ENGCOR
ENGINEERED SOLUTIONS

What’s the Change Control Number?

NOVEMBER 2025

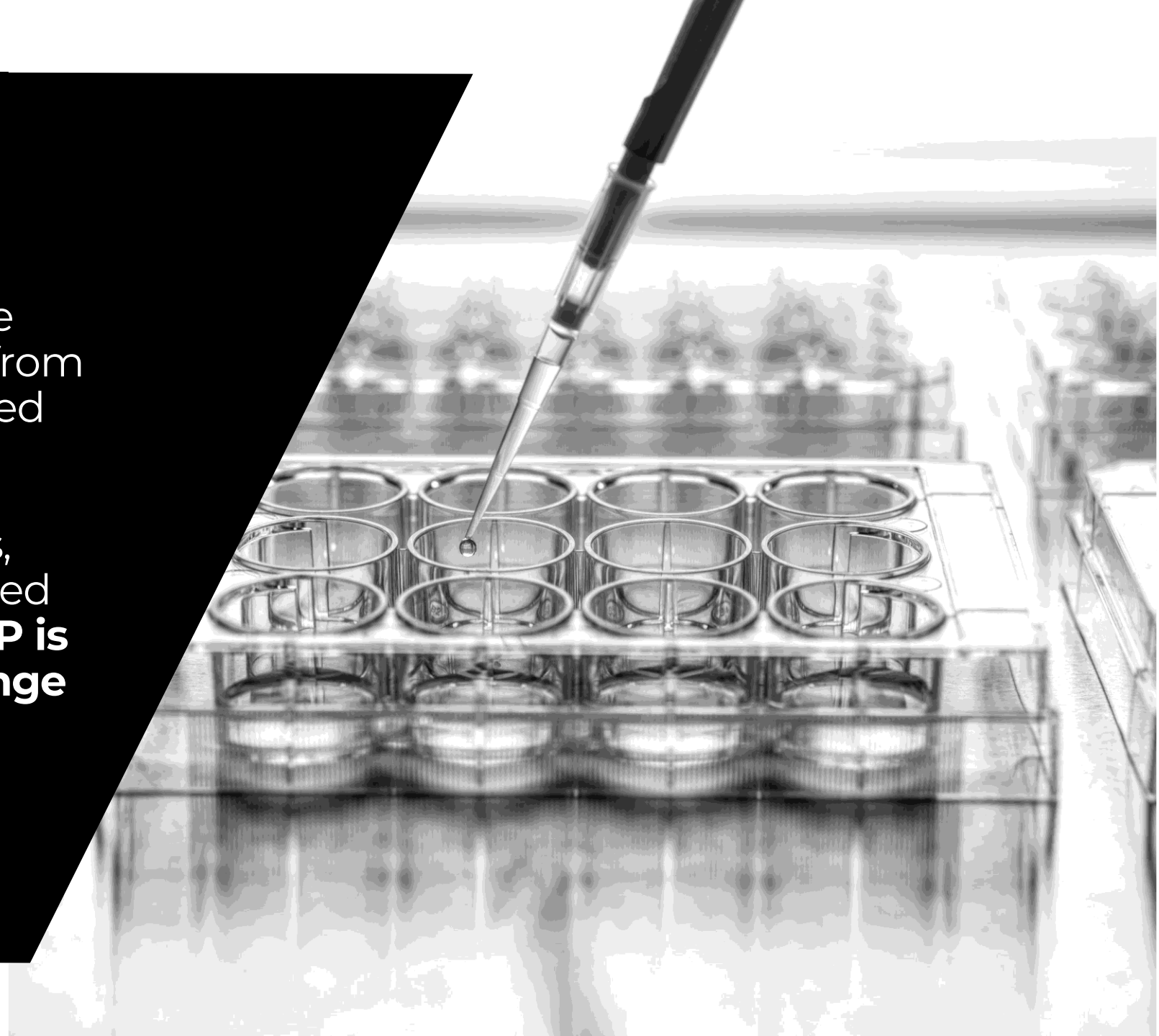
Would you like a change control with that?

In the life sciences industry, **change is not only inevitable** – it's essential. From evolving regulatory requirements and technological advancements to process optimization and scaling operations, companies must continuously adapt to remain competitive, compliant, and patient-focused. Yet, **in highly regulated environments, change cannot occur haphazardly**. It must be planned, controlled, documented, and executed with precision.

Change management serves as the backbone of a robust quality management system (QMS), ensuring that any modifications to processes, equipment, documentation, or systems are assessed for risk, properly authorized, and implemented without compromising product quality, data integrity, or patient safety.

So, what is it? Change management is a structure approach to transitioning from the current state to a desired future state.

In regulated environments, change needs to be assessed for various impacts. **SQuIPP is one tool used assess change in pharma.**



SQuIPP = Safety, Quality, Identity, Purity & Potency

The **SQuIPP framework is used in GMP and for product quality related changes**, helping assess how a proposed change might impact the critical attributes of a product, process or system against the future state.

HOWEVER, SQUIPP IS ONLY ONE EXAMPLE.

