PHARMA*process*

Innovation Forum in Pharmaceutical Process

29 - 30 OCTOBER 2013

Palau de Congressos de Barcelona. Montjuïc Venue, Hall 5.

THE LEADING INTERNATIONAL KNOWLEDGE AND NETWORKING FORUM FOR THE PHARMACEUTICAL INDUSTRY.

www.pharmaprocessforum.com

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THE BEST FORMULA TO OPTIMISE PROCESSES

The international knowledge and networking Forum is based on the development of Pharmaceutical, Biopharmaceutical and Life Science innovation.
Conceptually it has grown out of Expoquimia as a new, independent congress ***focussing on the production process and its efficiency*** *to deliver new and better solutions through the expertise of leading industry players and setting up an effective networking platform.*

A new internationally pioneering concept with a future vision offering you information about:

- *The main innovations in sterilisation.*
- *The management and optimisation of pharmaceutical plants.*
- *Compliance with Qbd, Learn-lab & FDA and new trends in quality.*
- *Innovations in biotechnology: cell cultures, large-scale purification and its regulatory framework.*

IF YOU WANT TO BE MORE EFFICIENT YOU HAVE TO BE HERE

- Pharmaprocess is the leading European congress platform created specifically for optimising the manufacturing process of pharmaceuticals.
- It will give you first-hand insight into new products, trends and cutting-edge technology defining the next generation of pharmacological processes.
- It will be attended by all the leading companies and major national and international sector associations.

1 **CONGRESS:**
Development
Biopharmatech
Operations

2 **EXHIBITION & NETWORKING AREA:**
Machinery manufacturers, quality managers and specialist drug producers will be present offering solutions, innovation and efficient interaction.

3 **SIDE EVENTS:**
Insight into the latest developments in the sector. To bring commercial offerings to the key decision-makers in the industry. Talks, networking areas and innovation capsules configure the side events programme.

1 +2 + 3 = SUCCESS

Forum Tracks

DEVELOPMENT

> Innovative international vision of the process from the molecule to the production chain to achieve maximum efficiency.

> Financial efficiency in pharmaceutical design from the materialisation of R&D to its marketing.

> The latest developments, discoveries and advances across the pharmaceutical industry.

BIOPHARMATECH

> Cross-cutting innovative approach to the industrial process, based on biotechnology, which contributes to the acceleration of the process as a differentiating factor delivering substantial progress in improving life.

OPERATIONS

> The latest global developments in industrial processes from demand to distribution.

> Cost and time optimisation resulting from service excellence.

