Your Partner in

GxP Compliance & Digital Transformation

forvis mazars

Compliance, Simplified for Pharma Tech

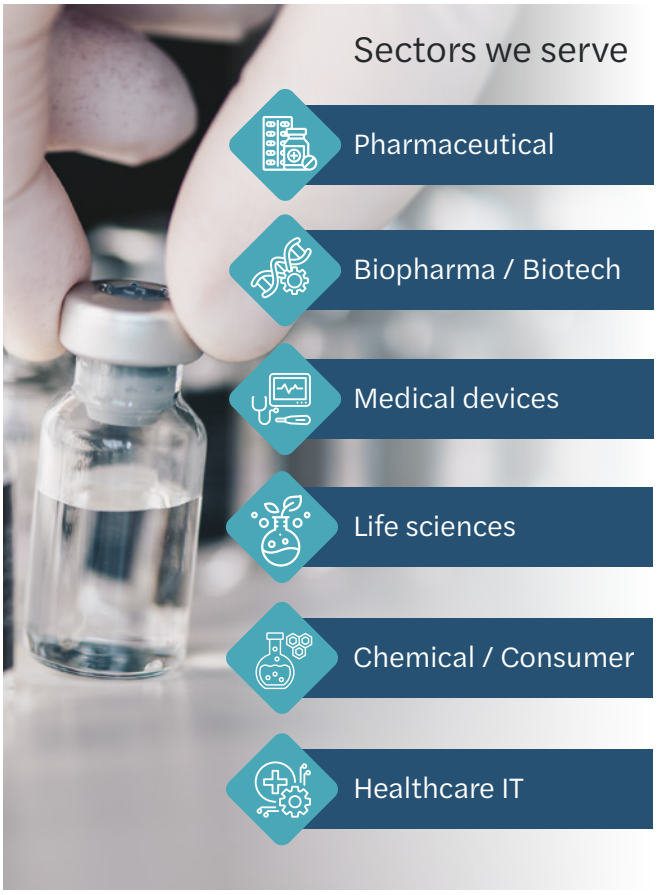
- Computer system validation
- Data integrity
- Quality management
- Regulatory compliance
- Emerging technology validation

100+
Years combined pharma expertise

8+
Avg. years team experience

25+
CSV / IT projects delivered

4
Global corridors
- APAC
- MENA
- EU
- Africa



PMP · ISO 9001 · Six Sigma Green Belt · US FDA · EU EMA · UK MHRA · PMDA · WHO · DCGI · NPCB

Integrated life sciences service offerings

End-to-end GxP compliance, validation and digital transformation

Computer System Validation (CSV/CSA)
- GAMP 5 Rev 2 / CSA frameworks
- ERP, LIMS, DCS, MES, QMS, Cloud & SaaS
- IQ / OQ / PQ protocol execution
- Validation master plans & SOPs
- Risk-based right-sized approach

Equipment & facility validation
- CQV & equipment qualification (DQ/IQ/OQ/PQ)
- GMP facility design & commissioning (FAT/SAT)
- Cleaning validation per Annex 15
- Decommissioning & technology transfer
- Aseptic process & media fill support

Digital & Emerging Tech Validation
- Cloud / SaaS: FDA CSA 2022 guidance
- AI/ML model validation & drift monitoring
- RPA / intelligent automation GxP compliance
- IoT & connected devices (IEC 62443)
- Paperless validation & zero human-intervention

Quality Management Systems (QMS)
- QMS design & implementation (ISO 13485)
- CAPA, deviation & change control
- Supplier qualification programs
- Continuous improvement (Lean / Six Sigma)
- eQMS platform selection & validation

Regulatory affairs & compliance
- FDA 21 CFR Part 11 remediation
- EU Annex 11 gap assessments
- Data integrity audits (ALCOA+)
- Mock FDA / EMA inspections
- CAPA management programs

Pharmacovigilance & safety tech
- ADR reporting & safety database management
- Signal detection & risk-benefit analysis
- ICH E2B(R3) & 21 CFR Part 11 compliance
- Oracle Argus, Veeva Vault Safety, ArisGlobal
- AI/NLP automation in PV workflows

Why choose Forvis Mazars?

Senior-Led Expertise · Risk-Right Delivery · Global Regulatory Reach

Risk-Right Validation Approach

Risk-based, right-sized methodology — every deliverable calibrated to regulatory environment, system criticality and business risk. No over-engineering, no shortcuts.

AI-Augmented Delivery

RPA, LLM-assisted gap analysis and intelligent document review reduce validation timelines by up to 40% without compromising quality or regulatory defensibility.

True Global Regulatory Presence

Hands-on experience across US FDA, EU EMA, UK MHRA, PMDA, WHO and DCGI environments — with in-country teams and multilingual delivery capabilities.

Senior-Led, Every Engagement

8+ years average experience per consultant. Direct audit backgrounds in FDA/PMDA/MHRA. PMP, ISO 9001 and Six Sigma Green Belt credentials across the team.

