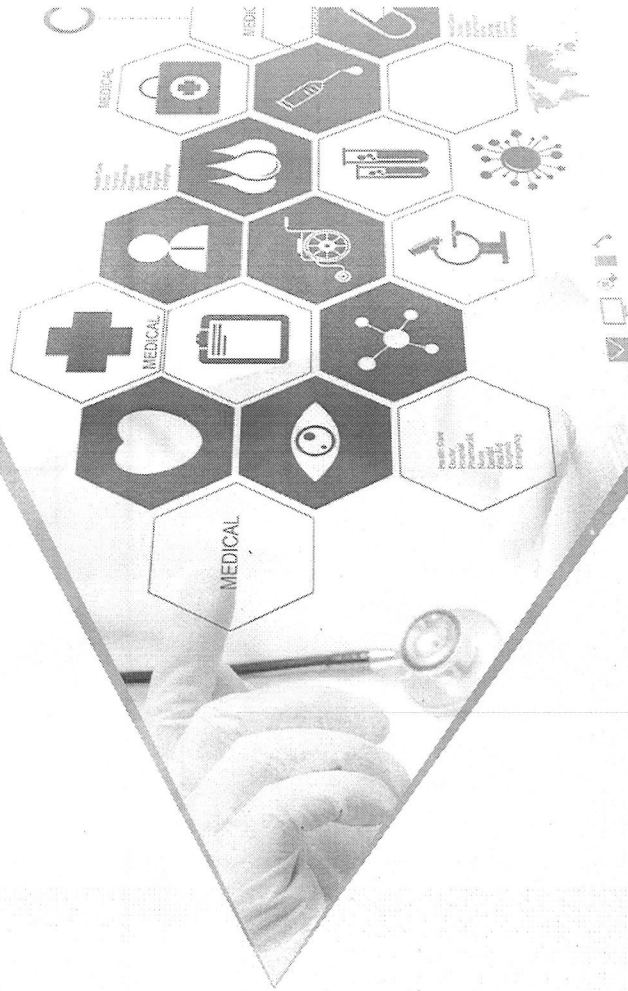


WHY THIS COURSE ONLY :

1. Along with theoretical knowledge, this is the first course which will give you practical training workshops as well.
2. This is first course which will cover all three major areas in placements- clinical research, PV and Medical Writing.
3. Admissions will be open on continuous basis and repeat lecture facility will be available for those who will join late.
4. Experienced faculties will be available to guide students anytime
5. 100% placement assistance
6. Personality development session will be available along with academic knowledge.



**Ingenious Healthcare
& Biorustin Solutions Pvt. Ltd.**



📍 Opp SP Infocity, Sadaguru Society, Hadapsar, Pune-412308

Biorustin Solutions Pvt. Ltd.,
704, 1 wing, Building Number 1,
Shankeshwar Presidency,
Tawaripada, Kalyan west,
Thane 421301

☎ 9615057070

✉ ingenioushealth21@gmail.com

Professional Certificate in
CLINICAL RESEARCH

Advanced Certificate course In Clinical Research & Medical Technologies

ABOUT RESEARCH :

Most modern medical treatments are emerged from the result of clinical research. The research test whether particular treatments are safe and effective in patients after conducting clinical trials. Clinical trials are essential for the development of new medical treatments and diagnostic tests. Without clinical trials, we cannot properly determine whether new treatments developed using animal models are effective or safe or whether a diagnostic test may work properly. Advanced treatments for all life threatening diseases including cancer, heart disease, asthma etc have been developed through clinical research. Clinical trials also help to improve health care services by raising standards of treatment. Researchers conducting clinical trials can be part of hospitals, pharmaceutical, medical device and biotechnology companies, or a combination of these. These all members involved in clinical trials are continually trained to provide best practice patient care. Clinical trials are sponsored or funded by various organizations or individuals, including government departments or pharmaceutical, medical device and biotechnology companies.

NEED TO CLINICAL TRIALS :

- It helps to prevent diseases by testing a vaccine
- It detect or diagnose diseases or conditions, for example by testing a blood sample
- It treat diseases or conditions by testing a new medicine or other medical procedure.
- It finds out how people can control their symptoms or improve their quality of life by testing how a particular diet affects a condition.

ABOUT COMPANIES :

Ingenious helathcare is pune based Site management organization (SMO) and clinical reserach service provider. Experienced in conducting clinical studies in various therapeutic area which includes primarily Oncology, Haematology, Diabetes, Rheumatoid arthritis, Pain management, Cardiology. Ingenious helathcare academy is experienced in conducting certificate courses in clinical reserach and medical technologies including PV, CDM, and Medical writing in order to educate people involved in clinical research.

Biorustin solutions is contract service provider in the domain of Clinical reserach, Pharma and Biopharma regulatory services, intellectual property rights, strategic sourcing and procurement and human resource. We provide contract clinical trial monitoring, auditing services to Pharmaceutical companies.

