CLINICAL RESEARCH & PHARMACOVIGILANCE

RAISE YOUR CAREER WITH GLOBALLY ACCLAIMED INSTITUTE

Global Institute Of Health Science™

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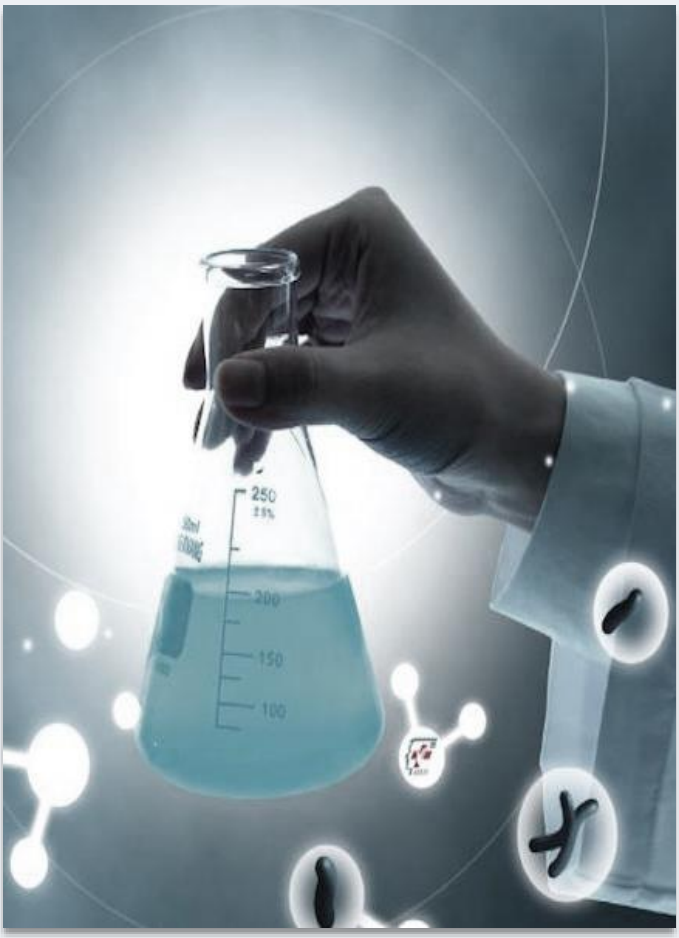
CLINICAL RESEARCH & PHARMACOVIGILANCE

Global Institute of Health Science is a pioneer in health science education especially in distance & online education. Global Institute of Health Science is an ISO 21001:2018 Certified health science Institute & globally acclaimed, also certified with copyright approval from IPR Government of INDIA. GIHS have international certification from UASL UK for Quality Control Management System.

WHY CHOOSE US

- *BRINGING EXCELLENCE TO HEALTH PROFESSIONALS*
- *10+ YEARS OF EXPERIENCE WITH INTERNATIONAL EXPOSURE*
- *INTERNATIONAL ACLAIMED WITH ISO & GOVT APPROVED*
- *LIFETIME FREE PERSONALIZED TUTORING FOR SUCCESS*

GHIS Clinical Research and Pharmacovigilance courses online program is designed to provide total overview and skill globally in the field of clinical research.
It would help professionals to upgrade & develop their knowledge about ICH GCP Guidelines, regulatory issues and other major aspects of clinical research & trial management.
It is designed to provide total overview and skill globally in the field of clinical research, and pharmacovigilance.
It would help professionals to upgrade & develop their knowledge about clinical trials, data management, pharmacovigilance, regulatory issues and other major aspects of pharmacovigilance. to understand the key concepts in the responsible conduct of research and that conforms to the highest standards for the protection of human research subjects. It can be able to critically appraise the medical scientific literature, including the methodology of published and proposed investigations



