



सत्यमेव जयते
Government of Gujarat



SHRI RAMKRISHNA SEVA MANDAL
Devotion towards humanity...



One Day National Seminar on CURRENT STATUS & PERSPECTIVE OF QbD: PRODUCT DEVELOPMENT TO LIFE CYCLE MANAGEMENT A Skill Enhancement Initiative for Pharmaceutical Professionals

Sponsored by:
Student Startup & Innovation Policy (SSIP)
Govt. of Gujarat

Organized by;

ANAND PHARMACY COLLEGE

Managed by Shri Ramkrishna Seva Mandal
Opp. Town Hall, Anand, 388 001, Gujarat, INDIA.
Tele-Fax: +91-2692-250020 | www.apc.ac.in

Approved and affiliated with



28th SEPTEMBER, 2018

Executive Committee

Chief Patrons

Shri Hemantbhai Patel
President, SRKSM, Anand

Smt. Jyotsnaben Patel
Hon. Secretary, SRKSM, Anand

Convener

Dr. Tejal R. Gandhi
Professor & Principal,
Anand Pharmacy College, Anand

Program Director

Prof. Mukesh C. Gohel
PG Director,
Anand Pharmacy College, Anand

Dr. Purvi A. Shah

SSIP Coordinator | +91.9427637064 | purvi2210@yahoo.co.in

Dr. Vaishali T. Thakkar

Coordinator | +91.9724431131 | vtthakkar@rediffmail.com

Ms. Dipika D. Chavda

Coordinator | +91.9727579377 | dchavda3@gmail.com

Registration Deadline: 21st September, 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.

ORGANIZING COMMITTEE

Convener
Dr. Tejal R. Gandhi

Program Director
Prof. Mukesh C. Gohel

SSIP Coordinator
Dr. Purvi A. Shah

Coordinators

Dr. Vaishali Thakkar
Ms. Dipika Chavda

Registration Committee

Ms. Zankhana Patel
Ms. Janki Patel

Inauguration & Valedictory committee

Ms. Hiteksha Panchal
Ms. Ruby Christian
Ms. Mital Patel

Catering & Hospitality Committee

Mr. Hardik Rana
Mr. Devang Tandel
Mr. Sunny Macwan

How to reach milk city of Gujarat?

The Institute is situated in the heart of Anand city as a part of Shri Ramkrishna Seva Mandal campus, near an area known as Town hall, at a distance of about 3 km from the Anand Railway Station. The transportation facility of bus, auto and taxi are regularly available from railway/bus station since early morning till late mid night.

Resource persons

Eminent Speaker **Dr. Mukesh C. Gohel [PG Director]** will enhance the skills of pharmaceutical professionals by giving detailed knowledge on ICH Q12 guidelines and importance of RPN.

Preamble

"Quality cannot be tested into products, it should be built in, or by design". With this notion, we bring to you a comprehensive skill enhancement national seminar on Quality by Design (QbD) as well as introduction of new ICH Q12 guideline for enhancement of pharmaceutical professionals knowledge which lead to enhance the problem solving capacities of product development to life cycle management. QbD is a scientific, risk based, holistic and proactive approach for the development of Pharmaceutical products. It is an systematic effort from product conception through commercialization. Quality metrics will help the FDA develop compliance and inspection policies and practices, and inform risk-based scheduling of drug manufacturing facilities, which can result in a decrease in inspection frequency for high performers. Lifecycle Management and Innovation which will be covered in ICH Q12; the current topics regarding drug application submissions, post-approval changes, aging facilities, process validation, combination products, and quality risk management. With India being the home to the highest number of FDA approved plants outside USA, it becomes evident that both the academic and industrial domains become well-versed with the concept and execution of QbD as well as new ICH Q12 guideline. QbD knowledge will help in identifying and justifying target product profiles, product and process understanding thereby helping in continuous product improvement. Hence this seminar can go a long way in helping us to get skilled and stay up to date with the latest trends in the pharmaceutical industry.

Learning Outcomes

By attending this Seminar participants will learn.....

- Essential elements of QbD, and Designing of Experiments (DoE)
- Development of Design Space: Risk Reduction of CMAs &/or CPPs.
- Quality Metrics (QM) - Introduction to QM and calculation of the FDA suggested quality metrics.
- ICH Q11 and Q12 Guidelines regarding life-cycle management
- Importance of Risk Probability Number (RPN) in QbD.

Who Should Participate?

This course is valuable for industry personnel, R & D staff, QA staff and personnel engaged in marketing of pharmaceutical products to the developed countries. The course will be of immense value for the postgraduate and research scholars.

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:

Students/Research Scholar: Rs. 150

Academician : Rs. 200

Industry person: Rs. 300

For online registration; open the following link:

[Registration Form QbD 2018](#)

Scan the QR Code for hard copy of registration form:



Notes:

- Entry in seminar is limited to 150 participants.
- Registration fee covers day time hospitality during seminar and kit for the registered delegates.
- Registration fee is non-refundable.
- Last Date of Registration is 21/09/2018.
- The organizers reserve the right to change the published programme and course content as circumstances dictate.