

### **Program information**

<b>Title of Activity</b>	: Online Certification Course on "Pharmacovigilance and Drug Safety Assessment"
<b>Co-ordinator, Co-convenor</b>	: Dr. Shailesh M. Kewatkar
<b>Date</b>	: 10 <sup>th</sup> October 2021 to 10 <sup>th</sup> November 2021
<b>Expected Outcome</b>	: Students will understand the scope of Pharmacovigilance in pharmaceutical industry.
<b>Program schedule</b>	: 10 <sup>th</sup> October 2021 to 10 <sup>th</sup> November 2021

### **Objectives:**

- To impart proper understanding of core concept and background of PHARMACOVIGILANCE AND DRUG SAFETY ASSESSMENT
- To Aware students about
  - a) The understanding of the importance of PV.
  - b) Development of an effective ADR reporting channel, such as the online reporting system  
Establishment of a centralized database for safety reports to facilitate systematic follow-up and detailed analyses
  - c) Improvements in the communication for adverse drug reaction between stakeholders, the health care providers, manufacturer and regulators for pharmacovigilance.
  - d) Career opportunities in the field of PHARMACOVIGILANCE

### **Important Instructions:**

1. This is online Course (useful platform Zoom, Google Meet etc)
2. Course contains Total 8 chapters
3. Duration - 30 Hrs
4. Mandatory to attend all the lectures
5. At the end of all the topics there will be online test of 50 marks (MCQ Based)
6. Certificates will be provided to those participants who have 100 % attendance and minimum 60% Marks in online test

### Course outcomes

1. Students will learn a variety of topics in pharmacovigilance, including adverse effects and serious side effects, and documentation methods.
2. Students will learn skills that are in high demand in the pharmaceutical industry.
3. Students will aware about clinical research, data management, regulatory affairs, and medical writing.
4. Students will aware about latest methodologies and techniques used to improve the health of human beings.
5. It enables students to build their skills in the field, such as clinical trial design.
6. Trained students about how to prepare for a job interview.



**Online Certificate Course On  
PHARMACOVIGILANCE  
AND DRUG SAFETY  
ASSESSMENT**

Start up Date: 10<sup>th</sup> Oct. 2021  
Last Date of Reg.: 9<sup>th</sup> Oct. 2021

**Module: 08**  
**Duration: 30 Hrs**  
**60% Marks in online test mandatory for Certificate**

**Who May Apply?: Diploma, UG, PG and  
Ph. D in Pharmacy**

**Only for RSCP Students**

Dr. S. M. Kewatkar Co-ordinator	Prof. M. D. Chakolkar	Dr. S. P. Jain Convener
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Contact for Details: 9589941146

 **RAJARSHI SHAHU**  
COLLEGE OF PHARMACY, BULDANA.

Website: [www.rscp.ac.in](http://www.rscp.ac.in)  
Email: [principalrscp@gmail.com](mailto:principalrscp@gmail.com)

*Journey Towards Academic Excellence*

## Summary

On a virtual platform, Rajarshi Shahu College of Pharmacy in Buldana has conducted the Online Certification Course 'Pharmacovigilance and Drug Safety Assessment.' This informative session was scheduled for pharmacy students (Diploma, UG, PG, and Ph.D.) from October 10th to November 10th, 2021. The meeting was held using the Zoom Meeting App. The orientation programme for the online certification course was held on October 10th, 2021. Dr. Manoj Swaminathan, founder/director of the vigiserve foundation, has been invited as the Main Speaker for this session. Dr. Manoj Swaminathan explored all the facts regarding the history, introduction, and career options in pharmacovigilance in his session.


We invited seven lecturers to talk throughout the online course. Mr. Vivek Chakole, Lead TCS, Nagpur, joined us as a guest speaker on October 14th, 2021. He explained data input, medical coding, narrative writing, causality evaluation, and labelling of the adverse event. On October 17th, 2021, we invited Dr. Shrinivas Sharma, who works at the PMS.RM. Specialist Philips Healthcare Innovation Center in Pune, as a guest speaker. He addressed aggregate report writing, signal and risk management of product information, and review of regulatory recommendations.

Mr. Vikas Gangurde, Senior Consultant, Business Consulting Infosys, Pune, was invited as a guest speaker on October 23rd, 2021. He provided thorough details about Pharmacovigilance, Quality Assurance, Internal audits and Regulatory inspections. Mr. Vikas Gangurde provided thorough information regarding Pharmacovigilance requirements in Europe, the United States, Canada, Australia, and India on October 22nd, 2021. We asked a guest speaker, Pankaj Wadibhasme, a Senior Medical Writer from Mumbai, to talk on October 30th, 2021. He provided thorough information and guidance on how to build up a master file in a pharmacovigilance system. We invited Mr. Anand Attal, Team Manager Labcorp Drug Development Ltd. Pune, to speak on November 3rd, 2021. He shared detailed information and advised on fresher trainings for non-pharmacovigilance staff, as well as training record maintenance. Dr. Satish A. Polshettiwar, Associate Professor and Head Career Services School of Pharmacy MIT World Peace University Pune, was invited to lecture on November 6th, 2021. He gave detailed information and guidance on interview questions, mock interviews, and pharmacovigilance career opportunities.

We arranged an online MCQ test linked to the session conducted by all of our respectable speakers during the valedictory event. At the end of the session distributed the certificates to all participants and the participants completed a Feedback Form, and we received extremely positive feedback and great reviews from them.



Dr. S. M. Kewatkar  
Co-coordinator

  
**Principal**  
**Principal**  
Rajarshi Shahu College of Pharmacy,  
**Malvihi, Buldana.**  
Dr. S.P. Jain  
Principal, RSCP, Buldana