

Quality & Traceability:

Achieving Compliance and Efficiency in GxP

FEATURING



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AGENDA

01

Overview

Why does this matter?
What are we looking to achieve and how do we achieve it.

02

Hands-on Demo

Show how you can implement these methodologies and guarantee quality and traceability throughout.

03

Best Practice / Tools to Accomplish

Discuss best practices for achieving these goals, and the features you can use to enable them.

04

Resources / Takeaways

Share resources to aid these goals and summarize key takeaways.

Core Quality & Traceability Objectives - ALCOA+

☐ **Attributable**

Every piece of data should be clearly associated with who created or modified it and when.

☐ **Legible (or Intelligible)**

Data must be readable, unambiguous, and understandable both in the moment and later.

☐ **Contemporaneous**

Data must be recorded at the time the event.

☐ **Original**

The record should be the first capture (the original).

☐ **Accurate**

The recorded data should correctly reflect what happened. If corrections are necessary, in a way that preserves the original, shows who made the change, when, and why.

☐ **'+' i.e. Complete, Consistent, Enduring and Available**



Core Quality & Traceability Implementation

✓ **Attributable**

Via user IDs, audit trails, digital signatures + date/time for manual records.

✓ **Error-Proofing Your Process**

Clarity in how metadata, audit entries, and context are stored so a reviewer can interpret the data.

✓ **Contemporaneous**

Timestamping on record creation

✓ **Original**

The record is first captured as the original.

✓ **Accurate**

Validation checks, consistency checks, etc. to support accuracy and audit trail.

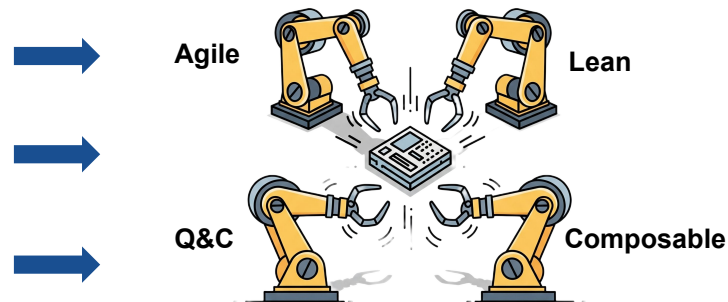
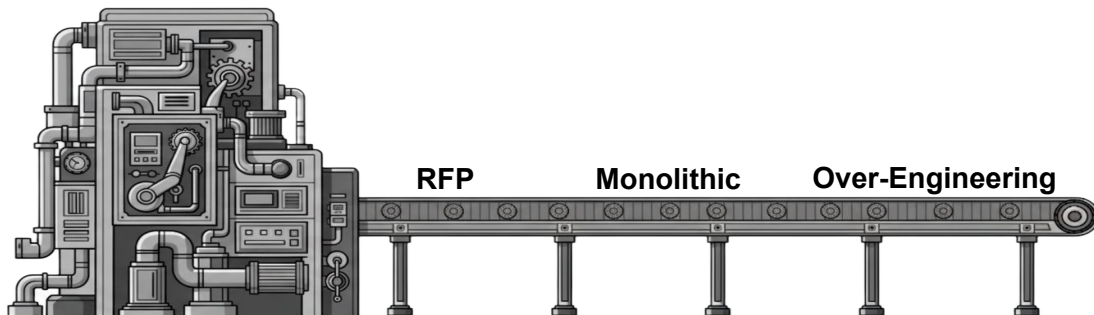
✓ **'+' i.e. Complete, Consistent, Enduring and Available**

This is a mindset shift

1. No need for an RFP
2. No need to build a monolithic system which won't keep you competitive for years
3. No need to over engineer a solution

Instead

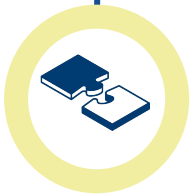
1. Stay agile
2. Build incrementally
3. Keep it lean and improve



Goals for Today:

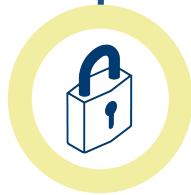
1. Walk-in
2. Under
3. Engage

Step 1



Minimalist App

Step 2



Error-Proofing

Step 3



Corrections

Step 4



Extend & Scale

Step 1



Minimalist App

- ✓ Room logbook app
- ✓ Track inside temperature
 - ✓ Track inside humidity
- ✓ Track outside temperature
 - ✓ Take a picture of the sensor



Connector

Weather Connector

Tables

Apps

Logbook

Automations

Operator Apps

Logbook

App Start

Record Location,
Humidity, and TempComplete
App

✓ Simple app that meets the stated business requirements

✓ No additional assumptions or planning for future requirements

✓ Collecting data in completion records

Quality & Traceability Guidelines



Composable Architecture

Keep it Simple:

Focus on solving the current, clearly defined requirements.

