



INDUSTRY INTEGRATED EXPERIENTIAL TRAINING PROGRAM IN DRUG REGULATORY AFFAIRS

Organized by
NIPER Raebareli

in collaboration with **Roche Products (India) Pvt. Ltd.**



Duration: 36 hours



Sept - Nov, 2026



3 hours/week



Fee: ₹12,000

**Eligible
Participants**



Students/Research scholars



Faculty members



Aspiring learners



Professionals from industry

MODULES

MODULE 1



**Fundamental of
Regulatory Affairs**

- Global regulatory landscape
- Regulatory intelligence, and role of patents in business strategy
- Accelerated approval pathways
- Regulatory Reliance models

MODULE 2



**Regulatory Dossier &
Approval Process**

- CTD, eCTD, ACTD and Indian framework
- Regulatory strategy for generics and biosimilars
- Clinical study reports, trial designs, ethics committee
- Medical device regulation in India, US and EU

MODULE 3



**Regulatory Lifecycle
Management**

- Pharmacovigilance in India and US, EU
- Postmarketing surveillance
- Post approval CMC changes
- Role of AI in regulatory decision making

1. Scan the Payment QR
2. Payment category: Select Conference seminar symposium and short term course
3. Fill the applicant details
4. Make payment
5. Scan the Register QR for filling the registration form

Mode: Online (on weekends; 6 PM onwards)

Contact: **7567503983 (Prof. Sanjay Tiwari)**
Email: **etp.dra2026@gmail.com**

Application deadline: September 11, 2026

★ Highlights



**Certificate from NIPER
Raebareli**



**Learn from Industry Experts &
Health Authorities**



Case study driven sessions



Career ready skills



Make Payment



**Registration
form**