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PROGRAMME - Oct 29th, 2013

	Track 1 DEVELOPMENT	Track 2 BIOPHARMATECH	Track 3 OPERATIONS
8.30 - 9.30	RECEPTION		
9.30 - 10.15	OPENING ACT: HORIZON 2020		
10.30- 11.30	**PLACING SCIENCE ONLINE: THE MANY FACES OF PAT** **Tomas Vermeire.** Product manager Lighthouse Probe. GEA Process Engineering The latest advances in product development. Continuous processes. The latest advances in product development. Continuous processes. ***Moderator: Miguel Sambola. Area Sales Manager. GEA Pharma Systems***	**BIOTECHNOLOGY IMPACT: INTO THE PHARMACEUTICAL INDUSTRY: A RADICAL CHANGE** **Jordi Martí.** CEO. Celgene S.L. Big Pharma pharmaceutical business standpoint due to the development of biotechnology. Important to know the financial impact that biotechnology is having and will have on the "traditional" business of Big Pharma.	**DESIGN OF MODULAR FACILITIES** **Paul Stewart.** General Manager Business Development. Pharma & Biotech Equipment Solutions. Telstar Life Sciences The new flexible site. Important for companies to address expansion while minimising structure costs in terms of both time and value.
11.30- 12.15	COFFE BREAK AND VISIT EXHIBITORS		
12.15 - 13.15	**PATIENT DRUG SAFETY 2.0** **Alberto Duque.** Head of Drug Safety. Novartis **Edurne Lázaro.** Service Manager. Pharmacoepidemiology and Pharmacovigilance Division. Department of Medicines for Human Use. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) European Regulations. New patient role in pharmacovigilance after the introduction of new regulations. Post-marketing monitoring of a drug is a crucial part of safety information in terms of side effects or other unexpected events.	**BIOCATALYSIS: MOVING CHEMICAL AND PHARMACEUTICAL PRODUCTION FURTHER** **Pierre Monsan.** Director Toulouse White Biotechnology (TWB) How is industrial biotech transforming drugs production? State of the art and new developments. ***Moderator: Josep Castells. President of Board of Directors. InKemia UCT Group***	**JUMPING FOR A CONTINOUS PRODUCTION** **Michael Van Den Bossche.** Sales Manager. GEA Pharma Systems, Collette™ Envisioning the factory of the future: case study on continuous granulation and tabletting. PAT techniques are a tool to improve production effectiveness and efficiency in drug manufacture. Save time and improve quality throughout the process. ***Moderator: Miguel Sambaloa. Area Sales Manager. GEA Pharma Systems***
13.15 - 14.15	LUNCH TIME		
14.30 - 16.00	**PLENARY: ANTI FALSIFICATION, WHAT'S THE STRATEGY IN PLACE?** **Belen Escribano.** Head of the Medicine Inspection and Control Department. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) **Martin Friedrich.** Head of Product Tracking and Authentication. Technology Services GmbH European situation on anti falsification. Where we are, what we do. The risk that counterfeit products, besides having no therapeutic effect, can also cause poisoning, illnesses, etc., is of paramount importance for all companies due to the financial loss it means for them and from the ethical standpoint for the whole of society.		
16.15 - 17.15	**INDUSTRY SESSIONS**	**INDUSTRY SESSIONS**	**INDUSTRY SESSIONS**
17.15 - 18.00	COFFE BREAK AND VISIT EXHIBITORS		
18.00 - 19.00	**PERSONALIZED MEDICINES FOR XXI CENTURY** **Olga Fidalgo.** Corporate Director Business Development & Licensing. Ferrer Internacional, S.A. Future medicines. Changes in the system for developing new medicines. Medicines for each patient. The new "on demand" drugs; emphasise and evaluate whether it is future or illusory medicine. Case study of how it is being addressed at Grupo Ferrer.	**ANIMAL CELL TECHNOLOGY: THE ENABLING PLATFORM FOR PHARMACEUTICAL DRUG PRODUCTION** **Andy Racher.** Head of Process Development Sciences. Lonza The last developments in cells technologies for the production of biological molecules. The increased demand for biopharmaceuticals requires scaling production capacity and facilities.	**ACTIVE INGREDIENTS, CAN WE BELIEVE IN THEM?** **Santi Alonso.** Independant consultant **Belén Crespo.** Director. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) Development challenges, fast Access to market, co-development, homologation issues. Important for all companies using APIs in drug manufacture. Implementation of the new European regulations; "curious" case studies. ***Moderator: Rafa Beaus. General Manager. Auditgmp Pharma S.L.***

