ISPE D/A/CH Young Professionals: Future Leaders´ Day 2018

The Speakers
Speaker

Antonio Buendia
Head of manufacturing process controls, Novartis AG

Antonio Buendia is Senior Principal Automation Engineer at NOVARTIS, responsible for the Automation of the 32 plants of the Solids Platform.

Previously, Antonio has worked for Elli Lilly in Madrid, where he shaped the site automation strategy and subsequent implementation driving productivity and quality.

He has more than 20 years of experience in the areas of Industrial Automation, Operational technology, Project management, Facilities master planning, Pharmaceutical manufacturing, R&D laboratories, and qualification of facilities, utilities and equipment.

This wide experience in Engineering very close to Operations, allows him to link the technology dimension with the business needs.

Antonio holds a Master for Industrial Engineering from the University of Comillas in Madrid. He is a founding member of the ISPE Spain, which chaired from 2007-2009 and as well as a member of the international board of Directors of the ISPE, Tampa from 2009-2011

Dr. David Y. H. Chang
Head of PT Global Engineering and Strategy, F. Hoffmann-La Roche AG

Dr. David Chang obtained his Bachelor’s degree in Chemical Engineering from National Taiwan University. He then came to the US to pursue graduate study at MIT, where he received his Master’s and PhD degrees in Biochemical Engineering.

Dr. David Chang has more than 20 years’ experiences in the biotechnology industry. Skilled in Bioprocess Research and Development (R&D), Manufacturing Operations, Facility engineering and Health authority regulations (especially US and China), and experienced in working in China and other emerging markets, he has held important positions in biotech companies with cutting-edge science and innovative medicine, including Senior Chemical Engineer at Schering-Plough Research Institute, Group Leader at BASF Bioresearch, Director at Biogen IDEC, Senior Director at Genentech, and Vice President at Roche Pharmaceuticals. Currently, Dr. David Chang is the
Global Head of Roche Pharma Technical Strategy and Engineering stationing in Basel, Switzerland.

Christine Eckardt
Lead Process Engineer, Fill Finish, CRB Group GmbH

Christine Eckardt is Lead Engineer Process Fill Finish at CRB Group GmbH based in Basel, Switzerland. CRB is a full-service network of engineers, architects, constructors and consultants, assisting advanced technology organizations in the planning, design, construction and operational support of facilities across the globe.

Christine Eckardt holds a diploma in Pharmaceutical Technology and has over 15 years’ experience in the pharmaceutical area. During her professional career Christine was responsible for preparing and overseeing technical specifications and datasheets as well as developing process layouts, material, personnel and process flow diagrams. She is an expert in the areas of injectable and oral solid dosage. Additionally Christine’s experience also includes project management, cost estimating, procurement support, construction supervision and preparation of qualification documents in compliance with GMP requirements.

Previously, Christine Eckardt held roles as project Leader at Triplan Ingenieur AG and Senior Project Engineer at Foster Wheeler Engineering.

Lina Ertle
External Relations, regulatory compliance, Europe and East Africa, F. Hoffman-La Roche AG

Lina Ertle joined Roche in November 2013 as Head of Compliance and External Relations EMEA, PTQE.

Previously, she worked at the French Regulatory Agency ANSM where she was the Head of Quality Assessment Unit. Her prior role at the Agency was Senior GMP Inspector (May 2002 to October 2013). Lina Ertle also has extensive industry experience having worked in quality roles of increasing responsibilities at Solvay Pharma, Tours, France, Merck (MSD), France and the Netherlands.

Currently, she leads the Roche European based PTQE Compliance and External Relations team responsible for Europe and other regional external relations functions important to Roche. Lina Ertle is an integral part of those activities working with PT and regulatory colleagues commenting on important regulatory documents, providing advice to PT colleagues, communicating important regulatory and compliance activities and trends in the
external environment, and maintaining open dialogue and transparency with Health Authorities.

Mareile Fuß
Head of Business Process Excellence/ Strategic Projects Focused factory Solids, Boehringer Ingelheim

At Boehringer Ingelheim, Mareile Fuß is responsible for strategy implementation in operations where she leverages her operational experiences and drives projects on a site level. Her current role in the pharmaceutical production covers project management for investment projects, operational excellence in projects e.g. for end-to-end transformation and balanced scorecard paired with a strong focus on future innovation for the pharmaceutical production.

Following her education as a pharmacist, she has been in the pharmaceutical industry for more than 17 years as. Mareile Fuß previously held roles in corporate functions for Quality defect and Potential Market Action Management; and Management System Owner for Complaints in the global network. Furthermore, she has been manager in a contract research organization for respiratory drug delivery development, head of production for primary packaging of inhalative bulk supplies for clinical supplies and for storage and stability samples and clinical trial supplies coordination incl. secondary packaging, labelling and project planning.

Ralf Reinle
Head of Technical Services Basel & Kaiseraugst, F. Hoffmann-La Roche AG

Mr. Reinle has more than 20 years of experience in the chemical but mainly pharmaceutical industry. He worked as a Galenical Engineer and was responsible for Site Engineering at the Roche Site in Sydney, Australia. In Penzberg, Germany he had different responsibilities managing major capital biotech projects. Transferring to Basel he worked for the Small Molecules Network as an internal Key Account Manager. In this global role he worked closely with Roche Sites around the world on Capital project planning and execution. Transferring to Site Engineering in Basel and Kaiseraugst in 2015 he was Head of Building Engineering and since recently he is heading the Technical Service Department of these sites.
Before joining Roche in the year 2000 Ralf Reinle worked at the BASF in Ludwigshafen as a Project and Design Engineer.

Ralf Reinle studied Process Engineering at the Hochschule in Mannheim, Germany.

**Andreas Salge**
Head of Global Engineering Pharmaceuticals Division, Bayer AG

**Marcel Staudt**
Head of Global Engineering Consumer Health Division, Bayer AG (Vice Chair ISPE DACH).

As a leading company in the OTC and consumer health business we need engineering to bring the opportunities Ind4.0 offers to our sites and make them more flexible at best reliability of the assets and processes.

ISPE DACH is second largest affiliate of ISPE globally and we have multiple Communities of Practice, where industry leading experts collaborate to jointly develop best practices for common challenges. For the next years we want to grow our network, in particular by bringing the ideas and energy of young professionals to our network.

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**Christian Wölbeling**
Senior Director Global Accounts at Werum IT Solutions

Christian Wölbeling is Senior Director Global Accounts at Werum IT Solutions based in Lueneburg, Germany, part of the Körber Medipak Systems Group. Werum is the market leader in Manufacturing Execution Systems / MES Solutions for the Life Science industries, working for 17 out of the Global Top 30 Pharma Companies with more than 800 installations. He holds a Master Degree in Mechanical Engineering. With more than 25 years working experience in Life Sciences Manufacturing IT, Christian has had great experience in all GMP related processes. He leads broad activities inside the ISPE as Chairman of the Special Interest Group “Pharma 4.0”, ISPE “GAMP MES Special Interest Group” Co-Chair, “Knowledge Network Council” Co-Chair, “PAT & Lifecycle Control Strategy” CoP Steering Member, and ISPE Affiliate DACH Board Member.