31, 2015 the company employed a total workforce of 17’213. In the financial year 2015, Clariant recorded sales of CHF 5.8 billion for its continuing businesses. The company reports in four business areas: Care Chemicals, Catalysis, Natural Resources, and Plastics & Coatings. Clariant’s corporate strategy is based on five pillars: increase profitability, reposition portfolio, add value with sustainability, foster innovation and R&D, and intensify growth. Biotechnology is one of Clariant’s Group Technology & Innovation strategic R&D pillars. The Clariant Biotechnology Center located in Planegg/Germany has specialized in the development and implementation of bio-based processes. Clariant is member of Cefic, the European Chemical Industry Council; EuropaBio, the European Association for Bioindustries; SusChem, the European Technology Platform for Sustainable Chemistry, and BIC, the Bio-based Industries Consortium (www.biconsortium.eu), the private partner in the BBI JU (www.bbi-europe.eu), a Public Private Partnership between the EU and BIC to promote the bio-based industrial sector under the Horizon2020 framework program. The presentation of Dr. Kettling will focus on those programs and how they aim to promote sustainability and innovation within Europe’s bio-based industry.



Suren Erkman, Professor, Faculty of Geosciences and Environment, University of Lausanne, Lausanne, Switzerland.

Studies in Humanities (philosophy, literature) and Sciences (Biology) at University of Geneva. Then trained as a business and science journalist. Worked as an independent science writer and consultant before receiving a PhD on Industrial Ecology at University of Technology of Troyes (France). Co-founder, among others, of SOFIES Group (www.sofiesgroup.com) and ROI (www.roionline.org).

Since 2005, Professor of Industrial Ecology at University of Lausanne.

Biotechnology in the light of the future of the industrial system

Humanity has invented many socio-economic systems. But one appears really special: The Industrial System, emerging for the past 250 years. Modern biotechnology is an important and typical aspect of today's global industrial economy. But it should be seen in a more integrative perspective: the convergence of biotechnologies with information sciences and technologies, cognition sciences, and nanosciences. And, most crucial of all, the likely emergence of self-reproducing autonomous artefacts.

Session 2: Sustainable production of chemicals, materials and energy



Pau Ferrer, Associate Professor at the Universitat Autònoma de Barcelona (UAB), Barcelona, Spain.

(See his CV at the Scientific Committee section)

Chair of **SESSION 2**

José Luis García, Research Professor at Consejo Superior de Investigaciones Científicas (CSIC), Madrid, Spain.

Prof. José Luis García born in Madrid (Spain) in 1955 has a PhD in Chemistry and Bachelors of Chemistry and Pharmacy from the University Complutense of Madrid (UCM). He has worked as a teacher in the UCM, and as a Senior Research Leader in the company Antibióticos SA. He is currently Research Professor at the Center for Biological Research (Madrid) of CSIC (Spanish Research Council) as leader of the Environmental Biotechnology group. His research expertise focuses on the fields of Biochemistry, Genomics and Biotechnology with more than 300 publications

between articles, books and patents. He has worked as Scientific Policy Manager at CICYT, as Deputy Director General of CSIC, and as Advisor at the Ministry of Science and Innovation. He has been the President of the Spanish Society of Biotechnology. Currently, he is advisor of the State Secretary of R&D&I (MINECO), the National Representative of the ERC Program of the European H2020 Program and manager of the National EXPLORA Program (MINECO). He has founded two spin-offs companies of CSIC devoted to the analysis of genomes (Lifesequencing) and genetic diagnosis (Secugen).

