

Supplier Code and Responsible Sourcing Standard

What we require of the organisations that supply us, including the ones that supply our containment.

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Owner	Procurement and Quality
Applies to	All suppliers, CROs, CMOs and contracted laboratories

A supplier is part of the control environment, not outside it. This Standard sets the baseline for organisations that provide materials, services, research, manufacturing, logistics, technology or facilities to Baxtra Research Labs. It is read with the contract, quality agreement, statement of work and applicable law.

1. Scope and flow-down

The Standard applies to suppliers, contract research organisations (CROs), contract manufacturing organisations (CMOs), carriers, consultants and contracted laboratories. A supplier must communicate equivalent requirements to sub-tier suppliers whose work, materials, data, people or premises support Baxtra work. Flow-down must be visible in purchase terms or a written subcontract, not left to assumption.

Supplier duty	Know the work being performed, the risks it creates and the controls promised to Baxtra.
Sub-tier duty	Select, brief and monitor sub-tier organisations; remain accountable for their performance.
Baxtra duty	Describe requirements, qualify proportionately, inspect where needed and raise issues without asking for concealment.
Evidence	Maintain current licences, training, quality records, risk assessments, change notices and corrective-action evidence.

2. Qualification and audit

Baxtra qualifies suppliers using a risk-based review of capability, history, regulatory standing, capacity, financial resilience, information security, biosafety where relevant and the criticality of the supplied item or service. Qualification may include questionnaires, technical assessment, references, sample or method review, on-site or remote audit and quality-agreement approval. Commercial convenience does not replace qualification.

A supplier must provide truthful, complete and timely information. It must notify Baxtra of an inspection, warning, suspension, recall, serious quality event, data-integrity concern, cyber incident or material change that could affect supplied work. Do not wait for the next business review to disclose a risk.

3. Quality and GxP expectations

Supplier category	Primary expectation
CMO, packager or critical material maker	GMP controls under the applicable quality agreement, including approved instructions, traceability, deviation, release and change control.
CRO or clinical service provider	GCP for human research activities; controlled records, protocol compliance, safety escalation and participant protection.
Contracted analytical or in vivo laboratory	GLP where the work supports non-clinical safety or regulated study decisions; method control, raw data and specimen traceability.
Calibration, maintenance or validation provider	Documented, trained service under approved procedures; objective evidence that equipment remains fit for intended use.
Technology, logistics or general service supplier	Contractual controls for confidentiality, security, continuity, personnel access and any regulated hand-off.

GMP, GLP and GCP are not interchangeable labels. The applicable expectation is set by the activity, the intended use of the output and the quality agreement. When a supplier identifies a gap, it must contain affected work and inform Baxtra Quality.

4. Containment-critical suppliers and change control

Suppliers of HEPA housings, filters, seals, suit materials, decontamination equipment, facility systems, respiratory protection, secure transport or other containment-critical items must understand that a specification is a safety control. No substitution, unannounced material change, manufacturing-site change, software change or obsolescence decision may be made outside the agreed change-control process.

An unannounced change to a HEPA housing or a suit material is a safety event, not a commercial one. Stop use, preserve the affected stock and notify Baxtra immediately so the risk can be assessed.

For the public record, see the **Statement on a containment failure**, 29 August 2026, ref BXRA-PS-2026-08, at [assets/pdf/containment-statement.pdf](#). It confirms only that an event occurred, was found by Baxtra's own staff, that work stopped, an independent review is open, and authorities were notified. It declines to name the programme, suite, material, quantities, dates or individuals, and states there is no identified risk outside the facility.

5. Data integrity and ALCOA+

Supplier records must be attributable, legible, contemporaneous, original or a verified true copy, and accurate. ALCOA+ also requires records to be complete, consistent, enduring and available. This applies to laboratory data, batch records, electronic records, instrument files, environmental monitoring, training, shipping, invoices where they support a quality decision, and the metadata that gives those records meaning.

- Use individual accounts and protect audit trails. Do not share passwords, disable controls, overwrite raw data or create an undocumented parallel record.
- Retain original files, method versions, calculations, audit-trail reviews and approvals for the contractual and legal retention period. Make records available in a usable form.
- Correct errors transparently with reason, date and attribution. A late result, failed run or atypical observation must be visible to the quality reviewer.
- If data may be unreliable, quarantine the affected output, notify Baxtra Quality and support a documented impact assessment.

6. Labour and human rights

Suppliers must respect internationally recognised human rights and applicable labour law. Work must be freely chosen, with no forced labour, trafficking, debt bondage or retention of identity documents. Child labour is prohibited. Workers must receive lawful wages, working time, rest, benefits and a safe workplace, and may raise concerns without retaliation.

Suppliers must not discriminate in hiring or employment on unlawful grounds and must prohibit harassment, violence and degrading treatment. Recruitment fees must not be charged to workers. Suppliers must monitor labour brokers and sub-tier facilities where they create risk and must provide records or access reasonably needed to verify these requirements.

7. Environment

Manage emissions, waste, water, energy, chemicals and hazardous materials in accordance with permits and law. Identify significant environmental risks, prevent releases, segregate and dispose of regulated waste appropriately, and maintain emergency controls. Suppliers should measure material impacts and pursue practical reduction without weakening worker safety, product quality or containment.

