



**DCVMN**  
**INTERNATIONAL**

Developing Countries Vaccine  
Manufacturers Network International

**MERCK**

# **PROCESS AUTOMATION ENHANCING DATA INTEGRITY COMPLIANCE - BEST PRACTICE AND CASE STUDY WORKSHOP**

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December 7th, 2023  
12 PM - 2 PM (CET)

# Agenda

<b>Topic</b>	<b>Speaker (s)</b>	<b>Time (CET) &amp; Location</b>
Introduction	DCVMN International	12 PM Main Room
1. Digital Transformation of Vaccine Manufacturing	Minh Tran	12:05 PM Main Room
2. Regulatory considerations in data integrity and compliance in Computerized System of vaccine manufacturing	Larry Zhu Shaoqing Xing	12:25 PM Main Room
3. Convergence of technologies - Tools to success	Ashok Kumar Nishant Gupta	12:55 PM Main Room
4. Workshop brief & and grouping	All	01:15 PM Breakout Rooms
5. Workshop outcome sharing and Q&A session	All	01:40 PM Main Room
Closing	All and DCVMN International	01:55 PM Main Room

# Content & Speakers

## Topic I - Digital Transformation of Vaccine Manufacturing

Bringing lifesaving medicines to market faster while lowering costs and maintaining quality are key drivers for the biopharmaceutical industry. Consequently, the sector looks to optimize and innovate its processes by building a Facility of the Future enabled by single-use technologies, intensified processes, process analytical technology (PAT), and automation and advanced analytics software. This future requires organizations to begin a digital transformation.

This talk will present:

- Common challenges and current realities faced by pharma manufacturers.
- Principles that anchor a digital transformation
- How to get started with the key components needed on this journey.
- What does a Facility of the Future framework encompass?
- Why an end-to-end application of systems, analytical tools, software, services, and expertise is crucial for manufacturing execution success.



## Minh Tran

**Global Head of Bio4C™ Commercial  
Process Automation, PAT, and Data Analytics  
Merck KGaA**

Minh Tran leads a technical commercial team in helping organizations adopt innovative technologies to drive their digital transformation. Minh applies his 30+ years' of industry experience when designing and implementing control, automation, and data analytics solutions for pharma and biopharma manufacturers. Prior to joining Merck, Minh was Chief Operating Officer at Stelis Biopharma and a Senior Manufacturing Process Engineer at Amgen. Minh holds a Bachelor of Science (honors) degree in Microbiology from the University of Washington.

# Content & Speakers

## Topic 2 - Regulatory considerations in data integrity and compliance in computerized system of vaccine manufacturing

Introduce the requirement of a computerized system and data integrity regulations and guidelines. The detailed introduction for computerized system validation for compliance considerations. The operation compliance for computerized system introduction combined with data integrity requirement.

This talk will present:

- Regulatory and Guideline of Computerized System and Data Integrity.
- Detailed introduction for computerized system compliance.
- Operation compliance for the computerized system with Data Integrity requirement.



### Larry Zhu

**Senior Consultant  
Merck KGaA**

Above 5 years working experience in management. Familiar with the drug manufacturing process, sterility assurance, construction management, commissioning and qualification activities, validation practices, in pharmaceutical industries.

Familiar with process and CQ activities for process equipment, QC instruments, especially familiar with clean utilities and facility.

Familiar with the laws & regulations related to validation, participated in internal and external audit, experience in supplier quality audit.

# Content & Speakers



## Shaoqing Xing

**Quality Consultant | 12 years working experience  
Biological Pharmaceutical  
Merck KGaA**

More than 12 years of Quality management experience in the pharmaceutical industry, with specific expertise in laboratory operation, equipment/instrument management, data integrity and computerized system validation.

Lead/support several authorities inspections with successful results: EMA, FDA (Conducted by Peter Baker), NMPA. Lead Data Integrity project of China Bio-Reliance Validation Services Lab with successful result.

Subject Matter Expert of Root Cause Analysis and Data Integrity.

## Topic 3 - Convergence of technologies – Tools to success

Biomanufacturing operation is constantly evolving to address the changing market needs. Building capabilities for Bioprocessing 4.0 would require the convergence of Process Technologies, PAT, and Digital technologies. Bioprocessing 4.0 would involve data-driven decision-making to enhance process and product understanding hence a holistic strategy is required to build an ecosystem of automation, data governance and information processing. A phased approach that brings synergy across the process life cycle through integrated process control, data management tools will be critical to success in this journey. In this presentation, we will share our vision of this convergence and, also introduce to you to the various tools built to support this convergence.

# Content & Speakers



## **Ashok Kumar**

**Head of Bio4C™ Commercial, APAC  
Merck KGaA**

Ashok Kumar leads the Bio4C™ Commercial team for Asia and has been with the company for 13 years. His areas of expertise include Single-use and Integrated systems processing. He has experienced all custom engineered Fermentation systems.

Ashok has a Master of Science in Biotechnology and also holds the Master's degree in Operations and Marketing Management.



## **Nishant Gupta**

**Bio4C™ Sales Consultant-South Asia  
Merck KGaA**

Nishant Gupta holds an experience of over 12 years in the life sciences industry across several roles in core manufacturing operations, MSAT, tech-transfers and consulting. He has a strong background in process technologies and process data analytics and is actively involved in interactions with biopharma companies around the world to understand their current challenges and needs for digital maturity. He is a part of commercial development and customer engagement team for Bio4C™ software suite in APAC region. Nishant holds a bachelor's and master's degree in Biochemical Engineering and Biotechnology.