



OFFICE OF THE PHARMACOLOGY DEPARTMENT
Subharti Medical College

Recognized by Govt. of India, Ministry of Health & Family Welfare, Govt. Letter No. U.12012/89/98-ME(P)
Website: medical.subharti.org, e-mail: medical@subharti.org, Ph.: 0121-3055000 (Extn: 2118), Telefax: 0121-2439127, 2439067
A constituent college of



SWAMI VIVEKANAND SUBHARTI UNIVERSITY

(Established under U.P. Govt. Act no. 29 of 2008 and approved under section 2(f) of UGC Act 1956)

Value added course

Certificate course in Basics of Pharmacovigilance and Materiovigilance

Goal:

- Student should be well versed in adverse drug and medical device event monitoring & reporting.
- He/ She should be able to apply various assessment scales on ADR and MADR report.

Objectives:

1. Know about Pharmacovigilance programme of WHO & India.
2. Able to collect ADR and MADR report and fill it in CDSCO ADR and MADR forms
3. Able to apply various ADR assessment scales/ tools on ADR reports.
4. Be aware about drug alerts received periodically from CDSCO, Government of India.

Eligibility:

MBBS, BDS, MDS, B.Sc., Nursing, B. Pharma, M. Pharma, M.Sc Pharmacology students, BPT and MPT

Proposed lecture topics/Self directed learning modules

S. No.	Topic	Hours allotted	Teacher
1.	Definition of ADRs, types of ADRs, difference between adverse drug event & adverse drug reaction	02 hours	Dr. Surabhi Gupta/ Dr. Jyoti Singh
2.	Pharmacovigilance Programme of WHO	01 Hour	Dr. Rajeev Sharma
3.	National Pharmacovigilance programme of India	01 Hour	Dr. Sharmendra Singh
4.	System of ADR monitoring & reporting by various countries –UK, Australia, Canada	01 Hour	Dr. Gaurav Kapil
5.	ADR assessment tools for causality, severity, preventability	02 Hour	Dr. Rajeev Sharma
6.	Materiovigilance Programme of India	01 Hour	Dr. Jyoti Singh
7.	Drug banned in world & India due to ADR	01 Hour	Dr. Sharmendra Singh
8.	Drug alerts, black box warning for specific ADRs	01Hour	Dr. Gaurav Kapil



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Practical Skills/Clinical work -

S. No.	Topic	Hours allotted	Teacher
1.	Filling of suspected ADR and MADR reporting of CDSCO, Govt of India	01 Hour	Dr. Sharmendra Singh
2.	Apply ADR assessment tools	02 Hours	Dr. Gaurav Kapil
3.	Online submission of ADR and MADR report through vigiflow software	01 Hour	Dr. Jyoti Singh
4.	Visit to OPD, IPD, ICU for ADR and MADR report collection.	02 Hours	Dr. Jigyasa Poonia

Venue : Department of Pharmacology, Subharti Medical College, Meerut

Contact Details: Dr. Surabhi Gupta (Professor & Head)

Mob. 09897363174, E- mail: surabhi.gupta32@gmail.com

Contact no. 0121-3055000 (Ext. No. 2150, 2152)

Department e-mail – smc_pharmacology2001@rediffmail.com

Registration Fee: Rs. 100/-

Programme:

Course overview- Pharmacovigilance is a scientific discipline which mainly pertains with identifying, validating, quantifying, evaluating & minimizing the ADR of drugs, devices or biologics in order to increase their safety. The clinical research regulatory agencies worldwide including US FDA, Indian DCGI etc are strengthening the safety laws for adoption of a systematic Pharmacovigilance framework. Pharmacovigilance focuses on adverse events, which is the science & activities relating to the detection, assessment, understanding & prevention of adverse effects or any other possible drug related problems.

As Pharmacovigilance & clinical research are becoming an important part of drug development as it deals with the patient safety keeping this in mind, SMC, Meerut has introduced value added certificate course in basics of Pharmacovigilance and Materiovigilance.

Course duration: 16 hour

Date of start: 08.11.2021

Resources: Name of website : www.ipc.gov.in, www.cdsco.nic.in

- Dr. Yogesh Gulati, Dr. Sumit Verma, Fundamentals of Pharmacovigilance, 1st Edition, 2017.

