ULTRA BIO INSTRUMENTS

PHARMA SERVICES

www.ultrabio.org

Ultra Bio Instruments is your trusted partner for impurity assessment, risk evaluation and regulatory compliance solutions tailored to global standards that help pharmaceutical organizations ensure product quality and safety. Our expert team combines scientific depth, advanced computational tools and extensive regulatory experience to deliver credible solutions for regulatory submission.

SCIENTIFIC AND REGULATORY CONSULTANCY

Mutagenicity Assessment of Impurities (ICH M7)

- ***Hazard assessment and classification using validated (Q)SAR software***
  - Statistical-Based Models
  - Expert Rule-Based Models
- ***Scientific justification reports and regulatory documentation for global submissions.***

Nitrosamine Risk Assessment & Safety Evaluation

- ***End-to-end risk evaluation and mitigation strategies.***
- ***Advanced computational (quantum mechanics) approach for higher Acceptable Intake (limit) of nitrosamines.***

Extractables & Leachable Qualification (ICH Q3E)

- ***Study design and qualification of packaging materials.***
- ***Risk-based evaluation aligned with regulatory expectations.***

Elemental Impurities Assessment (ICH Q3D)

- ***Acceptable daily intake assessment and limit setting.***
- ***Data interpretation and submission-ready documentation.***

Qualification of Non-Mutagenic Impurity

- ***Biological safety evaluation of the impurity or degradation product above qualification level.***
- ***Integrated toxicological assessment as recommended by the EMA Reflection Paper***

Control Strategy for Genotoxic and Nitrosamine Impurities

- ***Scientifically designed Control Strategy based on purge assessment for Genotoxic & Nitrosamine impurities .***
- ***In line with the requirement of ICH M7***

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PHARMA CONSULTANCY

Validated Tools & Recognized Methodologies

- ***We use internationally recognized (Q)SAR and computational tools validated under ICH M7.***

- ***All platforms are recognized by FDA and EMA, ensuring high credibility and acceptance of scientific evaluations.***

Trusted by Industry Leaders

- **Regulatory-compliant & validated methodologies**
- **Experienced team with proven domain expertise**
- **Quick turnaround & quality-assured deliverables**
- **Competitive pricing and scalable service models**
- **Strong relationships with leading pharma clients**

Partnership

- **Collaborate with a team that blends scientific excellence with regulatory precision.**
- **Our consulting services ensure compliance, minimize risk, and accelerate your product development journey**

Request a Consultation

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PHARMA TRAINING PROGRAMS

Advance Your Scientific and Regulatory Competence - Empowering pharma professionals through expert-led training on ICH guidelines, impurity assessment, nitrosamine control and regulatory compliance.

Ultra Bio Instruments offers specialized training programs that equip professionals with the skills and regulatory insight required to meet evolving global standards. Our modules are curated by domain experts with deep experience in impurity control, regulatory strategy and analytical sciences. Each program combines scientific theory with real-world application — ensuring knowledge that is both compliant and practical.

Customized Training Sessions by Subject Matter Experts

Mutagenic Impurities and ICH M7 requirements

- ***Understanding impurity classification, (Q)SAR analysis, and acceptable limit determination.***
- ***Regulatory updates and current challenges.***

Nitrosamine impurities in API and dosage forms

- ***Identification, evaluation, and mitigation aligned with latest global guidance***
- ***Safety evaluation and toxicity assessment***
- ***Documentation for regulatory submission***

Extractables & Leachable Qualification (ICH Q3E)

- ***Regulatory requirements and scientific context.***
- ***Guidance on experimental design, data interpretation***
- ***Analytical techniques used for E&L studies***

Elemental Impurities Assessment (ICH Q3D)

- ***Identification, risk assessment, and control of impurities as per ICH guidelines***
- ***Understanding permitted daily exposure (PDE) values***

Forced degradation Studies

- ***Comprehensive forced degradation studies for API and dosage forms.***
- ***Degradation characterization. Analytical strategies***

Excipient Qualification

- ***Methods for qualifying specific levels of excipients in drug products***
- ***Technical standards needed to approve and manage excipient suppliers.***

PHARMA TRAINING PROGRAMS

Training Format

Flexible, Practical & Impact Oriented

- Customizable Programs – Designed for organization-specific needs and product categories.
- Flexible Delivery – Available as classroom sessions, virtual training, or blended modules.
- Real-World Case Studies – Focused on practical learning through regulatory examples.
- Certification of Completion – Formal acknowledgment of participant competence.

Who should Attend

Ideal for Professionals across Key functions

- Quality Assurance (QA)
- Quality Control (QC)
- Regulatory Affairs
- R&D (Synthesis and Formulations)
- Analytical Development
- Operations

Hydrochloric acid 35%

Why Choose Us

- Experienced scientific and regulatory professionals
- Curriculum aligned with ICH, FDA, EMA expectations
- Hands-on learning with proven implementation insights
- Trusted partner for global pharmaceutical organizations

Request a Tailored Training Program

We customize training to align with your organization's needs, regulatory priorities, and product portfolio.

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