

Pharma 4.0: Digital Transformation and Smart Manufacturing APAC Conference: Agenda at a glance

December 3, 2020 | India Standard Time (GMT+5:30)

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10:00	Welcome
10:10 Approx. 1hr 30 mins with Q&A	Panel Discussion: Managing Data in Smart Manufacturing
11:45 45 min with Q&A	Managing Data Integrity Risks and Compliance
12:35 35 min with Q&A	Tackling Cybersecurity and Increasing Resilience
On demand Approx. 15 mins	Breakout: Simplifying Validation & Qualification Operations
On demand Approx. 25 mins	Breakout: Simple Steps for Effective Facility Management
On demand Approx. 15 mins	Breakout: How Digitization can Improve Asset Compliance
On demand Approx. 15 mins	Breakout: Data Management Software to Aid Data Integrity
On Demand	Exclusive access to sessions and resources for all attendees for a month, post-event

Exhibitor Booths

Alliance Controls Singapore

-

Delta Elmech Thailand

-

ESEC Vietnam

-

Microcon India

-

NAPL India

-

Ocean Data Systems:

Dream Report Data Visualization
France

-

PT Asia Indonesia

-

SAN Process Automation India

-

SV Controls India

-

VSV India

Virtual
Networking
&
Interaction

Analyst: Complete
Position: #120498_05
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Main Auditorium

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1. Panel Discussion: Managing Data in Smart Manufacturing:

- Find out how leading manufacturers are implementing digital data management
- Hear about facility management and smart factory technologies

Speakers share their views and experiences and the real value of Pharma 4.0

2. Managing Data Integrity Risks and Compliance:

- Understand the latest Data Integrity requirements based on ALCOA (+) principles and risk analysis methodology

Rick Jarrell talks about Data Integrity requirements based on ALCOA (+) principles and risk analysis, with Q&A

3. Tackling Cybersecurity and Increasing Resilience:

- Learn about Cybersecurity standards and best practice between IT/OT

Gabriel Faifman talks about cybersecurity and the challenges of ISA and IEC 62443, with Q&A

Main Auditorium

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10:00 Welcome
Speaker: Paul Sear
Welcome Keynote: Pharma 4.0 Digital Transformation & Smart Manufacturing

10:10 Panel Discussion: Managing Data in Smart Manufacturing
Facilitator: Sébastien Girard
Panel:
Louis Coutinho
Jean Louis Jouve
Benoit Jaquemin
Amitkumar Sawant
How does industry 4.0 change pharmaceutical manufacturing?
Transitioning to Pharma 4.0 offers new opportunities and challenges. Particularly around data integrity, automation, the workforce of the future, technical and operational transformation and end-to-end integration.
Key questions arising within life sciences:
Is it the right time to invest on Pharma 4.0 technologies?
Does Pharma 4.0 present risks for compliance?
What are the expected benefits in adopting Pharma 4.0 principles?

11:45 **Managing Data Integrity Risks and Compliance**
Speaker: Rick Jarrell
Never, before have Life Science companies been able to collect and analyze such large amounts of data. Big Data is here for this industry, as is the ability to analyze that data. However, how can businesses work to increase assurances that the data collected is of the highest integrity possible? This is of an even higher concern when data is collected from a regulated GMP process or environment. What guidance is available from the market and regulatory agencies that will ease the choice of high data integrity solutions? What risk mitigation strategies can be employed to support high levels of data integrity in control systems and processes? In the end, high data integrity is of paramount concern for those needing to address both product quality and product safety issues

12:35 **Tackling Cybersecurity and Increasing Resilience**
Speaker: Gabriel Faifman
Last year, there was a significant increase in requirement for cybersecurity and resilient manufacturing consultancy work. According to a Deloitte report, the pharma sector is a primary target for cyber-criminals looking to steal intellectual property (IP) and the estimated cost of cyber-crime for the market is estimated at \$18 billion for 2020. Cybersecurity improvements can be carried out in stages to meet the requirements of ISA/IEC 62443 standard

13:10 Closing Remarks
Sebastien Girard, Global Business Development Manager, CPG Segment
A round up of the day's events

Break Out Track

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- **Simplifying Validation & Qualification Operations**

Saju Varghese discusses IPSE Gamp® 5 templates and how Eurotherm can help

- **Simple Steps for Effective Facility Management**

Vicki Pearson discusses effective control (BMS) and Monitoring (EMS) solutions in Pharma facilities

- **How Digitization can Improve Asset Compliance:**

- Discover how Eurotherm Data Management Solutions and Services help to simplify regulatory compliance and enhance trust

- Eurotherm Data Reviewer

Darren Mardell highlights how this aids Data Integrity within Life Sciences

- EcoStruxure Manufacturing Compliance Advisor

Warwick Vercoe highlights the software and key benefits for organizations and their suppliers

Break Out Track

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On demand
15 minutes

Simplifying Validation & Qualification Operations

One of the Life Science industry's key differentiators is that it is highly regulated and guided due to its impact on patient safety. Current trends indicate that audits are becoming more frequent and stringent. Traditionally organizations such as the FDA, EMA and CDSCO manage audits on-site. Today there is a growing requirement for manufacturers to audit their own suppliers e.g. Contract Manufacturing Organizations (CMOs). Computer System Validation (CSV) qualification/validation of automation systems is a key auditor focus during on-site visits. The engineering project delivery management approach known as the ISPE GAMP® 5 V-Model is a leading method of implementation. Hear Saju Varghese talking about the Eurotherm risk-based approach towards ISPE GAMP® 5 qualification and validation documentation, followed by a Q&A session.

On demand
25 minutes

Digitizing & Reforming Facility Operations

This session will explore current industry thinking on digitizing & reforming for effective facility management systems. Looking at BMS/EMS system architecture, decision making around criticality & impact. The latest evolution to cloud based validation & using analytics to improve your operational efficiency

On demand
15 minutes

Digitization designed to Improve Asset Compliance

Discover EcoStruxure™ Manufacturing Compliance Advisor - a cloud hosted digital services platform, designed to reduce testing costs, increase productivity and be audit-ready with a robust scheduling and testing process.

On demand
15 minutes

Data Management Software aids Data Integrity in Life Sciences

Discover Eurotherm Data Reviewer – Product tour of Eurotherm proprietary software application for the viewing, analysis and printing of Eurotherm data files, designed to aid compliance with FDA 21 CFR Part 11 and ALCOA (+) principles

Analysis: Complete.
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sessions | breakout tracks | resource library
Available on demand to all attendees for one-month post event