Information Brochure

Professional Certificate in Pharmacovigilance

Catalyst Clinical Services Pvt. Ltd.

Unit No. UG-11, Upper Ground Floor, Aggarwal Prestige Mall, Plot No. 2,
Road No. 44, Pitampura, New Delhi- 110034 (India)
Ph**:** +91-9818356273, 8826806862

Email: info@catalystclinicalservices.com; **Web:** www.catalystclinicalservices.com

Program Objective

Professional Certificate in Pharmacovigilance is skill development program (purely through correspondence) of 6 month duration with a primary focus on key topic of Pharmacovigilance. The prime objective is to provide a high-end training thereby enhancing the employment prospects of the participants.

Program Highlights

- Optimal Duration: 6 months
- Ease of Training and Evaluation: Assignment based evaluation, no formal written examination
- Optimal Course Fee

Pharmacovigilance and Its Potential

Pharmacovigilance is the pharmacological sciences relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of the therapeutic drugs, devices and biologics. Setting up of stringent laws by regulatory bodies (e.g. US-FDA, DCGI, EMEA etc.) has led to the adoption of a systematic Pharmacovigilance framework worldwide. This in turn had led to the creation of large number of jobs pertaining to this field.

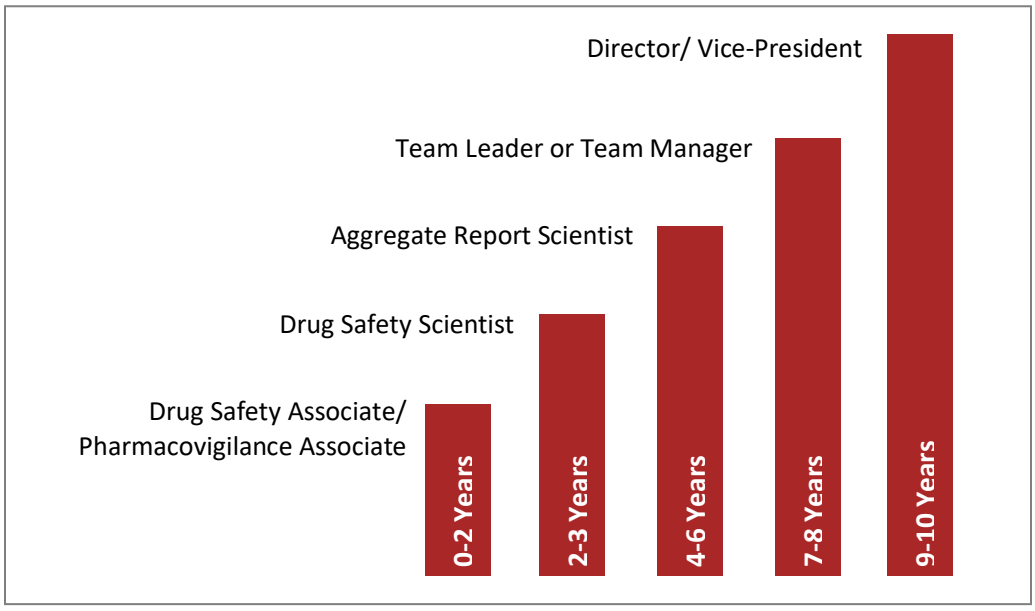
Worth of Pharmacovigilance market worldwide was U.S. $186 million in 2008 and according to a newly released report by Global Market Insights, Inc., is expected to exceed USD 8 billion by 2024. At present, India is the fourth largest producer of pharmaceuticals in the world and therefore is a surfeit of drug brands with more than 6,000 licensed drug manufacturers and over 60,000 branded formulations. India offers unique advantages for the growth of pharmacovigilance that include:

- Rapid induction of New Chemical Entities (NCEs) and high technology pharmaceutical products in market
- Abundance of patients with genetic diversity
- Presence of lacs of formulation in domestic market
- Presence of large number of licensed drug manufacturers in India
- Potentially large world scale Adverse Drug Reaction (ADR) database

In order to cater the unmet training needs, we are pleased to announce the enrolment notification for the **"Professional Certificate in Pharmacovigilance"** program.

Job Prospects

Following positions are available to pursue a career in Pharmacovigilance:



Company Profile: Catalyst Clinical Services Pvt. Ltd.

Catalyst Clinical Services Pvt. Ltd. is a contract research organization with a prime focus on clinical research training and development activities. With regards to clinical research training Catalyst has made pioneering initiatives such as:

- Professional Diploma in Clinical Research (PDCR ®);
- Advance Certificate Program(s) in Clinical Research (ACPCR);
- Professional Certificate in Pharmacovigilance;
- Advance Certificate in Clinical Research (ACCR ®);
- GCP Training Workshop(s);
- 21 CFR Part 11 Training

Program Director

Sanjay Gupta (M.B.A., M.Pharm) is a well-known clinical research expert having 22 years of extensive clinical research experience. He has personally conducted and supervised over 100 clinical trials (Global registration trials, Exploratory Phase-II trials, Phase-I trials, Investigator initiated trials etc.) across a wide range of therapeutic areas including Oncology, Endocrinology, Psychiatry, Critical Care, Infectious Diseases, Andrology, Ophthalmology etc.

He has presented his research work in various International Journals and Conferences including American Society of Clinical Oncology (ASCO), Seminars in Oncology, British Journal of Cancer (BJC), Gastric and Breast Cancer (GBC) and British Journal of Radiology (BJR). He has authored 9 books and written thought provoking articles on clinical research field for periodicals. His recent books **"The Big Book of Clinical Research"** and **"All You Need To Know about Clinical Research"** have received wide acclamations from various stakeholders.

