

INFORMATION BROCHURE OF DISTANCE LEARNING PROGRAM



PROFESSIONAL DIPLOMA IN CLINICAL TRIAL MANAGEMENT (PDCTM™)



Bestowing research to life
KPS Clinical Services Pvt. Ltd

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Clinical Research Profession: an unmet need India is today poised as one of the favorable destination for Clinical research field in terms of large research & development (R&D).

Clinical research is a highly specialized field that requires specialization in pharmaceutical science & training to carry out various job functions. The need and complexity of the specialization and training at the level of R&D, quality assurance (QA) as well as academics, increases as they move up the professional ladder thereby shifting the focus from 'trouble shooting' to 'planning & forecasting'.



KPSCS is aimed at imparting clinical research training / education as per the company act 1956, Government of India in the visual appearance of PDCTM, with specialization in clinical trial methodology and management science skills required for the professional growth & competency development at the level of R&D and clinical research professionals.

Training Objective(s)	<ol style="list-style-type: none"> To provide an in-depth knowledge & opportunity for skills development in Clinical research To nurture the culture of 100% clinical research-Competency development
Target audience	Specialization in clinical research professionals employed in pharmaceutical companies, Hospitals, contract research organizations (CROs), research & academic institutions <i>etc as</i> job prospects.

Following positions are available to pursue a career in clinical research:

Minimum Eligibility	Placement
Fresher	Clinical Research Coordinator
Fresher	Regulatory Affair Associate
Fresher	Business Development Associate
Fresher	System Analyst
Fresher or 1-2 year experience	Clinical Research Associate
1-2 years experience	Data Manager
3- 4 years experience	Project Manager
5- 6 years experience	Manager-Clinical Research
5-7 years experience	Auditors
>7 years clinical experience	Medical Advisor

Clinical Research Scenario in India:

India became a member of WTO/GATT/TRIPS in 1995 and implemented the product patent regime in 2005. As part of WTO/GATT/TRIPS, Pharmaceutical Industry has the right to patent products as well as processes throughout the world including India. This has led to a significant growth in pharmaceutical industry and increased stakes of multi-national companies in Indian operations.



"The quality of global trials and academic clinical research is not uniform. There are also issues of inadequate permanent research staff and lack of adequate infrastructure for communication, drug / sample storage, archival. The situation is worse in non-metro cities that have tremendous potential for participation in global trials. In addition, the institutional policies are not yet geared up to support the investigator in managing clinical trials efficiently." It has noted.

Most medical / Pharmaceutical institutions lack a formal course in training for clinical research, and clinical research professional like investigators / monitors have relied on mentors to learn how to conduct clinical trials. There is a shortage of trained manpower. India has about 500 - 1000 clinical research professional in the country, as compared to United States that has 50,000 clinical research professional. With the projections made for the industry in 2010, India would need about six times its present number of investigators. Regulatory approvals in India can take three months or more, compared to 30 days in the US.

In light of these changes, Clinical Research has emerged as a leading knowledge based industry of the new millennium. Clinical research is carried out on healthy volunteers and patients with diseases to ensure that the drug, which is to be marketed, is safe & effective. It takes approximately 12 years and US \$900 million to introduce a new drug to the market.

Being a signatory of GATT/TRIPS, India is being looked upon as a favorable destination for conducting global clinical trials. India offers unique advantages that include:

- Lower drug development cost
- Abundance of patients with genetic diversity
- Wide spectrum of disease
- Trained medical professionals

- Skilled manpower and IT enabled infrastructure at a lower cost
- Proficiency in English language

An estimate of total market of clinical trial conduction either directly or through contract research organization in India by 2010 is projected at US \$ 1.5 billion by major Pharmaceutical companies. This in turn offers **huge employment opportunities for the pharmacy/Medical /life sciences graduate and post-graduate students**. However, clinical research is highly specialized and regulated profession therefore it requires specific skill sets to carry out various operations, as per global norms.

We at **KPS Clinical Services Pvt. Ltd.** are committed towards developing India as a hub for global clinical research by catering to the ever-growing training and compliance needs of the profession, through specialized training courses and workshops.