Job prospects: AMC under PvPI, IPC, CDSCO, Pharma industry, Corporate Hospital & BPO


(Dr. Surabhi Gupta)
Professor & Head
Department of Pharmacology

DEPARTMENT OF PHARMACOLOGY
SUBHARTI MEDICAL COLLEGE, MEERUT

Teaching Schedule of Value added course on Basics of Pharmacovigilance & Materiovigilance

DATE	DAY	Time	TOPIC	TEACHER
08.11.21	Monday	11.00 – 01.00 pm	Definition of ADRs, types of ADRs, difference between adverse drug event & adverse drug reaction	Dr. Surabhi Gupta/ Dr. Jyoti Singh
		02.00 – 03.00 pm	Filling of suspected ADR and MADR reporting of CDSCO, Govt of India	Dr. Sharmendra Singh
09.11.21	Tuesday	12.00 – 01.00 pm	Pharmacovigilance Programme of WHO	Dr. Rajeev Sharma
10.11.21	Wednesday	12.00 – 01.00 pm	National Pharmacovigilance programme of India	Dr. Sharmendra Singh
11.11.21	Thursday	12.00 – 01.00 pm	System of ADR monitoring & reporting by various countries –UK, Australia, Canada	Dr. Gaurav Kapil
		02.00 – 03.00 pm	Online submission of ADR and MADR report through vigiflow software	Dr. Jyoti Singh
12.11.21	Friday	11.00 – 01.00 pm	ADR assessment tools for causality, severity, preventability	Dr. Rajeev Sharma
		02.00 – 04.00 pm	Apply ADR assessment tools	Dr. Gaurav Kapil
13.11.21	Saturday	12.00 – 01.00 pm	Materiovigilance Programme of India	Dr. Jyoti Singh
15.11.21	Monday	12.00 – 01.00 pm	Drug banned in world & India due to ADR	Dr. Sharmendra Singh
		02.00 – 04.00 pm	Visit to OPD, IPD, ICU for ADR and MADR report collection.	Dr. Jigyasa Poonia
16.11.21	Tuesday	12.00 – 01.00 pm	Drug alerts, black box warning for specific ADRs	Dr. Gaurav Kapil


 Registrar
 Swam Vivekanand
 Subharti University
 MEERUT


 (Dr. Surabhi Gupta)
 Professor & Head
 Department of Pharmacology

Report of value added course on “Basics of Pharmacovigilance and Materiovigilance” conducted by the Pharmacology Department Subharti Medical College

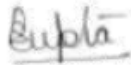
Pharmacovigilance is defined as the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems. The Central Drugs Standard Control Organization, under the control of ministry of health and family welfare, Government of India initiated a nationwide Pharmacovigilance Programme of India (PvPI) for reporting of adverse drug reactions. There are many career options in this field.

Materiovigilance is the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices and protection of patient’s health by preventing its recurrences.

A value added course on Basics of Pharmacovigilance and Materiovigilance was conducted by Pharmacology department, Subharti Medical College, Meerut. The classes started from 8th November 2021 & ended on 16th November 2021. Total numbers of students who registered and participated in the course were 28. The course comprised of interactive lectures on various aspects of Adverse drug reaction reporting and medical device adverse event reporting and Pharmacovigilance, Materiovigilance and hands-on-training on filling of CDSCO ADR reporting forms, MDAE Reporting form, analysis of ADRs for causality, severity and prevention. Students were supposed to collect ADR data and MDAE reports from CSSH, Meerut and submit as an essential part of course completion.

Valedictory ceremony was held on 16th November 2021 which was graced by Dr. Surabhi Gupta, Coordinator of AMC Subharti Medical College, Meerut. Dr. Gaurav Kapil, Assistant Professor, department of pharmacology, Subharti Medical College, Dr. Rajeev Ranjan Sharma, Assistant professor, department of pharmacology, SMC and Dr. Jyoti Singh, Jr. Pharmacovigilance associate, IPC were also present in the valedictory ceremony.