Tools for a revolution in biotechnology production platforms

A platform can be defined as “a common or standard method, equipment, procedure or work practice that may be applied to the research, development or manufacture of different products” or as “a group of technologies or tools that are used as a base upon which other applications, processes or technologies are developed”. Different technology and process platforms are now used extensively in the biotech sector, both throughout the various phases of product development and in the facilities used to manufacture commercial bioproducts. A biotech platform may refer to many things, e.g., a biological gene expression system, a high throughput screening system based on robotics, an bioanalytical method, a bioproduct purification system, a method for cell culture, a process unit operation or even a complete process comprising multiple unit operations. Standardisation of approaches and tools across multiple products will lead to improved quality and consistency,

cost-savings primarily as a result of more efficient resource utilisation (equipment/people), and faster process and product development. A number of revolutionary biotech platforms and tools have been developed during the last years, e.g., metabolic engineering, synthetic biology, omics, systems biology, combinatorial biology, bioinformatics, nanobiology, bioengineering, tissue engineering, bioprinting, biosensing and lab on a chip microfluidics, high-throughput screening, directed evolution, etc., which are contributing to expand the frontiers of bioeconomy.



Christine Lang, General Manager, **Organobalance GmbH**, Berlin, Germany.

Christine Lang studied biology at the Ruhr University Bochum and University of Sussex, UK. She finished her PhD doctorate in 1985 at the Department of Botany in Bochum. She started her professional career as a leading scientist and group leader for molecular biology in the Chemical Industry. While dedicated to working in an industrial environment and bringing ideas into application, she never lost touch with the academic world and took up a senior scientist position at Technical University Berlin in 1993. She received her habilitation in 1996 and was appointed Associate Professor for Microbiology and Molecular Genetics at Technical University Berlin. She holds this position since 2006. In 2001 Christine Lang founded the company ORGANOBALANCE GmbH and established it as an R&D facility to develop novel microbial active ingredients and strains for food, feed, personal care and pharma applications. The company is a part of Novozymes AS since 2016. She is the company's Managing Director. In 2010, Christine Lang and Bernd Wegener co-founded BELANO Medical AG (formerly: ORGANOBALANCE Medical AG). Christine Lang takes an active part in biotechnology and entrepreneurial networks, she is part of the DIB/VCI and the DECHEMA boards. She is a consultant for the German government for Bioeconomy topics (co-chair of the German Bioeconomy Council).

Industrial Biotechnology and Circular BioEconomy: opportunities and challenges

Using bioprocesses and introducing biobased materials into the market is becoming increasingly important. Major drivers include increased cost efficiency, new products categories and/or consumers asking for sustainable and ecologically friendly products. After the chemical industry has been successfully reducing its energy and resource intensity for many years, the move towards bioprocessing allows to push the sustainability frontier even further. It becomes key enablers of the biobased economy and more broadly the "biologisation" of the economy. Biological processes and renewable raw materials such as fats, starches, cellulose and sugar replacing fossil raw material are increasingly used, if and when they can save costs or offer ecological benefits. Today, bioprocesses deliver fermented complex molecules such as amino acids and vitamins, or are part of "hybrid" processes where individual synthesis steps by biocatalysis are introduced to provide, for instance, selective enzymatic steps. In the presentation, challenges encountered in this process of "biologisation" as well as application examples, potential drivers of innovation and market access will be discussed.



James Philp, Policy Analyst at **OECD**, Paris, France.

Jim Philp (PhD) is a microbiologist who has worked as a policy analyst since 2011 at the OECD, specialising in industrial biotechnology, synthetic biology and biomass sustainability. He was an academic for about sixteen years researching environmental and industrial biotechnology: bioremediation, biosensors, wastewater science and engineering. He became involved with various UK government initiatives in biotechnology, such as Biotechnology Means Business, and BioWise. He was a coordinator of the LINK Bioremediation Programme, at the academic-industrial interface for about six years. In all he spent 8.5 years working for Saudi Aramco in Saudi Arabia as an oil biotechnologist, investigating field problems related to chemistry and microbiology, and developing biotechnology solutions for improved oil recovery and exploitation. He has authored over 300 articles. In 2015 he was inducted into Who's Who. He was elected as a Fellow of the Royal Society of Chemistry in 2015, and a Fellow of the Institution of Chemical Engineers in 2016.

