We are pleased to announce the launch of the Drug Formulation, Solubility & Bioavailability Summit that will take place on 30–31 May 2016 in Barcelona, Spain.

This summit will provide a platform to discuss the latest effective formulation tools and technologies for enhancing solubility and bioavailability.

We invite you to join the leading formulation experts from around the world in this key discussion on formulation and delivery, and see how experts like you are developing poorly soluble drugs into scientifically sound, patient-centric formulations, and reducing their product development timelines.

This summit provides a perfect atmosphere for the top experts of drugs formulation, solubility and bioavailability leaders to network and engage in scientific discussions about the most exciting areas of research that will shape the future landscape of the industry.

It is an honour and privilege to invite you to take part in the Conference.
We are looking forward to welcoming you at this event in May!

Sincerely,
Anna Adler, Project Director

WHO SHOULD ATTEND
This summit is a must-attend event for Pharma, Biotech, Research, Drug Delivery scientific professionals with the following job titles and the fields of expertise:

Job Titles:
- CEOs/VPs/SVPs
- Managing Directors
- R&D Directors/Managers
- Business Development Directors/Managers
- Consultants
- Formulation Development Scientist
- Heads of Formulation / Drug Product Development
- CSO & CMOS
- Heads of External Innovation / Pharmaceutical Development
- Business Development Directors/Managers

Responsible for:
- Formulation/Preformulation
- Pharmaceutical Development
- Preclinical Development
- Pharmacokinetics/Pharmacodynamics/ DMPK/PKDM
- Pharmaceutics/Biopharmaceutics
- Physicochemistry
- Solid State Characterization
- Drug Delivery
- Drug Discovery
- Analytical Development
- Medicinal Chemistry
- Material Science
- Toxicology
- Chemical Engineering
- Solid State
- Product Development

KEY LEARNING POINTS
- Ensuring the quality and stability of biologic formulations as well as the formulation of highly potent molecules
- Legislation and regulations in developing new formulations
- Nanomedicines and nanosimilars
- Multiparticulates to enhance clinical outcomes in pediatric and geriatric patients
- Clinical Perspective on Formulation Requirements for Early Clinical Trials
- Overcoming Solubility and Bioavailability Challenges by Considering Alternative Technologies
- & others

ABOUT THE VENUE

NOVOTEL BARCELONA CITY
Avenida Diagonal 201 (Entrada por Ciutat de Granada) HB004414, 08018BARCELONA - SPAIN
Ph: (+34)933262499 | EM: h5560@accor.com

DIRECTIONS:
From France: take the AP-7/E-15 toward Barcelona, enter the city via the Rondes (ring roads) (Ronda Litoral, Zona Franca exit) and take exit 28 toward Pza Glòries. Once in the city, follow signs to Pza Glòries, Avenida Diagonal.

Railway Station: EL CLOT–ARAGÓ
Airport: EL PRAT DE LLOBREGAT
Underground station: line L1—station GLORIES
BUS: line 7—station GLORIES / line 62—LES GLORIES
TRAM: line T4—station GLORIES

MEDIA PARTNERS
Introduction into technology to enhance solubility of poorly soluble drugs

Physico-chemistry based methodology of formulation

Purposes of the guideline and general considerations

This presentation focuses on the use of solid micro-doses

Selection of strength in the context of study population

Process development and scale-up

General concept for selection of product strengths

The methodology used to screen and characterize

Screening of formulations for amorphous solid dispersions

Studies required for individual types and categories

Case study on how to achieve viable and improved formulations

Computationally-assisted design of protein structures

A reduction in dosage volume, delivery of the drug in solid form, and self-administration achieved using this method can obviate the solubility and stability challenges associated with many new drugs, vaccines and biologics

Overcoming Bioavailability Problems for Drugs With Poor Solubility

CASE STUDY
09:40 Overcoming Solubility and Bioavailability Challenges by Considering Alternative Technologies