SYLLABUS

- **Introduction of clinical research**
- Clinical Trial Phases / Pharmacological Principal of Clinical Research
- Drug Development and Launch
- **Indian Regulation (domestic regulation)**
- ICH GCP / Schedule Y / ICMR / Indian GCP
- **Key Stakeholders in Clinical Research**
- Ethics Committees and Institutional Review Board
- Responsibilities of Sponsor / Responsibilities of Investigator
- Responsibilities of Sponsor – Investigator / Responsibilities of Sponsor – Vendor
- **Clinical Trial Design and Project Managements**
- Clinical Trial Design / Vendor Selection and Managements
- Project Planning / Project Managements
- **Principles of good clinical practices**
- Protocol Design / CRF Design
- **Essential documents in clinical research and regulatory requirements**
- Essential Documents / IND Application
- Clinical Study Report / NDA Application
- Informed Consent Process and Documentation
- **Study setup process**
- Site Selection and Pre- Study Visits
- Site Initiation / Subject Recruitment and Retention Planning
- Site Contract and Budgeting
- **QC, Compliance & Auditing in Clinical Research**
- 21 CRF Part 11 / Site Auditing
- Sponsor Compliance and Auditing / SOP for Clinical Research
- **Clinical Monitoring**
- CRF Review & Source Data Verification
- **Drug Safety Reporting / Drug Accountability Work**
- Routine Site Monitoring / Site Close Out Visit
- PHARMACOVIGILANCE
- **Introduction of Pharmacovigilance**
- Overview of Pharmacovigilance
- Standard Terms and Terminology in Pharmacovigilance
- **Medical Evaluation of Adverse Events in Pharmacovigilance**
- Adverse Event Reporting System and Form / Diagnosis and Managements of ADRs / Medical Evaluation of AE
- **Case Processing**
- Global Perspective of Pharmacovigilance
- Single Case Processing / Case Narrative Writing
- **Pharmacovigilance Reporting Database, Signal Detection, Managements and Risk Assessments & Evaluation**
- Quality System in PV / Expedited Reporting Criteria
- PSUR & PBRER / PV Database and Signal Detection
- Risk Assessments & Management
- **Medical Dictionary for Regulatory Activities medDRA**
- medDRA
- **PV laws and Guideline**
- Regulatory Guideline @ Laws in PV / SOPS in PV
- PV Auditing And Inspection / Regulatory Aspects In PV

ADMISSION PROCEDURE

- *Enrollment online: www.gihsonline.com / Apply Online*
- *Online Access for Study Content within 48 Hours of enrollment*
- *Shipping of books with Latest updates with every enrollment (optional)*
- *Will Assign Personalized Professional Expert for Lifetime with no COST*
- *Online exam and Project submission*
- *Will award and ship two international certificates*

FEES DETAILS (All modes of payment available)

- *Post Graduate Diploma Program (One Year) – 32000/- INR & Fees for International Candidates – 699 $ USD*
- *Fast Track PG Diploma Program (4 Months) – 36000/- INR & Fees for International Candidates – 750 $ USD*

STUDY METHODOLOGY

- Freelance method of study
- Read the books
- Make notes of your queries
- Need to mail or contact to our expert
- Experts will resolve... via mail or via call or Can arrange Session based on your queries
- Experts will support for lifetime to raise your knowledge & Expertise
- Our content is totally based on live cases and Industries best practices

MODE OF EXAMS

- Login Details for online examinations after completion of the duration.
- 7 days to appear in online exams.
- Examination pattern would be Multiple Choice question MCQ
- PowerPoint project of minimum 30 pages of your own selected topic
- Successful Candidates would award with two certifications (DEGREE & TRANSCRIPTIONAL Degree)

PLACEMENT SUPPORT

Will Share your profile globally for career growth. With the support of GIHS programs more than 2000 professionals are working in healthcare industry and having strong student & professional base in India, UK, USA, Canada, UAE, Russia, Australia and more.

India UK USA Australia Canada Russia New Zealand UAE Africa Europe

Global Institute Of Health Science

Certificate

This is to certify that

RINA MISHRA

completed the four months programme of

Post Graduate Diploma in

Clinical Research & Pharmacovigilance

offered by

Global Institute of Health Science.

during November 2021 to February 2022

Upon successful completion of the programme

POST GRADUATE DIPLOMA

IN

CLINICAL RESEARCH & PHARMACOVIGILANCE

is awarded to him/her this day the 07th March 2022.

