Goa Pharmaceutical Manufacturers' Association & Indian Pharmaceutical Association Goa State Branch

Present One Day Value Loaded Seminar

Data Integrity – Issues: Understanding and Resolution

The considered views of a UK GMDP Inspector

On Monday, 8th September 2014

Venue	**Convention Hall, Hotel Mandovi, Panaji, Goa**
Time	**09:15 Hrs. to 17:30 Hrs.**

Honorary Speaker:

Ms. Rachel Carmichael

Good Manufacturing / Distribution Practice (GMDP) Inspector
UK Medicines and Healthcare Products Regulatory Agency

Introduction of the speaker

Rachel joined the MHRA in 2004 and leads approximately 30 to 40 inspections a year. Rachel has a BSc (Hons) in Biochemistry, an MSc in Industrial Pharmaceutical Studies and an MSc in Marketing.

Her first position was with an international engineering organisation which wanted to break into the pharmaceutical industry. Rachel had a two year traineeship, spending time with all departments from Project Planning to Control and Instrumentation with considerable focus on validation.

Rachel then joined a US pharmaceutical company, initially working in production technical support for capsules and tablets, moving on to Continuous improvement in Packaging and subsequently into the Quality Division and in time becoming eligible to act as an EU Qualified Person.

Rachel now inspects a wide range of operations within the UK and overseas and over the past five years has witnessed the data integrity issues that Industry is experiencing. This has been enlightening and the Agency recognises the need to address this issue, where necessary through Regulatory action but more generally through supporting understanding and resolution from within the Industry.

Please refer to the "Seminar Agenda' & 'Delegate Registration Form' enclosed with this communication to know the contents and to participate in this value loaded seminar.

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Agenda

Time	Topic
09:15 – 09:40	Registration / Networking
09:40 – 10:00	Welcome, introduction and setting the context **Mr. Salim Veljee**, *Director, Directorate of Food and Drug Administration, Goa and President IPA, Goa State Branch* **Mr. Suresh Kamath**, *Associate Vice President, Unichem Laboratories Ltd. and President GPMA*
10:00 – 11:00	**Session 1**
	(a) Introduction to the MHRA, the Inspectorate and inspections (b) Overview of data integrity & self-inspection programs
11:00 – 11:30	Tea / Coffee Break
11:30 – 13:00	**Session 2**
	(a) Requirements for Data Integrity - Chapter 4 (Documentation) (b) Examples of typical deficiencies
13:00 – 14:15	Lunch Break
14:15 – 15:45	**Session 3**
	(a) Requirements for Annex 11 - Computerised Systems (b) Is compliance to 'Annex 11' sufficient to prevent 'Data Integrity Issues'? (c) Examples of typical deficiencies
15:45 – 16:15	Tea / Coffee Break
16:15 – 17:15	Questions and Answers
17:15 – 17:30	Vote of thanks Mr. Sanjay Priolkar, Vice President - GPMA

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Delegate Registration Form

Investment

For individual delegates : Rs. 1500/- per delegate

For more than 5 delegates from a single company : Rs. 1200/- per delegate

This includes stationery, tea / coffee and lunch expenses

Name of the organization:

No.	Name of the participant	Function	Mobile Number
1			
2			
3			
4			
5			
6			
7			
8			

Kindly organize to send the registration form along with appropriate amount of investment by DD or Cheque payable to "Goa Pharmaceutical Manufacturers' Association' payable at Goa on or before 1st September 2014 on the following addresses:

Suresh Kamath , Unichem Laboratories Limited, Pilerne Industrial Estate, Bardez, Goa 403511
D.T.Pant, Indi Pharma (Pvt.) Limited, 2-9 Bethora Ind.Estate, Bethora, Ponda Goa 403409

Please register at the earliest to avoid any disappointment as the delegates will be enrolled on 'first-come, first-served' basis. There will not be any spot registrations.

So, Hurry Up and register Now!