

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) – 32999/- INR & Fees for International Candidates – 699 \$ USD
- Fast Track PG Diploma Program (4 Months) – 36999/- 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.



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.



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



ISO 21001:2018



Cert. ID : 608ed61855baac

Academic Head

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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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27/04/2022

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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

<https://www.youtube.com/@globalinstituteofhealthscience/videos>