Sustainable bio-production, a summary for policy makers

The transition to an energy and materials production regime based on renewable resources can be expected to be fraught with many setbacks and obstacles, technically and politically. Earlier transitions, such as from wood to coal and then from coal to oil, however, were not complicated by the so-called grand challenges such as climate change and resource depletion. For bioeconomy policy makers the issues start in regions (rural biorefineries), the R&D considerations are national and international, and the global reach is as a result of the complexities of biomass sustainability. One of the larger challenges for the bioeconomy, that of distributed manufacturing in small- and medium-scale integrated biorefineries, flies in the face of the current reality of massive fossil fuel and petrochemical economies of scale, married to gargantuan fossil fuel consumption subsidies. For the research community the challenges are also legion. Right now we see a burgeoning need for a blurring of the boundaries between the scientific method and the engineering design cycle. This calls for convergence of

green chemistry with industrial biotechnology and also for biotechnology to embrace the world of IT and computation. This also creates profound provocations for education and industrial training. Will the engineering biology graduate of the future look something like the chemical engineer of today? We need also to create a workforce with diverse, non-research skills, and perhaps there is a need for a different, less specialized, kind of PhD. Some of the issues have been lingering for decades, but rapid acceleration of bioeconomy policy is now forcing our hand.

Wednesday, February 15th, 2017

Session 3: Biopharmaceuticals production



Francesc Gòdia, Full Professor at **Universitat Autònoma de Barcelona (UAB)**, Barcelona, Spain.

(See his CV at the Scientific Committee section)

Chair of **SESSION 3**



Mathias Uhlen, Professor at the Science for Life Laboratory, **Royal Institute of Technology (KTH)**, Stockholm, Sweden.

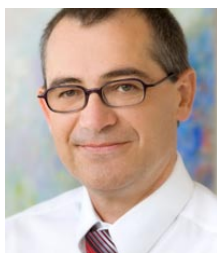
Dr Uhlen is a professor at the Royal Institute of Technology (KTH), Stockholm, Sweden. His research is focused on protein science, antibody engineering and precision medicine and range from basic research to more applied research, including clinical applications in cancer, infectious diseases, cardiovascular diseases, autoimmune diseases and neurobiology. The research has resulted in more than 550 publications with a current h-index of 98 (Google Scholar). Since 2003, he has led an international effort to systematically map the human proteome with antibodies and to create an open source knowledge-based resource called the Human Protein Atlas (www.proteinatlas.org). Based on the Protein Atlas effort (Uhlen et al, Science, 2015), he has launched a new wellness profiling effort in which individuals have been monitored every three months and analyzed using whole genome sequencing, cell analysis, proteomics, metabolomics and microbiome analysis. He is member of the National Academy of Engineering (NAE) in USA, the Royal Swedish Academy of Science (KVA), the Swedish Academy of Engineering Science (IVA) and the European Molecular Biology Organization (EMBO).. He was, starting in 2010, the founding Director of the Science for Life Laboratory (SciLifeLab), a national center for molecular bioscience (www.scilifelab.se).

Precision Medicine and the Human Protein Atlas

The human proteins constitute the major building blocks for the function of the various processes necessary for human life. We have classified all the protein coding genes in humans using a combination of genomics, transcriptomics, proteomics and antibody-based profiling (1). We have used this data to study the global protein expression patterns in human cells, tissues and organs (2) as well as a discovery tool to find potential biomarkers and drug targets for disease (3,4,5,6) and as standards in mass spectrometry based targeted proteomics (7,8). Recently, we have used this resource to launch a wellness profiling effort based on the Swedish CARDioPulmonary bioImage Study (SCAPIS), a large prospective clinical study. Individuals have been monitored every three months and analyzed using whole genome sequencing, cell analysis, proteomics, metabolomics and microbiome analysis.

