

2.12.2016 – Symposium

“Primary Packaging for injectables: analytical services and freeze-drying process technologies”

Organizers



Description and goals

To present and discuss innovations on injectable technology, from the manufacture of ampoules, syringes and cartridges, the progress in drugs production to innovations of the inspection equipment.

Event designed for:

Professionals in the areas of manufacturing, quality and safety control, technological development and regulatory issues in the pharmaceutical industry.

Programa:

08:00 – Registration

08:30 – Welcome: Dr. Lauro D. Moretto, Gabriele Peron and Daniel Fritelli

08:30 - Regulatory update on injectables and primary packaging. Speaker: ANVISA – TBC
09:00 – How to implement analytical services including delamination propensity control in glass containers Speakers: Vladimir Pena (CIM) and Odra Pinato (OMPI)
09:30 - Extractable & Leachable. Speaker: Piet Christiaens (Toxicon)
10:00 - Advanced glass containers manufacturing process for keep under control Delamination risk and lyo crack Speaker: Antonio Estevez (Ompi)
10:30 - Coffee break
10:45 – GMP for large containers, especially in Biotechnological Speaker: Christian Muro (Getinge)
11:15 – Technological Innovations in rubber components for Lyophilized products Speaker: Deolinda Martins (West Pharmaceutical Services)
11:45 – Innovative Fill&finish for Lyophilized products Speaker: Marcos Tilli Reis, IMAUTOMATICHE do BRASIL, Subsidiary of IMA S.p.A.
12:15 – Visual inspection systems for lyo and large volumes Speaker: Gaetano Baccinelli (Optrel)
12:45 – Perguntas / Respostas
13h00 – Lunch

Speakers:

Gabriele Peron, Degree in Sociology of Mass Communication in 1997 and member of Mass Communication Research Group at University of Padua, visiting professor at Media Unit Glasgow in 1999. Mr. Peron has been in the field of marketing services for 15 years, with experience in web applications and advanced interactive technologies for pharmaceutical companies. He is currently Marketing and communication manager at Stevanato Group (www.stevanatogroup.com), a multinational company focused on the production of glass containers for pharmaceutical use, based in Piombino Dese (PD). Coordination and execution of all

marketing activities - group communication, organization and coordination of international fairs, participation as a moderator , speaker and conference organizer, design technical presentations in coordination with the R&D, benchmark vs. competition, packaging , brochures, newsletters, corporate identity, media relations, and visual communication within the company. Member of PDA Italy Chapter www.pda-ir.org (secretary), Member of Steering Committee Pharmintech. Member of Steering Committee International Commission on Glass ICG (www.icglass.org).

Odra Pinato, Odra Pinato is the SG Lab Analytics Coordinator. SG Lab Analytics is an analytical laboratory entity, which operates under the R&D dept. of OMPI and performs chemical analyses, surfaces and materials characterization and mechanical tests on pharmaceutical packaging. She manages the research activities of the laboratory to support the strategic projects of the R&D dept. for the development of new products and processes, the development of analytical methodologies, as well as to support the internal needs of the manufacturing operation, QA and QC dept. for the products quality improvements, analytical transfers and troubleshooting.

Her role is related to the coordinator of the advanced analytical services that SG Lab Analytics offers to the Pharma customers to understand the containers properties and performances with respect to the customer needs and to mitigate and reduce the risk of interaction of containers with the drugs. Formerly, Odra Pinato is a pharmaceutical biotechnologist with a PhD in Biochemistry and Biotechnology. Her academic background is focused on protein chemistry and structural biochemistry with a 2-year post-doctoral experience in pharmaceutical biophysics. She has also GMP Pharma-related expertise on the development and validation of chromatographic methods, force degradation and stability studies for the quality assessment of drug products and on physical and chemical characterization of proteins for biopharmaceutical purposes. Based on these expertise, she is also involved in container-drug interaction consultancy.

Piet Christiaens, received his Ph.D. from the Analytical Chemistry Department of the University of Leuven (Belgium) in 1991. From 1992 to 1997, he was Lab Manager in two CRO's. From 1997 to 2000, he worked as an independent consultant with Shell Chemical Company in Houston, TX (US) working on hydrogenated triblock co-polymers. From 2001 onwards, Mr. Christiaens holds the position of scientific director at Toxikon Europe where he develops analytical methods and protocols for both extractables and leachables studies for the pharmaceutical and medical Industries. Dr. Christiaens oversees all laboratory operations at Toxikon and is also giving support to the business development.

Daniel Fritelli, After a career of Engineering, Daniel Fritelli worked principally as consultant for companies acting in energy field , automotives and micro electronic. During this time, he carries out the start up of a Brazilian entity with an Italian

company, integrating also the function of sales manager. He operates like responsible for sales in Latin America since 3 years in the Group Stevanato.

Christian Muro, Vicepresident for Infection Control LatAm at Getinge Group (2015) - Director of Sales & Service LifeScience LifeScience LatAm at Getinge (2013 to 2015) - Area Sales manager for Latin America at ELLAB (2008 – 2013) - Master degree in Economics, University of Copenhagen.

Deolinda Martins, Graduada em Farmácia Bioquímica pela Universidade Estadual de Maringá - PR, com Mestrado em Análises Toxicológicas pela Universidade de São Paulo, Doutorado em Saúde Pública também pela Universidade de São Paulo e MBA Executivo Internacional pela FIA/USP. Possui mais de 15 anos de experiência nas áreas técnico-comercial e marketing em empresas do segmento de saúde humana e ambiental. E mais de 20 anos de experiência como docente nas áreas de Toxicologia e Saúde Ocupacional. Atualmente, é responsável pela área de Suporte Técnico ao Cliente na West Pharmaceutical Services Brasil, gerenciando a interface entre clientes e a área comercial da empresa e entre a América do Sul e a Matriz, além de oferecer suporte aos clientes quanto à compatibilidade da embalagem e o medicamento, entre outras atividades.

Marcos Tilli Reis, is Sales Manager at IMAUTOMATICHE do BRASIL, Subsidiary of IMA S.p.A.

Marco has been working at IMAUTOMATICHE do BRASIL since 2009, with more than 33 years of experience in freeze-dryer maintenance and sales activities. For the last 7 years he has been developing the expansion of the Brazilian market for IMA S.p.A. - IMA LIFE Division in the aseptic processing field, including complete aseptic filling lines with integration of automatic loading systems and freeze dryers, isolation technology and RABS. Marco holds a degree in Business Administration and has a technical graduation in “Mechanics”.

Gaetano Baccinelli, is the Sales Manager of Optrel, company of Stevanato Group's Engineering Division, specialized in manufacturing inspection machines for parenteral products. He spent seven years from 1992 to 1999 working in the USA branch of a well known Italian group worldwide leaders in those field as skilled engineer into the after Sales Dept. He worked as manager of the After Sales and Service Dept. and as Area Sales Manager for Brevetti CEA Spa in Italy leading company in inspection systems following Japan and USA market. His academic background is mainly technical.

Date, Time and Venue

02.12.2016

Time: 08h00 to 13h30

Venue: Auditório Sindusfarma

Rua: Alvorada, 1280 - Vila Olímpia - São Paulo/SP

Next dates:

VAG PARK - Rua Casa do Ator, 975

ADONIS - Rua Caetano Velasco, s/nº

TRAVEL INN – Rua Gomes de Carvalho, 1005

ESTAPAR - Rua Alvorada, 1289

Information and Registration

Free registration – limited places

<http://www.academiafarmacia.com.br>

Information: secretaria@academiafarmacia.org.br

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