WE DO THIS BY :

- Providing a forum for discussion of key matters impacting clinical research.
- Encouraging good relations with other healthcare related groups.
- Providing opportunities for learning and development to improve professional competence.
- Improving confidence and understanding of clinical research.

OUR FOCUS :

CLINICAL OPERATIONS

- Introduction to Clinical Research • Clinical Trial Management
- Regulatory Guidelines • Stakeholders in Clinical Research

PHARMACOVIGILANCE

- Introduction to PV • ADR reporting • Seriousness assessment
- MEDRA • Labelling

MEDICAL WRITING

- Opportunities in MW • Plagiarism & Copywriting • Scientific Writing
- Various type of MW • Research Paper writing

CLINICAL DATA MANAGEMENT

- System & Process • Query Management • CRF
- Medical Coding in CDM • Data Lock

AWARD OF CERTIFICATION :

Certification is awarded to candidates only on successful completion of the course and after having paid all the dues with stipulated attendance.

Over all grades shall reflect on the final certificate as under:

Grade A 85% and above

Grade B 70-85%

Grade C 50-70%

Grade D Below 50% (Unsuccessful)

DURATION :

6 weeks

ELIGIBILITY CRITERIA :

MBBS, BDS, BAMS, BHMS, B.PHARM, Pharm/ Pharm.D, B.Sc./M.Sc. B.Sc./M.Sc. (Biotech , Nursing), B.PTh., B.E, B.Tech, M.Tech in Biotech.

DOCUMENTS REQUIRED :

Two - Passport Size Photographs,
Degree Certificate/ Mark Sheet,
Election Card / Passport / Driving License

PROGRAM FEES :

Contact Course Coordinator- 9615057070

CONDUCTING AGREEMENT

Ingenious Healthcare

AGREEMENT

Ingenious Healthcare, Pune

AND

Dayanand Education Society's, Dayanand College of Pharmacy, Latur

This agreement is executed on this 04/05/2020 between **Ingenious Healthcare (Henceforth mentioned as company)** and **Dayanand Education Society's, Dayanand College of Pharmacy, Latur (Henceforth mentioned as Institute)**.

Recitals

1. Whereas, Ingenious Healthcare is a Site Management Organization (SMO), engaged in undertaking the Clinical Trials AND conduct courses for clinical trials, pharmacovigilance, clinical data management, medical writing.
2. Whereas, **Dayanand Education Society's, Dayanand College of Pharmacy, Latur**, is a premier pharmacy Institute providing the degree course to students.

Obligations:

A. Obligations of the Institute

1. Agrees to provide its facilities including class room and projector to enable the Ingenious Healthcare to conduct the course if required. The sessions may be conducted online based on the current situation of Covid 19 disease.
2. Ensure the availability of due time slot during weekdays for completion of course syllabus as agreed. Also additional timeslot should be approved depending upon the need of time. The course may be conducted
3. Provide the single point of contact (SPOC) for ease of communication between Institute and Company. SPOC will intimate the Ingenious course coordinator in case there is any

holiday or non-working on the scheduled day due to unforeseen circumstances in priority.

B. Obligations of company

The company agrees to conduct Clinical Research certificate course in the institute:

1. Conduct lectures for the course including Clinical research operation, CDM, PV and Medical Writing.
2. Maintain quality and accuracy of the course.
3. Assignment of course related project to students and evaluation to ensure development of correct and deep understanding of subject.
4. Conduct the sessions as per the course overview enclosed as an annexure 1 to this agreement.
5. Prepare the adequate content/material for delivery of sessions in effective manner. Provide the softcopies of the course material to SPOC.
6. Evaluate the students at the end of Program and provide the completion certificate to successfully completed students.
7. Help students to clear their doubts any time after completion of the course.
8. Provide 100% placement assistance to all the enrolled students.
9. Students who failed to understand the sessions in this batch will be allowed to attain the same sessions in upcoming batch.

Terms of Agreement

1. The term of this Agreement shall be for a period of five years
2. This agreement will be effective from the date of commencement of 04May 2020 and ends on 03/May /2025.

Financial Terms:

1. Fees for the conduct of 50 hrs course will be ~~7,000~~ ^{10,000 Rs} INR per student.
2. All the payment for clinical course will be deposited in the account of Ingenious Healthcare.
3. In case of revision in the fees structure, fees will be decided after mutual discussion in between two parties.

Termination and Consequences:

Company and Institute can terminate this agreement under the following circumstances:

1. Both the parties does not adhere to responsibilities of mutual participation

2. Both the parties contravene any of the provision of this agreement
3. Both the parties can terminate the agreement after giving a prior notice before commencement of the course

IN WITNESS WHEREOF, this Agreement has been executed on 7/05/20 by duly authorized representatives of the Parties.

