Supply Chain Integrity
DCVMN Regional Training Workshop
Shenzhen, China, January 2019

The continuous supply of quality, safe, effective and affordable vaccines is one of the building blocks of every well-functioning health system. Good procurement practices play a key role in securing affordable prices and ensuring adequate and timely supply, while good supply chain management ensures that quality products are available at all levels of the health system.

The supply chain is often weakened by poor infrastructure and by lack of accurate data management systems. This can be particularly complex for vaccines and other temperature time sensitive health products that require careful handling and efficient cold chain systems. The complex, widespread and increasing challenges related to shortages of health products affect access to vaccines in countries at every level of development. In the case of infectious diseases, the implications of these shortages go beyond affecting just the individual to impact on public health.

Efficient distribution and use should lead to lower level of wastage with related improvements in availability, affordability and access. [1]

This activity area addresses the need for improved capacity for procurement and supply chain management and for better data and market analysis to inform policy decisions. DCVMN will continue to support collaborative efforts to optimize the procurement and supply chain for vaccines and will contribute to the global understanding of supply and demand dynamics of vaccines, for improved supply capacity.

Objectives
This workshop covers in-depth training on:

1) Supply chain traceability: bar coding and serialization tools.
2) Data exchange
3) Regulatory landscape across the world
4) Temperature monitoring of vaccines after they leave the factory
5) Understanding of evaluation required to ensure good distribution practices and partners, in the domestic and international markets

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

Expected outcomes
At the end of the workshop participants will be able to:
1) Identify products following global standards
2) Have an understanding of manufacturers' responsibilities around master data
3) Identify how to apply barcoding for their products and which developments are happening in the world,
4) Knowledge of how to plan and conduct external audits regarding supply chain.

[1] http://www.who.int/medicines/access_use/Roadmap_for_access_zero_draft_2_July_2018_FINALv1clean.pdf?ua=1

FINAL AGENDA

DAY 1, Monday 21st January 2018 – Supply Chain Integrity: Bar code & serialization Hosted by DCVMN - Delivered by GS1		
Time	Topic	Speaker
8h30 - 10h00	• Introduction to GS1 and GS1 Healthcare • Identification & Marking of vaccines for international supply ○ Identification	GS1 Global Office – Ulrike Kreysa GS1 China – Flora Sue
10h00 –10h30	Coffee Break	

10h30 –12h00	• Identification & Marking of vaccines for international supply - continued
	  ✓ Serialization
	  ✓ Marking / Labelling
	  ✓ Data Carriers
		Liu Wei, GS1 China

12h00 –12h30	Small groups discussion on practical issues and challenges	Participants
12h30 –13h30	Lunch	

13h30 –14h30	• Identification & Marking of vaccines for international supply – continued
	  ○ Logistic Units
	  ○ Aggregation
	  ○ Location ID
		Liu Wei, GS1 China

14h30 –15h00	Practical exercises and Q&A	All
15h00 –15h30	Coffee Break	
15h30 –17h00	Usage of GS1 standards worldwide through regulation or customer requirements	GS1 Global Office - Ulrike Kreysa
17h00 –17h30	Q&A and Conclusions Adjourn	All

DAY 2, Tuesday 22nd January 2018 – Supply Chain Integrity: Data sharing & traceability Hosted by DCVMN - Delivered by GS1		
Time	Topic	Speaker

8h30 - 10h00	• Traceability
	  ○ The different models – how to pick the right one
	  ○ The components
	  ○ Implementation and challenges
		GS1 China – Jackie Du

10h00 –10h30	Coffee Break	
10h30 –12:00	• EPCIS as an important tool for traceability • Traceability in China and other countries in the region	Prof. Wang, Fudan University
12h00 –12h30	Small groups discussion on practical issues and challenges, report back	Participants

12h30 –13h30	Lunch	
13h30 –14h30	• Product data ✓ Master data today ✓ Big data - why ✓ Role and responsibilities • Data sharing tools	GS1 Global Office - Ulrike Kreysa
14h30 –15h00	• Implementation reality – vaccines pilot in China	GS1 China/ Zhejiang Branch
15h00 –15h30	Coffee Break	
15h30 –16h30	What have we learned – repetition and tools for the future	GS1 & Participants
16h30 – 17h:00	Q&A and Conclusions Adjourn	All

DAY3, Wednesday 23rd January –Thermostabilty of vaccines Plenary for all participants - Hosted by Temptime		
Time	Topic	Speaker
8h30 – 9h30	• Introduction of Tepmtime Thermostability of vaccines: Importance of the maintaining the cold chain	Temptime
9h30 – 10h30	What is a vaccine vial monitor (VVM) and how does it work?	Temptime
10h30 – 11h00	Coffee Break	
11h00 – 12h30	How is the VVM category chosen for a vaccine? Implementation of VVM at vaccine manufacturer (Part 1)	Temptime
12h30 – 13h30	Lunch	
13h30 – 15h00	Implementation of VVM at vaccine manufacturer (Part 2) • VVM innovation	
15h00 – 15h30	Coffee Break	
15h30 – 16h15	Group activity – VVM category choice	Participants
16h15 – 17h00	Group activity – VVM receipt and 37°C testing at manufacturer	All
17h00 – 17h30	Q&A, conclusions and follow-up	All
17h30	Adjourn	

DAY 4, 24rd January 2018 – Supply Chain Integrity: Data sharing & traceability Hosted by DCVMN at TBC - Delivered by Goldenthal Consulting		
Time	Topic	Speaker
8h30 - 9h00	Introductions	A. Goldenthal
9h00 - 10h00	SECURITY OF THE SUPPLY CHAIN - General Overview - General Requirements of Auditing - Defining the Auditor - The Quality Agreement	A. Goldenthal
10h00 –10h30	Coffee Break	
10h30 –12:00	RAW MATERIALS - Requirements of Primary, Secondary and Tertiary Materials - Testing of Materials and Quality Control - Stepwise Auditing	A. Goldenthal
12h00 –12h30	Small groups discussion on practical issues and challenges, report back	Participants
12h30 –13h30	Lunch	
13h30 –15h00	THE AUDIT - The Paper Audit - The Physical Audit - The Audit Team - Frequency of Audits	A. Goldenthal
15h00 –15h30	Coffee Break	
15h30 –16h30	WORKSHOP: ANALYZING ACTUAL CASES	Participants
16h30 – 17h:00	Q&A and Conclusions Adjourn	All

DAY 5, 25th January 2018 – Supply Chain Integrity: Data sharing & traceability Hosted by DCVMN at TBC - Delivered by Goldenthal Consulting		
Time	Topic	Speaker
8h30 - 10h00	CROs and SERVICE PROVIDERS - Specialized Auditing Skills - Understanding GLP/ISO 17025 - Selection of Services - Test by Test Requirements - The Use of Subcontractors by the CRO/SP - Role of the Monitor	A. Goldenthal
10h00 –10h30	Coffee Break	
10h30 –12:00	REGULATORY AFFAIRS - Necessity for RA - Establishing an RA Department - Roles and functions of RA Personnel	A. Goldenthal
12h00 –12h30	Small groups discussion on practical issues and challenges, report back	Participants
12h30 –13h30	Lunch	
13h30 –15h00	DISTRIBUTION CENTRES - Conflicts of Interest - Repackaging - Traceability - Auditing a Warehouse	A. Goldenthal
15h00 –15h30	Coffee Break	
15h30 –16h30	WORKSHOP: ANALYZING ACTUAL CASES	Participants
16h30 – 17h:00	Q&A and Conclusions Adjourn	All