Selected own references:

1. Uhlen et al (2015) Science 347: 394
 2. Uhlen et al (2016) Mol Systems Biol. 12: 862
 3. Martinoglu et al (2014) Nature Communication, 5:3038.
 4. Wein et al (2014) Nature Medicine 20: 992-1000
 5. Kampf et al (2014), FASEB J 28(7): 2901-2914.
 6. Lee et al (2016) Cell Metabolism, 12;24(1):172-84
 7. Forsström et al (2014) Mol Cell Proteomics 13: 1585- 1597
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Ralf Schumacher, Head of Bioprocess & Pharmaceutical Development Biologicals at **Boehringer Ingelheim**, Biberach, Germany.

Currently, I'm the Head of Bioprocess and Pharmaceutical Development in the Biologicals Development Unit within Boehringer Ingelheim. In this capacity, I'm responsible for leading all technical development activities (from DNA to launch) for biologicals including process, pharmaceutical, and device development plus pilot plant operations. All these activities are tightly integrated in the design of the corresponding therapeutic biologicals molecule and lay the foundation of the future manufacturing process. Deep understanding of corresponding requirements (eg mode of action, efficacy/safety profile, CMC continuum aspects, Technical Regulatory, interaction with Health Authorities) and trustful interface management with Discovery experts on one hand and Operations on the other hand are key parts of my accountability. The position encompasses developing strategies for diverse topics as technology management, process platforms, process characterization concepts, Outsourcing or Operational Efficiency. Additional responsibility includes assigning resources to projects, communicating progress and issues to senior management, taking prioritization decisions, and establishing Biologicals portfolios that span across different indications and different modalities. I'm responsible that project teams and subject matter experts define the right CMC strategies (Right in Time versus Right First Time, Risk taking versus Frontloading) as well as the right CMC packages for submission.

Development of innovative biologics - obstacles and opportunities

Biologicals (especially monoclonal antibodies) are naturally occurring human proteins – therefore they lack of unspecific toxicity /chronic toxicity /carcinogenicity

Specific interaction with molecular target □ In general no off-target toxicity

General pharmacology usually clean

Predictable PK properties (high bioavailability); usually no metabolism issues

If a therapeutic effect is achieved the dose is in many cases not limited by side effects

Main risk is target quality (efficacy in preclinical studies & pivotal studies)

Recombinant biologics are heterogeneous by nature. Their quality depends on the manufacturing process

Manufacturing of biologics requires a robust and complex production process

Modifications of the process may have significant impact on potency and safety

Strategic technology development is a prerequisite for successful CMC organizations

Timelines for development and manufacturing are dependent on technical complexity (including HA requirements) and other parameters like e. g. cell growth

The manufacturing process has to be carefully validated and controlled to ensure consistent quality – however, tailored for the respective phase of development

Key challenge: quality and timelines, clinical outcome

Key opportunities: translating discovery knowledge in process design, platforms, constant technology upgrading, gated development paradigms



Josep Torrent, Professor of Clinical Pharmacology and Therapeutics, **Universitat Autònoma de Barcelona (UAB)** and Area of Medicine Director of **Servei català de la Salut (CatSalut)** Barcelona, Spain.

Josep Torrent-Farnell is a qualified Pharmacist with a degree in Medicine and Surgery from the University of Barcelona as well as postgraduate courses in Pharmacology and Toxicology, Public Health and European Institutions. Josep is a specialist in Internal Medicine and Clinical Pharmacology and obtained his doctorate in Clinical Pharmacology from the Autonomous University of Barcelona (UAB). He became a member of the Committee for Orphan Medicinal Products (COMP) at the European Medicines Agency in 2000, serving as Chair for 2 mandates. Currently, he is also a member of the Scientific Advice Working Party (SAWP) at EMA. Josep is Professor of Clinical Pharmacology and Therapeutics at the Autonomous University of Barcelona (UAB) and Director of the Fundació Doctor Robert, Advanced Centre of Services and Training for Health and Life Sciences.