> Introduction into technology to enhance solubility of poorly soluble drugs by using carrier (e.g., Silica) technology with amorphous loaded APIs
> Show opportunities on the other end of delivery by addressing opportunities to prepare sustained release tablets (without alcohol dose dumping) using direct compression tabletting

Dr. Dieter Lubda • Director R&D Franchise Formulation
Merck Millipore

CASE STUDY
10:20 Oral Formulation of Poorly Soluble Drugs with Solid Solutions and Solid Suspensions

> Case study on how to achieve viable and improved formulations containing class 2 molecules (as BCS), focused on formulation and the methodology used to screen and characterize viable formulations, scale-up, manufacturing of samples for “in vivo” studies
> Feasibility of industrial formulations obtained in the screening and development of stable dosage forms

Gemma Casadevall • CSO • Medichem

11:00 Morning Coffee and Networking Break

11:30 Novel Solid Microdose Injections to Overcome Product Solubility Issues

> An increasing number of drugs are facing solubility and stability issues, hindering their further development into viable dosage forms
> Injectable drugs have always been viewed with a bias towards liquid based delivery
> This presentation focuses on the use of solid micro-doses of drug delivered in the skin using a minimally invasive solid micro-delivery device
> A reduction in dosage volume, delivery of the drug in solid format, and self-administration achieved using this method can obviate the solubility and stability challenges associated with many new drugs, vaccines and biologics

Dr. Faz Chowdhury • CEO • Nemaura Pharma Ltd

12:10 Technology Platform, Polymer and Excipient Selection for 21st Century Modified Release Oral Dosage Forms – Challenges and Opportunities

Recent trends show that new drug substances are potent, insoluble and unstable. Regulators, health providers and consumers expect higher quality than ever, and consistent drug products from the manufacturers. Here, comment modified release technologies, plus recent advances made to accommodate the challenging new drug substances will be presented followed by examples of how the formulators, suppliers and machine manufacturers work together to bring appropriate modified release drug delivery solutions.

Dr. Ali Rajabi-Siahboomi • VP & Chief Scientific Officer
Colorcon

CASE STUDY
14:00 Nanotechnologies Development for Clinical Investigations

> Physico-chemistry based methodology of formulation and engineering
> Process development and scale-up
> Parenteral cGMP pilot designed for highly active product and able to be operated at high pressure and high temperature. The pilot is able to supply batches from few hundred of grams to kg of nanocrystalline suspension, emulsion and liposomes covering the needs from phase 1 to launch

Mostafa Nakach • Head of Pharmaceutical Engineering
Sanofi

CASE STUDY
14:40 Impact of the Newly Adopted EU Guideline on the Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms of Generic Drug Products

> Purposes of the guideline and general considerations
> Types of oral modified release products from the biopharmaceutics perspective
> General rules for types of required bioequivalence studies
> General concept for selection of product strengths for bioequivalence studies
> Selection of strength in the context of study population and study type
> Studies required for individual types and categories of formulations
> Primary PK parameters for demonstration of bioequivalence and their evaluation in single-dose and multiple-dose studies
> Case-by-case approach

Pavel Farkas, Pharm.Dr. • Senior Director – Biopharmaceutics/ Clinical Development • TLIVA, TEVA Group

CASE STUDY
15:40 Amorphous Solid Dispersions by Spray Drying: Formulation and Process Development

> Amorphous solid dispersions as an enabling platform for the enhancement of drug solubility and bioavailability
> Screening of formulations for amorphous solid dispersions
> Spray drying as a technology for the manufacture of amorphous solid dispersions: scale-up, quality by design and development by design initiative

Rui Ferreira • Particle Design & Pharmaceutical Development – R&D Drug Product Development • Hovione

