

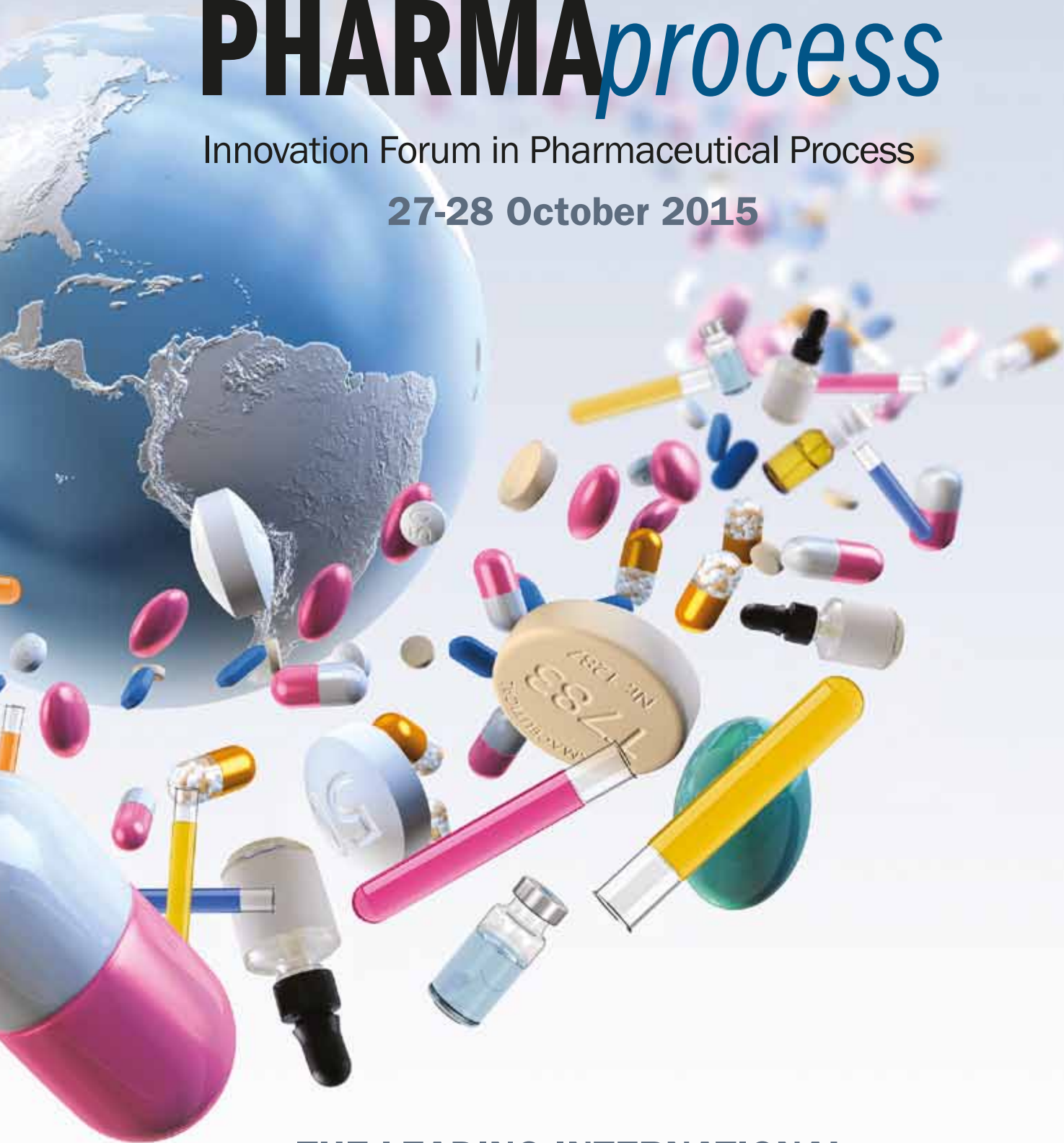
2015 REPORT

MEMORIA 2015 / MEMÒRIA 2015

PHARMAprocess

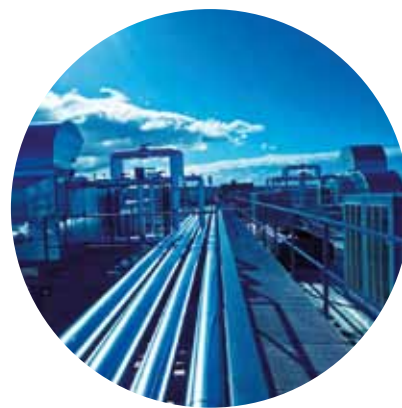
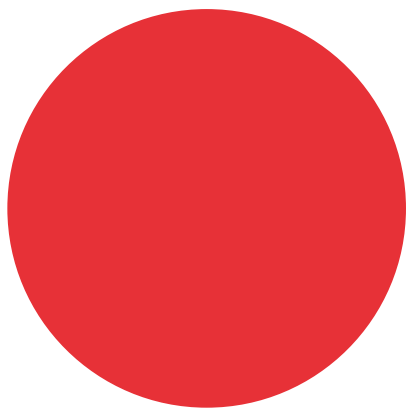
Innovation Forum in Pharmaceutical Process

27-28 October 2015



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As chairman of the Organising Committee for PharmaProcess, the Innovation Forum in Pharmaceutical Process, it is my great pleasure to welcome you to the second edition of this forum, first held in 2013 with the aim of analysing and reflecting, biennially, on the most important issues affecting this industry, which is essential for the well-being of us all.

Over the two years since the first edition was held, the PharmaProcess Forum has been working on starting to consolidate our event on the sector's international calendar. And I sincerely believe that we are well on the way, since we are now equipped with an advisory board—the International Advisory Board (IAB)—made up of eight important representatives of the international pharmaceutical industry, and which has been working with **the Scientific Committee in selecting the show's scientific content.**

I would like to take this opportunity to thank the members of the IAB and all the individuals, companies, organisations and associations which have been actively involved in this second edition of PharmaProcess, an event which encourages the exchange of knowledge and experiences in relation to organisational and technological innovation in pharmaceutical processes, with a view to optimising their resources to the full.

With the experience gained after the first edition, and with our knowledge of the sector, we have endeavoured to prepare a comprehensive programme of conferences organised around four central themes (Regulation and Development, Operations, Business Development and Good Distribution Practices).

In the second edition of PharmaProcess, we have also been eager to support the initiatives of exhibiting companies with the launching of the Presentation Project, in which all manner of projects may be presented in search of ideal suppliers, for the subsequent development thereof. We, the organisers, believe that the Presentation Project will be one of the principal distinguishing elements of PharmaProcess, leading to increased added value in relation to other events in the sector.



I am confident that all these features will make PharmaProcess a particularly attractive event for you all.

Thank you for placing your trust in us. Once again, welcome to PharmaProcess.

Kind regards,

A stylized, handwritten signature in black ink, consisting of a large, sweeping horizontal stroke followed by a vertical line and a small loop.