Session 4: Responsible innovation in Industrial Biotechnology



Ignasi López Verdeguer, Director, Science and Grants Department at "La Caixa" Foundation, Barcelona, Spain.

Working for "la Caixa" Banking Foundation in science related fields since 2000. Today contributing to coordinate its funding programmes of Research and Innovation, Fellowships and Science in Society - CosmoCaixa. He holds an extensive experience in Philanthropy of R&I, in Science and Innovation Policy and in Science in Society issues. He has been particularly active in the field of Responsible Research and Innovation as a leader of the EC funded project RRI Tools and as a participant and advisor in several H2020 projects. He is also Chairman of the ELSI Advisory Board of the EIT Health and a member of the Steering Committee of the Research Forum of the European Foundation Centre. He is a Physicist by the Universitat Autònoma de Barcelona and holds a postgraduate degree in Management by IESE-Universidad de Navarra.

Chair of **SESSION 4**



Børge Diderichsen, Vice President of Novo Nordisk, Barcelona, Spain.

Børge Diderichsen was born in 1952. He has a master's degree in biochemistry (1976) and a PhD in microbiology (1980) from the University of Copenhagen. In 1981, he joined Novo Industry as one of a small team of researchers who were to develop the use of genetically modified organisms for the production of insulin and industrial enzymes. Børge Diderichsen was appointed director of "Gene-Technology" in 1991 and Vice President of "Strategic Research Management" in 1993, a new unit coordinating research and patent strategies, the first of its kind in Europe. In 1996, he was appointed Vice President of "Corporate Research Affairs" to formulate Novo Nordisk's views on research policy, to interact with ministries, the European Commission, Chinese Academy of Sciences and other organisations in China, to build and maintain partnerships with universities, ministries, organisations etc., and to manage Novo Nordisk R&D Science, Talent, Attraction and Recruitment Program for PhD students and PostDocs. In 2012, he was appointed Vice President of "R&D Outreach", with focus on building research based relations with universities, research institutes and other public institutions in China, Argentina and other emerging markets.

Innovation and corporate social responsibility in health care

The cost of public health care is increasing in many countries that at the same time are struggling to keep their state budgets under control. This has had several consequences amongst which price pressure on medicines and a deteriorating reputation of pharmaceutical companies. This has also had an impact on Novo Nordisk, the largest provider of diabetes medicines in the world. Experiences and considerations on innovation and corporate social responsibility in relation to diabetes, one of the most important chronic diseases will be presented and discussed.



Pierre Monsan, Founding Director of the Toulouse White Biotechnology (TWB), Toulouse, France.

(See his CV at the Session 1)

TWB: An original public/private consortium for Industrial Biotechnology

Toulouse White Biotechnology (TWB) is a preindustrial demonstrator aimed at speeding up the development of industrial biotechnology by facilitating exchanges between public research and industry. TWB's mission is to contribute to the expansion of a bioeconomy based on the use of renewable carbon in the fields of chemistry, materials and energy. TWB is managed by INRA (French National Agency for Agricultural Research), under triple INRA/INSA/CNRS supervision. TWB's consortium gathers 52 partners (37 companies and 4 investment funds). A consortium agreement simplifies contract negotiations. The access fees of the private partners are invested in risky fundamental research aimed at generating intellectual property (IP). Within 4-year operation TWB has signed € 18m of industrial contracts, filed 13 patents, created 1 start-up (EnobraQ, 20 people), managed 57 projects, and accounts 86 collaborators. www.toulouse-white-biotechnology.com



Jordi Naval, Director of **Fundació Bosch i Gimpera (Tech Transfer Office of University of Barcelona)** and co-Founder and board member of **Aelix Therapeutics SL.**, Barcelona, Spain.