Our Delivery Methodology

01 Assess
Gap analysis, risk classification, regulatory landscape review

02 Plan
Validation strategy, right-sized documentation framework

03 Execute
Protocol authoring, testing, e-records & signatures

04 Report
Summary reports, submission-ready regulatory packages

05 Sustain
Periodic reviews, change control, ongoing compliance monitoring

Technology Platforms

We work across leading validated platforms and enterprise systems

Quality & Validation

- Veeva Vault QMS
- MasterControl
- OpenText Documentum
- Pilgrim SmartSolve

Enterprise & Cloud

- SAP S/4HANA
- Microsoft Azure
- AWS GovCloud
- Salesforce Life Sciences

AI & Automation

- UiPath RPA
- Power Automate
- LLM Audit Assist
- Oracle Argus / ArisGlobal

Trusted by global pharma, biotech and healthcare leaders to navigate complex regulatory environments with speed, precision and confidence.

Client case studies

Proven outcomes across global pharma, biotech and healthcare clients

1. Global Pharma Innovator — CSV / GxP Validation

Challenge	No standardized PoC validation framework; ERP, GxP & non-GxP systems across multiple countries lacked governance.
Solution	End-to-end CSV assessments; risk-based classification; PoC validation decision framework; re-validation lifecycle governance.

- Standardized validation approach
- Strengthened audit readiness
- Enhanced data integrity
- Reduced regulatory risk

2. Top-5 Global Pharma MNC (150+ Countries) — IT Compliance / CSV

Challenge	Complex GxP/non-GxP system landscape; ineffective change, incident & CAPA management; growing audit expectations.
Solution	Validated IT infrastructure, manufacturing & cloud/SaaS applications; SOP management; audit readiness support.

- End-to-end GxP compliance
- Improved system stability via RCA/CAPA
- Streamlined change & incident management

3. Global Dialysis & Renal Care Leader — Document & Change Management

Challenge	Fragmented controls across global subsidiaries; version control gaps; OS patch compliance risks.
Solution	Version control SOP; standardized change format for PRD patches; optimized client-server validation approach.

- Standardized version control
- Controlled patch management
- Strong internal control
- Reduced compliance

4. Plant-Based Pharma Excipient Manufacturer — Data Migration / CSA

Challenge	Migration from legacy DMS to Veeva RIMS; shift from CSV to CSA; limited visibility into control effectiveness.
Solution	CSA-based validation per technical assessment; structured migration strategy; standardized CSA framework.

- Risk-based compliant migration
- Strong data integrity controls
- Improved rollback planning
- Regulatory alignment

5. Leading Pharma CMO (Multi-site GMP) — Quality System Periodic Review

Challenge	Maintaining validated state during frequent system changes; ensuring access reviews and reliable backup/recovery.
Solution	Change control & periodic validation reviews; role-based access audits; automated backup & audit trail monitoring.

- Continuous compliance
- Enhanced data protection
- Better traceability
- Stronger policy adherence

6. WHO-GMP Compliant Generic Pharma — ERP Compliance Assessment

Challenge	Multi-module ERP with dynamic workflows; traceability & version control gaps increasing audit risk.
Solution	Standardized templates; controlled releases; structured test management; end-to-end integration validation.

- Consistent validation across modules
- Stronger GxP compliance
- Improved traceability
- Reliable audit trails

Value propositions

Our global, multidisciplinary, and culturally aligned teams provide strategic guidance, uncover facts, and offer comprehensive solutions to allegations of fraud or unfair business practices. Our clients benefit from our responsiveness, quality of execution, deep subject-matter expertise, industry knowledge, and tailored solutions based on each individual scenario.

Our goal is to help our clients make informed, fact-based decisions and take specific actions that minimise losses, disruptions, fraud risk, and exposure while maximising savings and efficiencies. We help organisations to strengthen fraud controls in a practical and cost-efficient manner to minimise the likelihood of future fraud.

Forvis Mazars in India- Built for forward

About us

Forvis Mazars in India is a leading global professional services network. Uniquely formed of just two members, it is designed to be agile, to deliver consistency and with the global scale to meet clients' needs.

- Two members operating under a single brand - Forvis Mazars Group SC, an internationally integrated partnership operating in over 100 countries and territories, and Forvis Mazars LLP in the United States.
- Committed to providing an unmatched client experience, delivering Audit and Assurance, Tax, Advisory, and Consulting services around the world.
- Our strategic mission is to move our clients, people, industry, and communities forward.

Our global strength

100+
Countries and territories

1,800+
Partners worldwide

40,000+
Professionals to serve clients around the world

Our local strength

11
Offices

55+
Partners

1500+
Professionals

Contacts

Rajan Arora
Partner and leader
Digital, Trust and Transformation, Forvis Mazars in India
rajan.arora@mazars.co.in

Pooja Gupta
Associate Director
Digital, Trust and Transformation, Forvis Mazars in India
pooja.gupta1@mazars.co.in

Forvis Mazars Global Limited is a leading global professional services network. The network operates under a single brand worldwide, with just two members: Forvis Mazars, LLP in the United States and Forvis Mazars Group SC, an internationally integrated partnership operating in over 100 countries and territories. Both member firms share a commitment to providing an unmatched client experience, delivering audit & assurance, tax, advisory and consulting services around the world. Together, our strategic vision strives to move our clients, people, industry and communities forward.

In India, we have an ambitious growth plan and already has a national presence with a strong team of over 1,700 professionals with 11 offices located in Ahmedabad, Bengaluru, Chandigarh, Chennai, Delhi, Gurugram, Hyderabad, Jaipur, Kolkata, Mumbai, Pune. Our professionals have in-depth experience in sectors like Energy, Telecom, BFSI, Automobiles, Technology, Real Estate, Shipping, Services, Manufacturing and Retail.

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