GMP change control

Process Definition Document (PDD): template and worked example

Example company (fictional): Corvane Contract Manufacturing S.A., a contract manufacturer of sterile and oral products in Lyon, France (about 450 employees).

Document control

Field	Value
Process name	GMP change control
Process owner	[Name, role]
Prepared by	[Name]
Reviewed by	[Names of the people who do the work]
Approved by	[Name, date]
Version	1.0 (as-is)
Status	Draft

How to use this template

This is a complete process definition document (PDD) for GMP change control, also called the change management procedure, change request process or pharmaceutical quality change control. It describes how changes to equipment, processes, facilities and controlled documents are proposed, assessed, approved, implemented and closed at a fictional contract manufacturer, with the roles, systems, decisions and controls you would expect in a regulated site.

Use it as a starting point. Replace the company details, keep the sections, and walk through each step with the people who actually raise and assess changes. Most sites change the classification rules, the list of assessors and the customer notification route. If you are not a contract manufacturer, remove the customer steps (10 and 11) and the regulatory notes that go with them.

- Replace the company, the quality system and the document system with yours. If you are not on Veeva, name the module or form where each step happens.
- Set your own classification rules in step 5. What counts as major or critical differs most between sites and between products.
- Decide who assesses what. The list of experts per change type is usually the first thing a new site has to define.
- Remove the customer steps if you are a marketing authorisation holder, and add your regulatory notification route instead.
- Check the percentages against a year of change records. The share of returned requests and of late closures is usually the most useful number.
- Keep the as-is version after you redesign the process. It is your baseline for measuring the change.

1. Purpose and scope

This procedure describes how Corvane Contract Manufacturing proposes, assesses, approves, implements and closes changes to equipment, processes, facilities and controlled documents. It gives the initiators, the quality unit, the subject matter experts and the customer one shared description of who does what, so that no change reaches GMP production without assessment, approval and evidence that it worked.

In scope

- Document changes, equipment changes and process changes

- Classification of each change as minor, major or critical
- Impact assessment by validation, quality control, regulatory and engineering
- Customer notification and approval for changes that affect a customer product
- Implementation tasks, qualification, document revision and training
- Closure after an effectiveness check

Out of scope

- Emergency repairs done under a maintenance work order
- Changes to the customer's marketing authorisation, which belong to the customer
- Deviations and CAPA, except where a change is implemented before approval

2. Process at a glance

Item	Description
Trigger	An employee raises a change request in the quality system.
Starts when	The change initiator enters the request in Veeva Vault QMS.
Ends when	The QA Manager closes the change after implementation and the effectiveness check.
Inputs	Change request with reason and affected items, Equipment and document records, Customer quality agreement, Vendor quotation or specification
Outputs	Approved or rejected change record, Impact assessments and qualification plan, Revised and trained documents, Closed change with evidence
Volume	About 360 change controls a year: roughly 150 document, 130 equipment and 80 process changes
Working hours	Monday to Friday, 08:00 to 17:00

