

# Optimization of vaccines' manufacturing, containers and testing for global supply

## DCVMN Regional Training Workshop

### Hyderabad, 07 to 10 May 2018

This workshop covers in-depth training on:

- 1) New trends in life sciences, immunology and manufacturing systems
- 2) Tools to improve primary containers' filling quality
- 3) New QC approaches for vaccines using in vitro based methods
- 4) Supply chain traceability: bar code and serialization tools.

#### Participants Profile

Who should attend: Research and development professionals, upstream and downstream process engineers, manufacturing technicians, QC and QA managers in the vaccine industry.

#### Expected outcomes

At the end of the workshop participants will be able to:

- 1) Apply best practices to your vaccine
- 2) Define new QC approaches to filling
- 3) Identify priorities for novel QC testing

## DRAFT AGENDA

Hyderabad 07th to 10th May 2018

DAY 1, Monday 7 <sup>th</sup> May – Welcome and Introduction		
Schedule	Topic	Speaker
8:00-8:30	Registrations -	DCVMN
9h00 - 9h30	Welcome and Introduction	Host-BE
9h30 - 10h00	Updates on DCVMN professional activities on training and E-learning platform, regulatory activities and new partnerships.	DCVMN
10h00 -10h30	Coffee break	
10h30 - 11h30	New trends in Vaccine upstream processing	B. Damien Univercells
11h30 - 12h30	Optimization of manufacturing process	Biozeen (tbc)
12h30 - 13h30	Lunch	
13h30 - 14h15	Future vaccine manufacturing technologies	Vaccine Manufacturing Hub
14h15 -15h15	New tools to improve vaccines' thermostability	Vaccine Manufacturing Hub
15h15 -15h45	Coffee break	
15h45 -16h45	Thermostability monitoring of vaccines for global supply	Temptime
16h45 – 17h30	Q&A and discussion	All
18h00 – 19h00	Welcome reception	All participants

<b>DAY2, Tuesday 8th May - Plenary session for all participants – Hosted by DCVMN at Radisson</b>		
<b>Time</b>	<b>Topic</b>	<b>Speaker</b>
9h00 -9h45	The impact of training in manufacturing solutions	U. Datta GEHC
9h45 – 10h30	Media-fill process validation for vaccines	Merck
10h30 -10h45	Coffee break	
10h45 -11h45	Pharmaceutical water (PW and WFI) in stable quality – a crucial material for vaccine production	R. Roepenack Bosch
11h45 – 12h30	Modern trends in liquid filling technology	G.Hedge Bosch
12h30-13h30	Lunch	
<b>Primary containers management - Plenary session for all participants Hosted by OMPI at Radisson</b>		
<b>Time</b>	<b>Topic</b>	<b>Speaker</b>
13h30 -14h30	Selecting the primary containers to match F&F efficiency	M. Marrocco OMPI
14h30 -15h30	Overview of principles in sterile manufacturing and packaging of vaccines	M. Marrocco OMPI
15h30 -16h00	Coffee Break	
16h00 -17h00	Tools to monitor consistency: visual inspection and inspection technology – global, regional and national expectations	G. Baccinelli OMPI
17h00 – 17h30	Q&A	
17h30	Adjourn	

<b>DAY 3, Wednesday 9th May, Hosted by DCVMN at Radisson New QC approaches for vaccines using in vitro based methods</b>		
<b>Schedule</b>	<b>Topic</b>	<b>Speaker</b>
9h00 – 9h30	Future QC approaches for efficient vaccines quality control: global initiatives	C. von Hunolstein Global NCL Network
9h30 – 10h00	Benefits of International Standards for vaccine's testing	D. Wilkinson NIBSC
10h00 –10h30	"Consistency Approach" for quality control of established vaccines	H. Depraeter EVI - Vac2Vac
10h30 - 10h45	Coffee break	
10h45 – 11h15	The aP proposal	JM Chapsal EDQM
11h15 - 11h45	The wP proposal	A. Sloots INTRAVACC
11h45 – 12h45	The rabies proposal	C. Goepfert PEI
12h45 – 14h00	Lunch	
14h00 – 16h00	Vaccine specific working groups' discussions : aP, wP, rabies, others	All
16h00 – 16h30	Coffee break	
16h30 – 17h30	Plenary discussions – conclusion	

<b>DAY4, Thursday 10 May – Supply Chain Integrity: Bar code &amp; serialization Hosted by DCVMN at Radisson - Delivered by GS1</b>		
<b>Time</b>	<b>Topic</b>	<b>Speaker</b>
8h30 - 10h00	<ul style="list-style-type: none"> <li>• Introduction to GS1 and GS1 Healthcare</li> <li>• Usage of GS1 standards worldwide through regulation or customer requirements</li> </ul>	S.Swaminathan GS1
10h00 –10h30	Coffee Break	
10h30 –11h30	<ul style="list-style-type: none"> <li>• Identification &amp; Marking of vaccines for international supply <ul style="list-style-type: none"> <li>✓ Identification</li> <li>✓ Serialization</li> <li>✓ Marking / Labelling</li> <li>✓ Data Carriers</li> </ul> </li> </ul>	S.Swaminathan GS1
11h30 –12h30	Small groups discussion on practical issues and challenges	Participants
12h30 –13h30	Lunch	
13h30 –15h30	<ul style="list-style-type: none"> <li>• Data sharing tools</li> </ul>	S. Swaminathan GS1
15h30 –16h00	Coffee Break	
16h00 –17h00	Presentation of groups and problem solving with open discussion	Participants