



**Pharmacovigilance Sensitization Training, Awareness and Exposure
Program on Pharmacovigilance
for Teaching Faculty Members and Pharmacovigilance Cell Committee
Members
(As per Criterion 10 of QCI-NABET)**

MAPPING OF EVENT WITH QCI-NABET CRITERION 10
(Vigilance, Safety, Risk Management & Continuous Sensitization)

QCI-NABET CRITERION 10: OVERVIEW

Criterion 10 emphasizes:

Institutional vigilance systems
Safety culture among faculty and staff
Risk identification, reporting, and corrective mechanisms
Continuous sensitization and training
Documentation, monitoring, and improvement
The Pharmacovigilance Sensitization Training, Awareness and Exposure Program on Pharmacovigilance directly fulfills multiple sub-components of Criterion 10, as mapped below.

CRITERION 10.1 – Vigilance Mechanism and Safety Culture Requirement

Institution should have a structured vigilance mechanism
Faculty and staff should be sensitized towards safety, vigilance, and compliance
Mapping with the Program

✓ The program sensitized teaching faculty, staff, and Pharmacovigilance Cell members regarding:

Vigilance in Ayurvedic drug usage
Patient safety
Institutional accountability

✓ Expert guidance by a QCI-NABET assessor and NCISM visitor strengthened understanding of:
Safety culture
Risk prevention
Institutional responsibility

Evidence To be Generated:

Event report
Attendance sheets
Expert lecture content
Committee participation records

CRITERION 10.2 – Risk Identification and Preventive Measures Requirement

Identification of potential risks
Preventive and corrective measures
Proactive approach to quality and safety
Mapping with the Program

- ✓ The lecture covered:
Adverse Drug Reaction (ADR) identification
Risks related to Rasashastra and Bhaishajya Kalpana formulations
Clinical and academic risk points

- ✓ Faculty members were trained to:
Identify early warning signs
Follow preventive SOPs
Ensure safe academic and clinical practices

Evidence To be Generated:

Proceedings documentation
SOP awareness
Interaction and discussion records

CRITERION 10.3 – Reporting, Documentation and Corrective Action Requirement

Proper reporting systems
Documentation of incidents and actions
Corrective and preventive action (CAPA)
Mapping with the Program

- ✓ Detailed explanation was provided on:
ADR reporting formats
Documentation timelines
Role of Pharmacovigilance Cell

- ✓ Faculty and committee members were oriented towards:
Record maintenance
Compliance-oriented documentation
Inspection-ready evidence preparation

Evidence To be Generated:

Training records
Committee sensitization details
Documentation awareness

CRITERION 10.4 – Sensitization and Capacity Building of Staff Requirement

Regular training programs
Continuous sensitization of faculty and staff
Mapping with the Program

- ✓ The event itself is a capacity-building and sensitization initiative:
Focused on teachers, staff, and committee members
Conducted by a nationally recognized expert

- ✓ Supports institutional commitment to:
Continuous professional development
Quality improvement initiatives

Evidence To be Generated:

- Attendance sheets
- Program schedule
- Event report
- Faculty participation

CRITERION 10.5 – Monitoring, Review and Continuous Improvement Requirement

- Periodic review of vigilance mechanisms
- Continuous improvement practices
- Mapping with the Program

- ✓ The session emphasized:
Internal audits
- Review of vigilance activities
- Improvement based on inspection observations

- ✓ Future scope and recommendations were defined for:
Regular training
- System strengthening
- Institutional preparedness

Evidence To be Generated:

- Event outcomes
- Future action plan
- Management review inputs

CRITERION 10.6 – Leadership Involvement and Institutional Commitment Requirement

- Active involvement of institutional leadership
- Policy-level commitment to safety and vigilance
- Mapping with the Program

- ✓ The program was:
Organized at institutional level
- Approved by the Principal
- Integrated with quality and accreditation goals

- ✓ Demonstrates:
Leadership commitment
- Strategic alignment with QCI-NABET

Evidence To be Generated:

- Approval records
- Principal's endorsement
- Official reports

Session Photography

