

## **Pharma Data Integrity Summit**

28<sup>th</sup> June 2019 | 09:30 to 17:00 Hrs The Park, Rajbhavan Road, Hyderabad



This is one of the #100 Knowledge Sharing Events that Anton Paar India is conducting on the occasion of its 10<sup>th</sup> year anniversary.

## **About this summit:**

Data Integrity is one of the most demanding topics that regulated industries like pharmaceuticals have to deal and comply with on a continued basis.

This industry-focussed event seeks to offer a knowledge sharing platform for pharma professionals to learn in-depth about regulatory requirements, industry best practices and applying these in a real world environment. The summit includes training sessions, panel discussions and keynote presentations from industry experts.

Topics	Speaker	Time
Training Session :  Avoiding data integrity related issues by implementing best practices in system design, monitoring and control		
<ul> <li>GxP Work flow Control</li> <li>SDLC Life Cycle Control</li> <li>Data Life Cycle control</li> <li>Using GAMP5 Drivers, CFR Part11 and Annex 11 to prevent, detect and eliminate Data Integrity related issues.</li> <li>Audit Citations and Remediation to 483 and Warning letters</li> </ul>	Mr. Kalpesh Vaghela CEO, Infra Control Systems	09:30 – 13:00
Lunch Break		13:00 – 14:00
Keynote Presentation :  Data Integrity and Data Security	Dr. Gopal Vaidyanathan Vice President - Analytical R&D & Developmental QA, Natco Research Center	14:00 – 14:30
Analytical Measurements : #IntegrityByDesign	<b>Dr. Nils Bertram</b> CEO, Anton Paar OptoTec GmbH	14:30 – 15:00
Keynote Presentation :	Mr. Katipally Vittal	
Best Practices towards ensuring Compliance and Data Integrity	General Manager - Quality Control, Hetero Drugs	15:00 – 15:30
Tea/Coffee Break		15:30 – 16:00
Expert Panel Discussion : Upcoming Trends in Data Governance Systems	Moderated by : Mr. Kalpesh Vaghela	16:00 – 16:30
Question and Answer Session		16:30 – 17:00

## Speakers:



**Mr. Kalpesh R. Vaghela** has 33 years of experience as automation and software validation specialist. He has attained expertise as a trainer on topics like CSV- Data Integrity,

GAMP5, 21 CFR Part 11 compliance, ICH Q9 risk assessment, proactive CSV approach, Annex11, GDPR. Since the last two decades, Mr. Vaghela has been helping Indian and International pharmaceutical companies achieve compliance. He is currently the CEO of Infra Control Systems.



**Dr. Nils Bertram** is a Doctorate in Physics and currently heads Anton Paar OptoTec GmbH in Hanover, Germany as the CEO. Having worked for the pharmaceutical market for nearly a

decade, he has experienced the evolution of compliance requirements where anticipating the market need and transforming it into most suitable instrument and software design is crucial.



**Dr. Gopal Vaidyanathan** is currently the Vice President for Analytical R&D and Developmental Quality Assurance at Natco Research Center. After completing his Ph.D from the State

University of New York, he has worked with market leaders in the pharmaceutical industry in various capacities. He has played a key role in establishing regulatory and quality systems. He also takes keen interest in training and development of the next generation of scientists.



Mr. Katipally Vittal is the General Manager for Quality Control at Hetero Drugs. After completing his Masters in Chemistry from Madurai Kamaraj University, he has spent more than 20

years working with leading pharmaceutical companies. This has given him a well-rounded exposure to tackle the strict requirements of quality and data compliance within highly regulated environments.

Click here to register for the summit.

To know more, contact:

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We look forward to welcoming you at the summit.

With best regards,

Anton Paar India