8. Animal welfare for contracted in vivo work

Contracted in vivo work must have scientific justification, prior ethical review, trained staff, appropriate housing and veterinary oversight. Apply the 3Rs: replace animals where a suitable alternative answers the question, reduce numbers through sound design, and refine procedures to limit pain and distress. Use approved humane endpoints and report unexpected welfare concerns and protocol deviations promptly.

9. Information security and confidentiality

Protect Baxtra confidential information, participant and patient data, unpublished research, pathogen and facility information, credentials and personal data. Restrict access by role, use approved encryption and secure transfer, maintain malware and patch controls, and test recovery of critical systems. Notify Baxtra without delay of a suspected breach, lost device, unauthorised access or ransomware event; do not investigate by deleting evidence.

10. Conflict minerals and responsible sourcing

Suppliers must maintain a reasonable, risk-based process to identify and address the use of tin, tantalum, tungsten and gold originating from conflict-affected or high-risk areas. Provide country-of-origin and smelter or refiner information when requested, use recognised due-diligence practices, and flow the expectation to relevant sub-tier suppliers. The requirement applies to components and products in the supply chain, not only to direct invoices.

11. Business continuity and single-source risk

A supplier must maintain continuity plans proportionate to its criticality. Plans should cover people, premises, utilities, cyber disruption, equipment failure, raw-material shortage, transport interruption, severe weather, infectious disease controls and loss of a sub-tier supplier. Test recovery assumptions and provide Baxtra with an escalation contact and an estimated recovery time when requested.

Risk signal	Required supplier response
Single source for a containment-critical item	Declare the dependency, hold qualified safety stock where agreed, and propose a qualified alternate or recovery plan.
Material capacity or site constraint	Notify before service is affected; provide impact, allocation logic and recovery milestones.
Sub-tier disruption	Assess affected lots, data and lead times; do not substitute without approved change control.
Cyber or facility outage	Activate continuity plan, preserve evidence and notify Baxtra through the agreed incident route.
Repeated late or failed delivery	Provide root cause, corrective action and a sustainable prevention plan, not only an expedited shipment.

12. Anti-bribery and fair dealing

Suppliers must not offer, request or accept bribes, kickbacks, facilitation payments or concealed benefits in connection with Baxtra work. Keep accurate books and records. Do not provide gifts, travel, hospitality, employment or charitable support to influence a Baxtra employee, healthcare professional, investigator, public official or procurement decision. Report a suspected request to Procurement, Legal or the channel named in the contract.

13. Audit rights and termination

Baxtra may review records, interview relevant personnel, inspect facilities and audit sub-tier controls to the extent provided by contract and law. Routine audits may be scheduled; serious concerns may require short-notice or unannounced access where lawful and necessary to protect participants, product quality, data integrity or containment. The supplier must provide access without coaching witnesses or withholding relevant records.

Baxtra may require a containment action, reject affected work, suspend a supplier, require a corrective and preventive action plan, recover reasonable costs or terminate for material breach. Nothing in this Standard prevents Baxtra from notifying a regulator or other authority when required or appropriate.

14. Supplier quality events

A supplier quality event includes a suspected data-integrity failure, out-of-specification result, unapproved change, lost sample, mix-up, contamination, falsified record, missed critical test, significant deviation, recall signal or event that may affect safety, identity, strength, purity, quality, participant protection or containment. Protect people first, contain the material and notify the Baxtra contact named in the agreement.

Stage	Escalation path and expectation
1. Detect and protect	Supplier stops or contains the affected activity, protects people and material, and preserves records.
2. Notify	Quality contact is notified promptly using the agreed route; critical events are escalated immediately, not held for a report.
3. Triage	Baxtra Quality and the supplier classify impact, affected lots or records, patient or participant risk, regulatory duty and need for authorities.
4. Investigate	A documented root-cause investigation tests evidence, scope and recurrence; it does not assume operator error without proof.
5. Correct and prevent	CAPA has an owner, due date, effectiveness measure and change-control linkage. Baxtra may require interim controls.
6. Close and learn	Quality approves closure only when evidence supports the conclusion; trend data and supplier status are updated.

Escalation is not a commercial failure. Late notice, incomplete records or a workaround that bypasses change control can increase the severity of a quality event.

15. Working relationship

Baxtra expects suppliers to raise bad news early and to challenge an unclear requirement. Suppliers may ask Procurement and Quality for clarification, but a commercial contact cannot approve a quality, safety, data-integrity or regulatory exception. We will use risk-based oversight, pay for agreed work according to contract and seek a factual, documented resolution.

16. Acceptance

Acceptance of an order, quality agreement or statement of work confirms that the supplier has communicated this Standard to relevant personnel and sub-tier suppliers, maintains the controls needed for its scope and will provide evidence when reasonably requested. Where a contract is stricter, the contract controls; where law is stricter, law controls.

The supplier closest to a risk is often the first organisation able to prevent it. We expect that organisation to speak.

Important. Baxtra Research Labs develops investigational medicines and investigational medical devices. No Baxtra investigational medicine has been approved by any regulatory authority in any country, and the safety and efficacy of none of them has been established. This document is published for information. It is not medical advice, not biosafety or biosecurity guidance, not an offer to sell or a solicitation to buy securities, and not a forecast that any programme described in it will succeed. Forward-looking statements about timing, enrolment, regulatory interactions and intended indications are subject to change without notice.

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