

### Understanding Your Lab's Context

Understanding the context of your laboratory is essential for effective quality management. It means identifying the internal and external factors that influence your operations, strategy, and success. Think of it as stepping back to see the bigger picture of where your lab fits in the broader scientific and organisational landscape.

### Types of Research Laboratories

Let's begin by considering the different types of research labs:

- **Infrastructure-sharing labs** (e.g. **ANSTO**) focus on providing shared instrumentation and resources.
- **Design and development labs** work on innovations like new anticancer drugs.
- **Testing and calibration labs** (e.g. **National Measurement Institute Australia**) provide accredited measurement services.
- **Analytical labs**, like the **Ramaciotti Centre for Genomics**, perform specialised scientific analyses.
- **Training labs**—common in universities—support workforce or student development.

Many labs are a hybrid of these types. Ask yourself: *Which category best describes your lab?*

### Clarifying Your Lab's Purpose

Understanding **why your lab exists** is more than just a philosophical question—your purpose shapes your goals, operations, and quality management priorities.

For example, if your lab provides cutting-edge bioprocessing techniques, your purpose will:

- Influence the skillsets needed in your team,
- Guide how you engage with stakeholders,
- Drive the development of your quality systems.

### Internal Challenges in Research Labs

Many quality issues stem from internal factors. A 2023 **OMIRA** study found:

- Only **50%** of NHMRC-funded scientists could reproduce their own published results.
- This drops to **30%** when attempting to reproduce the work of others.

The study identified four key internal issues:

**1. Resource management**

- Instruments may not be maintained or calibrated regularly.
- Labs often lack documented maintenance schedules or procedures.

**2. Human competency and staffing**

- Staff may not be adequately trained in conducting high-integrity experiments.
- High staff turnover (e.g. casual or contract-based postdocs) can lead to data loss and reduced continuity.

**3. Organisational culture**

- Academic pressure to publish can tempt researchers to manipulate or falsify data.
- Many institutions lack robust data integrity policies or traceable data storage systems.

**4. Operational processes**

- Practices may be based on informal knowledge (e.g. “how we’ve always done it”), rather than international standards.
- For example, how many researchers measure buffer pH using a validated method rather than inherited lab habits?

To manage internal context, assess your:

- Organisational performance
- Physical and intellectual resources
- Staff competence and culture
- Operational capabilities
- Governance and decision-making structures

Be honest: *What are your lab’s strengths, and where do you need to improve?*

### Influencing External Factors

External context includes broader forces that affect your lab’s operations. Some examples:

- **Economic:** Funding availability, inflation, and exchange rates can influence project viability.
- **Social:** Local workforce skills, safety perceptions, public holidays, and education levels affect recruitment and operations.
- **Political:** Government stability, national research priorities, infrastructure investments, and trade agreements can open opportunities—or pose risks if priorities shift unexpectedly.

### Identifying Interested Parties

Interested parties are individuals or groups who can affect—or are affected by—your work.

For a shared facility like ANSTO, stakeholders might include:

- Academic researchers
- Industry collaborators
- Government funders
- Regulatory bodies

Knowing who your stakeholders are—and understanding their expectations—helps align your quality efforts to meet their needs.

### Why Context Analysis Matters

Context analysis isn’t just a one-time task or paperwork exercise. It actively informs:

- Your **quality objectives**,
- Your **risk management**, and
- How you **adapt to change**.

For example, an analytical lab might revise its quality control procedures in response to updated regulatory requirements identified through context analysis.

By regularly reviewing your lab’s internal and external context, you can remain responsive, relevant, and resilient.

### Tools to Support Context Analysis

You don't have to start from scratch—use structured tools to guide your analysis:

- **SWOT analysis:** Identify your internal strengths and weaknesses, and external opportunities and threats.
- **PESTEL analysis:** Examine Political, Economic, Social, Technological, Environmental, and Legal factors.
- **Stakeholder analysis:** Map your interested parties and understand their influence.
- **Risk assessments:** Prioritise issues based on likelihood and impact.

You'll find downloadable templates in the **Resource Section** to help with these:

### **ZTQ Resources**

1. Organisational context procedure template (*Advanced*)
2. SWOT analysis (*Foundational*)
3. PESTEL analysis (*Advanced*)
4. Stakeholder analysis (*Advanced*)
5. Internal and external factor examples (*Foundational*)

### **Key Takeaway**

Understanding your lab's context isn't about ticking boxes—it's about enabling excellent science. By staying aware of your internal capabilities, external influences, and stakeholder needs, you can build a lab that's robust, adaptive, and positioned for lasting impact.