COMPLIANCE TRAININGS

2 Day In-Person Seminar on

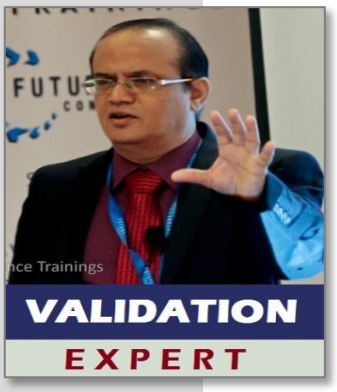
21 CFR Part 11 and Risk Assessment
– Avoid Warning Letters and Reduce Costs

Course Director: **KALPESH R. VAGHELA**, Validation Specialist and Expert Trainer

Location 1:	**Hyderabad, India**		**August 3rd - 4th, 2017**
Location 2:	**Bangalore, India**		**August 7th - 8th, 2017**
Location 3:	**Goa, India**		**August 10th - 11th, 2017**

21 CFR Part 11

PRESENTER



KALPESH R. VAGHELA, Validation Specialist and Expert Trainer

Mr. Kalpesh R. Vaghela, is the CEO of Infra Control Systems. He has 30 years experience as Software Validation Specialist, Expert Trainer CSV, cGMP, Data Integrity, GAMP5, 21 CF Part 11 Compliance, ICH Q9, Risk Assessment. He has also worked in Elecronics and Instrumentation Engineering fields. Since last two decades Mr. Vaghela has been helping Indian and International Pharma Companies achieve Compliance by training and motivating professionals for Right First Time Approach. He has supported many USFDA, MHA, ANVISA, MCC, TGA Customer Audits, as a consultant.

Over 10 year of work experience on high level CSV Validation in India and Abroad has made Mr. Vaghela an expert in special Data integrity Audit for Pharma Industry.

He has worked with and trained professionals in numerous major Indian companies. He has close to a decade of international experience of working with companies located in USA, Canada, South America, Norway, Africa, Middle East, Japan and Far East. Wherever he has worked and trained, he has unanimously been recognized as a brilliant course director and guide.

Mr. Vaghela has joined hands with Compliance Trainings as an Expert Trainer and Consultant with a common mission to share knowledge and empower the Indian Life Sciences Industry.

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LEARNING OBJECTIVES

- ✓ 21 CFR Part 11 Compliance
- ✓ Key Requirements of Part 11
- ✓ Annex 11
- ✓ Learning from Recent Warning Letters
- ✓ Computer System Validation
- ✓ Achieving Data Integrity
- ✓ Meeting Data Integrity Regulations
- ✓ VMP & Design Specifications
- ✓ Risk Assessment
- ✓ Risk Based Validation
- ✓ SOPs and Best Practices
- ✓ CASE STUDIES ….*and More*

COURSE DESCRIPTION

This 2-day Seminar on 21 CFR Part 11 and Risk Assessment will help you get completely familiar with the FDA – compliant implementation of 21 CFR Part 11 requirements applicable to the regulated industry. Today, the FDA performs both GxP and Part 11 inspections, with an updated Annex 11 regulation that expands Part 11 requirements, and companies must update their systems and processes to maintain compliance.

You will get a full understanding of how to perform Risk Assessment as part of the step-by-step risk-based approach to computer system validation. This distinct approach will help minimize project time. You can ensure compliance with QA, FDA, and clients.

Majority of inspection reports such as 483's and Warning Letters quote issues with 21 CFR Part 11 and data integrity as deviations from GxP regulations. Only way to control and avoid warning letters is by receiving effective Training. Mr. Kalpesh Vaghela's extensive years of experience in the field of third party audit can help your team to better understand & could help reduce your vulnerability of getting 483's and warning letters, by great amount.

Our instructor will use examples and real life case studies to better illustrate the application of the techniques for any validation project. Using recent warning letters as examples, this seminar will demonstrate how current Part 11 requirements will be met. With effective implementation of learnings from this seminar, you can avoid warning letters, reduce costs, improve quality, increase compliance with less documentation.

WHO WILL BENEFIT

A must attend seminar for professionals in Pharmaceuticals, QC Laboratories, Manufacturers of drug substances (APIs), Finished Products, Contract Laboratories, CROs, Medical Device & Biotech companies, and Suppliers of Computer Systems.

DEPARTMENTS:

- ✓ Quality Control & Quality Assurance
- ✓ Research and Development
- ✓ Laboratory
- ✓ Regulatory Compliance
- ✓ IT/IS & Software Departments
- ✓ Validation
- ✓ Production & Manufacturing
- ✓ Documentation
- ✓ Training Departments

PROFESSIONALS:

- ✓ Managers and Supervisors
- ✓ Senior Managers and Team Leaders
- ✓ Directors, VP's, CxO's, General Managers
- ✓ Analytical Chemists
- ✓ Validation Specialists
- ✓ Laboratory Managers and Supervisors
- ✓ Regulatory Affairs Managers
- ✓ Documentation Specialists & Analysts
- ✓ Consultants and Systems Administrators

www.ComplianceTrainings.in

861, Peripheral Road, Koramangala, Bangalore - 560095 | Ph: +91-(0)80-4170-0521

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AGENDA

DAY 1:

