

**Workshop on Supply Chain Management:  
Quality by Design and Supply Chain Modelling  
25-28 November 2019, Hanoi, Vietnam**

Scope: In Partnership with DCVMN, the [Future Vaccine Manufacturing Research Hub](#) (FVMR Hub), led by Imperial College London, will deliver an educational content on quality by design methodology and vaccine supply chain modelling & optimization. The workshop aims to define current challenges in vaccine development as well as supply chains in developing countries and discuss proposed solutions to the identified challenges.

QbD: Quality by design (QbD) is a systematic approach to product development that begins with predefined objectives and emphasizes product and process understanding and controls based on sound science and quality risk management (ICH Q8). The emphasis of QbD began with the recognition that increased testing does not necessarily improve product quality and cost-effectiveness; however, quality must be built into the product from the R&D. The regulatory agencies encourage risk-based approaches and the adoption of QbD principles in product development and manufacturing.

Supply Chain modelling will focus on theoretical and interactive discussions:

Theoretical background for vaccine supply chain modelling:

- Understanding the fundamentals and importance of supply chain modelling for vaccines
- Use of mathematical optimization for vaccine supply chain modelling
- Overview of vaccine supply chain modelling workflow: problem identification, objective and constraint formulation, solving the problem, interpreting results
- Vaccine supply chain cost reduction example: a Kenyan case study

Interactive session for vaccine supply chain model development:

- Vaccine supply chain problem identification based on input from participants
- Vaccine supply chain problem ranking/prioritization based on voting of the participants
- Objective and constraint formulation based on discussion with the participants

The QbD training will focus on:

- Designing manufacturing process to consistently produce product meeting pre-defined quality criteria
- Understanding impact of input parameters on product quality to adequately build the controls at the critical points in the process

The Modelling training will focus on:

- Challenges and framework
- Potential solutions
- Feedback for improvements from workshop attendees

Participants: This workshop is aimed at professionals working at the vaccine industry in emerging countries, particularly in R&D and in distribution of vaccines.

DAY 1, Monday 25 November 2019 – QbD		
Time	Topic	Speaker
08:30-09:00	Registration	DCVMN
09:00-09:30	Welcome and introductions Updates on initiatives, objectives and expected outcomes	S. Pagliusi, DCVMN
09:30-10:00	Introduction to the FVMR Hub	B. Pierce, Imperial College London, FVMR Hub
10:00-10:30	Coffee Break	Group photo
10:30-11:30	QbD principles and methodology: platform to accelerate the development, production and supply of vaccines	M. Papathanasiou & Z. Kis, Imperial College London, FVMR Hub
11:30-12:30	QbD impact for vaccine manufacturing: examples of collaborations with Imperial College London's FVMR Hub	F. Micoli (GSK) & C. Campa (GSK)
12:30-13:30	Lunch Break	
13:30-15:30	QbD issues: Vaccine production exemplar	All participants: group discussions
15:30-16:00	Coffee Break	
16:00-16:30	Discussion and conclusions	F. Micoli (GSK), C. Campa(GSK) & M. Papathanasiou (FVMR Hub)
16:30-17:00	Bill Gates Video	DCVMN
17:30	Discussion & Adjourn	All participants

**DAY 2, Tuesday 26 November 2019 – Supply Chain Modelling**

Time	Topic	Speaker
08:30-09:00	Introduction to the Global and DCVMN Supply Chain initiatives: Objectives and expected outcomes	S. Jarrett, DCVMN
09:00-09:30	Fundamentals and importance of supply chain modelling for vaccines	M. Papathanasiou & Z. Kis, Imperial College London, FVMR Hub
09:30-10:00	The use of mathematical optimization for vaccine supply chain modelling	M. Papathanasiou & Z. Kis, Imperial College London, FVMR Hub
10:00-10:30	Coffee Break	
10:30-11:30	Vaccine supply chain modelling workflow: problem identification, objective and constraint formulation, solving the problem, interpreting results	M. Papathanasiou & Z. Kis, Imperial College London, FVMR Hub
11:30-12:30	Vaccine supply chain cost reduction example: a Kenyan case study	M. Papathanasiou & Z. Kis, Imperial College London, FVMR Hub
12:30-13:30	Lunch	
13:30-14:00	Interactive discussion session: vaccine supply chain problem identification	M. Papathanasiou & Z. Kis, Imperial College London, All participants
14:00-15:00	Interactive discussion session: vaccine supply chain problem ranking	M. Papathanasiou & Z. Kis, Imperial College London, All participants
15:00-16:00	Interactive modelling exercise: objective and constraint formulation	M. Papathanasiou & Z. Kis, Imperial College London, All participants
16:00-16:30	Coffee Break	
16:30-17:30	Presentation of QbD Application in Aseptic Filling Line	J. Zhao, Tofflon
17:30-17:45	Q&A and adjourn	All participants

<b>DAY 3, Wednesday 27 November 2019 – Supply Chain Modelling</b>		
<b>Time</b>	<b>Topic</b>	<b>Speaker</b>
08:30-10:30	Moderated Discussion of parameters that influence supply chain in emerging countries and Q&A	S. Jarrett, DCVMN
10:30-11:00	Coffee Break	
11:00-12:30	Traceability standards and Q&A	B. Chinh, GS1
12:30-13:30	Lunch Break	
13:30-14:00	QbD learnings: Overview and specific vaccine challenges identified	Z. Kis, Imperial College London, FVMR Hub
14:00-15:30	QbD application potential to supply chain issues: a forecast	Z. Kis, Imperial College London, FVMR Hub
15:30-16:00	Coffee break	
16:00-17:00	Joint discussion and conclusion	All participants
17:30	Adjourn	

**DAY 4, Thursday 28 November 2019 – Supply Chain Working Group recommendations**

Time	Topic	Speaker
09:00-09:30	Introductions and brief statement by participants on their interest in the group	L. Yang, CNBG, Working Group Chair
09:30-10:30	Summary of rationale for the group, TOR, White Paper and decisions of 25 June meeting, with Q&A	S. Jarrett, DCVMN
10:30-11:00	Coffee break	
11:00-12:30	In-depth review of group's agenda – traceability, stockpiling and new packaging technologies, with Q&A (Draft report available)	S. Jarrett, DCVMN
12:30-13:30	Lunch break	
13:30-15:00	Sharing experiences by participants on agenda items	All participants
15:00-15:30	Initial suggestions on specific tasks to be carried out by the group on the agenda items	L. Yang, CNBG, Working Group Chair
15:30-16:00	Coffee break	
16:00-17:00	Agreement on next steps, tasks & assignment of responsibilities and proposed timelines	All participants
17:00-17:30	Conclusion, next meeting and adjourn	L. Yang, CNBG, Working Group Chair