

# Life Sciences

Manufacturers need to meet the challenges of global competition, higher production costs and increasingly stringent environmental standards. That means streamlining manufacturing processes while minimizing water, energy and material costs. Manufacturers must also improve product quality, productivity and capacity while reducing downtime. This Forum will address issues to help manage production for greater profitability.

Thursday, November 12, 2009

9:00 AM to 11:30 AM

Room 304 A-B

## Who Should Attend?

The Life Science Industry Forum will appeal to manufacturing, engineering and quality personnel in biotechnology, pharmaceutical and medical device companies, especially:

- Engineering management
- Manufacturing management and above
- Quality and information management

## You Will Learn

Life Sciences industry leaders will discuss best practices and innovative solutions that:

- Reduce time-to-market
- Assure repeatable quality, security and safety
- Enhance financial performance
- Optimize manufacturing

## Agenda

### Best Practices for Track & Trace with Mass Serialization in the Regulated Production Environment

**SANDRO GISLER**  
Manager, Marketing and Product Development, Bosch Packaging Services, Inc.

Drug counterfeiting has become a major issue for pharmaceutical companies and Governments around the world. The threat to patient safety and the economic impact of drug counterfeiting has made this a top priority. The Bosch modular concept of printing and control systems can be integrated into new or existing packaging lines or complete production plants of all manufacturers.

Learn more about:

- The national and international marking and coding standards
- Verification methods of Data Matrix Codes
- High speed coding, verification and aggregation of items to higher packaging level like cases and pallets
- Flexible and efficient format change via toolless quick-change system
- Efficient integration of mass serialization into validated environments

### Successful MES Implementation at Roche

**ROBERT FRETZ**  
Global Head of Process Automation and MES, F. Hoffmann-La Roche AG

This presentation will discuss the Roche approach to MES implementation, based on global governance and a core system roll-out driven by the business. It will also reference the resulting architecture embedded into the enterprise landscape, and the benefits achieved as well as obstacles and success factors. Last, Roche's experience with their recent introduction of Pharma Suite for material-tracking in API manufacturing will be discussed.

### Optimizing Manufacturing Line Performance - Utilizing OEE

**DUANE W. HIVELEY**  
Manager, Controls Engineering, Teva Pharmaceuticals, Inc

Implementing software that monitors manufacturing line equipment and provides an OEE (Overall Equipment Effectiveness) and Process Reliability visualization tool is worth the investment. Improving operational efficiencies targets line effectiveness and addresses the growing efforts to reduce costs and make a positive impact to the bottom line. The implementation of line monitoring software is relatively simple. The biggest hurdle is a commitment to create manufacturing visibility. However, without knowing/measuring line performance, how can you improve it? The collection of data and the translation of data into knowledge to make lasting process improvements is what OEE is about. The Rockwell Automation FactoryTalk Metrics solution establishes a key link between the financial and operational performance of production line assets and personnel. The presentation builds on a case study, which was implemented at Teva Parenteral Medicines (Irvine) in 2009. The presentation elaborates also on the basic architecture for the FactoryTalk Metrics solution, how it works and what the critical success factors are for a successful installation. Implementation cost and issues are also highlighted.

## Speakers

**SANDRO GISLER** is the Manager of Marketing and Product Development for the North American division of Bosch Packaging Services. Bosch Packaging Services provides after-market services ranging from Field Service and Spare Parts to comprehensive modernization, asset relocation and consulting solutions for the pharmaceutical, food and confectionary industries. Sandro Gisler has over nine years experience in the packaging industry, covering areas as diverse as secondary packaging applications for the pharmaceutical industry, obsolescence solutions for various machinery and OEE improvement of complex packaging lines. He currently focuses on bringing new after-market products like OEE Consulting or Track & Trace solutions to the market. Before moving into marketing, Sandro served as a Field Service Manager for Bosch Packaging Services and as a Site Manager for Sigpack Systems AG in Switzerland. He holds a degree in Electrical Engineering and an MBA from the University of North Carolina.

**ROBERT FRETZ** is presently responsible for Process Automation and system integration in all chemical, biotech and galenic/drug product manufacturing sites of the Hoffmann-La Roche Pharmaceuticals Division and leads the corporate Manufacturing Execution Systems program. He has a degree in Chemical Engineering from the Swiss Federal Institute of Technology (ETH Zurich) and joined Hoffmann-La Roche more than 30 years ago. His wide international experience covers all levels of control/automation projects from instrumentation to the enterprise level. Many of these projects included computerized system validations and Part 11 compliance and he has co-authored the Hoffmann-La Roche corporate guideline on Process Automation Qualification. Recently he has been concentrating on a collaborative system architecture and Electronic Batch Records leading to system supported product release decisions and the introduction of a material-tracking system into the chemical API production.

**DUANE W. HIVELEY** is Manager, Controls Engineering at Teva Parenteral Medicines, Inc. Duane manages a group of automation engineers and technicians to support a fast-paced Small Volume Parenteral (SVP) fill finish facility. He has over 18 years experience within the Life Science industry including project engineering, metrology management, automation engineering management, and validation. At Teva, he has played a key role with several major facility expansions, capital equipment integration, equipment upgrades, and network expansion/sustainment. He is currently involved with an overall continuous improvement plan for optimizing the manufacturing lines and specifically responsible for the installation of OEE software to enable manufacturing visibility.