DCVMN INTERNATIONAL
Developing Countries Vaccine Manufacturers Network International

Tofflon

INNOVATIVE TECHNOLOGIES FOR VACCINE MANUFACTURING

December 13th–14th
8:45 AM – 12 PM (CET)

AGENDA

Day 1
December 13th, 2023
08:45 AM - 12 PM (CET)

08:45 AM	Introduction & Opening	DCVMN International
9 AM	Session 1 - Fast to Market: New Construction Approach of Vaccine Manufacturing Facility	Mr. Zhichao Wang
09:45 AM	Q&A	
10 AM	Session 2 - Single Use Technology for Vaccine Production	Ms. Claire Chong
10:45 AM	Q&A	
11 AM	Session 3 - How to realize a fast-track and regulation conformance recombinant protein vaccine DS workshop?	David Luo
11:45 AM	Q&A	

End of Day 1

AGENDA

Day 2
December 14th, 2023
08:45 AM - 12 PM (CET)

08:45 AM	Introduction & Opening	DCVMN International
9 AM	Session 4 - Key Consideration of Aseptic Filling Line in Vaccine Manufacturing	Edison Zhu
09:45 AM	Q&A	
10 AM	Session 5 - Lyophilisation of mRNA vaccines	Mr. Tom Wang
10:45 AM	Q&A	
11 AM	Session 6 - Understanding the impact from the recently introduced GMP Annex 1 on Visual Inspection and CCIT	Mr. Stefano Arletti
11:45 AM	Q&A	

End of Day 2

Content

Session 1 : Fast to Market: New Construction Approach of Vaccine Manufacturing Facility

The presentation "Fast to Market: New Construction Approach of Vaccine Manufacturing Facility" 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.

Content

Session 2 : Single Use Technology for Vaccine Production

There has always been a growing demand for delivering new technologies and expertise that helps to get vaccines faster and cheaper to the patients globally. The continued success and subsequent expansion of the vaccines market is met with significant industry pressures. To meet global demand, it is predicted that next generation vaccines will be based on recombinant approaches and be produced by using single-use system to increase capacity at reduced costs. However, despite their benefits, single-use system for vaccine manufacturing face a number of key challenges. In this webinar, we will explore and compare single-use system versus traditional stainless-steel system.

Session 3 : How to realize a fast-track and regulation conformance recombinant protein vaccine DS workshop?

DS manufacturing of vaccine involves a complexity of the process. Multiple elements are involved when you plan and execute a project of vaccine DS (Drug Substance) workshop. How to realize vaccine fast-tracked development as well as in compliance with regulatory requirements? Many challenges, such as, how to managing different manufacturing platform, how to do process analysis and calculation, what's operation sequence, how to define spatial design, interfaces between different equipment, utilities definition, contamination control, energy saving, different waste water handling, etc. are involved in the initial planning stage.

During project execution, there are still many challenges involved such as design confirmation, document review, test validation, installation and commissioning, etc. This presentation will present a project of recombinant protein vaccine DS workshop, including the overview of the project, challenges and solutions during the design and execute the project, which is an informative and significant project.

Content

Session 4 : Aseptic Filling System for Vaccine Manufacturing

• Introduction to the different vaccine type and their properties.
a. Package form: Vial, Ampoule, PFS etc.
b. Storage form: Liquid form, lyophilized form, powder form.
c. Liquid properties: Suspension, viscosity, like water, bio-active and etc.
d. Other special about vaccine: High added value and etc.

• Filling Machine special design to different kinds of vaccine
a. Different production capacities at different vaccine development stages
b. Different solutions to different properties:
i) High Added Value: IPC, auto re-fill, loss reduction
i i) Isolator protection to bio-active (live) vaccine
iii) Filling Method: piston, peristaltic, time pressure, and others
iv) Temperature protection
v) Require lyophilization?

• Packaging forms that are becoming increasingly popular
a. Nasal spray
b. Dual chamber syringe

- Case Sharing
- History and Future of the vaccine development.

