REGULATORY AFFAIRS, IPR & PATENT

RAISE YOUR CAREER WITH GLOBALLY ACCLAIMED INSTITUTE

Global Institute Of Health Science™

www.gihsonline.com | info@gihsonline.com | +91-9033768588

REGULATORY AFFAIRS, IPR & PATENT

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*

Regulatory affairs (RA), also called government affairs, are a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking.

Regulatory affairs also have a very specific meaning within the healthcare industries globally and professionals can be recruited in Pharma companies, medical devices, biotech, biologics and functional food areas.

It deals with government or law. Global regulatory agencies are as USFDA (United States Food and Drug Administration) and European Union of Drug Regulatory Affairs (EUDRA).

This Program is developed to prepare professionals for regulatory affairs positions in the pharmaceutical, biopharmaceutical and medical device industries i.e. to facilitate them with the educational foundation that will support them advance in the regulatory affairs profession.

The program will provide the students with the fundamentals required in both regulatory affairs and quality operations.

SYLLABUS

Regulatory Affairs

- Pre-Clinical Trial
- Clinical Trial
- Regulatory Bodies in India
- Central Drug Regulatory System
- Drug & Cosmetics Act
- Schedule – Y
- Medical Device Registration in India
- Product Development Protocol
- Environmental Protection Act –1986

Pharmaceutical Legislation in India

- The Narcotic drug & psychotropic substance act
- Medicinal & Toilet preparation
- Drug price control order in force
- Laws on trademarks and copy rights
- Prevention of cruelty to animal act
- Consumer protection Act 1986

Pharmaceutical Regulation Process in India

- Regulatory consideration for pre-clinical and clinical testing
- Regulation and registration of medical devices
- Regulation and registration of cosmetics
- General drug approach
- New drug development procedure in India & In different market
- Guideline on the WHO certification in India & import export policy

Regulation of Generic Pharmaceutical and Bio Similar Product

- Introduction and regulation of biosimilar in Indian & Europe
- Introduction and worldwide regulation of herbal product
- Introduction and regulation of Orphan drug
- Submission of Drug Master File to USFDA
- Legal environment of business
- Common Technical Documents

Introduction to USFDA

- ICH Guidelines
- Drug Regulatory Authorities in European union with special reference to EMA & UKMHRA
- WHO Guidelines
- Auditing of Manufacturing Facility
- Development of Orphan Drug
- Guideline for rest of World
- IPR, Patents, Quality Assurance, Projects

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

Neha Sharma

completed the four months programme of

Post Graduate Diploma in

Regulatory Affairs, IPR & Patent

offered by

Global Institute of Health Science.

during January 2023 to April 2023

Upon successful completion of the programme

POST GRADUATE DIPLOMA

IN

REGULATORY AFFAIRS IPR & PATENT

is awarded to him/her this day the 26th May 2023.

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Academic Head

Global Institute Of Health Science

POST GRADUATE DIPLOMA
IN
Regulatory Affairs, IPR & Patent
(January 2023 to April 2023)

Neha Sharma

GRADE SHEET & TRANSCRIPT

Regulatory Affairs | Pre-Clinical Trial | Clinical Trial | Regulatory Bodies in India
Central Drug Regulatory System | Drug & Cosmetics Act | Schedule – Y
Medical Device Registration in India | Product Development Protocol
Environmental Protection Act –1986 | Pharmaceutical Legislation in India
The Narcotic drug & psychotropic substance act | Medicinal & Toilet preparation
Drug price control order in force | Laws of trademarks and copy rights
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Regulatory consideration for pre-clinical and clinical testing
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Legal environment of business | Common Technical Documents
USFDA | ICH Guidelines | DRA in European union with special reference to EMA & UKMHRA
Auditing of Manufacturing Facility | IPR, Patents, Quality Assurance, Projects

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

Total: 80/100
GRADE: A+

Cert. ID :63cbad181b22f

ISO 21001:2018

Copyright Office Government of India

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

Academic Head
26/05/2023

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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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