

# K2Pharma Compliance Forum 2009\*

## SESSION 1 FACILITY INSPECTION READINESS

## SESSION 2 COMPUTER SYSTEM VALIDATION

\* an initiative of



MUMBAI - 19-20 MARCH 2009 - EMERALD HOTEL, JUHU

### 3 good reasons to participate:

- ▶ New FDA office in New Delhi: are you ready for inspections? ...and without advance notice?
- ▶ Are you updated on regulatory trends, inspection techniques and International best practices?
- ▶ Are you aligned with best practices and tools to comply with Computer Validation requirements?

### Session 1 - 19<sup>th</sup> March 2009 Facility Inspection Readiness

The **US FDA has actually set up an office now in New Delhi**. The implication of this is that Facilities in India could experience surprise Inspection without the “advance notice” one is used to receiving till now. So are you **inspection ready? At all times?**

The growth of Indian companies is increasingly in the **export market** and therefore strictly related to the capability of the Facility to **comply with standards of regulated markets** (US and European Regulatory standards), that are driving the international markets.

This is evident by the role of **ICH (International Conference for Harmonization)** involving Europe, US, Canada and Japan health government agencies and pharmaceutical industry associations), that is providing a **new regulatory framework** which is becoming mandatory for those companies that want to grow in international markets.

This seminar will give you an opportunity to better understand the international requirements, the **regulatory auditors' expectations** and what it takes to be Inspection Ready as a “way of life”.

### Session 2 - 20<sup>th</sup> March 2009 Computer System Validation

A large number of remarks during **US or European GMP inspections** are related to deficiencies of Computer Systems Validation or an appropriate management of **ER/ES (Electronic Record and Signatures** i.e. 21 CFR part 11).

The computerized systems controlling the **critical manufacturing data, processes and associated equipment/utilities** must be validated according to all applicable US/EU regulations in order to avoid **serious problems during GMP Inspections**, and this involves a correct understanding of the requirements and applicable best practices to cover the same.

This session will explain these regulatory requirements and will go through the important **guidelines or best practices** that can be used as a driver to compliance. You will also get some **practical examples through a case study of software validation**.

A special focus of the presentation will be given to **ER/ES requirements**, or those requirements needed to manage the critical data according to regulations.

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## PROGRAM DETAILS

The seminar is organized by **K2C Compliance Consulting**, an Italian company operating at international levels providing consultancy to **more than 150 pharmaceutical companies** worldwide, now in India. For full 2009 program visit [www.k2c.com](http://www.k2c.com).

### Who will benefit:

- ▶ Technical Directors of Export Units
- ▶ Regulatory Affairs Managers
- ▶ Quality Assurance professionals
- ▶ Production, Operations and IT deputies

### Speakers:

- Gopal Nair – ISPE India Affiliate Vice President, ex Technical Director GSK (GlaxoSmithKline), India.  
Jacopo Montigiani – Managing Director and Lead Auditor, K2C Compliance Consulting and Solutions, Italy.  
Michele Gragnani – CEO and Technical Director of K2C Compliance Consulting and Solutions, Italy.  
Parsa Al Famili – President & CEO, Novatek International Inc, Montreal, Canada.  
Marco Gimondo – Validation Manager, Schering-Plough, Italy.  
Sachin Jain – Director of Kawarlal Pvt. Ltd., India.

### Session 1 - 19<sup>th</sup> March 2009

#### Facility Inspection Readiness

##### Morning

- 09.30 Registration of participants  
10.00 Welcome message by Organizer and Sponsor  
10.20 Main Regulations for EU / US Compliance (G. Nair)  
11.00 Compliance evidence: expected documentation (J. Montigiani)  
12.00 How to implement a Pharma Quality System according to actual regulation and ICH standards (tbc)  
12.45 Lunch break

##### Afternoon

- 14.00 Quality Risk Management: the regulatory trend becoming a new requirement (M. Gragnani)  
14.45 CAPA System requirements (G. Nair)  
15.30 Auditor Expectations (M. Gragnani)  
16.15 Software to manage QMS and CAPA (Parsa Al Famili)  
17.00 Question and answer

### Session 2 - 20<sup>th</sup> March 2009

#### Computer System Validation

##### Morning

- 09.30 Registration of participants  
10.00 Applicable Regulations for EU / US Compliance (G. Nair)  
10.45 Validation Management and Lifecycle: expected documentation, content and responsibilities (M. Gragnani)  
11.45 The Testing Phase: what, when and how (J. Montigiani)  
12.45 Lunch break

##### Afternoon

- 14.00 The expectation of an US/EU Inspector (J. Montigiani)  
14.40 Electronic Record and Signature: the requirements and system subject to (M. Gragnani)  
16.10 Implement a Risk Based Approach to save effort and improve CSV compliance (M. Gragnani)  
16.40 Case Study for software validation (M. Gimondo / M. Gragnani)  
17.00 Question and answer

the event is sponsored by





## K2Pharma Compliance Forum

### Registration Form

Mumbai, 19<sup>th</sup> - 20<sup>th</sup> March 2009

Hotel Emerald, Juhu Tara Road, Juhu Mumbai 400059, ph. 022 26611150

### **Session 1 - Facility Inspection Readiness** **Session 2 - Computer System Validation**

First Name \_\_\_\_\_ Last Name \_\_\_\_\_  
Company \_\_\_\_\_ Job Title \_\_\_\_\_  
Address \_\_\_\_\_ Office ph. \_\_\_\_\_  
\_\_\_\_\_ Mobile \_\_\_\_\_  
\_\_\_\_\_ Fax \_\_\_\_\_  
\_\_\_\_\_ e-mail \_\_\_\_\_

#### REGISTRATION FEES

- ▶ Before 28th February: Day 1 Rs 1200, Day 1+ 2 Rs. 1800
- ▶ After 28th February: Day 1 Rs 1800, Day 1+ 2 Rs. 2700
- ▶ 3 or more participants (any time), Day 1 Rs 1200, Day 1+ 2 Rs. 1800 each

I want to participate in :

session 1 only       session 2 only       both sessions 1 and 2

date \_\_\_\_\_ signature \_\_\_\_\_

**Cheque made out to K2C Pharma Consultancy Pvt Ltd**  
**send to: 501 Parajat Building, 3 Rd Road Khar West 400 052 Mumbai**

- \* No refund will be given on cancellation.
- \* Delegates can be replaced.
- \* Order of topics and speakers may be changed to benefit participants.

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