NIPER RAEBARELI

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

Make Payment

Registration form

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