CASE STUDY
16:20 Designing Protein Solubility

> Protein-based biopharmaceuticals have an inherent propensity to aggregate
> Protein aggregation impacts the product’s developability, stability, formulation and immunogenicity
> Computationally-assisted design of protein structures and solutions permits to overcome these limitations

Salvador Ventura • Professor of Molecular Biology
Autonomous University of Barcelona (UAB)

17:00 Chairman’s Closing Remarks and End of Day One

19:00–21:00 Networking Dinner

Meet and confer with colleagues in a relaxing atmosphere during the networking dinner which will provide a great opportunity to discuss the first day of the summit and socialize.
Formulation Factors and Effect on Clinical Outcome

09:00 Opening Address from the Chairman / Recap of Day One

09:10 Bioavailability Improvement on Various Levels Along the Value Chain

Highlights include:
> Fluid Bed Technologies & its applications with industrial case studies showing the following topics
> Solubility & bioavailability enhancement: In-Situ solubility enhancement by micro-environment optimization (coating)
> Solubility & bioavailability enhancement: Co-Precipitation using fluid bed technologies (co-precipitation)
> High shear vs. fluid bed granulation: Which shows a faster disintegrating tablet?
> Alternative pelletization technologies: Particle & release profile design by multiple coating &/or direct pelletization (batch vs. continuous approaches)
> Process development: QbD approach for process optimization & scale up

Ahmad Ghoniem • Business Development Pharmaceutical Services • Glatt

09:50 Micro- and Nanoformulation of APIs Using Co2-Expanded Solvents

> Nanotechnology is a promising alternative to overcome the problems of the administration of APIs and therapeutic biomolecules
> Large-scale production of drug nanof ormulations is still challenging
> CO2-based technologies allow the one-step preparation of drug nanof ormulations with high batch-to-batch and scale-up reproducibility.
> New colloidal systems with large shelf-stability and additional antimicrobial properties, named quatsomes and prepared using CO2-based technologies, will be presented as smart nanocapsules for the delivery of proteins

Dr. Nora Ventosa
Scientific Researcher • CSIC and CIBER-BBN
Co-Founder and Scientific Advisor • Nanomol

10:30 Morning Coffee and Networking Break

11:00 Multiparticulates to Enhance Clinical Outcomes in Pediatric and Geriatric Patients

> Understanding the impact of patient centric product design on safety and effectiveness
> Developing and conceptualizing the product profile
> Approaches to multiparticle for special patient populations
> Transferring patient centric design into efficient manufacturing

Sven Stegemann, PhD.
Professor for Patient Centric Drug Development and Manufacturing • Graz University of Technology
Director • Capsugel

11:40 Nanomedicines and Nanosimilars: Current Regulatory and Market Status

Dr. Erem Bilensoy • EUFEPS President; Professor of Pharmaceutical Technology • Hacettepe University

12:20 Pharmacokinetics Aspects of Nanoparticles

Dr. Erem Bilensoy • EUFEPS President; Professor of Pharmaceutical Technology • Hacettepe University

13:00 Business Lunch

14:00 Mesoporous Nanoparticles for Theranostics and Drug Delivery

Dr. Jean-Olivier Durand
Research Director • Institut Charles Gerhardt de Montpellier
Co-founder and Scientific Advisor • NanoMedSyn

14:40 Panel Discussion

Technologies to Explore the Potential Physiological Option Space for Improved Formulations

Dr. Victor Puntes • ICREA Research Professor
Catalan Institute of Nanotechnology (ICN)

15:20 Chairman’s Closing Remarks and End of Summit
SPEAKER PROFILES

Dr. Dieter Lubda
Director R&D Franchise Formulation
Merck Millipore

Dr. Dieter Lubda, Director R&D Franchise Formulation at Merck-Millipore – Pharm Chemical Solutions, Darmstadt, Germany. His department R&D is focusing on the development and formulation of excipients for oral and parenteral administration of drugs. Main topic is the implementation and optimization of new technologies addressing the needs of novel chemical entities during formulation and supporting bioavailability enhancement questions.

