Piramal Pharma Limited

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Piramal Pharma Limited
FAQs

A Reference Guide for Current and Prospective Suppliers Across Piramal Pharma Solutions (PPS), Piramal Critical Care (PCC), and Piramal Consumer Healthcare (PCH)

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1. About This Document

This FAQ provides answers to common questions from current and prospective suppliers across the Piramal Pharma group, covering Piramal Pharma Solutions (PPS), Piramal Critical Care (PCC), and Piramal Consumer Healthcare (PCH).

This FAQ is intended for general guidance only. Supplier qualification, documentation requirements, audits, assessments, timelines, and contractual obligations may vary by business unit, material or service category, regulatory market, risk profile, and applicable contractual terms. In case of any inconsistency, the relevant contract, quality agreement, policy, or applicable law shall prevail.

2. Supplier Onboarding & Registration

Q. How do I become a Piramal supplier?

A. Register your interest through our Supplier Expression of Interest portal. Your profile is reviewed by the relevant business unit (PPS, PCC, or PCH) based on your offering. Shortlisted suppliers are invited for qualification, which may include a self-assessment questionnaire, technical evaluation, and an on-site or virtual audit.

Q. How long does supplier qualification take?

A. Timelines depend on the category, risk profile, documentation readiness, applicable regulatory requirements, audit outcomes, and business requirements. Direct or critical material suppliers may generally require longer qualification timelines than indirect or service suppliers. PPS may apply additional CDMO-specific requirements where applicable. Actual timelines may vary on a case-by-case basis.

Q. Will I be required to sign any documents during onboarding?

A. Yes. All suppliers must acknowledge the Piramal Pharma Supplier Code of Conduct and confirm compliance with the Sustainable Procurement Policy. Category-specific Quality and Technical Agreements may also apply.

3. Quality in Piramal

Q. What quality systems are mandatory for our suppliers?

A. Suppliers must operate a robust Quality Management System (QMS) covering deviation management, change control, CAPA, OOS, customer complaints, returns, and recalls.

Q. Are unannounced audits possible?

A. Yes, where applicable and subject to contractual terms, quality agreements, and applicable laws. Piramal may conduct scheduled, for-cause, third-party, or unannounced audits based on supplier criticality, risk profile, regulatory requirements, or business need. Audits may also be requested or conducted by customers or regulatory authorities, where applicable.

Q. What happens if a non-conformance is identified during an audit?

A. We collaborate with the supplier to develop a CAPA with clear timelines. Closure of CAPA is tracked, and unresolved or repeated non-conformances may be considered during supplier performance review, qualification status review, or future sourcing decisions, subject to applicable contractual terms and internal governance processes.

Q. Are process or material changes allowed once a supplier is qualified?

A. Any change to materials, processes, equipment, manufacturing site, sub-tier suppliers, or analytical methods must be notified to Piramal in advance through a formal change-notification process. Implementation may require prior written approval from Piramal, following impact assessment and in accordance with applicable quality agreements, regulatory requirements, and contractual terms.

Q. Which records are suppliers required to retain?

A. Complete batch records, raw material traceability, analytical data, stability data, validation records, training records, and change-control documentation. Records must be retained in accordance with applicable regulations, quality agreements, and contractual terms. Retention periods may vary depending on product category, market requirements, and regulatory obligations.

4. Regulatory Affairs

Q. What regulatory documentation may suppliers be required to submit?

A. Depending on the material, service category, business unit, and end-market requirements, suppliers may be required to provide Certificates of Analysis (CoAs), relevant declarations such as TSE/BSE, allergens, nitrosamines, elemental impurities and residual solvents, Safety Data Sheets, regulatory filings or DMF/CEP references, and product-specific certifications applicable to the markets served.

Q. Are all suppliers expected to be USFDA or EDQM compliant?

A. Not necessarily. Regulatory expectations are aligned to category and end market. PPS and PCC suppliers of regulated APIs, intermediates, excipients, or other critical materials may be expected to demonstrate appropriate regulatory compliance, certifications, approvals, or inspection history such as USFDA, EDQM, PMDA, or equivalent, depending on the product, market, and applicable regulatory pathway. PCH packaging or nutraceutical suppliers may have different applicable standards (e.g., BRCGS, FSSC 22000).

Q. What about statutory regulatory fee payments?

A. Suppliers are expected to comply with applicable statutory and regulatory fee obligations, such as DMF, CEP, and plant registration fees, where relevant. Delays that affect Piramal's product registrations, approvals, or supply continuity may be reviewed as part of supplier performance and risk management processes.

Q. How should suppliers handle regulatory alerts, recalls, or safety concerns?

A. Suppliers are expected to notify Piramal promptly of any regulatory action, recall, safety concern, warning letter, import alert, suspension, or significant compliance issue that may affect supplied materials, services, quality, regulatory filings, or supply continuity.

