DCVMN INTERNATIONAL

Developing Countries Vaccine Manufacturers Network International

Tofflon

INNOVATIVE VACCINE TECHNOLOGY TRANSFER AND LOCAL MANUFACTURING

April 30th, 2024
11 AM – 1 PM (CET)

AGENDA

11 AM	Introduction & Opening	DCVMN International
11:05 AM	Session 1 - WHO-PQ Quality Management System for Vaccines	Mr. Justin Khng
11:35 AM	Session 2 - Navigating Successful Vaccine Technology Transfers: Insights and Lessons from Walvax	Mr. Lokender Kaushik
12:05 AM	Session 3 - Innovative Modular DS and DP Facility for Innovative Vaccine Manufacturing	Mr. Zhichao Wang
12:40 AM	Q&A	

Content

Session 1 - WHO-PQ Quality Management System for Vaccines

This presentation introduces the World Health Organization's (WHO) Prequalification (PQ) program for vaccines, which aims to ensure the safety, efficacy, and quality of vaccines for global procurement. It outlines the role of National Regulatory Authorities (NRA) in the PQ process and the criteria for vaccines to be eligible for prequalification. The also details the assessment timeline, inspection procedures, and key focus areas for compliance, including warehouse management, production practices, and quality assurance measures.

Session 2 - Navigating Successful Vaccine Technology Transfers: Insights and Lessons from Walvax

Technology transfer is a complex, yet pivotal process that ensures innovative vaccine products can be scaled up and successfully commercialized to reach patients. This presentation will share several compelling case studies at Walvax, highlighting the strategies, challenges, and key lessons learned throughout the technology transfer journey.

Key topics to be covered include: (i) regulatory requirements and compliance during technology transfers; (ii) effective collaboration and knowledge-sharing between tecnology partners; (iii) robust quality management systems to ensure product quality and consistency; (iv) Strategies for optimizing technology transfer timelines and reducing operational bottlenecks; and (v) developing a skilled and adaptable workforce to support successful technology transfers.

By the end, attendees will gain valuable insights and practical takeaways that they can apply to their own technology transfer initiatives, ultimately contributing to the timely delivery of life-saving vaccine.

Content

Session 3 - Innovative Modular DS and DP Facility for Innovative Vaccine Manufacturing

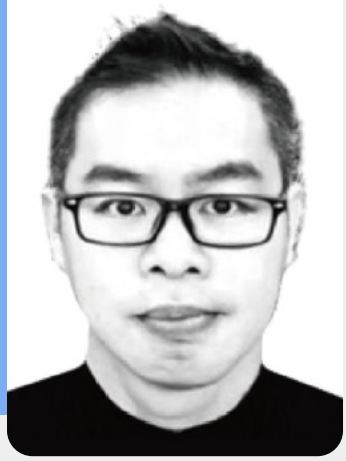
The presentation will delve into the trending technologies and advancements in vaccine modular production facilities. We will showcase the importance of modular facilities in meeting the evolving needs of the industry. Specifically, we will introduce Tofflon's approach to modular factory solutions, highlighting our innovative contributions to the field.

- Gain insights into the latest trends and technologies in vaccine manufacturing.
- Discover the benefits of modular facilities in addressing the evolving needs of vaccine production.
- Learn about Tofflon's innovative approach to modular factory solutions.
- Explore the concept and showcase of a new-age vaccine manufacturing facility.
- Understand the value that Tofflon modular factories bring to clients and their ultimate impact on patient benefits.

Overview

- Trending in Vaccine Manufacturing
  - New vaccine manufacturing technologies
  - Modular Facilities to address the trending needs
- Tofflon Modular Facility Introduction
- Approach of Tofflon Modular Factory Solution
- New Age Vaccine Manufacturing Facility
  - A Facility Concept and Showcase
- Client's Value Gained from Tofflon Modular Factory
  - All for the Ultimate Benefit of Patients.

Speakers



Mr. Justin Khng

Senior cGMP Consulting Director - Tofflon Abioplus (a company of Tofflon Group)

Mr. Justin Khng has over 22 years of experience both in China and overseas. He has undertaken positions with Fortune 500 pharmaceutical companies and consulting firms specializing in greenfield pharmaceutical projects. He has personally assisted numerous companies in attaining US FDA, EMA, PIC/s, and WHO PQ GMP manufacturing licenses and statuses.

Mr. Lokender Kaushik

Associate Director - Walvax Biotechnology

Mr. Lokender Kaushik, an expert in Quality Management Systems (QMS) and Good Manufacturing Practices (GMP), holds a Master's degree in Science with extensive experience in the vaccine industry. He is skilled in leadership, quality audits, CAPA analysis, and regulatory compliance strategy. With a track record of achievements including managing a Bill & Melinda Gates Foundation (BMGF) funded WHO Prequalification (PQ) project, reducing technology transfer timelines by 30%, and setting up Quality Management Systems, Mr. Kaushik is a dynamic and motivated professional. In his current role, he provides high-level strategic and operational regulatory direction, oversees global regulatory submissions, and manages critical issues related to technology transfer and regulatory affairs.

Speakers

Mr. Zhichao Wang

Manager of Modular Engineering Department - Tofflon Group

Zhichao Wang, Manager at Tofflon Smart Engineering Co., Ltd., holds a master's degree from Tianjin University. With expertise in designing and managing pharmaceutical projects, he understands biopharmaceutical processes, GMP, and building regulations. Wang established Tofflon's Modular Engineering Department and developed modular factory projects, optimizing processes and ensuring compliance. He excels in modular factory construction and is recognized for innovation and industry influence.

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