GMP deviation management

Process Definition Document (PDD): template and worked example

Example company (fictional): Marbrook Pharmaceuticals Ltd, a manufacturer of oral solid dose products in Cork, Ireland (about 380 employees).

Document control

Field	Value
Process name	GMP deviation management
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 deviation management, also called the deviation procedure, non-conformance handling in pharmaceutical manufacturing or event and deviation investigation. It describes how departures from approved procedures, specifications and process parameters are recorded, contained, classified, investigated, assessed for their effect on batches, approved by quality assurance, linked to CAPA and closed at a fictional manufacturer, with the roles, systems, decisions and controls you would expect on a regulated site.

Use it as a starting point, not as a ready-made quality procedure. It describes one plausible way of working and does not make a site compliant with GMP. Adapt it to your own quality system, your marketing authorisations and the expectations of your inspectors, and have your quality unit approve the result. Most sites change the classification criteria, the target days and the list of people who approve each class.

- Replace the company, the products and the quality system with yours. If you work on paper or in another QMS, name the form or module where each step happens.
- Set your own classification matrix in step 6. Define minor, major and critical against patient safety, product quality, validated state and data integrity, and have it approved by your quality unit.
- Set the target days for each class from your own quality system and the commitments in your quality agreements. The numbers here are examples.
- Align the process with your OOS, CAPA, change control and complaint procedures. Say where one ends and the next starts.
- Check the percentages with real data from your quality system. The share of records returned and of investigations sent back for root cause shows where training is needed.
- This template describes one way of working and does not by itself show compliance with GMP. Have your quality unit review it against the regulations that apply to your site and products.

1. Purpose and scope

This procedure describes how Marbrook Pharmaceuticals records, contains, classifies, investigates and closes deviations from approved procedures, specifications and process parameters in GMP areas. It gives production, quality control, engineering and the quality unit one shared description of who does what, so that every deviation is recorded

when it is found, product is protected while the cause is investigated, the effect on each batch is assessed and documented before release, and corrective and preventive actions are tracked to completion.

In scope

- Deviations from procedures, batch records, specifications and process parameters in manufacturing, packaging, warehouse and QC laboratories
- Equipment failures and environmental excursions that affect GMP operations
- Immediate containment, classification and investigation
- Assessment of the effect on affected batches
- Link to CAPA and to change control where actions require it
- Closure within the target days

Out of scope

- Out of specification laboratory results, which follow a separate OOS procedure and are linked when they arise from a deviation
- Customer complaints and product recalls
- Batch certification and release, which uses the deviation as an input
- Non-GMP events, such as health and safety incidents

2. Process at a glance

Item	Description
Trigger	An employee notices that something has not been done as the approved procedure, batch record or specification requires.
Starts when	The employee tells their supervisor and records the event in the quality system.
Ends when	The QA Manager closes the deviation after all actions and the linked CAPA are in place and the batch impact is documented.
Inputs	Event description and evidence, Batch record and procedures, Equipment, environmental and laboratory data, Training and maintenance records, Similar past deviations
Outputs	Deviation record with classification, Containment record, Investigation report with root cause, Batch impact assessment, QA approval, Linked CAPA, Closed deviation
Volume	About 520 deviations a year: roughly 360 minor, 140 major and 20 critical
Working hours	Manufacturing runs on three shifts, Monday 06:00 to Saturday 06:00. QA is on site Monday to Friday, 07:00 to 18:00, with an on-call QA contact for nights and weekends.

3. Roles and responsibilities

Role	Responsibilities
Reporter	Any employee who finds a deviation. Informs the supervisor straight away and records the facts: what happened, when, where and which batch or equipment.
Area Supervisor	Takes immediate containment actions, stops or holds product and equipment where needed, confirms the facts and approves the initial record.
QA Deviation Coordinator	Reviews the record for completeness, numbers it, proposes the classification, assigns the investigation owner and tracks due dates.
Investigation Owner	The manager of the area where the deviation happened. Leads the investigation, writes the root cause and the proposed actions and answers QA questions.
Subject Matter Expert	Engineering, QC, validation and microbiology specialists who give technical input to the investigation and the batch impact.
QC Analyst	Provides laboratory data or additional testing requested by the investigation and records the results against the deviation.
QA Manager	Approves the classification of major and critical deviations, the investigation, the batch impact and the closure with an electronic signature.

Role	Responsibilities
Qualified Person	Uses the approved deviation and its batch impact assessment when deciding on batch certification. Is informed at once of any critical deviation.
CAPA Owner	Accepts the corrective or preventive actions, completes them by the due date and provides the evidence.
Contract Partner (external)	A customer or supplier that must be told under the quality agreement when a deviation affects their product or material.

