

ICSQA Training Programs 2021



Dr. Satheesh V K

*Test Facility Management
Syngene International Limited*

Topic 1

Data Integrity (with reference to OECD draft
Advisory document on GLP data integrity)



Dr. Natesan S

*Vice President, Business Excellence and Corporate QA
Eurofins Advinus Limited*

Topic 2

**Two Decades of Indian GLP Compliance
Monitoring System – Learning from Impact
Analysis of National GLP Program**



Dr. Labhu Sanghani

*Director QA
Jai Research Foundation Global*

Topic 3

**Possible Influence of Sponsors on Conclusions of GLP
Studies** (with reference to OECD Position Paper
No.21)

*Promoting Regulatory Quality
and Compliance*

ABOUT SPEAKERS

Labhu Sanghani, Ph.D

Jai Research Foundation (JRF), Gujarat, India. Email: sanghanilu@jrffonline.com

Dr. Labhu is Director of Global QA of JRF Global. He has a post graduate degree in Agricultural Chemistry and Soil Science and Doctorate in Chemistry. Dr. Labhu joined Jai Research Foundation in 1993 as Soil Analyst and worked as Study Director for Field Studies. Since 1996 he has been associated with GLP QA. Dr. Labhu had undergone various training on GxP quality system, ISO and various auditing techniques. Dr. Labhu actively involved in the development of system SOPs and GLP training at Jai Research Foundation. He is technical assessor for ISO 17025 accreditation. Dr. Labhu is an active member of SQA and RQA since 1996. Dr. Labhu is actively involved in the establishment of Indian Chapter of Society of Quality Assurance (ICSQA), holding a position of President in ICSQA.

Natesan S, Ph.D

Eurofins Advinus Limited, Bengaluru, India. Email: natesan.s@advinus.com

Dr. Natesan Settiagounder has over 30 years of Research & Development experience, including over 19 years of pre-clinical regulatory studies in compliance with the principles of GLP, covering OECD GLP, FDA GLP and EPA GLP. He published over 65 articles in national and international journals/books, including a book. A certified Quality Assurance Professional (SQA, USA) as well as a certified auditor for Tata Business Excellence Model (TBEM), which is based on Malcolm Baldrige National Quality System. Currently he is the Trustee and Founder President of the Indian Chapter of the Society of Quality Assurance and works closely with the SQA organization in USA. He has extensive experience in facing several GLP audits by the Monitoring Authorities of OECD countries, Indian National GLP Compliance Monitoring Authority, and several sponsors world-wide. Coordinated and facilitated GLP and GMP audits by several global clients of pharma, agrochemical and other industries.

Satheesh V K, Ph.D

Syngene International Limited, Bengaluru, India. Email: Satheesh.velath@syngeneintl.com ; svelath@gmail.com

Dr. Satheesh joined Syngene International Limited in 2010 and he is currently assuming the role of Test Facility Management. He is also responsible for ISO/IEC:17025 and ISO 9001:2015 at Syngene and actively involved in monitoring computerised system validation as per 21 CFR Part 11 & OECD document No. 17 and data governance. Dr. Satheesh is one of the Directors of Indian Chapter of the Society of Quality Assurance and has over 25 years of GLP experience in various roles. He served as Sr. Manager of QA at Nektar Therapeutics, Hyderabad from 2006-2010. He started his career at Jai Research Foundation, Vapi, Gujarat in 1996 and worked as Study Director in Ecotoxicology, Quality Assurance Officer, Study Director in Genetic Toxicology and Head-Genetic Toxicology.

TRAINING AND INTERACTIVE MEET ON GLP

The key objective of this training is to provide an insight of current understanding. The **three-day event (one training a month)** intends to bring all professionals together for an exchange of information and interactive discussions, resulting in promoting regulatory quality and compliance.

TARGET AUDIENCE

- ✓ **Test Facilities and Test Sites**
 - Quality Assurance professionals
 - Study personnel (study directors, principal investigators and others)
 - Test Facility Management
 - Computer system administrators
 - Project Management
 - Business Development
- ✓ **Sponsors**
 - Sponsor representatives
 - Monitoring scientists
 - Sponsor QA and RA professionals
 - Personnel managing regulatory data
- ✓ **Consultants**
- ✓ **Students**

REGISTRATION PROCESS

- Please send your registration to email ID: secretary@icsqa.org
- No registration cost.

ORGANIZING COMMITTEE

Dr. Natesan S	Founder Trustee
Dr. Labhu U Sanghani	President
Dr. Satheesh V K	Director
Dr. Maheswari S T	Director
Mr. Satish V Murthy	Secretary
Ms. Muktha Bhagavan	Treasurer
Dr. Maya M	Documentation and Communication

EVENT SCHEDULE

	Training	Time	Speaker
Topic 1	Data Integrity <i>(with reference to OECD draft Advisory document on GLP data integrity)</i>	28 August 2021 10.30am - 12.00 noon	Dr. Satheesh V K
Topic 2	Two Decades of Indian GLP Compliance Monitoring System – Learning from Impact Analysis of National GLP Program	18 September 2021 10.30am - 12.00 noon	Dr. Natesan S
Topic 3	Possible Influence of Sponsors on Conclusions of GLP Studies <i>(with reference to OECD Position Paper No.21)</i>	9 October 2021 10.30am - 12.00 noon	Dr. Labhu U Sanghani

The training link will be shared to your registered email for this event in due course.

For further details or any queries please contact:

Mr. Satish V Murthy
Secretary, ICSQA
Mob: 9901971805



For becoming an ICSQA Member, please contact Secretary, ICSQA

For more details, please visit www.icsqa.org