For the last 18 years I have built a number of start-ups, successfully creating and developing new business concepts in the biopharmaceutical industry. I am also involved in philanthropic and educational ventures. At my current position at Fundació Bosch i Gimpera my mission is to transform the world-class research at University of Barcelona into projects that benefit the society as a whole. In 2014 I joined the world-class team at HIVACAT and co-founded AELIX Therapeutics, aimed to develop immunotherapies to cure HIV infection globally. AELIX raised 11.5 m € in 2016 from several international investors. Co-Founder and Scientific Advisor at Genocosmetics, where I conceptualized the idea of personalized cosmetics based on the genetic profile of the customer in 2011. (www.genocosmetics.com)

The role of spin-off companies in responsible innovation ecosystems

Somebody defined “Open innovation” as “Closed innovation but with different boundaries”. What is becoming more and more relevant is that the innovation ecosystem needs three basic components: academic research (Universities and research centers), investors (public and private) and industry to in-license or acquire technologies. But at least three other elements have to be included in the mix: professional tech transfer offices, specialized providers and experienced entrepreneurs. Spin-offs, specially in the biotechnology industry, can be conceptualized as a minivan that transports a licensed technology from the academia to the industry, jump-started thanks to a smart tech transfer office, fueled by investor’s money, driven by a small team of entrepreneurs and scientists, and guided with the help of specialized experts and providers along the way. But like all road-movies, there is a “why”, a mission that should drive the endeavour, and what gives sense to all of it: the responsibility to solve people’s problem’s, being it new medicines, new diagnostics, new healthy products, cheaper food or cheaper materials.

PRACTICAL INFORMATION

Venue: CosmoCaixa Barcelona



CosmoCaixa Barcelona
C/ Isaac Newton, 26
08022 Barcelona, Spain

Conferences
Agora room on -2 floor

Contact persons during the event



Francesc Gòdia

Full Professor, Universitat Autònoma de Barcelona (UAB)
Francesc.Godia@uab.cat | Phone: +34 639687699
www.uab.cat



Marta Soler

Head of Research and Scientific Debate, Biocat
msoler@biocat.cat | Phone: +34 662315500 | +34 93 310 33 57
www.bdebate.org | www.biocat.cat

SUGGESTED READING

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ORGANIZERS

OUTCOMES

B·Debateca

On the website of **B·Debate**, you will find all the information related with the celebration of the meeting that includes reports, conclusions, scientific documents, interviews with the experts, speaker's CVs, videos, images, press documentation and other related materials. We invite you to visit the section **B·Debateca** on www.bdebate.org

Contents of the meeting “**Industrial Biotechnology. Questions Today for Tomorrow's Needs**”

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Artificial Intelligence: Dreams, Risks, and Reality

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B-Debate International Center for Scientific Debate Barcelona is a **Biocat** initiative with support from “**la Caixa**” **Foundation**. It drives first-rate international scientific debates, to foster dialogue, collaboration and open exchange of knowledge with prestigious national and international experts, to approach complex challenges of high social interest in life sciences. B-Debate sees debate as a powerful, effective way to generate knowledge and strives to help position Barcelona as a benchmark in generating knowledge and Catalonia as a country of scientific excellence.

B-Debate sees debate as a powerful, effective way to generate new knowledge. The debates are top-notch international scientific meetings featuring a selection of experts of renowned international prestige and scientists that work in Barcelona and Catalonia, moderated by scientific leaders. Since 2009 B-Debate has invited about 1200 recognized speakers and over 7.000 attendees. B-Debate seeks out answers to the challenges and needs of society in the field of life sciences, taking into account the complex, ever-changing conditions of this global world. The debates foster the integration of different disciplines of science and deal with such diverse topics as ageing, new therapeutic approaches to various diseases, innovative technology to improve knowledge of the human genome, food resources, new tools to integrate knowledge management, clinical genomics, neurosciences, climate change, and new energy sources, among others. The knowledge and results obtained through these events is spread throughout both the scientific community and general society through the various **B-Debate** channels and instruments.

