

Quality Management Statement

The quality system behind an investigational medicine and a cleared medical device, described plainly.

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Owner	Head of Quality
Applies to	Baxtra Bio and Baxtra Surgical

Quality is the controlled way Baxtra turns a question into evidence and a design into a device. It is not a final inspection and it is not a promise of outcome. This statement describes the governance, records, review and escalation expected across Baxtra Bio's investigational medicines and Baxtra Surgical's medical devices.

1. Quality policy

Baxtra will protect participants, patients, users, animals, staff and the public by designing quality into work, keeping reliable records, using qualified people and suppliers, and making decisions from evidence. We will meet applicable law, regulatory commitments and approved procedures; make issues visible early; investigate root causes; and verify that corrective action works.

- Quality decisions are independent of schedule and commercial pressure. A person may stop work, quarantine material or escalate a concern without retaliation.
- Records are attributable, contemporaneous, accurate, complete and retrievable. We do not create a cleaner story by removing inconvenient evidence.
- The quality system is proportionate to risk but never optional for regulated work. Leaders provide resources, training and access to the systems needed to do the work correctly.
- The Head of Quality reports significant risks through the governance route and has authority to require containment, reject work or delay release until evidence is sufficient.

2. Frameworks that apply

Framework	Activity or boundary
21 CFR Parts 210 and 211	Current good manufacturing practice for drug components, drug products, production, laboratory control, packaging and release activities within the pharmaceutical quality system.
21 CFR Part 820	Quality-system requirements for the medical-device business, including design, production, purchasing, records, complaints and corrective action.
ISO 13485	The device quality-management framework used with the applicable US requirements for design, manufacture, servicing and post-market processes.

Framework	Activity or boundary
ICH Q9 and Q10	Quality risk management and pharmaceutical quality-system principles used to structure risk decisions, management review and continual improvement.
GLP	Non-clinical laboratory work that supports safety and regulated development decisions, with controlled protocols, raw data and independent quality oversight.
GCP	Human clinical research, including protocol conduct, participant protection, consent, essential records and reliable reporting.

The applicable framework depends on the activity and intended use of the output. A single project can therefore have more than one set of controls. The stricter approved requirement governs where a procedure, agreement, regulatory commitment or law sets a higher bar.

3. Pharmaceutical quality system elements

For Baxtra Bio, the pharmaceutical quality system connects development knowledge, clinical supply and manufacturing controls. It includes quality policy and objectives, trained personnel, document and record control, deviation and nonconformance management, CAPA, change control, supplier qualification, complaints and safety interfaces, product quality review, internal audits, management review and inspection readiness.

- Development and technology transfer: capture critical quality attributes, process knowledge, analytical methods, material controls and the rationale for operating ranges.
- Manufacturing and laboratory control: use approved master records, qualified equipment, validated or verified methods, environmental controls, sampling plans and independent review.
- Release and distribution: preserve identity, status, chain of custody, storage conditions and reconciliation. Quarantine is a real status, not an informal suggestion.
- Knowledge management: trend deviations, complaints, stability, analytical performance, supplier signals and audit observations so repeated weak signals are acted on.

4. Quality risk management

Risk management starts with a clear question, affected users or participants, credible hazards, existing controls and the evidence needed to make a decision. Teams use a documented, science-based method to assess severity, likelihood and detectability or equivalent dimensions. Risk controls are assigned owners and reviewed when knowledge changes; a risk score never substitutes for a required legal or procedural control.

Risk review is triggered by a new process, new facility or equipment, change in supplier, unexpected result, serious deviation, complaint trend, inspection observation, emerging information or an assumption shown to be wrong. Quality may require interim controls while a full assessment is completed.

The useful question is not whether a process has a risk score. It is whether the people making the decision can show what could go wrong, what prevents it, and why the remaining risk is acceptable.

5. Deviation, CAPA and change control

A deviation or nonconformance is recorded when approved requirements are not met or an unexpected event could affect quality, safety, data integrity or compliance. The record describes the event and immediate containment without

assigning blame. The investigation establishes scope, root cause or the limits of what can be concluded, and product or data impact.

