Vaccine Safety Monitoring
DCVMN Regional Training Workshop
Sao Paulo, February 2019

Objectives
This workshop covers in-depth training on:

1) Supply chain traceability: bar coding and serialization tools
2) Innovative tools for safety vaccines from manufacturing angles
3) Pharmacovigilance: building blocks and global landscape

Participants Profile
Who should attend: Research and development professionals, downstream process engineers, QC/QA managers, pharmacovigilance, clinical and regulatory affairs managers.

Expected outcomes

At the conclusion of this workshop, participants will be able to demonstrate an understanding of:
- The global concept of vaccine safety and vaccine safety monitoring
- Supply and cold chain management
- The importance of a robust systematic Vaccine Safety / Pharmacovigilance Management System
- Regulatory requirements for vaccine safety within the global context
- Requirements for the implementation of a robust cross-functional Pharmacovigilance System in SMEs (small / medium entities) to meet regulatory requirements globally

DRAFT AGENDA

DAY 1, 27 May 2019 – Supply Chain Integrity: Bar code & serialization Hosted by DCVMN - Delivered by GS1 experts		
Time	Topic	Speaker
8h30 - 10h00	• Introduction • GS1 and GS1 Healthcare • Usage of GS1 standards worldwide through regulation or customer requirements	DCVMN GS1 Brazil
10h00 –10h30	Coffee Break	
10h30 –11h30	• Identification & Marking of vaccines for international supply - continued ✓ Serialization ✓ Marking / Labelling ✓ Data Carriers	GS1 Brazil
11h30 –12h30	Traceability: The different approaches – how to pick the right one The components ✓ Implementation and challenges ✓ EPCIS as an important tool for traceability ✓ Product data	GS1 Brazil

	✓ Master data today ✓ Big data - why ✓ Role and responsibilities Data sharing tools	
Temperature monitoring session hosted and delivered by Temptime experts		
12h30 –13h30	Lunch	
13h30 –15h30	Temperature monitoring of vaccines after they leave the factory ✓ Thermostability of vaccines: vaccine vial monitor (VVM) and how does it work? ✓ Evolution/Digitization of VVMs with traceability and temperature-monitoring capabilities ✓ Cell-phone and scanner reading capabilities ✓ Global traceability policies and pilots	M. Rush Temptime
15h30 –16h00	Coffee Break	
16h00 –17h00	Implementation of VVM at vaccine manufacturer	M. Rush
17h00 –17h30	Small groups discussion on practical issues and challenges	All

DAY 2, 28 May 2019 – Process/purification tools and Blow-Fill-Seal technology Hosted and delivered by Rommelag experts		
Time	Topic	Speaker
8h30 - 10h00	Blow-Fill-Seal technology benefits Automated monitoring of critical product features within in-process control: lowering aseptic risk	T. Kram
10h00 – 10h30	Q&A and Conclusions	All
10h30 – 11h00	Coffee Break	
Safety monitoring and pharmacovigilance Hosted by DCVMN and delivered by PATH experts		
11h00 – 12h30	Post-authorization vaccine safety surveillance • Specificities of vaccine pharmacovigilance • Stakeholders in global vaccine safety	PATH
12h30 – 13h30	Lunch	
13h30 – 14h30	• Introduction to WHO Vaccine Safety Basics • PV requirements for WHO prequalification	PATH
14h30 – 15h30	• Basic definitions and tools in pharmacovigilance • Regulatory requirements for pharmacovigilance	PATH
15h30 – 16h00	Coffee Break	
16h00 – 17h00	Exercise: Self-assessment using PV questionnaire	All
17h00 – 18h00	Feedback to plenary	All

DAY 3, 29 May 2019 – Safety monitoring and pharmacovigilance Hosted by DCVMN delivered by PATH experts		
Time	Building blocks of a strong PV and Maintaining a strong PV	
8h30 - 9h30	Pharmacovigilance systems and their quality systems • Role of QPPV*, staff and management • Training of personnel for pharmacovigilance • Facilities and equipment for pharmacovigilance	PATH
9h30 –10h30	Pharmacovigilance systems and their quality systems • Documentation and record management • Compliance monitoring and system performance • Critical pharmacovigilance processes and business continuity	PATH
10h30 –11:00	• Coffee Break	
11h00 –12h00	Pharmacovigilance systems and their quality systems • Audits and inspections • Contractual agreements	PATH
12h00 – 12h30	Group exercise: Practical steps to establishing a pharmacovigilance department/system	All
12h30 –13h30	Lunch	
	Building blocks of a strong PV and Maintaining a strong PV	
13h30 –15h30	Group exercise: Practical steps to establishing a pharmacovigilance department/system	
15h30 –16h00	Coffee Break	
16h00 –17h30	The PV System Master File (PSMF): Purpose & content	
(*)	*QPPV: Qualified Person for Pharmacovigilance	

DAY 4, 30 May 2019 – Safety monitoring and pharmacovigilance Hosted by DCVMN delivered by PATH and DCVMN		
Time	Building blocks of a strong PV	Maintaining strong PV
8h30 - 9h30	Introduction to Signal detection and management	
9h30 – 10h30	Risk management plans: an industry perspective o Pharmacovigilance planning o Risk minimization measures o Safety communication	
10h30 –11h00	Coffee Break	
11h00 –12:30	PSUR* production and Co-ordination • Scheduling and preparation • Content and formatting	
12h30 –13h30	Lunch	
13h30 –14h30	Adverse event case management • ICSR receipt and handling including follow up and reconciliation • Safety database operation, validation, back-up, disaster recovery • Expedited reporting to Regulatory Authorities	
14h30 –15h30	• Introduction to MedDRA* coding procedure • Medical/causality assessment of ICSR*	
15h30 –16h00	Coffee Break	
16h00 –16h30	Exercise 2: Causality assessment of AEFI – case study	
16h30 –17h30	Q&A , conclusions and wrap up	

*PSUR: Periodic Safety Update Report
*ICSR: Individual Case Safety Report
*MedDRA: Medical Dictionary for Regulatory Activities
*AEFI: Adverse Event Following Immunization