Content

Session 5 : Lyophilisation of mRNA vaccines

mRNA vaccine has been very popular in recent years, and have proven to be very successful in fighting against the COVID-19 pandemic. This presentation is aimed to share some basic information about mRNA vaccine lyophilisation. Although mRNA vaccines can be produced in large scale with good record in both safety and potency, long-term storage of mRNA vaccine is still a big challenge for the pharmaceutical industry.
However, the lyophilisation technique provides an ideal solution for this problem as the sensitive components in mRNA vaccine can be well protected with water removed gradually under a vacuum and low temperature. The most current researches indicate the physicochemical properties and bioactivities of lyophilized vaccines do not significantly change at 25 °C storage condition over 6 months. There is no doubt that these promising results are exciting but many difficult issues still need to be solved before large scale commercial manufacturing come into practice, such as solution environmental stress factors determination, lyophilisation cycle development & optimisation, nucleic acid degradation, lipid structure stability and so on.

Session 6: Understanding the impact from the recently introduced GMP Annex 1 on Visual Inspection and CCIT

On August 2023, Annex 1 of The Rules Governing Medicinal Products in the European Union “Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use” becomes effective. In this webinar we will cover the changes and impact that the new EU GMP Annex 1 brings to the Visual Inspection and Container Closure Integrity Test. The new Annex extends the requirements of CCIT to include the effects of transportation. More requirements are also made explicit for defects classification and inspection statistical data analysis to find out as soon as possible negative trends in the quality/safety level. More in general the reduction of human presence and intervention is recommended by automation wherever possible during all manufacturing process phases and carefully controlled and managed when still necessary.

Speakers

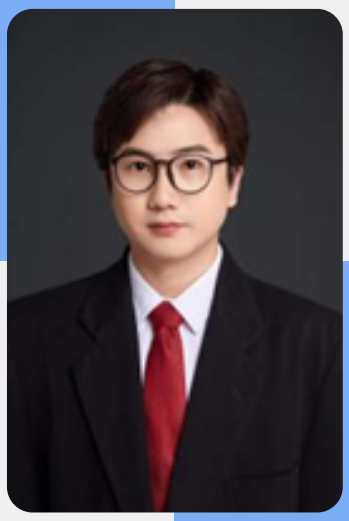
Ms. Claire Chong
Technical Application Manager

Claire Chong graduated with B.Sc. (Hons) in Biotechnology from University of Liverpool, with more than 8 years of experience in bioprocessing industry, familiar with both upstream and downstream of DS production. Upon graduation she was part of a Singapore government funded research team working on process development for transient protein production. She has also attended 1 year of exchange and training program in USA, focusing on the Single use technology (SUT). After which, she has also been involved in the start-up of the first fully operational single use facilities in Singapore, where she is supporting the PPQ and production runs for the upstream process. She is also in charge of the training team where she shares her knowledge of SUT. She has then moved her focus to downstream processes supporting customer within the SEA and TW regions. Part of the technical application team, her role is to support customers in scale-up trials and any downstream application studies, such as TFF, sterile and virus filtration and chromatography solutions. She is currently part of Tofflon Singapore Bioprocessing support team, supporting the single use needs for Tofflon's customers.

David Luo
Product Manager

With 20-year experiences in processing liquid industrials, including Chemical, Food and Pharma industrials, including 7 years experiences on equipment management and project management at EU & US multinational companies, and acted as project manager at Engineering company GEA. For 10 years engage in proposal design and project executive of Bio-processing system at Tofflon, and plenty of project experiences on human vaccine, veterinary vaccine, monoclonal antibody, insulin, plasma fractionation, etc.

Speakers



Edison Zhu
Product Manager

Edison Zhu, in 2021 obtained a master's degree in mechanical energy in France. After that, entered Tofflon filling department and began to provide filling line solutions for global pharmaceutical companies. Be responsible for providing complete solutions including freeze dryers, filling lines, and isolators for Europe and the United States.