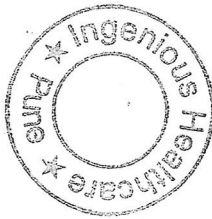
1. Agreed and executed for and on behalf of: Ingenious Healthcare (Company)

Signature [Signature]

Name Mrs. Parnavi Raval

Title: Director

Date: 5th May 2020



2. Agreed and executed for and on behalf of: Dayanand Education Society's, Dayanand College of Pharmacy, Latur

Signature [Signature]
Principal
Dayanand College Of Pharmacy
Name: Dr. Kranti Satpute

Title: Principal

Date: 4/05/2020



Witness:

1. Mr. Sonvane S.M. - [Signature]
2. Mr. Gadgew A.B. - [Signature]

Annexure 1:

Course outline: Clinical Research Education Program: Advance Certificate Course in Clinical Research and Medical Technologies

Total Hrs: 50 Hrs

Topic	Allotted hrs
1. Introduction to drug development	1
2. Clinical trial- History, present and future	2
3. Stakeholders of clinical trial, Good clinical practices- ICH GCP, ICMR guidelines, Informed consenting, Clinical trial Monitoring,	4
4. New clinical trial regulations in India, Clinical trial application requirements to CDSCO, EMA and US-FDA	5
5. Medical writing- Development of critical clinical study documents- Investigator brochure, Study protocol, and Clinical study report	6
6. Analysis of clinical trial data and reporting	3
7. Data management- Role and functioning	8
8. Pharmacovigilance- Role and functioning	8
9. Clinical quality assurance- clinical audits and Inspection by regulatory authorities.	5
10. Individual Project and evaluation, discussion on observation and learning	5
11. Special training on personality development, verbal and written communication (email writing), tips on resume development.	3

Annexure 2: Proposal for Advance Certificate Course in Clinical Research and Medical technologies.



Advance certificate course_College students

Questions

Responses

58

Student Registration Form

Please fill in below requested details. You will receive e-mail confirmation of registration after full payment of course fees as mentioned in fees section.

Name of Student (First name Middle Name Surname) *

Pallavi Balaji Suryawanshi

Email Id *

pallavisuryavanshi643@gmail.com

Name of College/Institute *

Dayanand collage of pharmacy Latur

Address for Correspondence *

At sarola, dist.Latur, TQ.Larhr





Advance certificate course_College students

Questions Responses **58**

Name of Student (First name Middle Name Surname) *

Nikhil balaji jadhav

Email Id *

nj6547513@gmail.com

Name of College/Institute *

Dayanand college of pharmacy,latur

Address for Correspondence *

Datta nagar rukmini niwas nilanga

Mobile Number (Preferably Whats-app) *

8087964810





Advance certificate course_College students

Questions

Responses

58

Student Registration Form

Please fill in below requested details. You will receive e-mail confirmation of registration after full payment of course fees as mentioned in fees section.

Name of Student (First name Middle Name Surname) *

Pradnya nitin sagar

Email Id *

pradnyasagar2001@gmail.com

Name of College/Institute *

Dayanand college of pharmacy ,latur

Address for Correspondence *

At.post.killari,tq:-ausa, dist:- latur



Rechallenge

- Indicates whether or not the adverse event reappeared upon reintroduction to the suspect drug
- **No-** The ADR did not reappear upon reintroduction of the suspect drug (Negative rechallenge)
- **Yes-** The ADR reappeared upon reintroduction to the suspect drug (Positive rechallenge)
- If dechallenge is unknown or Not applicable, by default, rechallenge is NA
- Rechallenge is N/A for overdose, drug exposure during pregnancy, medication error.

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← vbq-rifk-btp ▶



- Selecting qualified investigators...
- Providing information to investigator
- Contract / Agreement
- Duties and function allocation
- Clinical Trial Management
- Data Collection

Confidential

bharat kshirsagar

You Manishku... 29 others



Ingenious
Healthcare

CERTIFICATE

This certificate is presented to

_____ Mr. Nikhil Balaji Jadhav _____

for successful completion of

"Advance Certificate Course in Clinical Research, Pharmacovigilance,
Clinical Data Management and Medical Writing"

06/oct/2021

Date



Director,
Ingenious Healthcare

Reciene,
23/11/2021



Ingenious
Healthcare

CERTIFICATE

This certificate is presented to

_____ Ms. Pradnya Nitin Sagar _____

for successful completion of

"Advance Certificate Course in Clinical Research, Pharmacovigilance,
Clinical Data Management and Medical Writing"

06/oct/2021

Date



Director,
Ingenious Healthcare

Received

22 NOV. 2021.



Ingenious
Healthcare

CERTIFICATE

This certificate is presented to

Ms. Pallavi Balaji Suryawanshi

for successful completion of

**"Advance Certificate Course in Clinical Research, Pharmacovigilance,
Clinical Data Management and Medical Writing"**

06 / oct / 2021

Date



Director,
Ingenious Healthcare

Received

22-11-2021