Ton Capella
Chairman of PharmaProcess

	ROOM 3	ROOM 11	VIP ROOM	ROOM 12
	REGULATORY & DEVELOPMENT Management strategy to reduce time to market	OPERATIONS Factories for the future	GOOD DISTRIBUTION PRACTICES Regulatory impact from procurement to the client	BUSINESS DEVELOPMENT Future and current business
9:30 - 10:00 H	RECEPTION			
10:00 - 10:30 H	<p>Introduction: Mr. Ton Capella - PHARMAprocess President</p> <p>OPENING: EPIGENETICS IN HEALTH AND DISEASE: FROM KNOWLEDGE TO APPLICATIONS</p> <p>Dr. Manel Esteller, Director of the Cancer Epigenetics and Biology Program (PEBC) / Bellvitge Institute for Biomedical Research (IDIBELL)</p> <p>Moderator: Mr. Santiago Alsina - PHARMAprocess Scientific Committee Coordinator</p>			
10:30 - 11:30 H	<p>PLENARY: THE FIGHTING IN SPAIN AGAINST COUNTERFEITING: THE DIRECTIVE AND THE DELEGATE ACT</p> <p>Ms. Belén Escribano Romero, Head of the Department of Inspection and Control Medicines / Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)</p> <p>Ms. Sonia Ruiz Morán, President EMVO / Moderator: Sra. Iciar Sanz de Madrid, Director of International Affairs Farmaindustria</p>			
11:30 - 12:00 H	COFFEE BREAK AND VISIT EXHIBITION AREA - LEVEL 0			
12:00 - 13:00 H	<p>DATA INTEGRITY, A NOVARTIS APPROACH</p> <p>Mr. James Mann, Head Data Integrity Program Management - Novartis Pharma AG / Ms. Anna Coso, SQA - AS&T Manager Alcon, a Novartis Company / Moderator: Mr. Georg Roessling, Senior Vice President - PDA Europe</p>	<p>BARRIER TECHNOLOGY (ISOLATORS AND RABS) TRENDS AND ITS MANAGEMENT</p> <p>Mr. Jack Lysfjord, Principal Consultant - Lysfjord Consulting LLC / Moderator: Dr. Carles Cirera, Vice Chair - ISPE</p>	<p></p> <p>INDUSTRY SESSION*</p> <p>MAXIMIZING EFFICIENCY: PROCESS ANALYTICAL TECHNOLOGIES AND PROCESS INTENSIFICATION</p> <p>Mr. Alejandro Rosales, Scientific and Technological Manager - IRIS / Moderator: Mr. Enric Jo, Site Director - Reig Jofre Group</p>	<p>NUTRACEUTICALS ARE PART OF THE FUTURE? NYTADIUM RESAE® A SUCCESSFUL CASE</p> <p>Mr. Pere Joan Cardona, CEO / CSO - Manremyc / Moderator: Ms. Mercedes Rodríguez Barrera, Corporate Development & Strategic Planning Director - Grupo Juste S.A.Q.F</p>
13:00 - 14:00 H	<p>ANEX 15 AND NEW FDA/EMA VALIDATION GUIDE</p> <p>Ms. Rosa María González del Egidio, Process Quality Department - Quality Area - Boehringer Ingelheim / Mr. Xavier Casterat, Technical Inspector - Generalitat de Catalunya - Health Department / Moderator: Mrs Beatriz Artalejo, President - AEFI</p>	<p>GROUND BREAKING PCMM CONCEPT</p> <p>Mr. Michael O'Brien, Vice President - Pfizer Inc. / Moderator: Mr. Xavier Farrés Torrecabota, Operations Director - Uriach</p>	<p>GDP. WHAT IS THE IMPACT IN THE API MANUFACTURERS?</p> <p>Ms. Cristina Fernández Soligo, Quality Auditor - Laboratorios Dr. Esteve / Mr. Bertil Wagensveld, Global Logistics Director - TEVA API Division / Moderator: Dr. Georgina Pujals i Naranjo, GMP Inspector - Pharmaceutical and Medical Devices Control - Generalitat de Catalunya - Health Department</p>	<p></p> <p>INDUSTRY SESSION*</p> <p>E-BEAM STERILIZATION SYSTEM APPLIED FOR AND ISOLATOR - LAST NEWS</p> <p>Mr. Koji Kawasaki, President - Airex Co. Ltd / Moderator: Mr. Rafael Beaus, Area Sales Manager - Telstar</p>