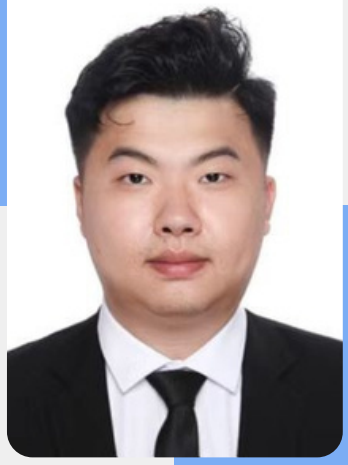
Mr. Stefano Arletti
Visual Inspection R&D Consultant

Stefano Arletti is a consultant working in the design of Artificial Vision based quality controls for over 25 years. After graduating as Electronic Engineer in Italy in 1997 with a specialization in Computer science and Artificial Intelligence he started developing different automatic quality control systems based on camera vision for the beverage, food and pharmaceutical sectors.

During the next 15 years he has focused more and more on the pharmaceutical sector, mainly the automatic visual inspection of parenteral products, developing entirely the vision and automation systems required into Automatic Inspection Machines installed and operating worldwide. The R&D work during this period has led to several new concepts patented under Italian and European Patent Offices.In 2012 joined Tofflon in Shanghai to support and lead the R&D team of the Automatic Inspection Division and the construction and commissioning of hundreds of systems worldwide.

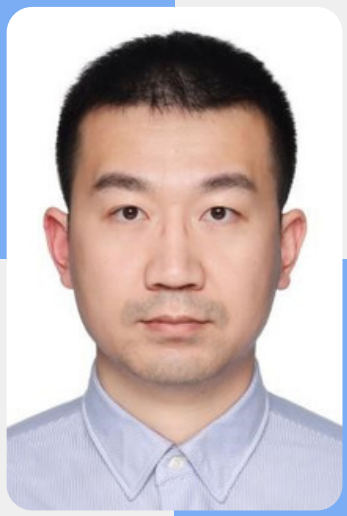
Always passionate about science &technology, their endless progress and their possibility to improve the performances and the manufacturing of products and finally the quality of everyone's life he's enjoying his work facing continuously new challenges, developing international cooperation and looking forward to provide better products and solutions for the final customers.

Speakers



Mr. Tom Wang
Research & Development Engineer

Tom Wang has served as a research assistant in University of Sheffield, focusing on high efficient self-assembled catalysts. He has developed good experimental techniques and has been passionate about solving challenging problems. Very early in his career Tom got involved in lyophilisation manufacturing, working as a field freeze-dryer engineer, where he built basic understandings about the lyophilisation process control and the lyo-machine maintenance. After joined Tofflon, Tom has been provided with more opportunities to conduct researches in lyophilisation field, making great progress in both theory and practice. Based on systematic training he has built expertise in both lyo-lab techniques and lyophilisation related trouble-shooting. Now he has developed in-depth understanding in lyophilisation recipe optimisation using PAT (Process Analytical Technology) tools and has successfully delivered many rational solutions to some tough issues happened in manufacturing sites of our customers.



Mr. Zhichao Wang
Manager of Modular Engineering Department

Zhichao Wang is currently serving as the Manager of the Modular Engineering Department at Tofflon Smart Engineering Co., Ltd. He hold a master's degree from Tianjin University, he possesses extensive expertise in designing and managing pharmaceutical projects He has a profound understanding of biopharmaceutical processes, international Good Manufacturing Practices (GMP), and building regulations. His contributions include the establishment of the Tofflon Modular Engineering Department and the successful development and implementation of modular factory projects.

His expertise lies in designing and managing pharmaceutical projects, leveraging his profound knowledge to optimize processes and ensure compliance with industry standards. He has played a pivotal role in establishing Tofflon's Modular Engineering Department, and under his leadership, the team has successfully developed and executed several modular factory projects. Mr. Wang's exceptional achievements in modular factory construction have equipped him with practical insights into the best practices and trade-offs associated with various modular factory approaches and solutions. With a passion for innovation and a keen understanding of industry demands, Mr. Zhichao Wang continuously seeks improvement in the field of modular engineering.

Tofflon Science and Technology Group Co., Ltd.

No. 1509 Duhui Road, Shanghai China 201108

 + 86 21 64901123

 + 86 21 64905148

 info@tofflon.com

 www.tofflon.com