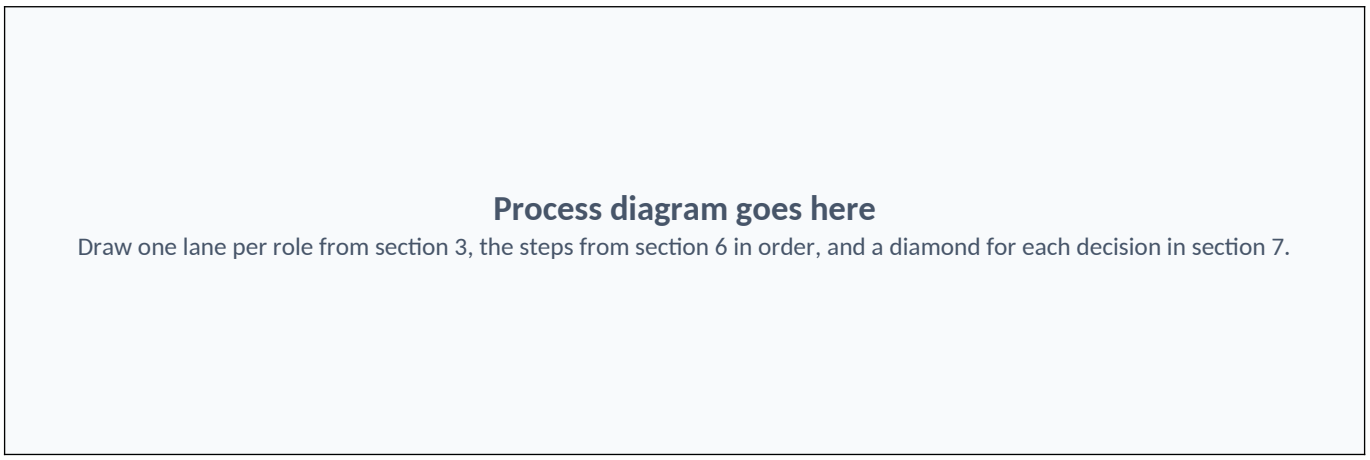
3. Roles and responsibilities

Role	Responsibilities
Change Initiator	Any employee who sees the need for a change. Describes the change, the reason and the affected items in the request and reworks it when it comes back.
Change Owner	The department head who accepts the change, answers questions from assessors, assigns implementation tasks and requests closure.
QA Change Coordinator	Screens requests for completeness, classifies each change, assigns assessment tasks, notifies the customer and checks the evidence before closure.
Subject Matter Expert	Engineering, QC and regulatory specialists who assess the effect of the change on validation, methods, documents, training and filings.
Validation Engineer	Writes the qualification or revalidation plan with an effort estimate and executes the protocols.
QA Manager	Reviews the full assessment and approves or rejects the change with an electronic signature, then closes it. Major and critical changes also need the site director's signature.
Engineering	Implements equipment changes with the vendor and updates the equipment record in SAP.
Document Owner	Revises the controlled documents affected by the change and routes them for review and approval.
Training Coordinator	Assigns read-and-understood training on the revised documents and tracks completion.
Customer (external)	The product sponsor. Reviews changes that affect their product and replies with approval, a request for more data or a rejection.
Equipment Vendor (external)	Supplies parts or modifications and works with Engineering during installation.

4. Systems

- Veeva Vault QMS: change control records, tasks and electronic signatures
- Veeva Vault QualityDocs: controlled documents
- SAP S/4HANA: equipment master data and purchase orders
- Shared change control mailbox for customer notifications
- Excel: list of open changes used in the weekly review

5. Process map



6. Procedure, step by step

#	Step	Who	What happens	System	Output
1	Raise the request	Change Initiator	Describes the change, the reason and the affected items in a new change request. This takes 20 to 30 minutes.	Veeva Vault QMS	Draft change request
2	Accept as change owner	Change Owner	The initiator submits the request to their department head, who accepts it as change owner. About 10% of requests are declined and closed without action.	Veeva Vault QMS	Owned request, or closed request
3	Screen for completeness	QA Change Coordinator	Checks the request within 1 to 2 days. The check itself takes about 15 minutes.	Veeva Vault QMS	Screening result
4	Return unclear requests	QA Change Coordinator	If the description is unclear or lacks information (about 20% of requests), sends it back to the initiator for rework. Otherwise continues.	Veeva Vault QMS	Complete request, or request returned
5	Classify the change	QA Change Coordinator	Classifies the change as minor, major or critical, based on its impact on the validated state, product quality and the licence. About 60% are minor, 33% major and 7% critical. This takes about 10 minutes.	Veeva Vault QMS	Classified change
6	Assign assessment tasks	QA Change Coordinator	Assigns impact assessment tasks to the experts needed for this type of change.	Veeva Vault QMS	Assessment tasks open
7	Assess the impact	Subject Matter Expert	Each expert assesses the effect on validation, QC methods, documents, training and regulatory filings, and records the result. Each assessment takes 30 to 90 minutes and the wait is typically 3 to 7 days.	Veeva Vault QMS	Recorded impact assessments
8	Rework the plan	Change Owner	If an expert finds a risk that is not addressed, asks the owner for more detail and the owner reworks the plan. This happens in about 18%	Veeva Vault QMS	Revised change plan