14:00 - 15:30 H	<p>NETWORKING LUNCH - LEVEL 0 (Only for delegates)</p>			
15:30 - 16:30 H	<p></p> <p>INDUSTRY SESSION*</p> <p>EU GMP CHANGE - IMPACT ON CLEANING AND PROCESS VALIDATION</p> <p>Mr. Walid El Azab, Technical Service Manager - STERIS Life Sciences / Moderator: Mr. Rafael Beaus, Area Sales Manager - Telstar</p>	<p>THE CHEMICAL AND PHARMACEUTICAL PROCESSES FROM THE BIG DATA POINT OF VIEW: A TRULY INNOVATION</p> <p>Mr. Toni Manzano, CSO - Bigfinite / Moderator: Mr. Juan Nuñez García, Operational Excellence Responsible - Almirall</p>	<p>GDP. WHAT IS THE IMPACT TO THE DISTRIBUTORS?</p> <p>Mr. Hanness Laessig, Global Product Manager Pharma Sea Logistics - Kuehne + Nagel (AG & Co.) KG / Mr. Marc Meseguer, European Developer Reefer - Kuene + Nagel / Mr. Marco Antonio Peralta, Iberia QA Manager - DHL Exel Supply Chain SLU / Moderator: Mr. Jaime Mira, Technical Director - ICIL Foundation</p>	<p>DEAL TRENDS: BD AND PRODUCTION IMPACTS</p> <p>Ms. Sharon Finch, CEO - Medius Associates / Moderator: Mr. Enric Turmó, Senior Licensing Manager Business Development - Laboratorios ESTEVE</p>
16:30 - 17:30 H	<p>MEDICAL DEVICE INNOVATION</p> <p>Ms. Ioana Riano Fernández, Unit Responsible for clinical research and clinical trials - Biodonostia Health Research Institute - Donostia University Hospital / Mr. Carlos Sisternas, Director - FENIN / Moderator: Ms. Mª Angeles Bravo, Technical Director - Proclinic</p>	<p></p> <p>INDUSTRY SESSION*</p> <p>CONTINUOUS MANUFACTURING CONCEPTS (ConsiGma TM) OPTIMIZING YOUR OPERATIONS</p> <p>Mr. Wim van der Goten, Sales Director - GEA Pharma / Moderator: Ms. Clara Campás - KERN Pharma</p>	<p>GDP. WHAT IS THE IMPACT TO THE FDF MANUFACTURERS?</p> <p>Ms. Iosune Galar Iribarren, Quality Assurance - Laboratorios CINFA / Mr. Carlos Clemente, General Manager - Disalfarm SA / Mr. Joan Sansalvador, Partner - Labware SA, Azbil Telstar Group / Moderator: Mr. Salvador Cassany, Head of Pharmaceutical and Medical Devices Control Unit - Ministry of Health - Generalitat de Catalunya</p>	<p>CHANNELING NICHE PHARMA PRODUCTS TO EUROPEAN MARKET</p> <p>Ms. Nina Fleck, Senior Director Corporate - Development LLM - Sobi / Moderator: Ms. Emma Gasol, Business Development Director, In-Licensing - Gebro Pharma</p>
17:45 H	PHARMA Experience - TECHNICAL GUIDED VISIT AT ALMIRALL PHARMA PLANT			
18:00 H	PHARMA Experience - TECHNICAL VISIT AT BARCELONA BIOMEDICAL RESEARCH PARK (PRBB)			