PROGRAM DIRECTOR:

Mukesh Kumar M.Pharm (Clinical Pharmacy), CPSR (USA) **Director-Clinical Operation & QA, KPS Clinical Services Pvt. Ltd., Having more than 4 years clinical research experience as Clinical Research Coordinator, Clinical Research Associate and Project Manager in various oncology trials (sponsored by Govt. of India) across various Indian hospitals.**

- **Vice President of IYPA (Indian Youth Pharmaceutical Association)**
- **Awarded certificate of FDA MedWatch and patient safety from US FDA**
- **Awarded certificate for membership of ISCR (Indian Society of Clinical Research)**
- **Executive Member of scrutiny council, Clinical Research Board, India**
- **Member of IPGA, India**
- **Visiting faculty in Department of Clinical Research, Sharda University, Greater Noida**

ABOUT TRAINING:

KPS Clinical Services (KPCS) is running Professional Diploma. KPCS is a Contract Research Organization with a prime focus on ethical clinical research with specialized clinical research training in different healthcare field. Concerning clinical trial management, KPCS has made pioneering initiatives in the visual appearance of; PDCTM.



Programs overview:

Clinical Trial Management consists of multi-disciplinary approach of skills enhancement including induction, self-reading and online examination. The total course duration is 6 months.

Programs Element	Duration	Mode	Description
Induction & dispatch of study material	10 day	Telephone, e-mail & courier services	1:1 interaction between the program director and the participant in order to ascertain the developmental needs, focus area and intensity of classes.
Self-reading	120 days	Study material	Customized study material holistically covering the respected program modules.
Online Examination	240 minutes	Online base	5 th Month of the duration of course (One objective paper in each module)
Evaluation	15 days	Online base	Evaluation of respected program modules
Result Preparation	5 days	Paper based	Dispatch of result in time line

STUDY MATERIAL

Module 1	Fundamentals of Drug Discovery Process
Module 2	Fundamentals of Good Clinical Practice (GCP) guideline
Module 3	Clinical Trial Methodology & Management
Module 4	Role & Responsibilities of Stakeholders (clinical trial personnel)

Course Curriculum

All the students enrolled for PDCTM™ are committed to uphold the highest standards of personnel & professional behavior. The PDCTM™ program consists of four modules in all. The components of four modules are as follows:

Module No.	Module Title & Components
1	Fundamentals of drug discovery process <ul style="list-style-type: none"> • Introduction & the drug development methodology • New drug discovery process • IND/ ANDA/New Drug application • Pharmaceutical formulations • Clinical process use in the development of drug • Clinical Trials Terminology
2	Fundamentals of Good Clinical Practice (GCP) guideline <ul style="list-style-type: none"> • History of GCP -mileposts in the evolution of GCP • Principles Of GCP And Applicable GCP Guidelines • Overview of Declaration of Helsinki • Disputes in the Implementation of GCP Guidelines • Health Insurance Portability and Accountability Act (HIPPA) Privacy Rule. • Introduction to Biostatistics
3	Clinical trial methodology & management <ul style="list-style-type: none"> • Essential Clinical Trial Documents • Process and Management of Clinical trial • Conducting BA/BE studies • Clinical Trial Application Logistics • Ethical process in Clinical Research • Introduction to Informed Consent • Overview of Regulatory Affairs • Logistics in Import- Export of Clinical Trial Drugs in India • Data Management
4	Roles & Responsibilities of stakeholders (Clinical trial personnel) <ul style="list-style-type: none"> • Roles & Responsibilities of Sponsor • Roles & Responsibilities of Investigator • Roles & Responsibilities of ERB/IRB/IEC • Roles & Responsibilities of CRA /Monitor • Roles & Responsibilities of Auditor • Roles & Responsibilities of Clinical Research Coordinator or Site Coordinator/Site Manager • Roles & Responsibilities of CRO • Roles & Responsibilities of Regulatory Authorities • Roles & Responsibilities of Clinical Data Manager (CDM) • Roles & Responsibilities of Clinical Biostatistician

ELIGIBILITY

1. Graduate & Post graduate in Pharmaceutical Science(B.Pharm, M.Pharm)
2. Graduate & Post graduate in Medical Science (MBBS, BAMS, BHMS,BUMS,MD, MS)
3. Graduate & Post graduate in Dental Science (BDS,MDS)
4. Graduate & Post graduate in Nursing Science
5. Graduate & Post graduate in Physiotherapy(MPT, BPT)
6. Graduate & Post graduate in Life Science
7. Working Professionals with relevant qualifications
8. Third year students of Pharmaceutical, Medical, Dental science are also eligible.