Registration Process: 8:30 AM – 9:00 AM

Session Start Time: 9:00 AM (Welcome and Introduction)

21 CFR Part 11

- ✓ Evolution of 21 CFR Part 11
- ✓ Annex 11
- ✓ Why they are Back in the News
- ✓ Avoid 483's and Warning Letters
- ✓ Key Requirements of Part 11 & Annex 11 in Detail
- ✓ Electronic signatures, digital pens, and biometric signatures
- ✓ Learning from Recent Warning Letters related to Part 11
- ✓ Detailed experience on validation / 21 CFR 11 compliance of a computer system

Data Integrity

- ✓ Understanding Data Integrity and Security
- ✓ How to Identify and Implement Data Integrity
- ✓ Applying requirements for Data integrity to computerized systems
- ✓ Data integrity Inspections – How FDA & other Regulatory Authorities Inspect
- ✓ Computerized Systems for Data Integrity
- ✓ Meeting domestic and international regulations

Q&A Session

Networking and Close: 5.30 PM – 6 PM

DAY 2:

Session Start Time: 9:00 AM

Risk Assessment

- ✓ Understanding Risk Assessment
- ✓ How to use a Risk Based Assessment to reduce work while still achieving Data Integrity and Compliance
- ✓ Which documents the FDA expects to audit
- ✓ How to use the Risk-Based Validation approach to lower costs
- ✓ How to link requirements, specifications, risk management, and testing
- ✓ Step-by-step instructions for performing and documenting a risk assessment, and how to use the results to reduce validation documentation
- ✓ Examples and Good Practices
- ✓ Benefits of larger project

Tools, Specifications & Requirements

- ✓ Validation Master Plan (VMP)
- ✓ Automated Test Tools
- ✓ Infrastructure Requirements
- ✓ Design Specifications
- ✓ Change Control
- ✓ Effective SOPs

CASE STUDIES

Final Q&A Session

Certification, Networking and Close: 6 PM – 6.30 PM

PRICING

	Early Bird Offer (INR)	**Regular Price** (INR)	Late / On the Spot (INR)
For One Delegate	~~29,000~~ **19,000** Save 10,000 (34%)	**29,000**	**39,000**
For Group of 4 Delegates (Register for 3 and get **1 Pass Free**)	~~116,000~~ **57,000** Save 59,000 (51%)	~~116,000~~ **87,000** Save 29,000 (25%)	N/A
For Group of 6 Delegates (Register for 4 and get **2 Passes Free**)	~~174,000~~ **76,000** Save 98,000 (56%)	~~174,000~~ **116,000** Save 58,000 (33%)	N/A
Registration Date	Before **28 June 2017**	Before **26 July 2017**	From **26 July 2017**

** Prices are inclusive of Training session, Lunch, Morning & Afternoon High Tea, Certification, Q&A Sessions and Networking sessions (on both days)

** Prices + Service Tax (per Government Norms)

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REGISTRATION FORM

Registration Information:

- ✓ **REGISTER ONLINE HERE** - using your Credit Card / Debit Card
- ✓ Get a Group to attend the seminar at a Discounted Price
- ✓ For assistance, please call 080-4170-0521
- ✓ To pay by Cheque / Demand Draft, the Payee name is "FutureCorp Consulting Pvt. Ltd.", our parent company.
- ✓ Please ensure to email a Scanned copy of the Cheque / DD to info@compliancetrainings.com, before sending it
- ✓ Mail your cheque/DD to: Compliance Trainings (FutureCorp Consulting Pvt. Ltd.), 861, Peripheral Road, Koramangala, Bangalore - 560095
- ✓ For Bank Wire transfer, please get assistance by calling us at 080-4170-0521
- ✓ Kindly call our Support Team to ensure the correct amount (Service tax)
- ✓ Please fill up the form with delegates details and email it to info@compliancetrainings.com

Please click here to view the Terms & Conditions, Substitution policies and Cancellation Policies

If you have any questions, please feel free to contact us at 080-4170-0521 or Email us at info@compliancetrainings.com

Seminar Topic: **21 CFR Part 11 and Risk Assessment – Avoid Warning Letters & Reduce Costs**

Choose Your Dates & Location:

☐ **August 3 - 4, 2017** **Hyderabad**

☐ **August 7 - 8, 2017** **Bangalore**

☐ **August 10-11, 2017** **Goa**

Please fill out the delegates details

	Full Names	Designation	Email ID
Attendee 1:			
Attendee 2:			
Attendee 3:			
Attendee 4:			
Attendee 5:			
Attendee 6:			

For additional attendees, feel free to use an additional form

* Email address is required, so you can receive Order acknowledgements, product information, updates and special offers

Company Information:

Organization Name: .....

Address: .....

.....

City: ..... State: .....

PIN CODE: ..... Country: .....

Phone: .....

Mode of payment: ☐ Credit / Debit Card ☐ Bank Wire Transfer ☐ Cheque / Demand Draft

Please fill this form and Email it to info@compliancetrainings.com

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