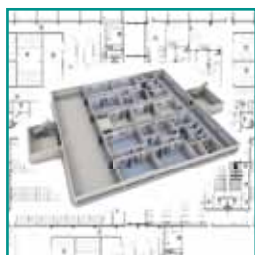
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GMP Equipment



Laboratory Equipment



Engineering



Construction (EPC/EPCM)



Consultancy



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Consultancy

- R&D
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- Industrial
- Business development

Engineering

- Feasibility Studies
- Concept Design
- Basic Engineering
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Construction

- Construction & project management
- Design / Build & turnkey delivery
- General contractor
- Mechanical / process / cleanroom contracting
- Commissioning / qualification
- Process equipment installation and Hook-up
- Process skid Manufacture

IT Solutions

- WMS / EMS / LIMS

Containment & Barrier Systems

- Aseptic & Containment Isolators
- Downflow Booths
- RABs & Modular LAF units

Freeze Drying Systems

- Laboratory Freeze Dryers
- GMP Production Freeze Dryers
- Loading & Unloading Systems

Sterilization Systems

- Moist Heat Sterilization Equipment
- Chemical Sterilization Equipment
- Dry Heat Sterilization Equipment

PW, WFI & Pure Steam

- Water treatment and purification equipment
- Multiple/Simple Effect Still
- Steam Generators
- Storage and distribution systems for pharmaceutical quality water

Process Systems

- System for cleaning CIP & sterilization SIP
- Biowaste

Cold Storage

- Ultra Low Temperature -45°C & -86°C Freezers

Clean Room Systems

- Wall panels, doors, view panels, lighting & sanitary finishing
- Pass through boxes & SAS
- Air Shower

Laminar Air Flow Systems

- Laminar Flow Benches
- BioSafety Cabinets
- Laminar Flow Booths

Customer Service

- Spare parts & maintenance
- Calibration

Process Laboratory

- Freeze Drying recipes
- Sterilization cycles

	ROOM 3	ROOM 11	VIP ROOM	ROOM 12
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9:30 – 10:30 H	PLENARY: ADVANCED METHODS FOR OPERATIONAL EXCELLENCE Dr. Hirozaki Sugiyama , Associate Professor - The University of Tokyo - Board Member of ISPE Japan / Mr. Àngel Albizu Mardones , Senior Leader Consultant - ASENTA Management Consultants Moderator: Mr. Xavier Farrés Torrecabota , Operations Director - Uriach			
10:45 – 11:45 H	MARKET ACCESS INTEGRATION IN QbD STRATEGY Ms. Mercedes Prior , Head of Global Market Access - Global Medical Affairs & Market Access - Almirall / Moderator: Mr. Carlos Maestro , Board of Director Member - ISPE Spain Affiliate	COST COMPARISON BETWEEN EU/USA AND EMERGING PLANTS. OPEX BENCHMARKING Mr. Nicolás Ponce , Research Associate Institute of Technology Management, University of St. Gallen / Moderator: Dr. Carles Cirera , Vice Chair - ISPE	CEIV PHARMA PROJECT Mr. Francisco Rizzuto , Cargo Manager for Western Europe - IATA - International Air Transport Association / Mr. Jaume Adrover , Managing Director - Gestió i Promoció Aeroportuària / Moderator: Ms. Carmen Martínez , Senior Advisor - GRF & Partners	 INDUSTRY SESSION* HIGH SOPHISTICATED TECHNOLOGIES FOR OSD: HOTMELT GRANULATION AND COATING Mr. Thomas B. Kordik , Area Sales Manager - Romaco Innojet GmbH / Dr. Detlev Haak , Director R&D - Hermes Arzneimittel GmbH, Division HERMES Pharma / Moderator: Mr. Santiago Alsina , Scientific Coordinator - PHARMAprocess
11:45 – 12:45 H	COFFEE BREAK AND VISIT EXHIBITION AREA - LEVEL 0			
12:30 – 13:30 H	QbD AT MINIMUM OR "FULL APPLICATION" Ms. Alicia Tébar , Director - QbD Pharmaceutical Services / Mr. Frédéric Vaurès , Technical Manager - Colorcon Ibérica / Moderator: Ms. Beatriz Artalejo , President - AEFI	 INDUSTRY SESSION* SAVE COST WITH PROPORTIONAL VALVE TECHNOLOGY FOR INERT GASES Mr. Thomas Schulz , Head of Industry segment & Key Account management Biotech/Pharma/ Cosmetics - Festo AG & Co. KG / Moderator: Mr. Juan Núñez García , Operational Excellence Responsible - Almirall	CIRCULAR ECONOMY AND ECOLOGICAL INTELLIGENCE: LIFE CYCLE AND CARBON FOOTPRINT WITHIN THE PHARMA SECTOR Dr. Pere Fullana i Palmer , UNESCO Chair in Life Cycle and Climate Change - ESCI-UPF / Moderator: Ms. Elvira Carles , Directora - Fundació Empresa i Clima	HOW TO BE AN EFFICIENT DIGITAL PLANT Mr. Rocco Lisi - Accenture / Moderator: Mr. Carlos Maestro , Board of Director Member - ISPE Spain Affiliate
13:30 – 15:00 H	NETWORKING LUNCH - LEVEL 0 (Only for delegates)			
15:00 – 16:00 H	NANO-DRUG DELIVERY Ms. M^a José Alonso , Professor - University of Santiago de Compostela / Prof. Dr. Victor F. Puentes , Professor VHIR / Moderator: Ms. Beatriz Artalejo , President - AEFI	 INDUSTRY SESSION* CONTINUOUS LYOPHILIZATION Mr. Robert Bullich , Process Laboratory Manager - Azbil Teslar Technologies / Moderator: Dr. Enric Jo , Site Director - Reig Jofre Group	SUPPLY SHORTAGE IN A GLOBAL CONTEXT Ms. Alison Dawson , QA Leader - EU Ext. Advocacy & Collabns - Lilly / Moderator: Mr. Salvador Cassany , Head of Pharmaceutical and Medical Devices Control Unit - Ministry of Health - Generalitat de Catalunya	MARKET ACCESS CONSIDERATIONS IN ASSET VALUATION Ms. Monique Martin , Vice President and General Manager - Mapi / Moderator: Ms. Rosa Domènech Montagut , President - PLGS (Pharmaceutical Licensing Group Spain)
16:15 – 17:15 H	PLENARY: DIGITAL MANUFACTURING IN PHARMA INDUSTRY Mr. Ben Salama , Managing Director - Accenture / Mr. Jordi Ibañez , Managing Director lead for Life Sciences - Accenture / Moderator: Mr. Joan Navales , Operations Director - Laboratorios Dr. Esteve			
17:15 – 19:00 H				

