RBVRR WOMEN'S COLLEGE OF PHARMACY
& 3-4-343, Barkatpura, Hyderabad - 500 027 (T.S), India
Office: +91 40-27563065, Mobile: +91 9848930555
Accredited by NAAC,
Approved by the PCI & Affiliated to Osmania University
Recognized under Section 2(f) of the UGC Act 1956
EAMCET Code: RBVW | PGECET Code: RBVW1
College Code: 1706
www.rbvrrwcp.org | Email: rbwrwcoph@rediffmail.com & rbvrrwcp2006@gmail.com

Certificate Course on
"Pharmaceutical Quality Management System"

Value Added Course

Course: Pharmaceutical Quality Management System

Code:RBVRRWCPCC003 **Credits:4** **Total No.Hours:30**

April 7th -12th, 2025.

Syllabus

Hybrid Mode

Objectives and Scope:

This course is a strategic asset for UG/PG students aiming for pharmaceutical industry placements. It lays a robust foundation in fundamental quality principles, including Good Manufacturing Practices (GMP) and key regulatory guidelines (ISO 9001, ICH), equipping students with essential knowledge for pharmaceutical roles. The curriculum emphasizes practical QMS expertise, covering design, implementation, and maintenance, including critical processes like document control, training, and audits, making graduates valuable assets in quality-focused pharmaceutical positions. Furthermore, the course cultivates analytical and problem-solving skills through data analysis, CAPA methodologies, and process improvement, all highly valued in the pharmaceutical industry. Completing this course signals a strong commitment to quality and patient safety, essential for pharmaceutical professionals, and provides a competitive edge in placements by showcasing specialized QMS knowledge.

Unit 1: Foundations of Quality Management

Objectives of QMS, Various clauses of QMS, Good Manufacturing Practices (GMP) – EU and USA. Pharmaceutical principles of QA, GMP, and QC, Traditional vs Modern QMS.

Unit 2: Quality Management Principles

GMP for APIs, dosage forms, Equipment qualifications. Process Validations, Cleaning Validations, Analytical Method Validations, Stability Studies, Development of specifications for APIs and Dosage Forms, Computer System Validation.

Unit 3: Designing a Quality Management System

Elements of an effective QMS, Comparison of ISO 9001 and GMP. Pharmaceutical QMS evolution, FDA's Quality System Model & ICH Q7,Q8, Q9 & Q10 guidelines, Schedule M of Drugs and Cosmetics Act 1940, Rules 1945, 21 CFR Part 210 and 211.

Unit 4: Implementing and Maintaining a Quality Management System

Roles and responsibilities (Heads of Production & QC, Qualified Person, QA, Top Management), Training and Evaluation (skills, competencies for GMP training), Quality Audits, Purchasing and supplier qualification. Supply chain, materials control, brokers, distributors, repackages. Deviations and change control. Out of specification (OOS) investigations, market complaints, handling of rejections, Calibration and preventive maintenance.

Unit 5: Improving a Quality Management System

Annual Product Quality Reviews. Economic and statistical indicators. Staff appraisals and performance management. Management review, Customer complaints and satisfaction monitoring, Correction, Corrective Action, and Preventive Action (CAPA).

Course Outcomes

- Design, implement, and maintain a robust QMS aligned with industry standards (e.g., USFDA, EU, ISO 9001, GMP etc.).
- Effectively manage core QMS processes, including documentation, training, and resource allocation.
- Evaluate QMS performance and drive continuous improvement through CAPA and data analysis.
- Understand key roles and responsibilities within a QMS, including leadership's impact.
- Apply quality principles to address challenges in dynamic environments and foster a quality culture.

Who can attend?

- Under Graduate or Postgraduate degree in Pharmacy or Pharmaceutical Sciences.
- Under Graduate or Postgraduate degree in Chemistry.
- Under Graduate or Postgraduate degree in Life sciences.

REGISTRATION LINK

https://forms.gle/gD3cHo1SLSFrNtGA9

REGISTRATION FEE: Rs 600/-
Phone Pay No:-8978942856

Last Date for Registration

5TH April 2025.

PROGRAMME SCHEDULE

TIMINGS: Morning Session [10:30 am -12 pm]

DAY-1
Inaugural session
7-04-2025

Dr.M V Narendra Kumar Talluri PhD,MRSC
Director, Knowledge Management (ARD)& Tech Support (SEA).
Daicel Knowledge Centre Daicel Chiral Technologies India

DAY-2
8-04-2025

Mr. Ramalinga Prasad Kuppa
Director,
KRP Consultants, Hyderabad.

DAY-3
9-04-2025

Mr. B.Sreekanth
DGM, Head -Quality Assurance
Caponex Labs Pvt Ltd, Hyderabad.

DAY-4
10-04-2025

Mr. Prabhanjan Kumar
CEO & Co-Founder,
Axygen Pharmatech, Hyderabad.

DAY-5
11-04-2025

Dr. Sreekanth Nama
Manager- QARA,
SS Innovations Private Limited, Haryana.

DAY-6
12-04-2025

Mr. Nagaraju Gandikota
Sr.Validation Engineer ,Computer System Validation,
Tata Consultancy Services (TCS)- Mexico City

CONVENER

Prof.M.Sumakanth, Principal
RBVRRWCP

PATRON

Prof.K.MuthyamReddy,
Hon.Secretary & Correspondent,
RBVRRWCP

Program Co-ordinator

Dr.K Bhavyasri,
Associate Professor & Head of Department - Pharmaceutical Analysis, RBVRRWCP

For Queries Contact: Dr.Charumathi Salva- 7660888879,
Mrs.C.A Sri Ranjani– 8143188673,
Ms.Md.Saba Fatima - 8978942856

About RBVRR Women's College of Pharmacy

RBVRR Women's College of Pharmacy, established in 2006 under the Hyderabad Mahila Vidhya Sangam, is driven by the visionary leadership of its Founder Principal, Prof. M. Sumakanth. The college is dedicated to empowering girl students through education and offers spacious classrooms, state-of-the-art laboratories, a well-equipped seminar hall, a conference room, and a library stocked with a wide range of the latest textbooks, reference materials and digital library.

The college is offering the following programmes:

B. Pharmacy (100)

Pharm. D (32)

M.Pharmacy (Pharmaceutics, Pharm. Analysis and Pharmacology).

VISION: To be a National Women Pharmacy Professional leader in transforming lives through innovative, vigorous and compassionate approach to Pharma education.

MISSION: RBVRRWCP preparing and empowering girl students by providing continuous awareness programmes to succeed in changing world apart from regular curriculum.

Laboratory Equipments in College

College Location

https://maps.app.goo.gl/TW35QRH2uWjL4dYj9