Dr. Dieter Lubda has got 20 years experience on different positions in research and development of inorganic materials used in chromatography and other application fields. Additionally he collected as Associate Director Strategic Planning 6 years of production experience being responsible for global operation topics. During the start of his career he was 6 years involved in the R&D Synthesis and production transfer of hormones/ steroids/prostaglandins/ beta-blockers at Schering AG (West Berlin) being mainly responsible for the development part of the APIs.

Dr. Dieter Lubda has got his Ph.D. degree in Analytical Chemistry from the University of Vienna, Austria and holds a degree “Diploma Engineer of Chemistry” after finalizing his thesis at the Technical University of West-Berlin, Germany.

During his career of more than 30 years with Merck Dr. Dieter Lubda has contributed to high number of publications, patents and presentations dealing with chemical and pharmaceutical topics.

Dr. Faz Chowdhury
CEO
Nemaura Pharma Ltd

Faz Chowdhury originally trained as a pharmaceutical scientist, and holds a Masters in Microsystems and Nanotechnology from Cranfield University, UK, and Doctorate from the University of Oxford on nano-drug delivery.

He is the founder of several companies specializing in Drug Delivery and Medical devices, and has experience in product development, manufacturing, and technical and corporate management spanning over 17 years. He is sole inventor on more than 18 granted and pending patents in the field of medical devices, and pharmaceutical formulations.

He is also the author of Textbook Chapters on Nano-biosciences for Wiley and Elsevier, and serves on the Board of Medilink East Midlands, UK.

Dr. Ali Rajabi-Siahboomi
VP & Chief Scientific Officer
Colorcon

Ali Rajabi-Siahboomi is Vice President and Chief Scientific Officer at Colorcon, based in Global Headquarter, USA. He obtained his B.Pharm. & Ph.D. in Pharmacy, from University of Nottingham (UK). Ali has held various academic positions in Nottingham and Liverpool JM Universities in the UK, before joining Colorcon as Technical Director, responsible for Europe, Middle East and Africa in 2000.

Ali’s main research interests are in the area of solid dosage form pharmaceutics and pharmaceutical technology with emphasis on oral drug delivery systems. He has published over 250 articles, book chapters, abstracts and patents.

Gemma Casadevall
CSO
Medichem

Gemma Casadevall, Ms.Pharm Sciences & PhD., is nowadays Chief Scientific Officer at Medichem, overseeing all corporate scientific research operations (Spain, Malta and China) for Active Pharmaceutical Ingredients and Finished Dosage Forms. With more than 20 years of experience in the Pharmaceutical Industry, her career has focused in: formulation, drug delivery, development and technology transfer. Her special fields of interest have been implementing QbD and PAT systems for pharmaceutical dosage forms, mostly oral controlled released products, for the US market. Also, she has led several technology platforms focused on drug delivery and bioavailability enhancement and site specific delivery with polymeric chemistry with applicability for oral, nasal, ophthalmic and otic products.

She has held several director and senior management and director positions at Salvat (Spain), Esteve (Spain), Lacer (Spain), Johnson and Johnson (USA) and Ferrer (Spain). She is also Associate Professor at School of Pharmacy at University of Barcelona.

Dr. Pavel Farkas
Pharm.Dr.
Senior Director – Biopharmaceutics/ Clinical Development
Pliva, TEVA Group

Pavel Farkas graduated and earned a Doctor of Pharmacy degree from J.A.Comenius University and Institute of Experimental Endocrinology of Slovak Academy of Sciences in Bratislava, Slovakia and Pharmaceutical Medicine at the Charles University in Prague, Czech Republic. He joined a generic pharmaceutical industry following a career in the field of basic pharmacological and endocrinological research and has been working in the area of clinical development of generic products for over 20 years. He joined PLIVA in 2004 with responsibilities and experience covering pharmacokinetic, bioequivalence and therapeutic equivalence studies for generic products, conducted mostly for EU/CEE, US and Canadian regulatory submissions as well as respective GCP and regulatory aspects. Pavel Farkas is currently responsible for PLIVA/TEVA’s R&D Biopharmaceutics operations, acting as a member of Bioequivalence Working Group of European Generic Association (EGA) and Steering Committee of AAPS Generic Pharmaceuticals Focus Group.

