Clinical Research & Quality Assurance /GCP Audits & Inspections

RAISE YOUR CAREER WITH GLOBALLY ACCLAIMED INSTITUTE

Global Institute Of Health Science™

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Clinical Research & Quality Assurance /GCP Audits & Inspections

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*

***Clinical Research** is a branch of medical science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.*

***Clinical Research** is different than clinical practice. In clinical practice, one used established treatments while in clinical research evidence is collected to establish a treatment. This **GIHS Clinical Research Program** 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. An Audit is a "systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsor's SOPs, GCP, and the applicable regulatory requirements."*

SYLLABUS

Clinical Research

- **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
- **Quality Assurance GCP Audits & Inspections**
- **QC & QA, Compliance & Auditing & Inspections**
  21 RF Part 11 / Site Auditing / Sponsor Compliance and Auditing
  SOP for Clinical Research
  Roles & Responsibility Lead & Principle investigator
  Clinical Monitoring Activities / CRF Review & Source Data Verification
  Drug Safety Reporting / Drug Accountability Work
  Routine Site Monitoring / Site Close Out Visit
- **GCP Audits & Inspection**

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

GagandeepSingh Shergill

completed the one year programme of

Post Graduate Diploma in

Clinical Research & Quality Assurance GCP Audits & Inspections

offered by

Global Institute of Health Science.

during April 2021 to March 2022

Upon successful completion of the programme

POST GRADUATE DIPLOMA

IN

CLINICAL RESEARCH & QUALITY ASSURANCE GCP AUDITS & INSPECTIONS

is awarded to him/her this day the 27th April 2022.

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Academic Head

Global Institute Of Health Science

POST GRADUATE DIPLOMA
IN
Clinical Research & Quality Assurance / GCP Audits & Inspections
(April 2021 to March 2022)

GagandeepSingh Shergill
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

QUALITY ASSURANCE / GCP Audits & Inspections

QC & QA, Compliance & Auditing & Inspections

21 CRF Part 11 | Site Auditing | Sponsor Compliance And Auditing | SOP For Clinical Research

Roles & Responsibility Lead & Principle investigator

Clinical Monitoring Activities | CRF Review & Source Data Verification | Drug Safety Reporting

Drug Accountability Work | Routine Site Monitoring | Site Close Out Visit

GCP Audits & Inspection

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

Total: 80/100

GRADE: A+

ISO 21001:2018

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

Academic Head
27/04/2022

Cert. ID :608ed6185baac

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INDIA | UK | AUSTRALIA | RUSSIA | CANADA | USA | NEW-ZEALAND | UAE | AFRICA

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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