5. Sustainability & ESG

Q. What are Piramal's sustainability commitments?

A. Piramal is committed to advancing sustainability across its operations and value chain, including efforts related to greenhouse gas emissions, responsible sourcing, supplier engagement, and ESG performance. Our sustainability disclosures and initiatives are guided by applicable reporting requirements and recognised frameworks such as GRI, BRSR, EcoVadis, CDP, S&P Global, and other relevant standards, as applicable.

Q. What is expected from suppliers on sustainability?

A. Suppliers are expected to measure and disclose greenhouse gas emissions, adopt science-based targets where possible, comply with Piramal Pharma Supplier Code of Conduct and Sustainable Procurement Policy, and participate in our ESG assessment program.

Q. Does Piramal accept third-party sustainability assessments?

A. Yes. To reduce duplication and audit fatigue, Piramal may consider relevant third-party assessments such as EcoVadis, PSCI, Sedex/SMETA, CDP, S&P CSA, SA8000, or similar assessments, where appropriate. Acceptance or reliance on such assessments will depend on scope, validity, recency, and relevance to Piramal's requirements.

Q. Does Piramal comply with modern slavery regulations?

A. Piramal is committed to respecting human rights and addressing risks related to forced labour and child labour across its value chain. Where applicable, Piramal complies with relevant modern slavery and supply chain transparency requirements, including disclosure obligations in jurisdictions where we operate. Suppliers are expected to support due diligence, risk assessment, and disclosure processes as required.

6. Supplier Audits & Assessments

Q. What types of audits and assessments does Piramal conduct?

A. We use a mix of Self-Assessment Questionnaires (SAQs), on-site audits, PSCI assessments, and for-cause audits. Audit frequency is risk-based and may vary depending on supplier criticality, category, prior performance, regulatory requirements, and business needs.

Q. How is audit frequency determined?

A. Audit cadence depends on supplier criticality, prior performance, risk classification, and category. High-risk and critical suppliers are audited more frequently.

Q. Can audits be conducted virtually?

A. Yes, particularly for low-risk suppliers or follow-up audits. We may also use hybrid or fully virtual audits depending on context.

7. Risk & Business Continuity

Q. What does Piramal expect from suppliers in terms of business continuity?

A. Critical suppliers are expected to maintain documented and tested Business Continuity Plans (BCPs) addressing operational, geopolitical, environmental, climate-related, and cyber risks.

Q. What are Piramal's expectations on dual sourcing and contingency planning?

A. Piramal encourages suppliers to strengthen resilience within their own supply networks and collaborate with us on contingency planning, alternate source development, and risk mitigation where relevant.

Q. What happens during a supply disruption?

A. Suppliers are expected to notify Piramal promptly of any actual or potential supply disruption and collaborate on mitigation actions, which may include alternate sourcing, expedited logistics, inventory planning, and transparent communication on recovery timelines.

Q. How does Piramal manage counterfeit and product-integrity risks?

A. Suppliers are expected to implement appropriate product-integrity and anti-counterfeit controls based on the nature of the material or service supplied. These may include secure packaging, tamper-evident features, traceable labelling, and supply chain traceability. Any suspected counterfeit, diversion, or product-integrity concern should be reported promptly.

8. Ethics, Compliance & Grievance

Q. What ethical standards must suppliers comply with?

A. All suppliers must adhere to the Piramal Pharma Supplier Code of Conduct, covering anti-bribery and anti-corruption (ABAC), human rights, fair labour practices, conflict of interest, data privacy, environmental responsibility, and responsible sourcing of minerals.

Q. How should I raise a concern or report a violation?

A. Concerns may be raised through the appropriate Piramal reporting channels, including the designated ethics, compliance, grievance, or whistleblower mechanism, where available, or through the relevant Piramal SPOC. Piramal does not tolerate retaliation against good-faith reporting.

Q. Does Piramal require its suppliers to complete ethics training?

A. Where applicable, yes. Suppliers may be required to complete ethics, ABAC, or compliance training as part of qualification or contractual obligations.

Detailed ethics, ABAC, human rights, and modern slavery expectations are set out in the Piramal Pharma Supplier Code of Conduct.

9. Supplier Development & Capability Building

Q. What types of workshops does Piramal organise for suppliers?

A. We conduct workshops on quality systems, regulatory compliance, sustainability and carbon reporting, digital procurement tools, and continuous improvement methodologies.

Q. How can suppliers participate in these workshops?

A. Invitations are shared via email. Active participation is encouraged for all qualified suppliers.

Q. Does Piramal support joint improvement initiatives?

A. Yes. Piramal may engage with suppliers through joint improvement plans, capability-building programs, and innovation partnerships aimed at strengthening supplier capabilities, improving quality, enhancing resilience, and supporting sustainability performance.

Q. Are there any sustainability-specific capability programs?

A. Yes. Piramal collaborates with industry initiatives (including PSCI) on sustainability training, decarbonisation workshops, and best-practice sharing for suppliers.