Avoid over engineering solutions for possible future needs.

Build processes and digital tools (like Tulip apps) to address what's most valuable today, adjust as requirements change.

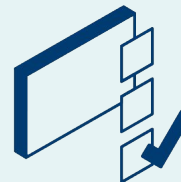


Data Management

Align Error Proofing with Business

Needs:

Tailor your error-proofing approaches to the actual business requirements. Use production data, quality reports, and user input to identify true pain points.



Review and Approvals

Approvals

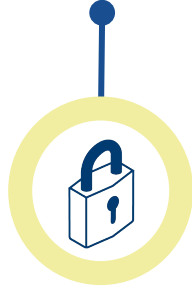
Gate the release of applications before release to the shop floor, to safeguard quality and reliability.

Step 1



Minimalist App

Step 2



Error-Proofing

Observation: Operator has been entering out of spec values.

- ✓ Second verifier when entering out of spec value
- ✓ Ability to review historical data

Connector

Weather Connector

Tables

Apps

Logbook

Logbook Review

Automations

Operator Apps

Logbook

Logbook Review

App Start

Record Location,
Humidity, and TempComplete
App

App Start

View logbook entries

Complete
App

OFD

- ✓ No changes to the data model
- ✓ Additional app to view completions log
- ✓ Still keeping things simple!

Quality & Traceability Guidelines



Composable Architecture

Human-Centric

Design applications around real user needs and the flow of the process.

Prioritize intuitive interfaces and workflows, making it easy for operators to do their jobs correctly and efficiently.

Gather user feedback and observe actual usage to continuously refine the app experience.

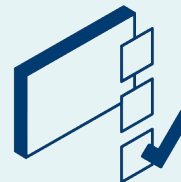


Data Management

Extensible

Add error-proofing features in response to real data and observed risks, not assumptions.

Use e-signatures and validation rules for extra verification only where elevated risk or compliance needs are identified.



Review and Approvals

Risk-Based Review

Keep the approval workflow streamlined and risk-based, only require detailed validation for higher-risk apps, avoiding unnecessary delays for straightforward or low-impact updates.

Use App Comparisons and app diagrams to quickly identify and assess changes, supporting an efficient, risk-based review process.

Step 1



Minimalist App

Step 2



Error-Proofing

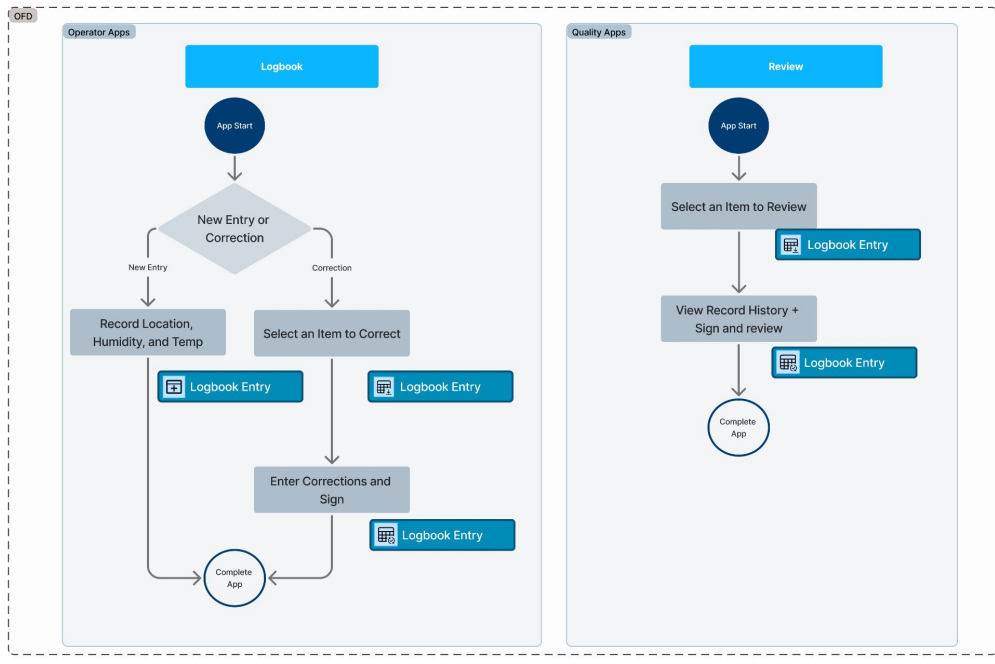
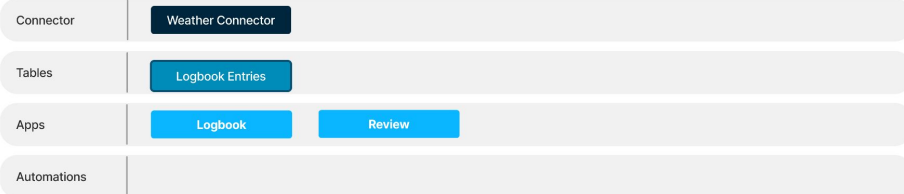
Step 3



