



AMITY
UNIVERSITY
— PUNJAB —

6 Months Certificate Program

**ASSOCIATE-REGULATORY AFFAIRS
AND INTELLECTUAL PROPERTY**

Medical Devices

Offered By

Department of Pharmaceuticals
Ministry of Chemical and Fertilizers
Government of India





For Industry Roles in Medical Device manufacturing, Quality Control, and regulatory Document submissions and compliance for approvals, as Assistant, Officer, Executive and higher roles.

Medical devices are broadly defined as instruments, apparatus, appliances, implants, materials, or other articles, whether used alone or in combination, including software, intended for use on humans or animals for specific medical purposes, that don achieve their primary intended action through pharmacological, immunological, or metabolic means. These devices are used for the diagnosis, prevention, monitoring, treatment, or alleviation of diseases or injuries.

The manufacturers have to appropriately submit regulatory documentation to appropriately justify the Safety and efficacy of these devices before the Central Drugs Standardization and Control Authority approve them for human use. This involves Regulatory knowledge and information.

Eligibility:

- B.Tech (Final Year Students can also enrol)
- B. Pharm (Final year students can also enrol)
- M.Sc (with relevant Subjects in Bio Sciences, Medical Sciences, Chem Sciences) (Final Year Student)
- Working Professionals in Pharmaceutical, Medical devices and Life sciences industry with above Qualifications
- **Intake: 30**

Details of Program:

This program is as per HRD Scheme for Medical Devices Sector by Department of Pharmaceuticals, which has established a Policy (Medical Devices) Division under Department of Pharmaceuticals and is responsible for:

1. Implementation of National Medical Device Policy 2023 & Strategy Document on National Medical Devices Policy, 2023.
2. Industry issues relating to the MediTech sector, manufacture of medical devices and allied subjects, except trade and pricing.

Life Sciences Sector Skill Development Council



Life Sciences Sector Skill Development Council (LSSSDC) is appointed by Department of Pharmaceuticals, as the authorized Project Management Agency (PMA) for the Human Resource Development Scheme in Medical Device Sector of the Department of Pharmaceuticals (DoP) to act on its behalf for Awareness & Outreach, Receipt and Appraisal of Applications, Verifications of Eligibility, Examination and Processing of Disbursement Claims.

Associate- Regulatory Affairs and Intellectual Property (IVD and Medical Devices)

QP Code: LFS/Q0513 QP Version: 1.0 NSQF Level: 5 Model Curriculum Version: 1.0



Training Outcomes

At the end of the program, the learner should have acquired the listed knowledge and skills.

- Discuss performance of Associate- Regulatory Affairs and Intellectual Property (IVD and Medical Devices) in compliance with Good Manufacturing Practices (GMP) and other environmental regulatory guidelines. Development, Submission & management of Technical Dossier as per the regulatory guidelines of intended market (India and Global) for medical devices and In- vitro Diagnostic Devices (IVD) NOS Version No. 1 NSQF Level-5.
- Understand fundamentals of the manufacturing process and its various components, manage production activities across the product line in a life science manufacturing facility, maintain a healthy, safe and secure working environment in the production and GMP controlled area, coordinate with supervisor, colleagues and respond to audit queries during GMP/regulatory audits.

Registration Form: The registration for the Program has to be done through the attached link.
<https://forms.gle/ndMrF2vXsFEu1WAV7>

Important Dates :

Last Date for registration : 15th September 2025
Start Date : 1st October 2025
End Date : 31st March 2026

Fees Details :

Fees: Rs 11800/-
By Cheque/online in favour of **Amity University Punjab CBSD**
FSC Code: MAHB 0002015
Account no. 60529927652 (Bank of Maharashtra)

Mode of Conduct:

The program will be conducted as Theory and Practical Sessions as 20-22 sessions weekly mode and cover 660 hours in the 6 months duration, leading to further internships in relevant areas. The program will be conducted by faculty certified by LSSSDC and will be from Academic and Industry backgrounds.

Contact Information:

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