TOFFLON WORKSHOP

End-to-End Solutions for Vaccine Manufacturing

January 10-11, 2023

08:50 AM - 12:00 PM (CET)

DCVMN
Developing Countries Vaccine Manufacturers Network

Tofflon

AGENDA

DAY 1
Jan. 10th, 2023
08:50 AM - 12:00 PM (CET)

Speaker	Topic	Time
DCVMN	Introduction & Opening	08:50 AM
Mr. Gordon Farquharson	Vaccine Manufacturing Facilities	09:00 AM
	Q&A Session	09:45 AM
Ms. Claire Chong	Single-Use Technology for Vaccine Production	10:00 AM
	Q&A Session	10:45 AM

AGENDA

DAY 1
Jan. 10th, 2023
08:50 AM - 12:00 PM (CET)

Speaker	Topic	Time
Mr. Vikrant Hedau	Large-Scale Manufacturing of Vaccines	11:00 AM
	Q&A Session	11:45 AM
DCVMN	Closing remarks	12:00 PM

End of Day 1

AGENDA

DAY 2
Jan. 11th, 2023
08:50 AM - 12:00 PM (CET)

Speaker	Topic	Time
DCVMN	Introduction & Opening	08:50 AM
Mr. Alan Huang	Application of Aseptic Filling Line in Vaccine Manufacuring	09:00 AM
	Q&A Session	09:45 AM
Mr. Yossi Shapira	Vaccines Freeze Drying Challenges	10:00 AM
	Q&A Session	10:45 AM

AGENDA

DAY 2
Jan. 11th, 2023
08:50 AM - 12:00 PM (CET)

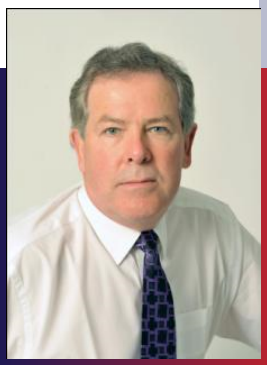
Speaker	Topic	Time
Mr. Stefano Arletti	Automatic Visual Inspection of Vaccines	11:00 AM
	Q&A Session	11:45 AM
DCVMN	Closing remarks	12:00 PM

End of Day 2

TOPICS - Day 1

Mr. Gordon Farquharson

Director & Principal Consultant, Critical Systems



Gordon Farquharson, B.Sc. (Hons), C.Eng. is a Chartered Consulting Engineer with more than 40 years' experience of quality & safety critical processes and facilities used by industries such as Healthcare, Life Science, Micro-electronics, etc. He is Principal consultant and Managing Director of Critical Systems Ltd, an international consultancy firm. In the Asian and ASEAN regions, he also provides consultancy services in association with Airex (Japan), Pharma solutions (Japan), FactoryTalk (Thailand), CM-Plus (Japan & Vietnam), Tofflon (China) and PharmOut (Australia).

Vaccine Manufacturing Facilities

This presentation is provided to set the scene with an overview of essential aspects of manufacturing facilities targeted at vaccine production. The experience with COVID-19 has heightened the pharmaceutical industry approach to delivering vaccines in record time.

It is very important to understand the regulatory background guiding the manufacture of these products and understand the process and materials drivers that influence the design. The presentation will also look at some industry trends and suggest how these might influence the factory of the future. In the light of COVID-19, the world has been thinking about rapid response to communicable diseases in our societies, and the presentation will briefly look at some examples of how this is being addressed in some countries.

The talk will lead on to more detailed presentations from colleagues on specific process technologies and their applications.

- Essential Regulatory reference points – EU, PIC/S & WHO;
- Key Facility design concepts & considerations for vaccine MFG;
- Achieving flexibility & adaptability for rapid response;
- Some options and key considerations for supply chain management;
- Manufacturing trends & Facility of the Future.

TOPICS - Day 1

Ms. Claire Chong

Technical Application Manager, Tofflon Group

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. 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.

Single Use Technology for Vaccine Production

This presentation is aimed to provide an overview of Single Use Technology (SUT) applications around vaccines production. The outbreak of the COVID-19 pandemic has boosted the demand for SUT which in turn propelled the rapid progression of SUT for vaccine production. We will discuss in detail on the advantages of SUT and how it has helped to change the current vaccine production scene. We will also talk about at the areas of restraints and challenges we faced with SUT and what the future holds for SUT. Lastly, we would like to end the presentation by sharing some of the success stories that we have with using SUT for vaccine production.

- Overview application of SUT and its impact on vaccine production;
- Pros and cons of using SUT;
- Success stories using SUT in vaccine production.

TOPICS - Day 1

Mr. Vikrant Hedau

Technical Support Manager, Tofflon Group

Vikrant Hedau is engaged with Tofflon since approx. 3 years and is the team lead for technical support of Bio division of Tofflon India and also heading operationally the upcoming project of Single use bag manufacturing facility. He is Bioprocess Engineer with an accomplished 12+ years of experience in bioprocess Industry with a major focus on technology transfer, scale-up & validation of vaccines and biosimilars molecules. He has expertise in validation, downstream processing unit operation viz. chromatography, filtration-Depth, TFF & Nano-filtration. He has also been engaged in designing and successful qualification of BSL 2 manufacturing facility.

