## James Lind Institute

James Lind Institute, on recommendation of the Faculty and on authorization of the Management, has awarded

Dr. SURUTHY RS

the Advanced Postgraduate Diploma in Pharmacovigilance & Regulatory Affairs With all the Honors, Rights, and Privileges to that Post Graduate Diploma appertaining.

This twenty-eighth day of June, in the year two thousand and twenty one

Award No.: JLI-2021/561-SS



Dean of the Institute

Joshil Warrel

Program Director













## JAMES LIND INSTITUTE

OFFICIAL TRANSCRIPT

Issue Date: FULL NAME : June 28, 2021

Dr. SURUTHY RS

AWARD NO.:

AWARD DATE:

1 of 1

JLI-2021/561-SS

MEDIUM OF INSTRUCTION: English
CATEGORY: Clinical Devel

**Clinical Development Sciences** 

TOTAL PROGRAM CREDITS:

June 28, 2021 32

TITLE AWARDED: Advanced Postgraduate Diploma in Pharmacovigilance & Regulatory Affairs

MODULE	TITLE	SCORE	GRADE	POINT VALUE	MODULE CREDIT VALUE	MODULE QUALIT
1	GENERAL INTRODUCTION	81	B-	2.7	2.0	5.4
2	EPIDEMIOLOGY AND EBM	88	B+	3.3	2.0	6.6
3	PRINCIPLES OF PHARMACOVIGILANCE	79	C+	2.3	2.0	4.6
4	PHARMACOVIGILANCE & SELECTED SYS. ORGAN CLASSES	84	В	3.0	3.0	9.0
5	PHARMACOVIGILANCE SYSTEMS	90	A-	3.7	3.0	11,1
6	GLOBAL PHARMACOVIGILANCE AND SAFETY STANDARDS	73	С	2.0	2.0	4.0
7	PHARMACOVIGILANCE REGULATIONS & GUIDELINES	78	C+	2.3	2.0	4.6
8	PHARMACOEPIDEMIOLOGY	85	В	3.0	3.0	9.0
9	INTRODUCTION TO THE JUDICIAL SYSTEM IN INDIA	87	B+	3.3	1.0	3.3
10	DRUGS AND COSMETIC ACT AND RULES	85	В	3.0	1.0	3.0
11	SCHEDULE Y	85	В	3.0	1.0	3.0
12	INDIAN REGULATIONS GOVERNING CLINICAL TRIALS	81	B-	2.7	1.0	2.7
13	REGULATORY REGIME IN US	79	C+	2.3	1.0	2.3
14	EUROPEAN MEDICINES AGENCY (EMEA)	76	С	2.0	1.0	2.0
15	REGULATIONS IN JAPAN	74	С	2.0	0.5	1.0
16	IN-VITRO & IN-VIVO PRE-CLINICAL STUDIES	79	C+	2.3	0.5	1.2
17	EFFICACY TOPICS RELATED TO CLINICAL STUDIES	86	В	3.0	1.0	3.0
18	COMMON TECHNICAL DOCUMENT (CTD)	81	B-	2.7	1.0	2.7
19	IND & NDA REQUIREMENTS	77	C+	2.3	1.0	2.3
20	CMC INFORMATION	77	C+	2.3	0.5	1.2
21	OVERVIEW OF GHTF	70	C-	1.7	0.5	0.9
22	REG. PROCESSES FOR MEDICAL DEVICES & VETERINARY PRODUCT	76	С	2.0	0.5	1.0
23	BIOSIMILARS EMEA GUIDANCE AND REGULATIONS	84	В	3.0	0.5	1.5
24	BIOPHARMACEUTICAL INDIAN REGULATIONS AND GUIDELINES	72	C-	1.7	0.5	0.9
25	REGULATORY STRATEGIC PLANNING, INTERFACING	71	C-	1.7	0.5	0.9
				TOTAL	32	87.0
	G.P.	A		2.7		



## Signature of Program Director

Module Quality Points = Point Value x Module Credit Value

GPA = Total Module Quality Points / Total Module Credit Value



Institute Seal

Score	Grade	Point Value		
97-100	A+	4.0		
93-96	A	4.0		
90-92	Α-	3.7		
87-89	B+	3.3		
83-86	В	3.0		
80-82	B-	2.7		
77-79	C+	2.3		
73-76	С	2.0		
70-72	C-	1,7		
67-69	D+	1.3		
65-66	D	1.0		
60-64	D-	0.7		
59-0	F	0		

<sup>\*</sup> Each program offered by the James Lind Institute is measured in units of credits. Each credit is equal to approximately 20 hours of study including lecture, tutorial, projects, assignment, field work etc. as may be applicable. The score obtained for each study module is based on the individual scores obtained in tests, assignments and discussions as may be applicable to the study module.