

National Seminar

DATA INTEGRITY AND QUALITY METRICS: REGULATORY COMPLIANCE



Organised by
ANAND PHARMACY COLLEGE, ANAND

Sponsored by
GUJARAT COUNCIL ON SCIENCE AND TECHNOLOGY

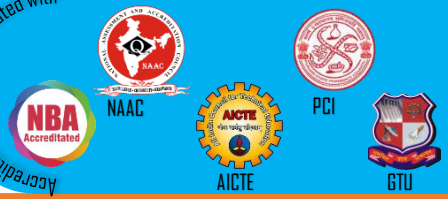


February 20, 2018

ANAND PHARMACY COLLEGE

Managed by Shri Ramkrishna Seva Mandal
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Accredited, approved and affiliated with



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Coordinator

Dr. Kalpana G. Patel, Professor, Academic Head and PG Coordinator,
Anand Pharmacy College, Anand

Co-Coordinators

Dr. Purvi A. Shah, Professor, Head, Department of Pharmaceutical Chemistry,
Anand Pharmacy College, Anand
Ms. Jigisha K. Patel, Assistant Professor, Anand Pharmacy College, Anand



Registration Deadline: February 12, 2018

About Shri Ramkrishna Seva Mandal (SRKSM)

Shri Ramkrishna Seva Mandal is a registered society and a public trust established in the year 1954-55, managing more than 27 academic institutions. The trust believes in providing scientific and value based education by maintaining pace with the ever increasing needs of modern educational environment.

About Anand Pharmacy College (APC)

ANAND PHARMACY COLLEGE is one of the leading institute of Gujarat established in 1998 by Shri Ramkrishna Seva Mandal. The institute is conducting All India Council for Technical Education (AICTE), New Delhi approved courses since 1998. Anand Pharmacy College offers B.Pharm, M.Pharm in Pharmaceutics, Pharmacology, Pharmaceutical Quality Assurance, Industrial Pharmacy & Pharmaceutical Technology and Ph.D. courses. The institute is re-accredited by NAAC-UGC (Grade A with CGPA 3.06) and accredited by NBA (UG Course). The institute regularly invites learned and eminent entrepreneurs, academicians, industrialists and dignitaries to deliver lectures and create an environment of enthusiasm and zeal among students and staff members for educational excellence.

About Gujarat Council on Science and Technology (GUJCOST)

The Gujarat Council on Science and Technology (GUJCOST) was established in September, 1986, to play a catalytic role in promoting the use of Science and Technology in the development process of the State. The S & T Council was constituted with a view to develop technologies appropriate to and in harmony with present conditions. The Council has been catalyzing interaction between developers and users of technologies, by bringing on a common platform to training Scientists and Engineers on the one hand and policy makers as well as administrators on the other.

Who Should Attend

This seminar is intended for the professionals in the research institute and pharmaceutical industries, Post-graduates, Research scholars and Academicians in the field of pharmacy.

ORGANIZING COMMITTEE

Coordinator

Dr. Kalpana G. Patel

Co-Coordinator

Dr. Purvi A. Shah

Ms. Jigisha Patel

Inauguration & Valedictory committee

Ms. Hiteksha Panchal Ms. Mansi Dholakia

Ms. Jenee Christian Ms. Ruby Christian

Registration Committee

Ms. Veena Patel Ms. Dipika Chavda

Ms. Hemangini Patel Ms. Zankhana Patel

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Mr. Hitesh Raval Mr. Hardik Rana

Mr. Sandip Patel Mr. Devang Tandel

Mr. Jagir Patel Mr. Shreyas Diwakar

Registration Link

https://docs.google.com/forms/d/e/1FAIpQLSffRuiv-Q4lxkCLDIEQppJA_q4UNuXLWs5HsL54ygy14x0KJA/viewform

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Preamble

Data integrity is a significant component of a company's Quality System, providing assurance of the data a company uses to operate in compliance with regulatory requirements and to demonstrate its products are safe and effective for their intended use. Data Integrity plays a noteworthy role in the organization's Quality management system to ensure a continuous improvement program in the organization.

Quality metrics are used throughout the pharmaceutical and biotechnological industries to monitor quality control systems and processes and drive continuous improvement efforts in drug manufacturing. Quality metrics can also be useful to FDA to develop compliance and inspection policies and practices, such as risk-based inspection scheduling of drug manufacturers; to improve the agency's ability to predict, and therefore, possibly mitigate, future drug shortages; and to encourage the pharmaceutical industry to implement state-of-the-art, innovative quality management systems for pharmaceutical manufacturing. It will also help students and academicians to understand the essentiality of quality metrics and voluntarily start the practice of quality metrics.

The prime objectives of seminar is to provide understanding on

- Significance of data integrity
- Quality Metrics tool to evaluate quality system and its calculation
- Guideline on Quality Metrics and critical topics to overcome data integrity issues.
- Implementations of non-compliance in data integrity and audits.

Registration:

Applicants are required to send/deposit their duly signed registration form along with registration fees through cash/cheque (in favor of Principal, Anand Pharmacy College, payable at Anand).

Registration charges:

Industry persons.....Rs. 400

Academicians.....Rs. 300

Students/Research Scholars.....Rs. 300

* **One complimentary registration per group of five**