Registrar
Swam Vivekanand
Subharti University
MEERUT


(Dr. Surabhi Gupta)
Professor & Head
Department of Pharmacology



SN.	Name	(8/11) Filling of ADRC Form	Vip (10/11) ADRC Collection	ADRC (12/11) Collection	ADRC (15/11) Collection	ADRC (16/11) Collection
1.	Jyoti Rani	P	P	P	P	P
2.	Rabia Najee	P	P	A	P	P
3.	Rabia Farooq	P	P	A	P	P
4.	Anjali Sharma	P	P	P	P	P
5. Nisha	P	P	A	P	P
6.	Avni Tomar	P	P	A	P	P
7.	Ragini	P	P	P	P	P
8.	Ayushi Ahlawat	P	P	P	P	A
9.	Shubham Kumar	P	P	P	P	P
10.	Ashley Peter	P	P	P	P	P
11.	Arnika Garg	A	A	A	A	A X
12.	Meenu	A	P	P	A	A
13.	Neha	P	P	P	P*	P P
14.	Aishwarya Rai	P	P	A	A	A W
15.	Madhu Kashyap	P	P	P	P	P
16.	Omkar Panda	P	P	P	P	P
17.	Manita Malik	P	P	P	P	P
18.	A	A	A	A	A
18.	Manoranjan Kumar	A	A	A	A	A
19.	Md. Amir	P	P	P	P	P P
20.	Lakhan Singh	P	P	P	P	P
21.	Vikrant Singh	P	P	P	P	P
22.	Rushi	P	P	P	A	P P
23.	Arshlan Chauhan	A	A	A	A	P P
24.	Riya sharma	A	A	A	P	P
25.	Babhanshu	A	P	P	A	P P
26.	Tushar Rajora	A	A	P	A	A
27.	Anshuman Balyan	A	P	A	A	A
28.	Agushtu	A	A	A	A	A

(8/11) Filling of ADRC Form
 Vip (10/11) ADRC Collection
 ADRC (12/11) Collection
 ADRC (15/11) Collection
 ADRC (16/11) Collection

Shiv
 Singh
 Singh
 Singh

25-	Riya Sharma	A	P	P	A	P	P	0/11/2021
26-	Prabhanshu	A	P	P	P	P	P	9/11/2021
27-	Tushar Rajora	A	P	P	A	P	P	10/11/21
28-	Anshuman Baliyan	A	P	P	P	P	A	11/11/21

Introduction, ADR, Types of ADR, ADE

Pharmacovigilance Programme of WHO

National Pharmacovigilance Programme of India

Various ADR Reporting Systems, UK, Canada, Australia

Application of ADR assessment tools.