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GRIFOLS

“PharmaProcess is a true meeting place, a space for debate and knowledge transfer. Initiatives like PharmaProcess have a positive and direct impact on the visibility of the pharmaceutical industry.”

JUAN ANTONIO LABAT / DIRECTOR GENERAL - FEIQUE

“Professionals need a forum where disruptive technologies (like big data, IoT or cloud computing) and the impact they will have on current and future manufacturing supply chain strategies will be discussed in order to improve and maximize industry processes.”

TONI MANZANO / CSO - BIGFINITE

“In a continuously regulatory changing environment, pharmaceutical and manufacturing engineers can create a basis for flexible approaches to support continuous improvement by adapting GMPs risk-mitigation, by integrating quality by design concept to achieve efficient cleaning and disinfection process and process manufacturing.”

WALID EL AZAB / TECHNICAL SERVICE MANAGER - STERIS LIFE SCIENCE, BELGIUM

“Quality by Design provides continuous improvement for a modern quality system and it aims at improving efficiency by optimizing a process and eliminating wasted efforts in production and will significantly help the companies re-build their capabilities in delivering high quality innovative medicines.”

ALICIA TÉBAR / DIRECTOR - QBD PHARMACEUTICAL SERVICES

“Plant managers will need to hone many skills that include: technology, regulatory and compliance, health economics and how to be a facilitator to technologies that allow levels of access and process customization that were previously inconceivable.”

MANEL ESTELLER / DIRECTOR OF THE CANCER EPIGENETICS AND BIOLOGY PROGRAM (PEBC) - BELLVITGE INSTITUTE FOR BIOMEDICAL RESEARCH (IDIBELL)

SIDE EVENTS

CONNECT-EU CONFERENCE

Organised by Acció/Government of Catalonia

27th October



The Conference was a key event for companies in order to find opportunities to take part in European research, development and innovation programmes as well as participate in new calls for applications for funding under the Horizon 2020 programme for 2016 and 2017.