4. Systems

- MasterControl Quality Excellence: deviation, CAPA and change records with electronic signatures
- Electronic batch record system: batch documents and in-process data
- LIMS: laboratory results and sample status
- SAP S/4HANA: batch status and stock blocking
- Environmental monitoring system: temperature, humidity and particle data
- Shared quality mailbox for notifications to contract partners

5. Process map

Process diagram goes here

Draw one lane per role from section 3, the steps from section 6 in order, and a diamond for each decision in section 7.

6. Procedure, step by step

#	Step	Who	What happens	System	Output
1	Report to the supervisor	Reporter	Tells the area supervisor straight away when a deviation is found and keeps the evidence unchanged, for example the printout, the affected material and the equipment settings.	Production floor	Deviation reported and evidence kept
2	Contain the situation	Area Supervisor	Stops the operation if product quality may be affected, segregates and labels affected material, blocks the batch in SAP if needed and informs the on-call QA contact outside normal hours. It takes 10 to 30 minutes.	Production floor, SAP S/4HANA	Containment actions in place
3	Record the deviation	Reporter	Enters the deviation on the same shift, with a description of the facts, the batches, equipment and rooms involved and the immediate actions. The target is 24 hours at most. It takes 15 to 30 minutes.	MasterControl Quality Excellence	Draft deviation record

#	Step	Who	What happens	System	Output
4	Confirm the facts	Area Supervisor	Checks the description against what happened and the batch record and approves the initial record. About 10% are corrected at this point because the batch or time is wrong.	MasterControl Quality Excellence	Confirmed deviation record
5	Review and number the record	QA Deviation Coordinator	Checks the record within 1 working day, returns it if the facts or batch numbers are incomplete (about 15% of records) and checks for similar open or past deviations on the same equipment or product.	MasterControl Quality Excellence	Reviewed record, or returned record
6	Classify the deviation	QA Deviation Coordinator	Proposes minor, major or critical using the classification matrix: effect on product quality, patient safety, validated state and data integrity, and whether it repeats. About 70% are minor, 27% major and 3% critical. Classification is revisited when the investigation shows a larger effect.	MasterControl Quality Excellence	Initial classification
7	Confirm major and critical classification	QA Manager	Confirms or changes the classification of every major and critical deviation the same or the next working day. For a critical deviation, also informs the qualified person and the site director immediately.	MasterControl Quality Excellence	Confirmed classification
8	Assign the investigation	QA Deviation Coordinator	Assigns an investigation owner and sets due dates: 5 days for minor, 20 days for major and 10 days for the first report of a critical deviation. The overall target for closure is 30 calendar days.	MasterControl Quality Excellence	Investigation task with due dates
9	Investigate and find the root cause	Investigation Owner	Collects the evidence, interviews the people involved and analyses the cause with a 5 Why or fishbone method, checking equipment, material, method, people, environment and documents. The investigation for a major deviation takes 5 to 15 working days. Human error is accepted as a root cause only after the process and training have been looked at.	MasterControl Quality Excellence, electronic batch record system	Investigation report with root cause
10	Give technical input	Subject Matter Expert	Gives an opinion on the technical effect, for example on the stability, the sterility assurance or the validated state, and records it in the investigation. This takes 1 to 3 days.	MasterControl Quality Excellence	Documented technical assessment
11	Run additional testing if needed	QC Analyst	Performs the extra tests requested by the investigation, such as retests on retained samples or extended testing, under a protocol approved by QA. The result is linked to the deviation record. If a result is out of specification, the OOS procedure starts in parallel.	LIMS	Test results linked to the deviation
12	Assess the effect on batches	Investigation Owner	Lists every batch, lot and piece of equipment that could be affected, including batches made before the deviation was found, and records for each the conclusion and the reason. It takes 1 to 3 hours.	MasterControl Quality Excellence, SAP S/4HANA	Batch impact assessment
13	Propose corrections and actions	Investigation Owner	Proposes the correction for the event and corrective and preventive actions for the cause, each with an owner and due date. Major and critical deviations always need at least one action.	MasterControl Quality Excellence	Proposed actions

