



Celebrating 50 Years of Excellence

Symbiosis School for Online and Digital Learning, Pune Diploma in Pharmacovigilance and Clinical Data Management Programme Structure 2023-24

1.	OBJECTIVE	1. Provide an overview of clinical research, regulatory issues and other major aspects of pharmacovigilance & clinical data management 2. Gain in-depth knowledge on reporting, adverse events, safety data and conduct of research, data management & pharmacovigilance.					
2.	DURATION (IN MONTHS)	12 (Open and Distance Learning)					
3.	INTAKE	100					
4.	RESERVATION	Not Applicable					
5.	ELIGIBILITY	Candidate should be a graduate in life sciences or medical sciences or statistics from any recognized university/institute.					
6.	SELECTION PROCEDURE	Verification of Eligibility Norms					
7.	MEDIUM OF INSTRUCTION	English					
8.	PROGRAMME PATTERN	Annual					
9.	COURSE & SPECIALIZATION	As per Annexure A					
10.	FEE		Academic Fee p.a	Institute Deposit	Total		
	Indian Students (Amount in INR)		46000	0	46000		
	International Students	NRI/ PIO/ OCI Category (Amount in US\$)	0	0	0		
		Foreign National Category (Amount in US\$)	0	0	0		
11.	ASSESSMENT	Each course will have continuous assessment of 70 % and term end assessment of 30% of total marks except campus contact session.					
12.	STANDARD OF PASSING	<p>Candidate should secure at least 50% passing in continuous assessment and term end assessment separately. Award of grade towards campus contact session be based on student's attendance to the same as below: AT: Attended AB: Not attended The student who fails to attend the campus contact session shall not be eligible for award of Diploma since this mandatory academic criterion is not fulfilled.</p> <p>The Class is awarded based on the performance of the student in continuous & term end assessment.</p> <table border="1" style="width: 100%; margin-top: 10px;"> <tr> <td style="width: 50%; text-align: center;">Percentage Range</td> <td style="width: 50%; text-align: center;">Class</td> </tr> </table>				Percentage Range	Class
Percentage Range	Class						

			50.00 to 54.99%	Second Class				
			55.00 to 59.99%	Higher Second Class				
			60.00 to 69.99%	First Class				
			70% and above	First Class with Distinction				
13.	AWARD OF DIPLOMA	Diploma in Pharmacovigilance and Clinical Data Management will be awarded at the end of program by taking into consideration the performance in all academic criteria.						
14.	CLASSIFICATION OF MARKS							
Year	Generic Core	Generic Elective	Specialization Core	Specialization Elective	Open Elective	Non-Letter Grade Mandatory Course/s	Non-Letter Grade Audit Course/s	Total
Common								
1	30	0	0	0	0	0		30
Total	30	0	0	0	0	0		30



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Annexure A

Catalog Course Code	Course Code	Course Title	Specialization	Credit	Continuous Assessment	Term End Assessment	Total Marks
Year : 1							
Generic Core Courses							
D4222	0407800101	Data Management Activities & Software		6	105	45	150
D4221	0407800102	Global Pharmacovigilance		6	105	45	150
D4219	0407800103	Project		6	105	45	150
D4217	0407800104	Introduction to Clinical Research		4	70	30	100
D4218	0407800105	Risk Management		4	70	30	100
D4220	0407800106	Standard Guidelines in Data Management		4	70	30	100
D4800	0407800107	Campus Contact Session		0	0	0	Non - Letter Grade Mandatory
Total				30	525	225	750



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Year	Continuous Assessment	Term End Assessment	Total Marks	Total Credits
Year 1	525	225	750	750
Total	525	225	750	750