Programme updated on 28 June 2013

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8.30 - 9.30	RECEPTION		
9.30- 10.30	**EXCIPIENT QUALITY: AN FDA / EMA PERSPECTIVE** **Iain Moore.** Chair EXCiPACT™ Certification Scheme, Global Steering Committee / Global Head of Quality Assurance. EXCiPACT / Croda International plcEXCiPACT / Croda International plc Contrasting FDA and EMA views about the quality of excipients. It is important to know the regulations that apply in major markets in order to successfully register a product for marketing. *Moderator: Carmen de la Morena Criado. Head of Service (Chemical Division Pharmatechnology) and Secretary of Real Farmacopea Española. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS). Ministerio de Sanidad, Servicios Sociales e Igualdad.*	**CHALLENGES AND NEW TECHNOLOGIES IN BIOPROCESS: MATCHING BIOPROCESS CAPACITIES TO MARKET DEMANDS** **Alain Bernard.** VP Govenance Prioritization Scientific Laison - UCB Pharma Belgium How to manage the production capacity and the introduction of single use manufacturing models. Two great challenges in modern biotechnology production systems are, on one hand, how to manage the production capacity (adapting factories and systems dimensions to pipelines and combining companies' own production capacities with CMO services) and, on the other, the introduction of single use manufacturing models. *Moderator: Dr. Francesc Gòdia. Chemical Engineering. Universitat Autònoma de Barcelona. UAB*	**INNOVATION AND CONTINUOUS IMPROVEMENT AS STRATEGIC DRIVERS OF HEALTHY INDUSTRIAL PHARMA OPERATIONS** **Theodore Iliopoulus.** Chief Scientific Officer. Abdi Ibrahim Management innovation.
10.30- 11.15	COFFE BREAK AND VISIT EXHIBITORS		
11.15 - 12.15	**HOW TO REGISTER A DOSSIER FOR A GENERIC IN USA (Q8, Q9, Q10, Qn+1)** **Inna Ben Anat.** Quality by Design Strategy Leader- Teva Pharmaceuticals Registering generics in the USA. Practical requirements for their registration and marketing. Important for all companies wishing to register their generic products for marketing in the USA. *Moderator: Ms. Alicia Tebar. Telstar*	**NANOTECHNOLOGY AND DRUG DELIVERY: REDESIGNING PHARMA PROCESS** **Teresa Pellegrino** National Nanotechnology Laboratory of CNR-INFM di Lecce. Italia. The importance of nanotechnology in drug delivery to manipulate molecules and supramolecular structures for producing devices with programmed functions. Nanotechnology has the potential of literally revolutionize drug delivery. Right now, systems like liposomes, polymeric micelles, and nanoparticles are called “nanovehicles”, but this is correct only in the size scale. The importance of nanotechnology in drug delivery is in the ability to manipulate molecules and supramolecular structures for producing devices with programmed functions.	**HOW TO OPTIMIZE THE SUPPLY CHAIN MODEL. LOOKING OUTSIDE** **Alex Pérez Klein.** Wharehouse manager. Desigual Looking outside the Pharma supply world. Importance of open innovation to improvein search of excellence. Distribution cost accounts for between 3-5% of invoiced value; how other environments do it may help in seizing new opportunities.
12.30 - 14.00	LUNCH TIME		
14.15 - 15.30	**PLENARY: DEMAND PLANNING + SO&P PROCESS, A KEY SUCESS FACTOR ON SUPPLY** **Montserrat Marimón Cruces** Demand Planning & Purchasing Manager- Nutrition & Santé Iberia How to manage the excellence on supply. Importance of stock control and customer satisfaction through excellent management of multidisciplinary teams and resources (supply, finance, sales, marketing, etc.).		
15.30 - 16.30	**NOVEL EXCIPIENTS. THE NEXT PHARMACEUTICAL FRONTIER.** **Carl Mroz.** Director Regulatory Affairs. Colorcon Limited Quality and challenges of new excipients: the European perspective. Developing new applications in excipients such as increasing solubilisation and bioavailability is important due to the complexity of new active principles.	**REGULATORY: CELLULAR THERAPIES** **Xavier Luria.** Senior Consultant. Drug Development and Regulation Review of the main regulatory issues related with advanced therapies based on human cells, tissues, and celular and tissue-based products (HCT/Ps). Cell therapies, those based on human cells, tissues, and cellular and tissue-based products (HCT/Ps), confront several challenges and constraints in their regulatory pathway both in Europe and US. This conference is intended to review the main regulatory issues related with advanced therapies.	**INSPECTION. DOES THE FRONTIERS ENSURE THE SAFETY OF THE INCOMING PRODUCTS?** **Cristina Batlle.** Spanish Agency (DGC) International overview on the frontiers for incoming safety goods. Important for companies which import (almost all of them). Knowledge of the regulations, practical situations of entry across the main borders.
16.30 - 17.30	COFFE BREAK AND VISIT EXHIBITORS		
17.30 - 18.30	**PLATFORM FOR INNOVATIVE MEDICINES** **Jordi Barretina.** Lab Head, Oncology Transiational Research. Novartis Case study of application in the development of new products. Resource optimisation. How to get high productivity and efficiency molecules. Importance of efficiency and effectiveness in discovering new drugs and/or applications. Patient access difficulties due to the decrease in new molecules marketed.	**BIOSIMILARS** **Fernando de Mora.** Professor of Farmacology. Universitat Autònoma de Barcelona. UAB How to maximize opportunities and overcome huddles to make the production of biosimilars easier in their regulatory framework? Biosimilars are the "generics" of biological drugs but neither their production nor their regulatory framework make it easy to produce biosimilars. How to maximize opportunities and overcome hudles?	**GUARANTEE FOR A WORLD SUPPLY OF MEDICINES.** **Brendan Cuddy.** Scientific Administrator Compliance and Inspection Sector **Edurne Fernández de Gamarra Martínez.** Pharmaceutical Assistant. Pharmacy Service of the Hospital of Santa Creu and Sant Pau **Ivan Pérez Cabeza.** Supply Chain Management. Novartis Farmacéutica How to ensure the medicines around the World?. Case studies and regulatory dilemmas.