Maternal vigilance Programme of India

Drug Recall in India and worldwide for ADR

Dypt Singh
Singh
Dypt Singh
Dypt Singh
Prakash

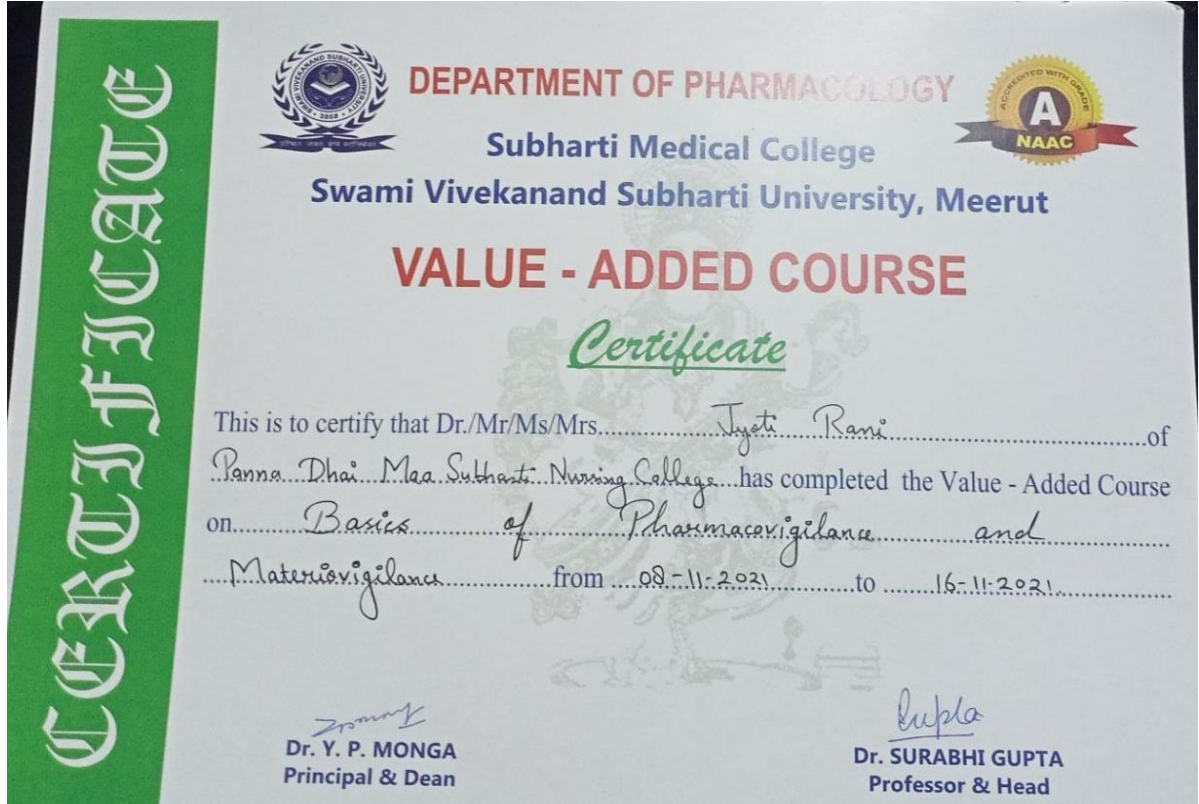
Date
Page

16/11/21

Basics of Pharmacovigilance & Medicovigilance

S.N.	Name	8/11/2021	9/11/2021	10/11/21	11/11/21	12/11/21	13/11/21	15/11/21	16/11/21
1.	Jyoti Rani	P	P	P	P	P	A	A	
2.	Rabia Najee	P	P	P	P	P	P	A	
3.	Rabia Farooq	P	P	P	P	P	A	A	
4.	Anjali Sharma	P	P	P	P	P	A	A	
5.	Nisha	P	P	P	P	A	A	A	
6.	Avni Tomar	P	P	P	P	P	P	A	
7.	Ragini	P	P	P	P	P	A	A	
8.	Ayushi Ahlawat	P	P	P	P	P	P	P	
9.	Shubham Kumar	P	P	P	P	P	A	A	
10.	Ashley Peter	P	P	P	P	P	A	A	
11.	Avnika Garg	A	A	A	A	A	A	A	X
12.	Meenu	A	A	A	P	P	A	A	X
13.	Neha	P	P	P	P	P	A	P	
14.	Aishwarya Rai	P	A	A	P	A	A	A	X
15.	Madhu Kashyap	P	P	P	P	P	P	P	
16.	Omkar Panda	P	P	P	P	P	P	P	
17.	Mamta Malik	P	P	A	P	P	P	P	
18.	Manorajan Kumar	P	A	P	P	A	A	A	X
19.	Md. Amir	P	P	P	P	P	P	P	
20.	Lakhan Singh	P	P	P	P	P	P	P	
21.	Vikrant Singh	P	P	P	P	P	P	P	
22.	Parvi	P	P	P	P	P	P	P	
23.	Arshlan Chauhan	P	A	A	A	A	A	A	X
24.	Ayushi	A	P	P	A	A	A	A	X

Definition of ADR
 Type of ADR, Diff ADR code
 WHO's Pharmacovigilance
 Programme



CERTIFICATE



DEPARTMENT OF PHARMACOLOGY



Subharti Medical College

Swami Vivekanand Subharti University, Meerut

VALUE - ADDED COURSE

Certificate

This is to certify that Dr./Mr/Ms/Mrs..... *Ayushi Ahlawat*of
Panna...*Dhai Maa Subharti Nursing College*...has completed the Value - Added Course
on.....*Basis*.....of.....*Pharmacovigilance*.....and.....
.....*Maternovigilance*.....from.....*08-11-2021*.....to.....*16-11-2021*.....

Dr. Y. P. Monga
Dr. Y. P. MONGA
Principal & Dean

Dr. Surabhi Gupta
Dr. SURABHI GUPTA
Professor & Head

CERTIFICATE



DEPARTMENT OF PHARMACOLOGY



Subharti Medical College

Swami Vivekanand Subharti University, Meerut

VALUE - ADDED COURSE

Certificate

This is to certify that Dr./Mr/Ms/Mrs..... *Anvi Tomar*of
Panna...*Dhai Maa Subharti Nursing College*...has completed the Value - Added Course
on.....*Basis*.....of.....*Pharmacovigilance*.....and.....
.....*Maternovigilance*.....from.....*08-11-2021*.....to.....*16-11-2021*.....

Dr. Y. P. Monga
Dr. Y. P. MONGA
Principal & Dean

Dr. Surabhi Gupta
Dr. SURABHI GUPTA
Professor & Head