Mostafa Nakach
Head of Pharmaceutical Engineering
Sanofi

Mostafa Nakach is a Pharmaceutical engineer from Ecole des Mines d’Albi and a Master 2 graduate from Paris-sud 11 university in Pharmacotechnie and Biopharmacy. He is preparing thesis on stabilization and production of nanocrystalline suspensions. He is working within sanofi group since 28 years. His current position is a head of pharmaceutical engineering section within pharmaceutical science operations. His mission is to build and to manage the required skills and capabilities in order to support R&D projects development mainly for:

1. Formulation design of nano-vectors
2. Fill&Finish Commercial process development of biotech products
3. Development and adaptation to pharmaceutical regulation of new manufacturing processes (nanotechnologies, amorphization, spray drying, freeze drying etc. . . .)
4. Identification of critical steps and relevant monitoring to manufacture a product exhibiting the expected quality attribute
5. Implementation of pharmaceutical engineering tool box that will contribute to the implementation of QBD approach
6. Modelling scale down and scale-up rules
7. Design and set-up/validation/qualification of equipments and pilots aimed at manufacturing nanotechnology-based product

Mostafa Nakch worked also as API physical quality research engineer within chemical development department. His mission was focused on the process development of solid chain: from crystallization to particles engineering.

Rui Ferreira, PhD
Particle Design & Pharmaceutical Development – R&D Drug Product Development
Hovione

Rui Ferreira is graduated in Chemical Engineering by Universidade de Aveiro (Portugal) and holds a Ph. D. in Engineering Sciences and Technology.

His thesis was focused in solid-liquid extraction processes and was performed in a joint collaboration between Universidade Nova de Lisboa (Portugal) and Regensburg University (Germany).

Rui Ferreira has joined Hovione NJ (USA) as a process engineer in 2014 and later moved to Hovione HQ (Portugal) where he integrated the Drug Product Development group as Process Development Scientist. Since then, Rui has participated in the scale-up of multiple spray drying processes for the production of amorphous solid dispersions. Rui Ferreira is co-author of 18 scientific papers in peer reviewed journals and book chapters. His main interests are in the areas of oral dosage forms and pharmaceutical technology.

Ali’s main research interests are in the area of solid dosage form pharmaceutics and pharmaceutical technology with emphasis on oral drug delivery systems. He has published over 250 articles, book chapters, abstracts and patents.

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"Less is more" and "make it simple" are surely his mottos on a personal and professional level. Salvador Ventura is Full Prof. at the Dep. of Biochemistry and Molecular Biology and leader of the Protein Folding and Design group at the Institute of Biotechnology and Biomedicine, Autonomous University of Barcelona (UAB). He has authored more than 120 peer-reviewed research and review papers on protein folding and aggregation, apart from several book chapters and patents. He got his Ph. D. in Biology at the UAB in 1998 and worked as postdoctoral fellow (1999-2001) at EMBL-Heidelberg. He has been researcher at Harvard Medical School (USA) and Karolinska Institutet (Sweden) among other centres. He rejoined UAB as a Ramon y Cajal researcher in 2003. Dr. Ventura received the UAB 2008 Excellence Research Award and the 2009 and 2015 the ICREA-Academia Awards for excellence in Biological and Medical Sciences.