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SECTORS

- Production machinery
- Quality (Quality control, Quality assurance)
- Biotechnology
- Logistics
- IT
- Technology for production process & control
- Packaging machinery
- Labeling, coding and marking
- Packaging materials
- Analytical instrumentation - Laboratory material
- Installations
- Cleaning, Disinfection, Sterilization
- Services, Consulting, Validation and Certification

VISITOR PROFILE

Production managers, operations managers, quality controllers, supply chain managers, procurement managers, regulatory departments, purchasing managers, laboratory technicians, factory operators and many other professionals in a highly technical industry.

BUSINESS TOOLS

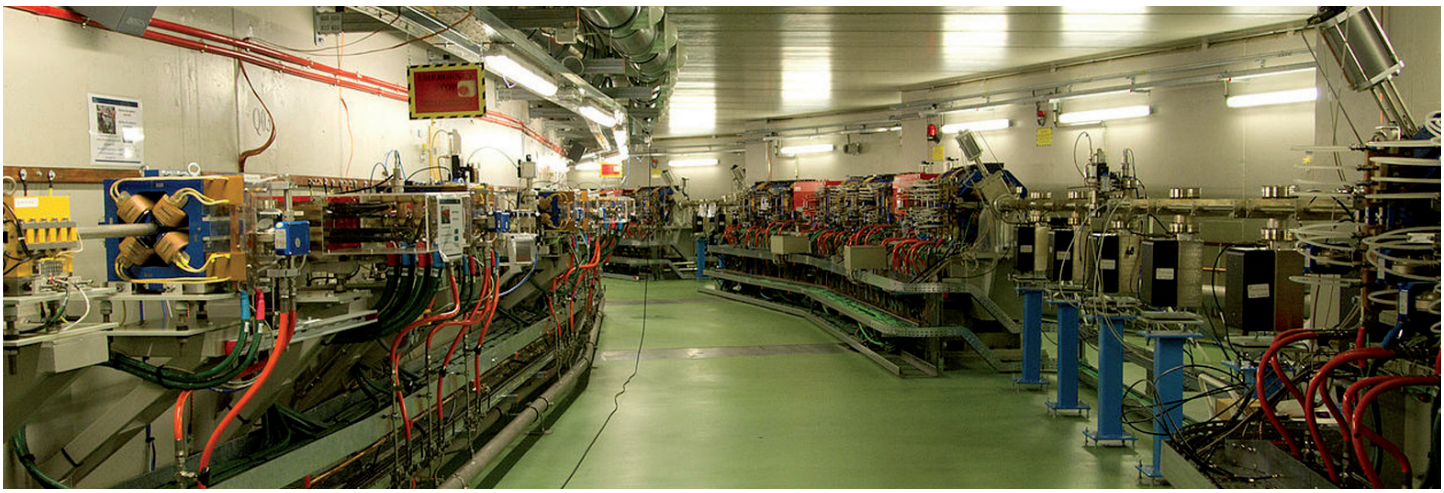
Pharmaprocess has different tools to build more flexible and effective relationships among attendees and exhibitors to promote products and services, create new contacts and identify new opportunities. An opportunity to make contacts and do business which will be facilitated through activities and venues.

Vip Buyers Programme *Personalised agendas*	With purchasing decision makers, prescribers and opinion leaders.
Business Match *Search, find and contact*	The tool to easily organise your agenda and manage your appointments before, during and after the exhibition with the visitor profile that interests you most.
Speed dating *Purchasing formula*	Optimise your time and schedule meetings to find the best product in your production process.

AND IN THE BEST INNOVATION HUB: BARCELONA

One of the most important and innovative cities in Europe, packed with talent, knowledge and infrastructure which help enhance and make more efficient pharmaceutical management plants and processes in the Life Sciences.
It is home to around 50% of Spain's traditional pharmaceutical industry, innovation and development clusters, science parks, universities and leading research hospitals. Facilities that are global leaders featuring the largest number of scientific developments that will set the tone for the future of the pharmaceutical industry.

ALBA SYNCHROTRON, Sant Cugat del Vallès.



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