TRADE PROMOTION AND INTERNATIONALIZATION OF CHEMICAL SECTOR

Organised by Feique

28th October



The Spanish Chemical Industry Federation (FEIQUE), on behalf of ICEX Spain Trade and Investment, organized this event during Pharmaprocess forum which provided an incentive to develop new markets through innovation and stimulated production efficiency.

CIRCULAR ECONOMY AND CHEMISTRY

Organised by Acció/Government of Catalonia

28th October



The chemical industry faces the challenge of improving competitiveness and at the same time being innovative, environmentally friendly and efficient in the use of resources. This conference analysed the situation of the sector in Catalonia and all over the world, including challenges, trends and success cases, putting an emphasis on the Circular Economy.

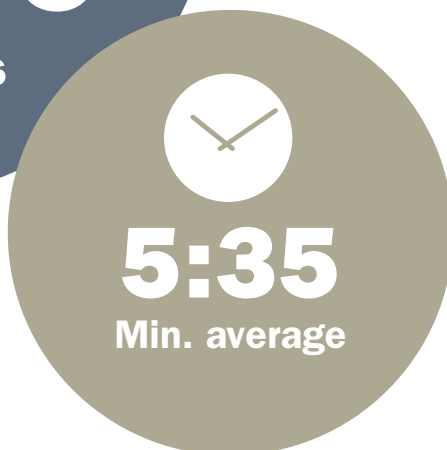
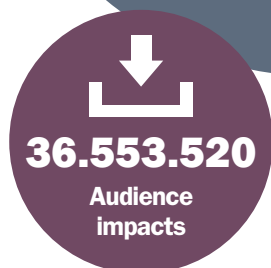
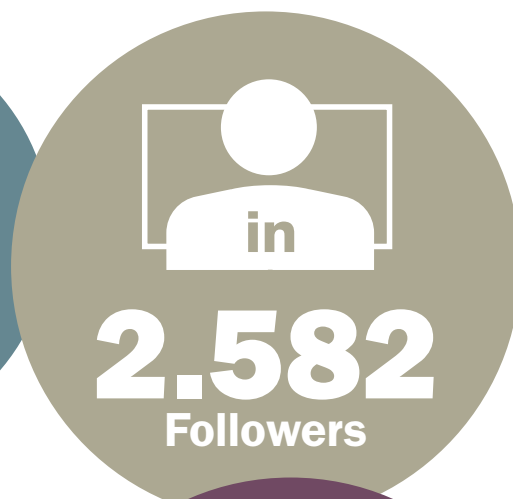
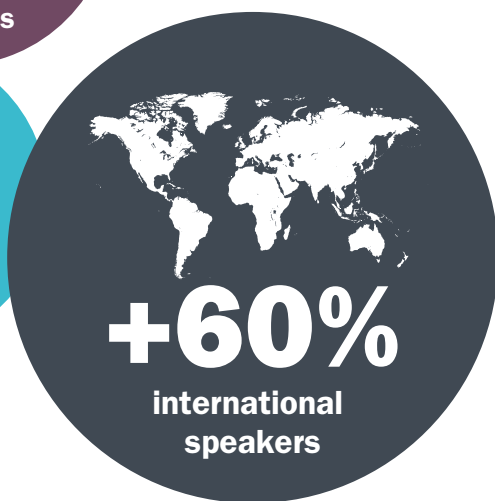
50TH ANNIVERSARY OF EXPOQUIMIA

Organized by Expoquimia

28th October



Expoquimia, the international chemistry event that takes place every three years in Barcelona, celebrated during Pharmaprocess 2015 its 50th anniversary in an event which analysed in depth the challenges to be faced by chemical industry in the future. The celebration, which was attended by more than 200 representatives of the sector, was an opportunity to launch the 2017 edition of the congress as well as pay tribute to the organisers of the first edition of the show, organised in 1965.





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- **EQUIPOS KIMO**
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Innovation Forum in Pharmaceutical Process

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US ESPEREM A LA PROPERA EDICIÓ DE PHARMAPROCESS, EL 2017

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