Ahmad Ghoniem is an Egyptian pharmacist, who pursued his PhD in pharmaceutical technology at the Eberhard-Karls University of Tubingen, Germany. His doctoral thesis was about formulation and process development for coating of moisture sensitive APIs by a novel moisture-protective formulation. He has worked for a few multinational companies in Cairo, Egypt (Sales & Marketing) prior to his PhD and is now working in the Business Development of Glatt Pharmaceutical Services, the CDMO division of Glatt. He has profound knowledge and deep expertise in fluid bed technologies, including direct pelletisation, pellet & table coating, granulation, scale up and more. “Less is more” and “make it simple” are surely his mottos on a personal and professional level.

Sven Stegemann is director, pharmaceutical business development at Capsugel, and professor of patient centric drug design and manufacturing at the Graz University of Technology, Austria. Over the course of his 18-year career at Capsugel, Dr. Stegemann has worked as an advisor to major pharmaceutical companies on ways to improve the design, development and manufacture of pharmaceutical products so they better address the individual needs of patients. In his academic role, Dr. Stegemann's focuses his research on the rational development of patient centric drug products and their associated manufacturing technologies, as well as education and training of students and young scientists. Dr. Stegemann is the founder and chair of the AAPS Focus Group on Patient-Centric Drug Development, Product Design, and Manufacturing as well as the founder and President of the Geriatric Medicine Society.

Erem Bilensoy is a full professor of pharmaceutical technology. She graduated from Hacettepe University Faculty of Pharmacy in 1992. She obtained her double Ph.D. degree with a co-tutelle thesis between Université Paris-Sud, France and Hacettepe University in 2002 on the evaluation of amphiphilic β-cyclodextrins modified on the primary face as novel excipients in the preparation of nanospheres and nanocapsules. She is the author of more than 55 scientific articles, 11 international book chapters. She has given several invited lectures, oral and poster presentations receiving more than 670 citations with an H-index of 18.

Dr. Erem Bilensoy has served as BA/BE Evaluation Commission member between 2007–2012 and Vice Dean of Faculty of Pharmacy between 2010–2013. She is serving as Treasurer and Executive Committee Member for EUFEPS European Federation for Pharmaceutical Sciences since 2012. She is founder member and scientific secretary for EUFEPS Network on Nanomedicine since 2010 and Executive Committee Member for European Cyclodextrin Society since 2009. She is Editorial Board Member of the journal Recent Patents in Drug Delivery and Formulation.

Erem Bilensoy was recently elected as President of EUFEPS starting from June 2015. Her current research interests include nanoparticles in cancer therapy, cationic nanoparticles, cyclodextrin-based drug delivery, wound healing, bioavailability/bioequivalence of oral drug delivery systems, bioavailability improvement through cyclodextrins and inkjet printed drug delivery systems. Erem Bilensoy is married and has a daughter Deniz aged 11.

Prof. Victor F. Puntes' research spans in the field of nanoparticles: synthesis and conjugation of inorganic nanoparticles, their properties, nanotoxicology and nanosafety, and a variety of applications including medicine and environment. In 1998 he obtained his PhD in Physics from the Universitat de Barcelona (UB). He had previously done his undergraduate studies in Chemical Engineering and Materials Science, at the Université Louis Pasteur Strasbourg, France. After his PhD he spent about 4 years at the University of California – Berkeley (UCB) and the Lawrence Berkeley National Laboratory (LBNL), USA, in the group of Prof. Paul Alivisatos. In 2003 he returned to Catalonia with a Ramon y Cajal research position at the UB, and in 2005 obtained an ICREA Professorship at the then Catalan Institute of Nanotechnology (ICN – now ICN2) in Barcelona, Spain, to create the Inorganic Nanoparticles Group, which he leads today. In 2015 he opened a new lab at the Hospital Universitary Vall de Hebron Research Center where he leads the nanoparticle design and pharmacokinetics group. He has co-authored of over 170 peer-reviewed publications with more than 9,300 citations and an H-index of 45. He is also well-known for his work in science dissemination among the general public and developments towards industrial and commercial applications.