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Rajarshi Shahu College of Pharmacy, Buldana

(Approved by AICTE, PCI, New Delhi and affiliated to Sant Gadge Baba Amravati University, Amravati)

Certificate Course in Pharmacovigilance and Drug Safety Assessment
Course Code: RPS/PV/21-1
Academic Year: 2021-22
Course Duration: 30 Hours

Module	Topic	Duration
Introduction and basics	career opportunities in pharmacovigilance, introduction to pharmacovigilance, history of pharmacovigilance, 4 minimum criteria, source of adverse events, metro coding, seriousness criteria, adverse events versus area	4
case processing life cycle	data entry, medical coding, narrative writing, causality assessment, labelling of adverse events quality review, medical review, labelling assessment, reporting assessment, submission of adverse events	5
benefit and risk management	aggregate report writing, signal and risk management product information update 5 minutes quality management systems, review of regulatory recommendations	5
quality management systems and audits	pharmacovigilance quality assurance, deviations, corrective and preventive actions, change controls come on business partner audits, internal audits, regulatory inspections	5
pharmacovigilance system	pharmacovigilance system master file setting up of pharmacovigilance system, qualified person for pharmacovigilance, safety data exchange agreement, medical information, product complaints, reporting of adverse events, document and record management	5
Pharmacovigilance requirement in various countries	Pharmacovigilance requirement in Europe, USA, Canada, Australia, India	2
Pharmacovigilance training	refresher trainings to non- pharmacovigilance staff, routine training to pharmacovigilance team, maintenance of training record	2
Other career aspects and assessment	interview questions mock interviews career prospects for pharmacovigilance	2
Total Duration		30 Hours

Dr. S. M. Kewatkar
Co-coordinator

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