CAPA is used when correction alone is not enough. Change control is required before a planned change to a process, material, method, facility, equipment, software, supplier or document is implemented. The change record identifies impact, validation or verification, training, regulatory assessment, effective date and post-implementation review.

CAPA lifecycle	Worked example
1. Event and containment	An assay control trend breaches its alert limit. The laboratory pauses affected reporting, preserves raw data and informs Quality.
2. Investigation	The team reviews audit trails, reagent lots, instrument history, analyst training and comparable runs; it defines the affected time window.
3. Root cause and impact	Evidence identifies an unrecognised reagent-storage excursion. Quality assesses results, released decisions and whether any submission or site must be notified.
4. Action plan	Add monitored storage, revise the handling procedure, retrain staff, evaluate the supplier and add a trend review trigger.
5. Verification	Quality checks implementation and reviews defined subsequent runs against an objective acceptance criterion.
6. Effectiveness and closure	No recurrence is observed over the agreed period, records are complete and Quality approves closure; unresolved risk remains open.

6. Computerised system validation and 21 CFR Part 11

Computerised systems used in regulated work are selected, configured, validated and maintained for their intended use. The validation plan is risk-based and covers requirements, configuration, interfaces, security roles, audit trails, calculations, data migration, backup and recovery, business continuity, test evidence, deviations and release approval. Changes are assessed through change control, not made directly in production to save time.

Where electronic records or signatures fall within the scope of 21 CFR Part 11, Baxtra controls access, authority checks, audit trails, record retention, system documentation and signature linkage. Users have unique credentials and are trained on the record they create. An electronic signature is an accountable action, not a button to bypass review.

- Data owners define the record, retention period, critical fields and permitted use. System owners protect availability and security; Quality assesses regulated-state impact.
- Audit-trail review is meaningful and risk-based. The absence of an alert is not evidence that an entry was correct.
- Manual transcription, spreadsheet use and interfaces are assessed for error risk. Reconciliation and independent review are used where the risk warrants them.
- If a system failure could affect a decision, quarantine the affected output, preserve logs and use the approved continuity procedure.

7. Batch release and the qualified person function

No batch is released on schedule alone. Release review confirms the approved manufacturing and testing records, deviations and CAPA impact, analytical results, environmental and process controls, status of materials, storage and shipping conditions, and required regulatory commitments. The disposition is documented and traceable to the person with the authority to make it.

For activities where a qualified person (QP) function is required by an applicable jurisdiction or agreement, the QP reviews the evidence within the defined quality system and may certify or refuse certification within that scope. The QP is not a substitute for the broader quality organisation, and commercial or programme leadership cannot direct a release conclusion.

8. Supplier quality

Suppliers are qualified according to risk and intended use. Quality agreements define responsibilities for specifications, testing, records, deviations, change notification, audits, complaints, recalls, data integrity, transport and subcontracting. A supplier is not qualified merely because it is familiar or inexpensive. Unapproved changes and unexplained data are quality events that require containment and assessment.

Supplier performance is trended using delivery, deviation, audit, complaint, change and data-quality signals. Oversight may include additional sampling, focused audits, remediation, suspension or disqualification. See the Supplier Code and Responsible Sourcing Standard for the escalation path and responsible sourcing requirements.

9. Device design controls and Lumavue post-market surveillance

Baxtra Surgical applies design controls to Lumavue, real-time tissue perfusion imaging, which was FDA 510(k) cleared in July 2026. Clearance is not a claim that every use is suitable or that a clinical outcome is guaranteed. The device file links user needs to design inputs, outputs, verification, validation, usability and risk controls, with documented review at defined gates.

- Design inputs are clear, testable and traceable to intended use, user needs, applicable requirements and identified hazards.
- Design outputs are approved specifications, drawings, software or other controlled information that can be verified and produced consistently.
- Verification asks whether outputs meet inputs. Validation asks whether the resulting device meets user needs and intended use under representative conditions, with appropriate human-factors evidence.
- Design changes are reviewed for risk, interfaces, labelling, manufacturing, cybersecurity, regulatory submissions and the need for additional verification or validation before release.