More info: www.bdebate.org



Universitat Autònoma de Barcelona

The **Universitat Autònoma de Barcelona (UAB)** is known for its excellence in research and teaching, and is a reference centre in Europe. It offers 81 bachelor's degrees, covering all areas of knowledge, promotes innovation, employability and entrepreneurship and strives to foster research and transfer working closely with the surrounding business and industrial community. The UAB leads the Spanish universities on number of PhD programmes, providing advanced training in research techniques and culminating in a doctoral thesis. In recent years, the UAB has seen recognition for its efforts in promoting quality in research, with a steady improvement in its positions in the most prestigious and influential international rankings. In the 2016-2017 edition of the Times Higher Education World University Rankings, the UAB is the best Spanish university, occupying position 163 in the world ranking.

More info: www.uab.cat



The **Spanish Network on Integrative Industrial Biotechnology** (Red de Biotecnología Industrial Integrativa, RBII) is a partnership of 9 research groups from different R&D institutions and universities active in industrial biotechnology and sustainable development, supported by the programme "Networks of Excellence" of the Spanish Ministry of Economy and Competitiveness.

The RBII aims to stimulate and strengthen R&D activities, cross-sectorial knowledge transfer and innovation in the field of industrial biotechnology, with particular focus on the integration of biocatalyst design (including synthetic biology) and industrial bioprocess engineering. It also aims to act as a catalyst for the establishment of a future pan-European distributed Research Infrastructure dedicated to industrial biotechnology (IBISBA, www.ibisba.com).

Members of the Network:

- Department of Chemical, Biological and Environmental Engineering, UAB. (Network Coordinator: P. Ferrer)

Web: <http://www.uab.cat/web/department-of-chemical-biological-and-environmental-engineering-1225094722779.html>

- Department of Bioengineering, Institut Químic de Sarrià (IQS) - URL (IP Antoni Planas)

Web: <http://www.iqs.edu/en/research/scientific-technical-area/departments/bioengineering>

- Departament of Biochemistry and Molecular Biology B & Immunology. Universidad de Murcia (IP Manuel Cánovas).

Web <http://www.um.es/web/bbmbi/contenido/departamento>

- Systems Biology Program, Group of Molecular Environmental Microbiology. CNB-CSIC (IP Víctor de Lorenzo)

web: <http://www.cnb.csic.es/index.php/en/research/research-departments/systems-biology/molecular-environmental-microbiology-laboratory>

- Group of Biotechnology for Lignocellulosic Biomass. CIB-CSIC (IP María J. Martínez)

web: <http://www.cib.csic.es/research/environmental-biology/biotechnology-lignocellulosic-biomass>

- Group of Metabolic Engineering. Instituto de Microbiología Bioquímica. Universidad de Salamanca (IP José L Revuelta)

- Centre for Biotechnological and Agrofood Developments. Universitat de Lleida (IP Ramon Canela Garayoa).

web: <http://www.dba.udl.cat/en/>

- Group of Biotechnology of Marine Microalgae. Department of Chemical Engineering. Universidad de Almería (IP Emilio Molina). web: http://cvirtual.ual.es/webual/jsp/investigacion/nuevo/plnicio.jsp?id_grupo=BIO173&idioma=en

- Group of Environmental Engineering and Bioprocesses. Department of Chemical Engineering. Universidade de Santiago de Compostela (IP Juan M. Lema). web: <http://www.usc.es/biogrup/?q=user/512>

COLLABORATORS

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CosmoCaixa offers interactive, enjoyable science and an open door for anyone who is eager to learn and understand and who never stops wondering why things are the way they are. **CosmoCaixa Barcelona** boasts the Geological Wall and the Amazon Flooded Forest, which features more than 100 plant and animal species that convince visitors they have been transported from the Mediterranean to the very heart of the tropical jungle. In addition to its permanent facilities and its open areas, CosmoCaixa offers a scientific and educational programme that includes exhibitions, workshops, conferences, courses and debates involving experts from all over the world.

More info: www.obrasocial.lacaixa.es
