



DSIR - CRTDH - NIPER SAS NAGAR

Common Research and Technology Development Hub (CRTDH)



5-DAYS TRAINING PROGRAMME FOR MSMEs

on EMPOWERING MSMEs: A PRACTICAL TRAINING ON GMP COMPLIANCE & QUALITY ASSURANCE IN PHARMA

Dates: 21st to 25th July 2025

Venue: NIPER SAS Nagar (Mohali)

Target Audience: Professionals from MSME Pharma Sector.

Key Topics:

Good Manufacturing Practices (GMP) – Overview & Implementation, Regulatory Guidelines & Documentation, Quality Assurance – Principles & Practices, Risk Management & Internal Audits, Case Studies & Industry Interaction.

Benefits of Participation:

Certificate of Completion, Expert Trainers & Practical Insights, Networking with Industry Peers, Exposure to NIPER Facilities & Infrastructure.



Organized by
CRTDH NIPER SAS NAGAR
Sector 67, Mohali
S.A.S. Nagar, Punjab



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COURSE INTRODUCTION

The pharmaceutical sector, especially within MSMEs, plays a pivotal role in ensuring access to quality medicines. However, these enterprises often face challenges in consistently meeting regulatory expectations and global quality standards due to limited resources and technical capabilities. To address these challenges, this 5-day intensive training program has been designed with a special focus on strengthening core competencies in Good Manufacturing Practices (GMP) and Quality Assurance (QA). The program is being conducted at NIPER SAS Nagar under Common Research and Technology Development Hub (CRTDH) scheme, which is a national initiative led by DSIR to support MSMEs. Through expert-led lectures, demonstrations, and hands-on sessions, this program aims to empower professionals with practical knowledge and regulatory insights essential for building a robust quality system in MSME pharmaceutical manufacturing.

COURSE OBJECTIVES / OUTCOMES

Upon successful completion of this training program, participants will be able to:

- ✓ Understand the current GMP regulatory frameworks including Revised Schedule M and their relevance to MSMEs
- ✓ Implement Good Documentation Practices (GDP) and ALCOA+ principles to ensure data integrity compliance
- ✓ Structure, prepare, and manage Standard Operating Procedures (SOPs) effectively
- ✓ Grasp the functional and compliance aspects of HVAC systems and their critical role in clean room control
- ✓ Apply effective change control, deviation, and incident management practices
- ✓ Navigate the investigation processes for OOS/OOT and market complaints, and plan for recalls
- ✓ Understand the process of equipment qualification and end-to-end validation
- ✓ Prepare for internal audits and external GMP inspections with confidence



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