Post-market surveillance for Lumavue includes complaint intake, service and repair signals, returned-product assessment, trend review, field information, literature or regulatory signals where applicable, and evaluation of reportability. A signal is recorded even when causality is not yet known. Corrective action, advisory communication, field action or regulatory reporting is considered through the approved process.

10. Complaint handling and vigilance reporting

A complaint is captured when information suggests that a product, service, study process or supplied item may have failed to meet a requirement or may have contributed to a safety concern. Intake records the reporter, product or programme, event description, dates, lot or serial information where available, and the initial assessment. Do not close a complaint merely because information is missing; document the follow-up and rationale.

Quality coordinates assessment with Medical, Regulatory, Clinical, Engineering and Legal as needed. Potential adverse events, device incidents, serious incidents, product defects and reportable events are escalated within the applicable timelines. Preserve the original communication, protect personal information and do not promise a reporter an outcome that has not been decided.

11. Internal audit programme

Internal Audit and Quality use a risk-based programme covering research, clinical operations, laboratories, manufacturing, suppliers, computerised systems, device design and post-market processes. Auditors are competent and sufficiently independent from the activity being assessed. Reports distinguish observations, evidence, risk and required action; owners and due dates are tracked to effective closure.

Period	Audits performed	Coverage
2025	18	Initial laboratory, clinical, supplier and system controls during the first operating year.
1 January-31 August 2026	27	Risk-prioritised Bio, Surgical, GxP suppliers, computerised systems and complaint processes.
Total reported in this statement	45	Completed audits recorded in the programme through 31 August 2026; open actions remain tracked until closure.

12. Inspection readiness

Inspection readiness means the organisation can show how it works on an ordinary day, not that it has prepared a special story. Controlled procedures, training records, quality agreements, study and device files, audit trails, deviations, CAPA, complaints and management review are maintained so an authorised inspector can follow an activity from requirement to evidence to decision.

1. Know the scope and appoint a trained inspection co-ordinator, subject-matter leads, a records room and an escort process.
2. Provide complete, legible and current records through the approved route. Retrieve the requested record; do not create a new retrospective explanation in its place.
3. Answer the question asked, distinguish knowledge from assumption and commit to a follow-up when the record is not immediately available. Never speculate, argue or conceal a relevant issue.
4. Log requests, responses, commitments and actions. Quality reviews draft responses for accuracy and ensures that any observation enters the formal remediation process.
5. After the inspection, assess observations for broader impact, communicate decisions and track CAPA and effectiveness to closure.

13. Management review and continual improvement

Management review considers quality objectives, audit results, deviations and CAPA, complaints and vigilance, supplier performance, process and product trends, inspection commitments, resourcing, training, system performance and emerging risks. The output is a documented decision: continue, improve, contain, resource, escalate or change. A metric is useful only when it prompts the right question.

14. Responsibilities and escalation

Role	Accountability
All personnel	Follow approved requirements, make reliable records, report concerns and stop work when necessary.
People managers and process owners	Provide competent staff, maintain controls, review performance and act on signals.
Quality	Own the quality system, provide independent oversight, approve or reject disposition, and escalate material risk.
Regulatory, Medical and Clinical	Maintain applicable commitments, participant protections, safety assessment and required reporting.
Engineering and IT	Control device and system design, cybersecurity, validation, maintenance and change implementation.
Executive management	Set policy, provide resources and review whether the system remains suitable and effective.

A quality system is credible when it makes the inconvenient fact visible early enough for someone to act on it.

15. Questions and records

Questions about this statement or a quality concern should go to Quality through the approved internal route. Do not send confidential study, participant, patient, pathogen, security or supplier information to a public channel. This public statement describes the system at a high level; controlled procedures, records and quality agreements govern the work.

The purpose of quality is not to make a file look complete. It is to make the decision worthy of reliance.

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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