SQuIPP matters as it standardises impact assessments, ensures product quality and compliance is maintained and there is alignment with regulatory expectations for a risk-based assessment. However, it is not a one-stop shop.

There are other change management frameworks that can be implemented for organisational and business transformations – e.g. SIPOC or ADKAR.

It all depends on context.

Let’s consider an example.

A company is changing a raw material supplier, the SQuIPP framework guides the impact assessment phase of a change control. In this case, each category prompts the team to review the following questions:

- **Safety:** Does the change impact safety to product, patient or process? Could this introduce new risk to patients? Are there new SDS / hazards that need to be considered?
- **Quality:** Will the change impact product quality? Could this introduce variability or increase deviations in processes?
- **Identity:** Does the change affect the chemical make-up of the product or physical aesthetic (e.g. labelling)? Does it impact product traceability or testing?
- **Purity:** Does this change impact the environment or introduce contaminants / impurities into the system?
- **Potency:** Could the active ingredient effectiveness or concentration be impacted? Does the change impact the product formulation or stability?

In this example, SQuIPP is an appropriate tool. But, if we were applying this to a new office fit-out or organisational change, SQuIPP wouldn't quite fit.

Managing change with agility, accountability and confidence requires a robust change management system and framework. In this case, **change controls become the cornerstone of compliance and operational excellence.**

But why are change controls needed?

Unlike less-regulated industries, life science companies operate under strict **Good Practice (GxP)** frameworks, where any uncontrolled change in a validated process, system, or product can have downstream effects, potentially compromising compliance, patient safety, or product efficacy.

Poor change control, and subsequent implementation, is often one of the most common root causes of regulatory citations and warning letters.

It can lead to:

- Product recalls or batch rejections
- Regulatory delays or inspection findings
- Data integrity issues
- Increased risk to patient safety
- Reduced productivity
- Increased costs

In contrast, a **robust change control process** enables organisations to adapt quickly and compliantly.

Regulatory agencies expect a traceable, risk-based, and cross-functional approach to change — not just a form to be filled, but a controlled decision-making process.

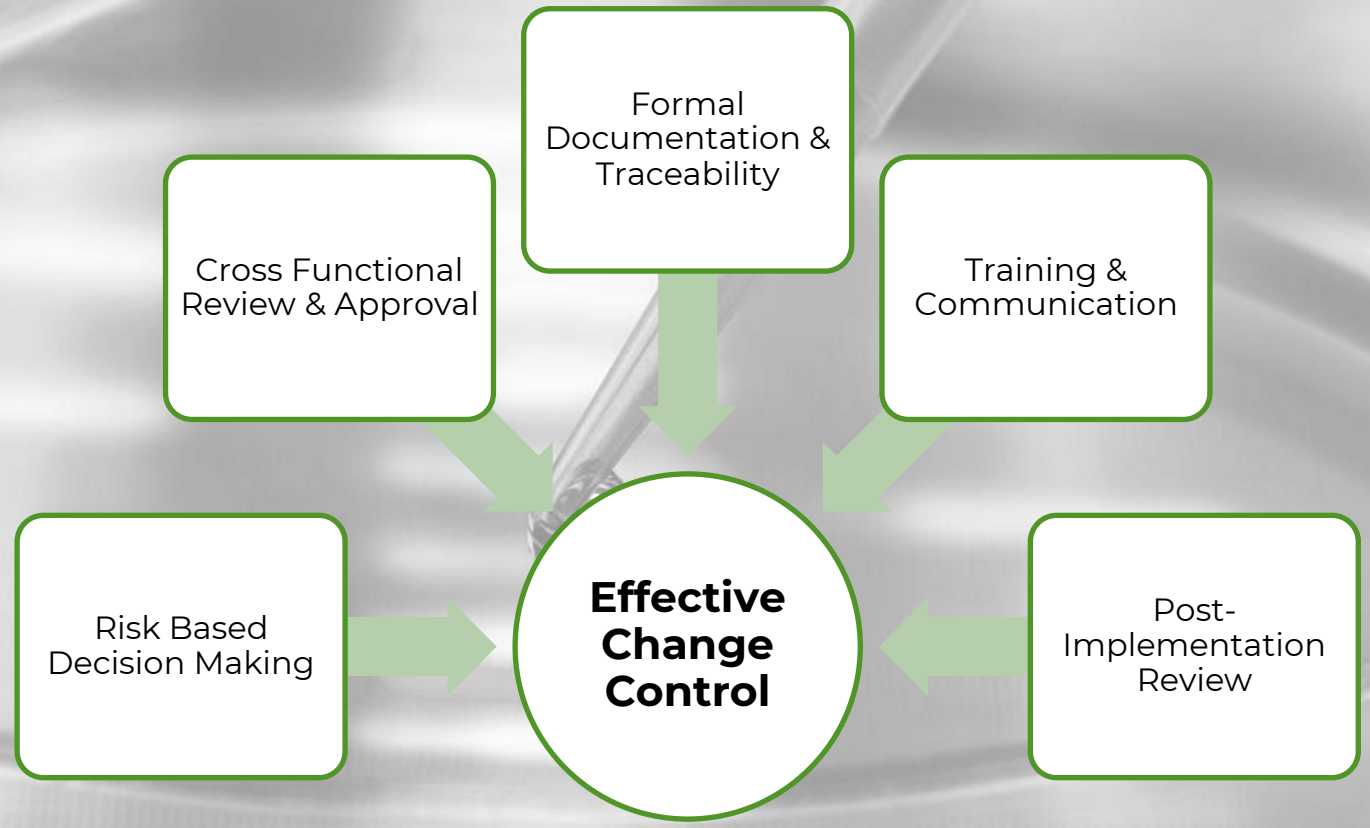
Key guidelines companies should be familiar with include:

