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Workshop on Computer System Validation (CSV)



Gain a holistic overview and understanding of the Validation of Computerized Systems (Including CSA). Register today for an insightful 1 day workshop cum networking event organized by VIMTA in collaboration with SeerPharma.

Topics:

- Common terms and definitions of Computerized Systems Validation
- Types and elements of System Development Life Cycles (SDLC)
- Good Automated Manufacturing Practices (GAMP)
- What is critical for data integrity in the eyes of GxP regulators
- How computerized systems are regulated in PIC/S (e.g. MHRA, TGA, etc) and FDA environments
- How to implement a CSA approach through worked examples
- How to recognize the compliance, risk and regulatory consequences of using computerized systems



Chief Guest

Dr. A. Ramkishan
Deputy Drugs Controller of India,
Ministry of Health, Government of India

Speakers



Ian Lucas
Director, Training Manager and Senior Consultant
SeerPharma (Melbourne, Australia)



Biju Kishor
Director / Commercial and Marketing
SeerPharma (Melbourne, Australia)

Register Now!

Fee per delegate:
INR 18,000 + GST (18%)

Limited Seats Available

Date & Venue:

10 SEPT 2024

Vimta Labs Limited.
Life Sciences Campus
#5, Neovantage Innovation Parks,
Genome Valley, Shameerpet, Hyderabad

Scan for Registration

For more details contact Srihari Vuta @ +91 8019216214 , sriharireddy.vuta@vimta.com

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Agenda

Registrations **8:30 - 9:15**

Inaugural Session **9:15 - 10:00**

Session 1 — 10:00 - 11:30

- History of CSV
- Definitions
- CSA and where if fits in Industry 4.0
- Common issues
- Data Integrity
- Regulations around the World

Tea Break

Session 2 — 11:45 – 13:15

- CSV in Context
- GAMP
- Models – Waterfall, V-Model, X-Model
- Agile Development and DevOps
- Risk Assessment

Lunch

Session 3 — 14:00 - 15:30

- Computer System Validation Master Plan
- Legacy Systems
- Validation Protocol / Plan
- Requirements
- Traceability
- Design / Configuration

Tea Break

Session 4 — 15:45 - 17:30

- Testing Definition (Test Plan / Cases / Scripts / Report)
- Testing Phases
- Qualification Phases (IQ, OQ, PQ)
- Validation Report
- Operational Phase
- Infrastructure Qualification
- Cloud Computing