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Academic Head

Global Institute Of Health Science

POST GRADUATE DIPLOMA
IN
Clinical Research & Pharmacovigilance
(November 2021 to February 2022)

RINA MISHRA

GRADE SHEET & TRANSCRIPT

CLINICAL RESEARCH

Introduction | Clinical Trial Phases | Principal | Drug Development And Launch | ICH GCP | Schedule Y

Indian Regulation (domestic regulation) | ICMR | Indian GCP | Key Stakeholders

Ethics Committees And Institutional Review Board | Vendor Selection And Managements

Responsibilities Of Sponsor, Investigator, Sponsor – Investigator & Sponsor – Vendor

Clinical Trial Design And Project Managements & Planning | Principles of good clinical practices

Protocol Design | CRF Design | Essential documents | Clinical Study Report | NDA Application

Informed Consent process And Documentation | Study Setup process | Site Selection And Pre- Study VIsits

Subject Recruitment And Retention Planning | Site Contract And Budgeting | 21 CRF Part 11 | Site Auditing

QC, Compliance & Auditing in Clinical Research | Sponsor Compliance And Auditing | Clinical Monitoring

CRF Review & Source Data Verification | Drug Safety Reporting | Drug Accountability Work

Routine Site Monitoring | Site Close Out Visit

PHARMACOVIGILANCE

Overview & Standard Terms And Terminology | Medical Evaluation Of Adverse Events

Adverse Event Reporting System And Form | Diagnosis And Managements Of ADRs

Medical Evaluation Of AE | Case Processing |Global Perspective | Single Case Processing

Case Narrative Writing | Reporting Database, Signal Detection | Managements And Risk Assessments & Evaluation

Quality System In PV | Expedited Reporting Criteria | PSUR & PBRER | Database And Signal Detection

Risk Assessments & Management | Medical Dictionary For Regulatory Activities medDRA

PV laws And Guideline | Regulatory Guideline @ Laws | SOPS | PV Auditing & Inspection | Regulatory Aspects

Examination: 45/50 **Project Work: 35/50**

Total: 80/100

GRADE: A+

ISO 21001:2018

MHRD (Higher Education)
Reg No: SW - 12032/2018
CR Act 1957

Academic Head
07/03/2022

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GIHS ADVANTAGE

GIHS provides best courses helps to get the start up in the healthcare field. These courses are ad-hoc to professional career and provides the additional benefit to be the part of an organization.

OTHER PROGRAMS

Health Management Programs

• Health Informatics	• Hospital Administration
• Pharma Management	• Hospital Planning & Management
• Healthcare Management	• Nursing Management
• Public Health Administration	• Health Insurance
• Blood Banking Management	• Medico-Legal Systems
• Medical Laboratory Technology	• Medical Radiology Technology
• Quality management for Hospital and healthcare organizations	
• Disaster management for hospitals and healthcare organizations	
• Hospital Infection Control & Patient Safety	

Clinical Research Programs

• Clinical Research & Quality Assurance GCP Audits / Inspections	• Pharmacovigilance & Medical/Scientific Writings
• Clinical Research & Pharmacovigilance	• Clinical Data Management & SAS
• Regulatory affairs IPR & Patent	• Clinical Trials Management

Allied Medical Programs

• Mother & Child Health	• Mental Health & Addictions
• Nutrition & Dietetics	• Medical Transcription
• Pregnancy Education	• Gynaecology & Obstetrics
• Electroencephalogram (EEG)	• Nuclear Medicine Technology
• Anaesthesia Management	• First AID (CPR/Emergency Care)

Environment Health & Safety Programs

• Industrial Health & Hygiene	• Environment Health Safety & RM
• Occupational Health & Safety	• Industrial Safety
• Food Safety & Quality Management	• Oil & Gas Safety Engineering
• Process Safety & Engineering	• Fire & Industrial Safety MGT

Ayurveda & Homeopathic Programs

• Panchkarma: Ayurveda	• Garbhsanskar: Ayurveda
• Naturopathy & Yoga	• Siddha: Medicine
• Ksharsutra: Ayurveda	• Classical Homeopathy
• Materia Medica: Homeopathy	• Repertory: Homeopathy

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