#	Step	Who	What happens	System	Output
14	Review the investigation	QA Deviation Coordinator	Checks that the root cause is supported by evidence, that all affected batches are covered and that the actions address the cause. About 25% of major investigations are returned for more work.	MasterControl Quality Excellence	Reviewed investigation, or returned investigation
15	Approve the investigation and batch impact	QA Manager	Approves or rejects the investigation, the batch impact and the proposed actions with an electronic signature. Minor deviations can be approved by an authorised QA reviewer. It takes 30 to 60 minutes.	MasterControl Quality Excellence	Approved investigation, or rejection with comments
16	Be informed of the deviation	Contract Partner	When the quality agreement requires it, QA sends the deviation summary and the batch impact to the customer or supplier and records their reply in the deviation. About 8% of deviations are notified to a partner.	Shared quality mailbox	Partner informed and reply recorded
17	Open the linked CAPA	QA Deviation Coordinator	Creates a CAPA record linked to the deviation for each approved corrective or preventive action. If an action needs a change to equipment, a process or a document, opens a change control as well. About 40% of deviations lead to a CAPA.	MasterControl Quality Excellence	Linked CAPA and change records
18	Complete the actions	CAPA Owner	Carries out the action, attaches the evidence, for example a revised procedure, a training record or a repaired and requalified machine, and marks the action complete.	MasterControl Quality Excellence	Completed actions with evidence
19	Use the deviation for certification	Qualified Person	Reviews the approved deviations and batch impacts before certifying the batch. An open major or critical deviation on the batch stops certification until it is approved.	MasterControl Quality Excellence, SAP S/4HANA	Batch decision based on documented deviations
20	Close the deviation	QA Manager	Closes the deviation when the investigation and batch impact are approved and all corrective actions are in place or tracked in an open CAPA. Overdue closure is reported at the weekly quality meeting.	MasterControl Quality Excellence	Closed deviation

7. Decision points and business rules

- Could product quality be affected now? Yes: stop, segregate and block the batch before anything else (step 2).
- Is the record complete and are the facts confirmed? No: return it to the reporter (steps 4 and 5).
- Minor, major or critical? Critical is escalated to the qualified person and the site director at once (steps 6 and 7).
- Is the root cause supported by evidence? No: return the investigation (step 14).
- Which batches and equipment could be affected? Including those produced before the deviation was found (step 12).
- Is additional testing needed, and is a result out of specification? Yes: run the protocol and start the OOS procedure in parallel (step 11).
- Does the quality agreement require us to inform a contract partner? Yes: send the summary and record the reply (step 16).
- Does a corrective or preventive action need a CAPA or a change control? Yes: open and link them (step 17).

8. Exceptions

- Deviation found outside QA hours (about 30%): the supervisor contains the event and calls the on-call QA contact, and the record is entered on the next working day with the time of the event.
- Investigation cannot finish within 30 days, for example waiting for a vendor report (about 12%): the owner requests an extension with a reason and QA approves a new date.
- Classification changes during the investigation (about 6%): QA reclassifies the deviation and sets the due dates for the new class.
- Same deviation repeats on the same equipment or step (about 9%): QA raises the classification and opens a trend review.
- Deviation discovered after the batch has been released or shipped (rare): the QA Manager and the qualified person assess the need for a field alert or recall under the separate procedure.

9. Controls

- Electronic signatures and audit trails in the quality system meet EU GMP Annex 11 and 21 CFR Part 11, and the reporter or investigation owner cannot approve their own deviation.
- Batches with an open major or critical deviation are blocked in SAP and cannot be certified until QA approves the deviation.
- Classification, root cause and batch impact are approved by the quality unit, not by the area where the deviation happened.
- Deviations are trended monthly by area, equipment, product and root cause category and reviewed at the quality management review.
- Overdue deviations and CAPAs are reported weekly to the QA Manager and monthly to the site director.
- Records are kept for at least 1 year after the batch expiry date and in any case for the period set by the marketing authorisation and regulatory requirements.

10. Known issues today

- Reporters describe events vaguely, and about 15% of records come back for facts and batch numbers.
- Root cause is often written as human error without looking at procedures or training.
- Batch impact is assessed by hand from several systems, so a related batch is sometimes missed.
- Investigations wait for expert input, and tasks in the system are not acted on until QA follows up by phone.
- Closure is delayed because open CAPAs on the deviation are not visible to the people who close it.

11. RACI matrix

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

Activity	Reporter	Area Supervisor	QA Coordinator	Investigation Owner	QA Manager
Report and contain the deviation	R	A/R	I		I
Record and confirm the facts	R	A	C		
Review and classify		I	R	C	A
Investigate and find the root cause	C	C	C	A/R	I
Assess the effect on batches		C	C	R	A
Review and approve the investigation			R	C	A
Open and complete CAPA		C	R	R	A
Close the deviation		I	R	I	A

12. KPIs

KPI	Definition	Target
Days from detection to closure	Average calendar days between the event and closure, by class. The target is 30 days for major and 15 for minor.	[set]
On-time closure rate	Share of deviations closed on or before the target date.	[set]
Records returned for rework	Share of records or investigations returned by QA for missing facts or weak root cause.	[set]
Repeat deviations	Share of deviations with the same root cause category, equipment or step as one in the previous 12 months.	[set]
Overdue open deviations	Count of deviations past their due date at month end, split by age.	[set]
Deviations per 100 batches	Deviations raised divided by batches manufactured, times 100, by product and area.	[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.