



*Promoting Regulatory
Quality and Compliance*

The Indian Chapter of the Society of Quality Assurance
cordially invites you for the

Asia QA Forum

4th International Conference 2019

on

**GxP Regulations
Expectations, Challenges and Quality Focus for Global Needs**

on

5th and 6th September 2019

at

**RG Royal Hotel
No 19, Behind Ravindu Toyota, Near ISKCON Temple,
Mahalakshmi Layout, Yeshwanthpur,
Bengaluru, Karnataka 560086**

The conference programme is attached for reference



Organized by ICSQA

Asia QA Forum – 4th International Conference Bengaluru, India

GxP Regulations Expectations, Challenges and Quality Focus for Global Needs

PROGRAMME: DAY 1		5 SEPTEMBER 2019
TIME	EVENT/TOPIC	SPEAKER
08:30 – 09:30	Registration	
09:30 – 09:45	Lighting the Lamp	Dignitaries
09:45 – 09:50	Prayer	
09:50 – 10:00	Welcome Speech	Dr. Natesan S. <i>President ICSQA, India</i>
10:00 – 10:30	Inaugural Address	Mr. Amaresh Tumbagi <i>Additional Drugs Controller & Licensing Authority, Govt. of Karnataka, India</i>
10:30 – 11:15	Keynote Speech: From Idea to Regulatory Approval: Expectations, Challenges and Quality Focus in the Indian Context	Dr. Vinita Sharma <i>Former Head, NGCMA, India</i>
11:15 – 11:45	TEA BREAK (<i>Group photo before tea break</i>)	
	SESSION 1: GLP	
	Chairperson: Dr. Vinita Sharma	
11:45 – 12:15	Is Japanese Unique Regulation “Standards of Reliability of Application Data” beyond GLP?	Mr. Ken Kawaguchi <i>JSQA, Japan</i>
12:15 – 12:45	Korean GLP	Dr. Kyu-hyuk Cho <i>KSQA, Korea</i>
12:45 – 13:00	Q & A and Chairperson’s Conclusion	Speakers and Chairperson
13:00 – 14:00	LUNCH	
	SESSION 2: GLP	
	Chairperson: Dr. Jahangir Bin Kamaldin	
14:00 – 14:30	Interpretation to NMPA New GLP and China Drug Regulation System Reforming	Mr. Jin Yi and Dr. Joe Zhang <i>CSQA, China</i>
14:30 – 15:00	The Wonderland of GLP Compliance: Through the Sponsor's Eyes	Dr. Geetha Rajashekhar <i>Qualtox Consultancy, India</i>
15:00 – 15:15	Q & A and Chairperson’s Conclusion	Speakers and Chairperson
15:15 – 15:45	TEA BREAK	
	SESSION 3: GMP	
	Chairperson: Dr. Joe Zhang	
15:45 – 16:15	GMP Aspects of NCE Development for Early Phase INDs – CMC Perspective	Dr. Balaram N. Rao <i>Aurigene Discovery Technologies Ltd, India</i>
16:15 – 16:45	Good Practice Regulations and Challenges of GMP Regulatory Creep into GLP	Dr. Natesan S. <i>Eurofins Advinus Limited, India</i>
16:45 – 17:30	Q & A and Chairperson’s Conclusion	Speakers and Chairperson
	Asia QA Forum Council Meeting	
18:00 – 18:30	Members of Asia QA Forum and Invitees	



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PROGRAMME: DAY 2		6 SEPTEMBER 2019
TIME	EVENT/TOPIC	SPEAKER
08:30 – 09:30	Networking Discussion (Interaction among participants in groups)	Group Leaders
	SESSION 4: GCP Chairperson: Dr. Ramachandra S. G.	
09:30 – 10:00	Current Status of Clinical Research Regulations in Japan (including Clinical Study & Clinical Trial)	Mr. Toshiro Asahina <i>JSQA, Japan</i>
10:00 – 10:30	A Multi-Layered Approach for CRO Compliance Management, A Sponsor's Proposition	Dr. Charles Mueller <i>Mylan Pharmaceuticals Private Limited, USA</i>
10:30 – 11:00	Clinical Trial Regulations Update and Global Quality Trends	Ms. Shehnaz Vakharia <i>ADAMAS Clinical Quality Consulting Pvt Ltd, India</i>
11:00 – 11:15	Q & A and Chairperson's Conclusion	Speakers and Chairperson
11:15 – 11:45	TEA BREAK	
	SESSION 5: Networking and Auditing Chairperson: Dr. Geetha Rajashekhar	
11:45 – 12:15	Networking GLP Labs in ASEAN for Nanosafety Studies	Dr. Jahangir Bin Kamaldin <i>MySoT, Malaysia</i>
12:15 – 12:45	The Auditor-Auditee Relationship and Attributes of Effective QA Auditor	Dr. Labhu U. Sanghani <i>Jai Research Foundation, India</i>
12:45 – 13:00	Q & A and Chairperson's Conclusion	Speakers and Chairperson
13:00 – 14:00	LUNCH	
	SESSION 6: Risk Assessment and Data Integrity Chairperson: Dr. Labhu U. Sanghani	
14:00 – 14:30	Risk Management and Quality Systems	Mr. Gurpreet Singh Saini <i>Corteva Agriscience, India</i>
14:30 – 15:00	Data Integrity in Quality Systems and Computerised Systems	Mr. Rama Krishna Budha <i>Laila Nutraceuticals, India</i>
15:00 – 15:15	Q & A and Chairperson's Conclusion	Speakers and Chairperson
15:15 – 15:45	TEA BREAK	
	SESSION 7: Panel Discussion Chairperson: Dr. Natesan S.	
15:45 – 16:30	Open Session and Q & A	Chairpersons of Sessions and Group Leaders of Networking Discussion
16:30 – 16:40	Closing Statement	Dr. Natesan S.
16:40 – 17:00	Announcement on 5 th International Conference of the Asia QA Forum	Asia QA Forum Member