Agenda for DCVMN Workshop
Hyderabad 04-08 April 2016.

Agenda	Topic	Speaker
DAY 1	**Monday 4th April 2016**	
Train the trainers Initiative - Chair: Dr. Harsha		
8:00 -8:30	Registration	Host
8:30 -9:00	Welcome and Introductions: Opening remarks by Chair Speech by Bharat, IIL, BE or VINS on QMS	Dr. Harsha, Bharat
9:00 – 9:30	The impact of training	Sonia Pagliusi
9:30 – 10:00	Train-the-trainers concept	Trevor Edwards
10:00 -10:15	Coffee Break	Group
Effectively and Efficiently Managing GMP Deviations using Quality Risk Management (QRM)		
10:15 -12:00	GMP Inspectors place critical importance on how GMP related incidents and deviations are recorded, assessed and resolved. This presentation will focus on key regulatory expectations for managing GMP Deviations according to WHO, PICs and FDA requirements. • WHO Draft Guidance for Deviation Handling • Process flow for deviation management systems • Applying risk techniques to quality events and deviations • Deviation Investigations, RCA, linkage to CAPA systems	Steve Williams
12:00 –12:30	**Test 1 assessment**	**All Participants**
12:30 -13:30	Lunch Break	Group
13:30 -17:00	Change management presents significant challenges to industry. Change control systems are often complex and can impact multiple aspects of GMP. This session will focus on: • Fundamental GMPs for change management • Regulator expectations and notification systems • Process flow for change management systems • Quality Risk Management (QRM) and change controls • Change and the “Validated State” • Documenting changes	Rai Karklins
16:00 -16:15	Coffee Break	Group
17:00– 18:00	Videos & group discussion	Trevor Edwards
18:00 adjourn		
18:30-	Welcome dinner reception	

DAY 2 Tuesday 05 April		
	Sterile Manufacturing GMPs	
8:00-8:30	Registration	Secretariat
8:30-11.15	**Sterile Manufacturing GMPs – what Regulators and Inspectors look for:** WHO, PICs and FDA have common requirements for sterile manufacturing GMPs although there are some specific challenges for vaccine manufacture. This session will cover some of the key points regulators look for when conducting sterile inspections: Areas covered include; • Control of bioburden and storage of sterile bulks • Material and equipment transfers into Grade B/A areas • Validation of Disinfectants and Sanitants • Aseptic processing, worst case conditions for validation • Fundamentals of environmental monitoring programs. • Overkill sterilization approach and worst case conditions. • Example FDA warning letter for sterile products.	Steve Williams
10:00-10:15	Coffee Break	Group
11:15 – 12:30	**Data Integrity** at the forefront of EU/TGA and FDA inspectors: what does it mean? In the last 3 years regulatory agencies have issued serious non-conformance and have taken regulatory actions on firms that cannot demonstrate suitable data integrity. Focus on: • Why inspectors are so concerned about data integrity • Likely causes of non-conformance • Examples of data integrity issues • Implementing data integrity policies and procedures • Example FDA Warning Letters for data Integrity	Rai Karklins
12:30-13:30	Lunch Break	Group
13:30-17.30	**Case Studies and Workshop: Deviations, QRM and CAPA** The participants will risk assess multiple industry case studies and examples of GMP related incidents using a range of techniques and decision trees. A QRM approach will be applied to the case studies. Attendees are encouraged to share/bring their examples, present their evaluations and propose CAPAs from the case studies	2 breakout groups with a dedicated trainer.
16:00-16:15	Coffee Break	Group
16:00-17:30	**Case Studies and Workshop: Deviations, QRM and CAPA (Continued)**	.
17:30– 18:00	Q&A, Feedback and Assessment	Adjourn

Parallel Stream - Day 3 Wednesday on 07 April (Change Management and Sterile Processing)		
Effectively Managing GMP Related Changes using Quality Risk Management (QRM).		
8:00-10:00	**Workshop: Case Studies and Workshop: Change Management using QRM.** The participants will risk assess industry case studies and examples of GMP related changes using a range of techniques and decision trees. A QRM approach will be applied to the case studies.	breakout groups with a dedicated trainer.
10:00-10:15	Coffee Break	
10:15 -12:30	**Workshop: Case Studies and Workshop: Change Management using QRM. (Continued)**	
12:30 -13:30	Lunch Break	Group
13:30 – 14.30	Validation Needs for Sterilization by Aseptic Filtration.	Mr. Ramesh Raju, Merck
14:30 -16:00	**Workshop Case Studies and Workshop: Sterile Manufacturing** The participants will develop protocols for media fills, disinfectant studies/Transfer studies and environmental monitoring programs using “worst case” conditions expected by PICs/TGA and FDA regulators..	One group with trainers.
16:00 -16:15	Coffee Break	Group
16:00 -18:00	**Workshop Case Studies and Workshop: Assessing OOS/OOT Events (Microbiological).** Participants will analyse a number of examples of microbiological OOS and potential OOT events and propose investigation plans.	One group with trainers

Parallel Stream - Day 3 Wednesday on 07 April (Regulatory Compliance, ICH Q8, OOS and OOT)		
Regulatory Compliance during Manufacturing Operations		
8:00-10:00	Introduction (To build Quality during Manufacture, QbD Concept of Risk Analysis, Data of Compliance vs Data of Exceptions)	Dr. Gupta
10:00-10:15	Coffee break	
10:15-11:30	Tracking and Trending, Critical Quality Attributes, Critical Process Parameters	Dr. Gupta
11:30 – 12:30	**Data of Exceptions – Deviations, Out of Trends (OOT), Out of Frequency (OOF), Out of Specifications (OOS), Non-Conformances**	Dr. Gupta
12:30-13:30	Lunch Break	Group
13:30 – 14.30	Sterilizing and Bioburden Filter Risk Assessment in Vaccine Processes as part of QRM.	Mr. G. Somasundaram, Merck
13:30-16:00	Out of Specifications, Averaging (masking a failing results), Barr's Average.	Dr. Gupta
16:00-16:15	Coffee Break	Group
16:15-18:00	Case of testing into compliance, Re-test Policy Design of Method to manage Variability and Error, How and when to	Workshop
18:00-	Adjourn	Group
Day 4 Thursday 7th April – Workshops Dr Gupta		
Quality metrics		
8:00-10:00	Investigations – Informal Investigation, Formal Investigations, Root	Dr. Gupta
10:00-10:15	Coffee Break	Group
10:15-12:30	Cause Analysis for data of exceptions Corrective and Preventive Actions 2 hrs	Workshop
12:30-13:30	Lunch Break	Group
13:30-16:00	Change Control, Categorization of changes, Reporting of changes	Workshop
16:00-16:15	Coffee Break	Group
16:00 - 17:00	Planned Deviations vs Changes	Workshop
17:00 – 17:30	Test 2 assessment	
18:00	End of the program	
Day 5 Friday 8th April – Train the trainers		
	Train the trainers tools	
8:00-10:00	Train-the-trainers: planning your training	Trevor Edwards
10:00-10:15	Coffee Break	Group
10:15-12:30	Tools to convey information/messages	Workshop
12:30-13:30	Lunch Break	Group
13:30-16:00	Test results and certificates, course feedback	Workshop
16:00-16:15	Coffee Break	Group
16:30	End of the program	