Note: KPS Clinical Services Pvt. Ltd. Is authorized organization to provide Education certification / corporate training / workshop / seminar for capacity building in the field of clinical research along with Clinical Trial Execution as per the company act 1956 of Government of India

Application Fee:

Fee Structure:	The fee for Indian Professional/ Student		
	Application Procedure 200/-	Course Fee Rs. 7600/-	Total 7800/-
	The fee for abroad Professionals/Students		
	Application Procedure US\$ 20	Course Fee US\$ 280	Total US\$ 300

DEMAND DRAFT:

Candidates are required to send their completed applications along with a Demand Draft of 'requisite program fee' drawn in favor of 'KPS Clinical Services Pvt. Ltd.' payable at Greater Noida. Candidates are advised to write their name and address at the back of demand draft.

Applications completed in all respects should be sent to:

PROGRAM DIRECTOR:

KPS Clinical Services Pvt Ltd.

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APPROVAL:

- ***KPS Clinical Services Pvt. Ltd Is authorized organization to provide Education certification / corporate training / workshop / seminar for capacity building in the field of clinical research along with Clinical Trial Execution as per the company act 1956 of Government of India***

SCOPE OF CLINICAL RESEARCH:

- ***A looming shortage of clinical research personnel estimated at 30,000 to 50,000." McKinsey has estimated, and Confederation of Indian Industries concurred, that India's clinical research sector, including pharmacovigilance would grow to at least Rs 4500 crores in 2010 from Rs 450 crores, a ten-fold increase.***

REPORT:

- ***The global clinical trials industry is currently worth an estimated \$10 billion and has the potential for considerable growth in the future. Global revenues from clinical trials have increased by almost 15% in the last year and the industry is prepared for an extended period of healthy growth. Efficient clinical trials are going to be vital for success and all pharmaceutical companies and CROs need to remain responsive to future changes in this fast moving market.***

RESULT:

The result is based on online Examination. There will be one graded exam for each module. The online examination is required to be attempt on the scheduled of every Sunday of the 5th month of the duration of course.

GRADING		
O	Out standing	81-100%
A	Excellent	71- 80%
B	Very Good	61- 70%
C	Good	56-60%
D	Satisfactory	50-55%
E	Unsatisfactory	< 50%

Note:

Only exam would be extended for individual Participants at his/her USER ID in case of emergency/medical related condition after sending the Written proof (By email with enclosed of scan copy/ fax).

Candidates securing aggregate "D" grade in Examination would be eligible to receive Professional Diploma in Clinical Trial Management (PDCTM).

If a candidate fails to secure "D" grade in the online examination of any particular module, he/she would be given another chance to re-exam in the next semester only on request by email. If a candidate fails to pass his/her re-examination, he/she would be ineligible for the award of certificate. In that case, the candidate has to apply for a fresh registration.

Process of re-examination

Candidates who are not able to qualify the exam in the first attempt can request by email only for the generated of new user ID. For all such requests a processing fee of Rs.2800/- will be payable in the form of **bank draft** drawn in the favor of "KPS Clinical Services Pvt. Ltd."

The same fee is applicable to those candidates also who are not able to attempt the online exam as per examination schedule*.

There is no provision for the re-evaluation of online examination. The decision of KPS Clinical Services Pvt. Ltd. would be final and binding to all the professionals/Students.

KPS Clinical Services Pvt. Ltd. reserves the right to change the rules & 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.

Process to Issue of Duplicate Copy of Grade Card & Certificate

Request for issue of duplicate copy of grade card and certificate can be made to the program Director stating the reason thereof. For issue of duplicate copy of grade card and certificate, a processing fee of Rs. 800/- will be payable in the form of **bank draft** drawn in the favor of "KPS Clinical Services Pvt. Ltd."

* The total program duration cannot exceed 12 months from the start date of a batch.