Corrections

Observation: Operators make incorrect entries and need to fix them.

- ✓ Allow for corrections of entered data.
- ✓ Ensure review of corrections before they're accepted.



- ✓ Logbook Entries table to enable easy corrections and track review lifecycle of the asset
- ✓ Built-in correction workflow to edit table records
- ✓ Add signature and status change workflow to the review app

Quality & Traceability Guidelines



Architecture

Introduce Table Artifacts Purposefully

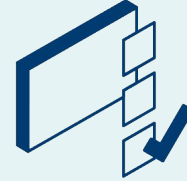
Introduce table artifacts as needed, such as to enable correction and review lifecycle.



Data Management

Table Records

Data collection with error proofing while allowing data correction in a controlled manager with e-sign



Review and Approvals

Full Data Audit Trail

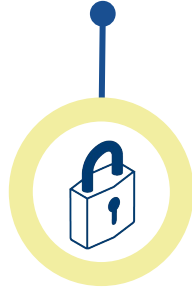
Audit trail and within 21 CFR-P11 compliance and manage review lifecycle of your table-record artifact.

Step 1



Minimalist App

Step 2



Error-Proofing

Step 3



Corrections

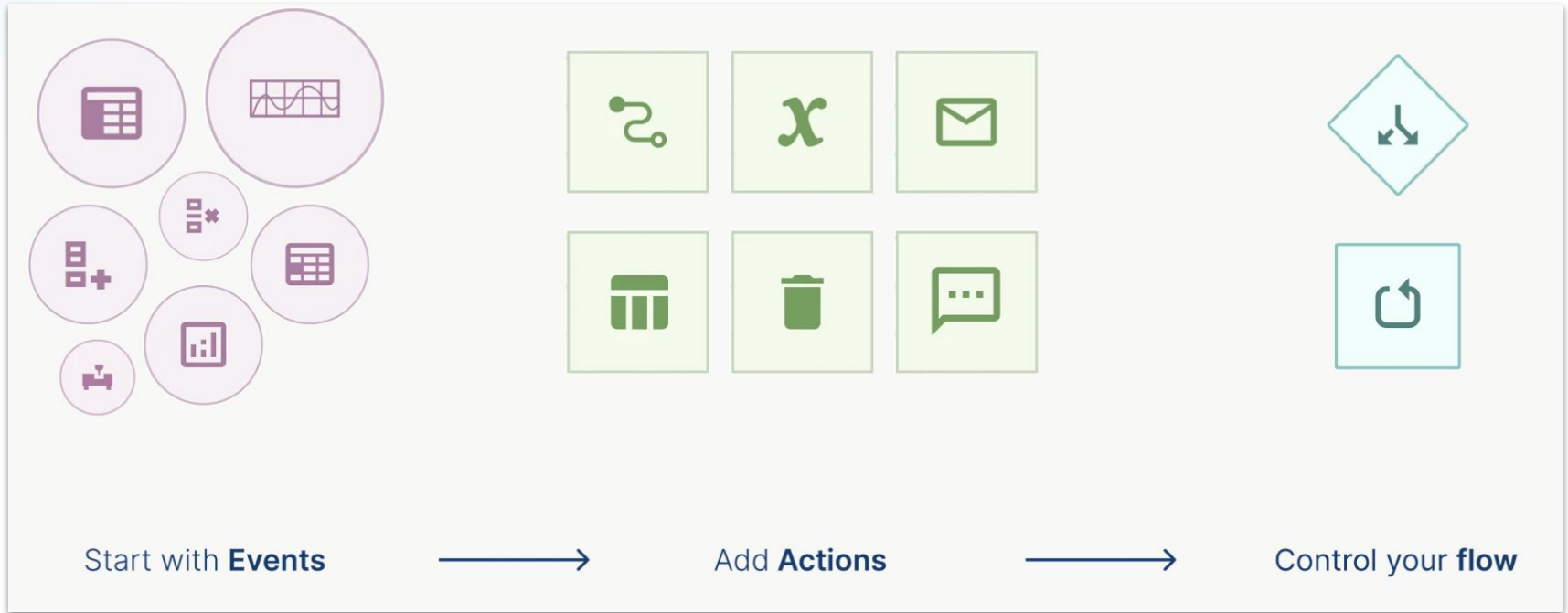
Step 3



Extend & Scale

- ✓ Automations
- ✓ Translations
- ✓ Analytics
- ✓ AI Composer
- ✓ Tulip Library

Extend & Scale with Automations



Extend & Scale with AI Translation and Frontline Copilot

Add Languages

Add translations to this app in your selected languages. You can choose to add translations manually or generate them with AI. We suggest reviewing AI-generated translations to ensure optimal accuracy.

Original Language ⓘ

🌐 English (Default)

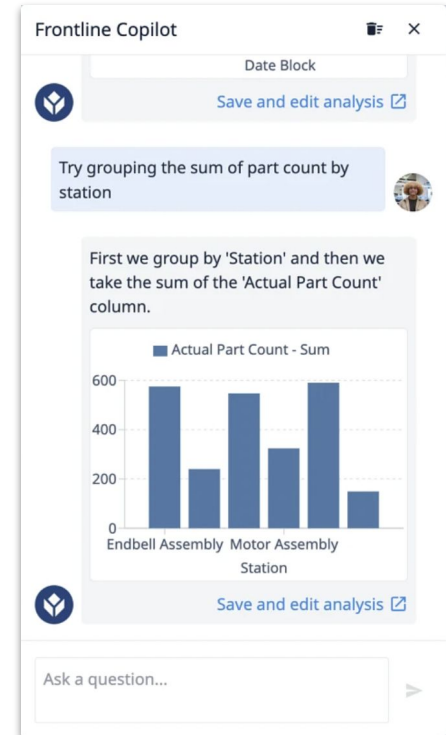
English (Default)