Large-scale manufacturing of vaccines

Vaccine industry is growing across the world for primary immunization, pandemic situations etc. Pandemic situation make world to rush to identify safe and effective vaccines and therapeutics but equally important to scale up and manufacture at large scale. Primary factor in vaccine manufacturing is operation cost. Vaccine end product cost is much lesser than the cost of the other biosimilar end products. Vaccine industries look for the cost-effective solution in term of the operation cost. The operational cost of the Single use solution after certain scale is much higher over Stainless steel. Due to which vaccine industries prefer stainless steel over Single use system for manufacturing of the traditional vaccine & high scale vaccine manufacturing.

As many aspects involved in SS platform for vaccine manufacturing like fermenters, CIP skids, TCU, vessel systems, piping, valve matrix etc. based on the product and containment requirement, the engineering solution should be provided in order to mitigate the process and BSL risks.

In this session, we shall be presenting the engineering solution for large scale manufacturing of the biologics/vaccine based on hybrid manufacturing platform.

TOPICS - Day 2

Mr. Alan Huang

Technical Application Manager, Tofflon Group

Alan Huang has been working in Tofflon for 2 years and is the leader of the DP technical support team for Europe and Russia Sales region. Before he joined Tofflon, he graduated with MEng in mechanical engineering from University College London. In Tofflon, he is mainly responsible for the aseptic filling line systematic solution. By working along with the product department and communication with customers on-site, he has a deep understanding of the machine structure and how to fulfil the customer's needs.

Aseptic Filling System for Vaccine Manufacturing

Introduction to the different vaccine type and their properties:

- Package form: Vial, Ampoule, PFS and etc.
- Storage form: Liquid form, lyophilized form, powder form.
- Liquid properties: Suspension, viscosity, like water, bio-active and etc.
- Other special about vaccine: High added value and etc.

Filling Machine special design to different kinds of vaccine:

- Different production capacity at different vaccine develop stage
- Different solution to different properties:

  (i) High Added Value: IPC, auto re-fill, loss reduction;
  (ii) Isolator protection to bio-active (live) vaccine;
  (iii) Filling Method: piston, peristaltic, time pressure and others;
  (iv)Temperature protection;
  (v) Require lyophilization?

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

TOPICS - Day 2

Mr. Yossi Shapira

Consultant, Tofflon with CLL – Yossi Shapira

- Lyophilization expert, containment expert, aseptic operations and Technology expert;
- Tofflon's consultant in freeze drying processes and technology.
- 20 years' experience at Teva pharmaceutical industries, in SVP production: mainly Sterile cytotoxic, anticancer, antibiotics and steroides. In liquid form vials and ampules and lyophilized drugs dosage forms. Clean rooms operations and aseptic Technik manufacturing and validation expert, operating team trainer, and production problems solving. Final function – plant manager.
- 15 additional years at Teva Pharmaceutical API division special project management: in bulk API lyophilization, lyophilizers specifying and testing, lyophilization processes problem solving containment design and review, HPAPI isolators construction, laboratories design and construction: analytical R&D, HPAPI pilot plant design and construction. Functioning in a global manner with different engineering teams and companies.
- 6 additional years In Teva Pharmaceutical industries – corporate in global engineering as MST for HPAPI handling technologies, lyophilization equipment and processes, and laboratories design.
- Currently - At Yossi Shapira CLL freelancer consultant to pharmaceutical companies regarding the above topics.

Vaccines Freeze Drying Challenges

- Different vaccines types;
- Tofflon's offer for sterile contained filling process, its machinery.;
- Problems: exposure, cross contamination during vaccines freeze drying.;
- Offered solutions.

TOPICS - Day 2

Mr. Stefano Arletti

Visual Inspection Consultant , Tofflon Group

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.

Automatic Visual Inspection of Vaccines

This presentation is aimed to provide an outlook to the automatic inspection systems of different vaccine presentations: pre-filled syringes and single or multi-dose vials updated to the end of 2022.

The Automatic visual inspection of parenteral products is an established method to comply with regulations and improve production's quality level combined with high speed & capacity. However more complicated containers such as pre-filled syringes and some specific features common in vaccines make their visual inspection more difficult and challenging. We will see how Automatic Inspection machines need to be designed and built to cope effectively with such difficulties.

The fallout of COVID-19 pandemic is putting enormous pressure on the whole Pharmaceutical Industry and all related Regulator Agencies to dramatically shorten the development time of new vaccines and have them mass produced on a scale never seen before while maintaining high level of quality and safety and a low final cost. The immediate consequence of this is the requirement for vaccine manufacturing plants to be easily and quickly adaptable to new products and containers while being able to consistently deliver very high volumes and capacity in a short time. Automatic Visual Inspection is the only technology able to combine the required speed and quality. We will end the presentation by reviewing the key points that the last 3 years of fighting with COVID-19 have taught in the Automatic Visual Inspection sector.

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

LinkedIn

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