- FDA (21 CFR Parts 210, 211, 820, 11)
- EU GMP Annex 15 and 11
- ICH Q10
- ISO 13485

Regardless of the standard followed, the key expectation is **that a formal change control is maintain a state of control across a product or project lifecycle.**

So, what are the **key principles of an effective change control**?!

An effective change control process is built on several key pillars



5 Change Control Pillars, in detail.

1. **Risk Based Decision Making:** All proposed changes should undergo a documented impact / risk assessment that determines potential effect on quality, compliance, process and safety. High risk changes may require revalidation , stability studies or regulatory submissions.

2. **Cross Functional Review & Approval:** Changes must be reviewed by all impacted departments. Which may include Quality Assurance (QA), Quality Control (QC), Regulatory Affairs, Automation/IT, EHS, Supply Change and Operations. This ensures a holistic impact assessment is considered, ensuring accountability from all involved.

3. **Formal Documentation & Traceability:** A change control should record all critical information, including, but not limited to:
   - A clear description of the current and future state
   - Rationale / justification of the proposed change
   - Risk assessment of the change – this could be a simple risk assessment (e.g., 5 Why's) or a more complex risk assessment (e.g., FMEA) depending on the type of change
   - Implementation plan / actions, including person responsible
   - Verification and closure steps

   This documentation must then be retained for audit readiness and future references.

4. **Training & Communication:** Personnel impacted by the change must be trained prior to the implementation. Updating procedures and training matrices must be made effective inline with the implantation plan.

5. **Post-Implementation Review:** In many cases, an effectiveness review of the change is required to ensure there are no unintended consequences from the change.

What’s best practice?

To move beyond reactive, paper-based change controls, leading organisations are adopting best practice that enable agility and compliance.

- **Digital Change Control Systems** – including automated routing / approvals, integrated impact assessments and real time tracking of KPIs
- **System Integration** – where production systems and integrated with the QMS and automatically raise change controls / deviations as required
- **Monitoring & Measure** – tracking KPI metrics (e.g. time to close, number of overdue changes, number of CAPAs etc.) using AI tools

Overall, fostering a culture where change is not feared, but embraced – **with quality and compliance as a shared responsibility**.

Companies need to encourage early engagement, cross-functional collaboration and transparency through the change life cycle.

Our considerations...

In the life sciences and pharma, where change is essential, **change control is not a formality — it's a fundamental safeguard**. When executed well, it becomes a strategic enabler that allows organisations to evolve with confidence, maintain regulatory compliance, and ultimately protect the patients and customers they serve.

As regulatory expectations rise and technologies evolve, life sciences companies must invest in modern, risk-based, and collaborative change control practices. Doing so not only ensures compliance – it builds agility, trust, and long-term operational resilience.

End-to-end project strategy and management – from concept to compliance.

EngCor brings a rare blend of deep operational insight and full-spectrum project leadership across the life sciences, food and beverage projects – from concept to compliance. With hands-on experience in design, construction, commissioning, and qualification, we bridge the gap between technical execution and regulatory readiness—ensuring that every project is not only delivered on time and on budget, but also fully aligned with regulatory standards and future operational needs.

We have a passion for streamline processes and driving efficient operations. Reach out to us at admin@engcor.com.au to schedule a **free call** or visit our website at engcor.com.au

Thanks for reading!

Get in Touch!

LinkedIn
https://www.linkedin.com/company/engcormelb

Website
engcor.com.au

Email
admin@engcor.com.au

Phone
+61 425 818 843

Acronym	Definition
ADKAR	Awareness, Desire, Knowledge, Ability, Reinforment – a change management framework
AI	Artificial Intelligence
CAPA	Corrective Action / Preventative Action
CFR	Code of Federal Regulations
e.g.	Example
etc.	Et cetera or ‘and other similar things’
EU	European
FDA	Food & Drug Administration
GxP	Good Process, where GMP = Good Manufacturing Practise
ICH	International Council for Harmonisation (of Technical Requirements for Pharmaceuticals for Human Use)
ISO	International Organisation for Standardisation
KPI	Key Performance Indicators
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SDS	Safety Data Sheet
SIPOC	Suppliers, Inputs, Process, Outputs and Customers – process mapping / change management tool
SOP	Standard Operating Procedures
SQuIPP	Safety, Quality, Identity, Purity, Potency
TGA	Therapeutic Goods Administration

ENGCOR
ENGINEERED SOLUTIONS