Bulgarian / български

Chinese / 简体中文

Cancel

Save

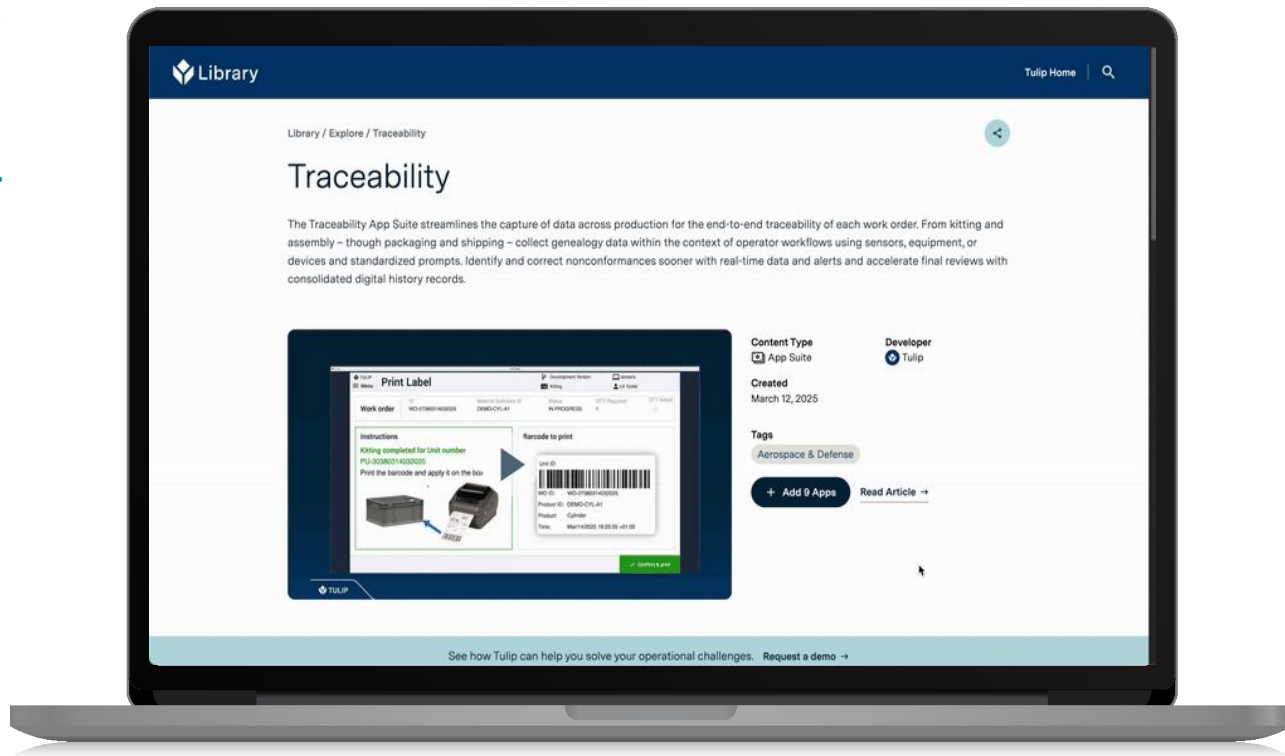


Extend & Scale with the Tulip Library



Get started quickly with fully configurable traceability apps.

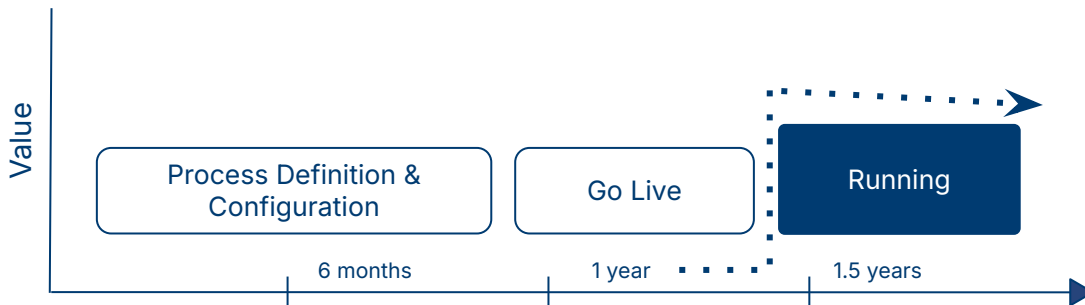
- Kitting and Assembly
- BOM Management
- Genealogy review
- eDHR review
- Packaging
- Environment monitoring



A composable approach means value in weeks, not years