#	Step	Who	What happens	System	Output
			of changes.		
9	Write the qualification plan	Validation Engineer	For equipment and process changes, writes a qualification or revalidation plan and estimates the effort. This takes 2 to 4 hours.	Veeva Vault QMS	Qualification plan and effort estimate
10	Notify the customer	QA Change Coordinator	If the change affects a customer product (about 35% of changes), sends the change summary to the customer by email and records the notification in the change record.	Mailbox, Veeva Vault QMS	Customer notification sent
11	Reply to the change	Customer	Replies with approval, a request for more data or a rejection. About 5% of customer changes are rejected, and the change is then cancelled or revised. The wait is 5 to 20 working days.	Email	Customer decision
12	Approve or reject	QA Manager	Reviews the full assessment, the plan and the customer response, then approves or rejects with an electronic signature. This takes 30 to 60 minutes. Major and critical changes also need the site director's signature.	Veeva Vault QMS	Approved or rejected change
13	Assign implementation tasks	Change Owner	Assigns tasks to the departments, for example installing equipment, updating SAP master data, writing procedures or setting up training.	Veeva Vault QMS	Implementation tasks open
14	Implement the equipment change	Engineering	Implements the change with the vendor and updates the equipment record in SAP. This takes days to weeks.	SAP	Installed equipment, updated SAP record
15	Execute qualification	Validation Engineer	Executes the qualification protocols. If a protocol fails (about 10% of equipment changes), the owner and validation fix the problem and repeat the test.	Veeva Vault QMS	Executed protocols
16	Revise controlled documents	Document Owner	Revises the affected documents and routes them for review and approval. This takes 2 to 5 days.	Veeva Vault QualityDocs	Effective documents
17	Train affected teams	Training Coordinator	Assigns the revised documents for read-and-understood training and tracks completion. This takes 3 to 10 days.	Veeva Vault QualityDocs	Training completed
18	Request closure	Change Owner	Confirms that all tasks are done and requests closure. This takes about 15 minutes.	Veeva Vault QMS	Closure request
19	Check the evidence	QA Change Coordinator	Checks the evidence of each task and the effectiveness check, for example that no related deviations occurred in 3 months. This takes about 30 minutes.	Veeva Vault QMS	Verified evidence
20	Close the change	QA Manager	Closes the change. If tasks are still open (about 25% of changes at the first closure request), sends it back to the owner.	Veeva Vault QMS	Closed change, or change returned to the owner

7. Decision points and business rules

- Will the department head own the change? No (about 10% of requests): close the request without action (step 2).
- Is the description complete and clear? No (about 20% of requests): return it to the initiator (step 4).
- Is the change minor, major or critical? The class sets the signatures needed, and major and critical changes also need the site director (steps 5 and 12).
- Did an expert find an unaddressed risk? Yes (about 18% of changes): the owner reworks the plan before approval (step 8).
- Does the change affect a customer product? Yes (about 35% of changes): notify the customer and wait for the reply (steps 10 and 11).
- Does the customer accept? No (about 5% of customer changes): cancel or revise the change (step 11).
- Did a qualification protocol fail? Yes (about 10% of equipment changes): fix the cause and repeat the test (step 15).

- Are all tasks done and evidenced? No (about 25% at first closure request): return the change to the owner (step 20).

8. Exceptions

- Temporary change for a limited period (about 8%): approve with an end date and a plan for reverting.
- Emergency change after a breakdown (about 4%): implementation starts first and the paperwork is completed within 5 working days.
- Change implemented before approval by mistake (about 2%): raise a deviation and assess the change retrospectively.
- Customer slow to respond (about 30% of customer changes): the coordinator sends reminders weekly.

9. Controls

- No implementation before QA approval, except under the documented emergency route.
- Electronic signatures in the quality system meet EU GMP Annex 11 and 21 CFR Part 11, and the initiator cannot approve their own change.
- Equipment changes are qualified before use in GMP production, in line with EU GMP Annex 15.
- Customer approval is documented in line with the quality agreement for each affected product.
- The coordinator reviews all open changes weekly and the QA Manager reviews them monthly.
- Closure needs documented evidence of each task and of the effectiveness check.

10. Known issues today

- Initiators describe changes vaguely, so many requests come back.
- Experts often do not act on system tasks until the coordinator follows up by phone.
- Customer emails are not linked to the change record, so responses are searched for manually.
- Documents are sometimes revised before the change is approved, which leaves inconsistent versions.
- Closure is delayed because nobody sees which tasks are still open.

11. RACI matrix

R = responsible (does the work), A = accountable (owns the outcome), C = consulted, I = informed.

Activity	Initiator	Change Owner	QA Coordinator	Experts	QA Manager	Customer
Raise and describe the change	R	A	I			
Screen and classify	C	I	R		A	
Assess the impact		C	A	R	I	
Notify and obtain customer approval		I	A/R		C	C
Approve the change		C	R	C	A	C
Implement and qualify		A	I	R	I	
Revise documents and train		A	I	R	I	
Verify evidence and close		R	R		A	

12. KPIs

KPI	Definition	Target
Days from request to approval	Average calendar days between the request being submitted and the QA Manager approving it.	[set]
Changes closed by the due date	Share of changes closed on or before the due date set at approval.	[set]
Requests returned for rework	Share of requests sent back to the initiator at screening. Today about 20%.	[set]
Open changes older than 90 days	Number of changes still open 90 days after submission, counted at the monthly review.	[set]
Changes implemented without approval	Number of changes found to have been implemented before QA approval. The target is zero.	[set]

13. Revision history

Version	Date	Author	Change
1.0	[date]	[name]	First as-is version

Free template from processfix.ai. You may copy and adapt it. The company in the example is fictional.