

GUJARAT TECHNOLOGICAL UNIVERSITY
GRADUATE SCHOOL OF PHARMACY

offered

Certificate Course

in

**Good Manufacturing Practice (GMP) for Biological
Products**



Graduate School of Pharmacy, Gujarat Technological University,
K-6, Near Polytechnic campus, Gandhinagar -382028
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About GTU-GSP:

Gujarat Technological University is a State University established in year 2007 to harmonize the technical education and to bring technical institutes under a single university by our Visionary Prime Minister Shri Narendra Modi who had been a Chief Minister of Gujarat at the time. Gujarat Technological University-Graduate School of Pharmacy (GTU-GSP) was established in year 2017 with a vision to emerge as a globally recognized premier Pharmacy Institute in Teaching, Research, Innovations, Consultancy and Entrepreneurial Training in Pharmaceutical Sciences.

About this Course:

GTU-GSP is offering an opportunity to get certified in Good Manufacturing Practice (GMP) for Biological Products. This certification course is meant for experienced professionals who are already a part of any manufacturing setup and are aware of the GMP regulations applicable in their line of work. This is an advanced certification having rigorous case studies based methodology throughout the duration. To enable the participant, clear the qualifying exam for obtaining the certification, the institute will be offering proper training materials which will be provided without any extra cost.

Scope of the Course:

The development of new biopharmaceuticals and biotechnology products promises to bring about a revolution in global healthcare because of growing interest for these products. The manufacture and control of such products brings with it special concerns and challenges. This focuses on good manufacturing practices of biological products which assures product quality and patient safety.

Target Audience:

The case study based approach in certification programme is designed for working professionals in full time employment who want to update their knowledge and gain required skills and attitude in the area in order to become a certified professional in the domain. This certification is also beneficial for professionals from different streams to help them intensify their knowledge.

An advanced training having rigorous case studies based methodology will be imparted to all participants for preparing for the Certifying Examination. The training in GMP imparted by GTU-GSP is approved and certified by GTU, Government of Gujarat.

Course Structure:

Duration of Course	3 months
Total hrs	30
Course Credit (if applicable)	2

Course Content:

Module	Content	Hrs (Approx.)
1	Concept of Biologics	1
2	How do Drugs and Biologics Differ?	2
3	Manufacturing Process for Biologics	3
4	Introduction: Good Manufacturing Practices and its Regulations	4
5	GMP for Biological Products	3
6	GMP for Biological Products in US FDA Perspective	3
7	GMP for Biological Products in Indian Perspective	3
8	WHO GMP Guidelines for Biologics	2
9	Good Documentation Practices: Integral Part of GMP	3
10	Qualification and Validation	2

11	Quality Audits and Inspections	2
12	Handling Complaints and Recalls	2
Total Hours		30

Expected Course Outcomes:

After completion of course, the attendee shall be able to

CO1	Explain biological products, differentiate between drugs and biologics
CO2	Describe manufacturing process for biologics in accordance with GMP regulations
CO3	Describe & differentiate GMP for biologics in USFDA, Indian and WHO perspectives
CO4	Prepare documentation as per GMP requirement for qualification, validation, quality audits and inspections
CO5	Handle various complaints and recalls of the biologics

Eligibility:

Any Life sciences graduate/B Pharm/ M. Pharm, MSc in science disciplines/ any diploma /degree holders. Working professionals of any of the following industry types Drugs or Food manufacturing, Medical Device, Ayurveda, Pharmaceutical Industry Regulation, Clinical Research, Homeopathic or Ayurveda Medicine Manufacturing, Cosmetic Manufacturing, Biotechnology or any related industry are highly encouraged to apply for the certification.

Registration:

The registration dates for this certification run by the institute are updated timely on the webpage. Effective E-learning tools incorporated into the design of the webpage make the certification lectures, videos and study material easily accessible. This gives huge window of self-regulated and self-paced performance to the participants. After registration confirmation by the institute, required study resources, assessment test papers will be dispatched to the participants. This study

material is considered sufficient for the preparation of the certification exam. However, the participants should feel free to go through other study resources as well. The certification examination will be notified after 3 months of the registration.

Course Fee:

Rs. 10000/- for Indian nationals and 200 USD for overseas professionals. This covers the certification registration fee and examination fee.

Evaluation, Assessment & Certification:

All the participants are expected to appear for continuous online evaluation/assessment. After successful completion the participants will be certified in GMP for Biological Products by GTU. For all the above mentioned elaborate study resources, Assessment test papers and case studies would be provided by the Institute from time to time. Details get updated on the webpage as well. The certification will be awarded after the required levels of knowledge, skills, professionalism and attitude are assessed through the GTU assessment process.

Re- Examination:

In case the participant is not able to pass the certification exam in first attempt/exam notification, he/she will have to re- register for the next scheduled examination by submitting re- registration form along with the re- registration fee of Rs. 1500/- (50 USD). However, the participants will be given sufficient flexibility in scheduling their “First” certification exam.

Course Deliverables:

A comprehensive study material for all the modules in hard copies ensuring the needs of the audience. The accompanying training material is appropriately aligned with the current Industry’s expectations.

- ✓ Assignments for all the course modules for continuous evaluation and guidance.
- ✓ Interactive or online live sessions on all key areas of the course giving all flexibility to the participants.
- ✓ Online classes for all the modules will be conducted on the weekends. Moreover, a doubt clearing session will also be scheduled before the examination.
- ✓ All the efforts are made by GTU-GSP faculty members to make the entire course modules easily understandable.
- ✓ Assessment and evaluation for all the course modules in order to enhance the levels of competencies and skills of the participants leading towards the objective of application in the job.
- ✓ At the end of each course modules, the trainers shall obtain feedback from the participants using specially designed questionnaires.
- ✓ All learning and training delivery initiatives shall be conducted in English.

Placement Assistance & Corporate Relations:

The Institute has partnered with many organizations for providing with placement assistance to its participants. Besides, GTU has a robust Industry Institute Interaction Cell (IIIC) comprised of senior level Human Resources professionals and Talent Acquisition experts which maintains close links with business and industry. This cell is continuously engaged in promoting the employability of our participants and encouraging the concerned Human Resources department and Hiring Managers to recruit/hire our participants for their vacant positions. The efforts of our placement cell also include helping with professional resume writing & interview skills.

In recent months the Institute has witnessed more and more participation from professionals working with global pharmaceutical, healthcare and food giants like Dr. Reddy's Laboratories, Aurobindo Pharma, Glenmark Generics, Cipla,

Wockhardt, Pfizer, Abbott, Medtronic, IPCA Laboratories, Mother Dairy, Sun Pharmaceutical, Novartis, GlaxoSmithKline, Ranbaxy , Biocon etc.

The GTU's Industry Institute Interaction Cell (IIIC) actively recommends our students and training participants for various job requirements and specialized roles to Human Resource, Talent Acquisition as well as the heads of various departments in Pharmaceutical, Healthcare and Food industries on regular basis.