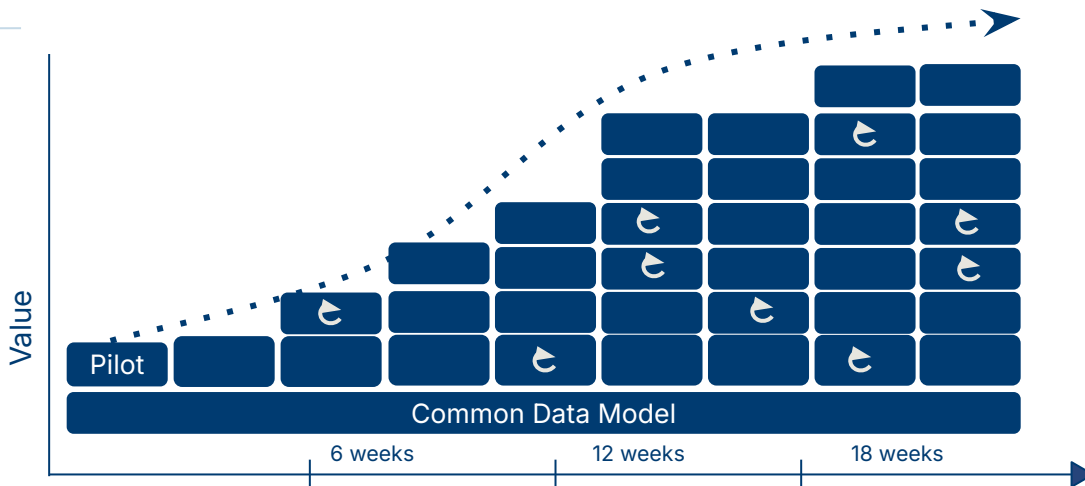
Monolithic System

- High-risk solution
- All-or-nothing
- Delayed value
- Declines over time



Composable System

- Low-risk solution
- Gradual growth
- Immediate value
- Continuously improves



Take home

**“Plan less and do more...
because doing is proving.”**

Says a Top 5 Life Sciences Enterprise
Customer of Tulip