He is the founder member of Society for the Promotion of Ethical Clinical Trials (SPECT) in India and also the Network Coordinator for a cancer trials set-up by University of Oxford, London (India and UK).

Program Curriculum

All the students enrolling for Professional Certificate in Pharmacovigilance are committed to uphold the highest standards of personnel and professional ethics. The curriculum of Professional Certificate in Pharmacovigilance is as follows:

Topic No.	Topic and Components
1.	**Introduction to Pharmacovigilance(PV) and Risk Management**
2.	**Standard Terms and Definitions**
3.	**Global Perspective of PV and ADR Reporting** • Basic Steps in Setting up PV Centre • How to Join WHO NPP • Practical Procedure for Joining WHO Drug Monitoring Program (ASCoMP) • Pharmacovigilance Methods
4.	**Guidelines and Standard Governing PV** • ICH Guidelines, US FDA Guidelines, CFR, EU Guidelines, CIOMS Guidelines
5.	**Global AE reporting System and Reporting Forms** • Introduction and Definition of AE • Introduction and Aspects Related to AE Reporting • Pre and Post Marketing Approval of a Drug • AE Reporting Procedure • AE Reporting Form - US FDA Form 3500 and 3500A

	- Vaccine Adverse Event Reporting System (VAERS) - Medicines and Healthcare Products and Regulatory Agency's Vigilance Reporting Form - Yellow Card - Medeffect Canada and Canada Vigilance Program - Suspected Adverse Drug Reaction Reporting (SADRR) Form - CIOMS I Form - Therapeutic Good Administration Australian Vigilance System – Blue Card
6.	**Individual Case Study Reports (ICSRs)**
7.	**Medical Directory for a Drug Regulatory Activities (MedDRA)**
8.	**Periodic Safety Update Reports (PSURs)**
9.	**Expedited Reporting and Requirements**
10.	**PV Inspection and Compliance Monitoring**

Duration

The program duration is 6 months. However it can be stretched to a maximum of 10 months (due to inability to qualify in the first attempt), failure of which would lead to cancellation of the candidature thereby requiring a fresh enrolment.

Eligibility

Candidates pursuing or completed:

- B.Pharm, M. Pharm, Ph.D
- MBBS, MD, DNB, DM
- BDS, MDS
- BAMS, BHMS, BUMS
- BPT, MPT
- Life Sciences: B.Sc, M.Sc, Biotechnology
- Working Professionals

Third year students of above curriculum are also eligible for enrolment in the program.

Application and Fee

The program fee of Professional Certificate in Pharmacovigilance is as follows:

S.No	Participants	Total Fee
1.	Indian Participants	Rs. 15,500
2.	Indian Participants Residing Overseas	Rs. 15,500 + Rs. 3000 towards postal charges
3.	Foreign Nationals	US $ 325

Candidates are required to send their Application Form along with a copy of highest qualification proof and program fee (through **Demand Draft** drawn in the favor of **"Catalyst Clinical Services Pvt. Ltd."** payable at Delhi**).** The candidates are advised to write their name and address on the back of demand draft.

The enrolment in the program is subject to the realization of Program fees.

Last Date of Application:
February 2021 Batch: 10th February 2021

Application Form Completed in all respect should be sent to:

Program Coordinator
Catalyst Clinical Services Pvt. Ltd.
Unit No. UG-11, Upper Ground Floor, Aggarwal Prestige Mall,
Plot No. 2,Road No. 44, Pitampura, New Delhi - 110034 (India)
Ph**:** +91-9818356273, 8826806862
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Evaluation

The evaluation is based on grading of assignments. The assignments are required to be submitted to the Program Coordinator on or before the scheduled date. **Assignments reaching after the scheduled dates will not be considered for the evaluation.**

Letter grade system is used for grading the assignments. These letter grades are:

A	**Excellent**	**80 and above**
B	**Very Good**	**≥ 60 and < 80**
C	**Good**	**≥ 50 and < 60**
D	**Satisfactory**	**≥ 40 and < 50**
E	**Unsatisfactory**	**< 40**

Candidates securing D grade and above in all four modules would be eligible to receive Professional Certificate in Pharmacovigilance. If a candidate fails to secure minimum "**D**" grade in the assignment of any particular module, he/she would be given another chance to resubmit the fresh set of assignments in the next semester only. The fresh set of assignments would be issued to the candidates on request. If a candidate fails to pass his/her second attempt, he/she would be ineligible for the award of certificate. In that case the candidate has to apply for a fresh registration or seek prior management approval for further proceedings. There is no provision for the re-evaluation of assignments.

The decision of Catalyst Clinical Services Pvt. Ltd. would be final and binding to all the students. All legal disputes would be subject to New Delhi jurisdiction only. **Catalyst Clinical Services Pvt. Ltd. reserves the right to change the rules and regulations from time to time in its sole and absolute discretion. If any such change is made, the latest amended rule/ regulation would be applicable.**

Issue of Fresh set of Assignments

Candidates who are not able to qualify the program in the first attempt can make a written request for the issue of fresh set of assignments. For all such requests a processing fee of Rs. 5000/- will be payable in the form of **bank draft** drawn in the favor of **"Catalyst Clinical Services Pvt. Ltd." payable at Delhi.** The same fee is applicable to those candidates also who are not able to submit the assignments within the stipulated time frame*.

Issue of Duplicate Copy of Grade Card and Certificate

Request for issue of duplicate copy of grade card and certificate can be made to the course coordinator stating the reason thereof. For issue of duplicate copy of grade card and certificate, a processing fee of Rs. 500/- will be payable in the form of **bank draft** drawn in the favor of **"Catalyst Clinical Services Pvt. Ltd." payable at Delhi.**

*The total program duration cannot exceed 10 months from the start date of a batch.