Batch record review and batch release

Process Definition Document (PDD): template and worked example

Example company (fictional): Alpenmed Generika GmbH, a generic oral solid dose manufacturer in Graz, Austria (about 320 employees).

Document control

Field	Value
Process name	Batch record review and batch release
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 batch record review and batch release, also called batch disposition, QA release or batch certification by the Qualified Person (QP). It describes the process as it runs today at a fictional generic medicines manufacturer, with the roles, systems, steps, decisions and controls you would expect in a real QA release team.

Use it as a starting point. Replace the company details, keep the sections, and walk through each step with the batch record reviewers and the QP, not only the QA head. Most sites change the review checklist, the way deviations and QC results are checked, and what is reviewed on paper or on screen. The structure stays the same.

- Replace the company, products and systems with yours. If you use electronic batch records or another QMS, name the system where each step happens.
- Set your own review checklist in step 5. Sites differ in what the reviewer checks on each page and what production checks before hand-over.
- Check the percentages with real data. A few months of batches usually shows how many are returned, how many query loops repeat and how many wait for deviations.
- Decide who confirms QC results and deviation status. Some sites make the reviewer do it, others have QC and QA send a status.
- Add your own rules for urgent batches, contract manufacturers and QP substitution.
- Keep the as-is version even after you redesign the process. It is your baseline for measuring the change.

1. Purpose and scope

This procedure describes how Alpenmed reviews the executed batch record of a finished medicine batch and how the Qualified Person certifies and releases the batch for sale. It gives production, QA, QC and the warehouse one shared description of who does what, so that no batch is released with open deviations, missing signatures or unapproved results, and so that every release can be explained to an inspector.

In scope

- Review of the executed batch record against the master batch record
- Query handling and GMP corrections with production

- Checks of deviations, change controls, QC results and certificate of analysis
- Packaging records from contract packaging partners
- Certification by the QP, status change in SAP and archiving

Out of scope

- Batch manufacturing
- Packaging line clearance
- Stability studies
- Importation from third countries

2. Process at a glance

Item	Description
Trigger	Production completes the batch record and signs the end-of-production page.
Starts when	The production supervisor checks the attachments and hands the record to QA.
Ends when	The QP certifies the batch in SAP and the stock status changes to released.
Inputs	Executed paper batch record, Master batch record, Analytical results and certificate of analysis, Deviation status, Change controls affecting the batch, Packaging record from contract partners
Outputs	Reviewed batch record, Release checklist and review summary, Signed batch certification register entry, Usage decision in SAP, Batch in unrestricted status, Archived batch file
Volume	About 410 batches released per year
Working hours	Office hours, 07:30 to 16:30, Monday to Friday

3. Roles and responsibilities

Role	Responsibilities
Production Supervisor	Completes and hands over the executed batch record, answers review queries and corrects the record.
QA Batch Record Reviewer	Checks the record for completeness and accuracy, compiles the release checklist and archives the file.
QC Laboratory Analyst	Finalises the analytical results in LIMS and issues the certificate of analysis once QC has approved the data.
QA Deviation Coordinator	Confirms that all deviations linked to the batch are closed or assessed.
Qualified Person	Reviews the file, confirms the authorisations and certifies the batch for release.
Warehouse Clerk	Moves released stock to the saleable location and prepares dispatch.
Contract Packaging Partner (external)	Returns the packaging records for outsourced packs.

4. Systems

- SAP S/4HANA (QM and MM): batch status, usage decision and stock
- Veeva Vault QMS: deviations, change controls and CAPA
- LIMS (LabWare): analytical results
- Shared QA drive: scanned batch records, with paper originals kept
- Excel: batch review tracker
- Shared QA release mailbox

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	Complete the batch record	Production Supervisor	Completes the last entries in the paper batch record and signs the end-of-production page. It takes about 20 minutes.	Paper record	Executed batch record
2	Check attachments and hand over	Production Supervisor	Checks that all attachments are present: printouts, labels, line clearance forms and weight tickets. Then hands the record to QA. It takes about 15 minutes.	Paper record	Record handed to QA
3	Receive, log and scan	QA Batch Record Reviewer	Receives the record, logs the batch in the Excel tracker and scans the record to the QA drive. It takes about 10 minutes.	Excel, QA drive	Logged and scanned record
4	First look	QA Batch Record Reviewer	If the record is missing pages or signatures at first look, returns it to production the same day. This applies to about 10% of batches. Otherwise the review starts.	Paper record	Record accepted for review, or returned
5	Review against the master	QA Batch Record Reviewer	Compares each page against the master batch record, checking dates, signatures, yields, equipment IDs and in-process checks. It takes 90 to 180 minutes.	Paper record, scan	Review findings
6	Send the query list	QA Batch Record Reviewer	Notes every discrepancy in a query list and emails it to the production supervisor. It takes about 10 minutes.	Email	Query list sent
7	Answer and correct	Production Supervisor	Answers each query and corrects the record with a signed and dated GMP correction. This takes 1 to 3 days. If the corrections reveal a process deviation, the supervisor opens a deviation in Veeva Vault QMS.	Paper record, Veeva Vault QMS	Corrected record, answers, possible deviation
8	Recheck and sign the review	QA Batch Record Reviewer	Rechecks the corrected pages. If new discrepancies appear (about 15% of batches), the query loop repeats. Otherwise the review is completed and signed.	Paper record	Signed batch record review
9	Check deviations are closed	QA Deviation Coordinator	Checks that all deviations linked to the batch are closed. If one is still open (about 12% of batches), the batch waits until QA approves it, which takes 3 to 15 days.	Veeva Vault QMS	Deviation status confirmed
10	Finalise results and CoA	QC Laboratory Analyst	Finalises the analytical results and issues the certificate of analysis once the QC reviewer approves the data. It takes about 20 minutes.	LIMS	Certificate of analysis
11	Check for OOS	QC Laboratory Analyst	If any result is out of specification (about 2% of batches), QC opens an out-of-specification	LIMS	Results in specification, or

#	Step	Who	What happens	System	Output
			investigation and the batch is put on hold until it is closed. Otherwise the process continues.		batch on hold
12	Get the packaging record	QA Batch Record Reviewer	For outsourced packaging, requests the packaging record from the contract packaging partner by email and waits for it. This takes 2 to 4 days.	Email	Packaging record
13	Check changes and materials	QA Batch Record Reviewer	Checks that the change controls affecting the batch are implemented and that the batch uses approved materials and suppliers in SAP. It takes about 15 minutes.	Veeva Vault QMS, SAP	Changes and materials confirmed
14	Compile the release file	QA Batch Record Reviewer	Compiles a release checklist and attaches the review summary in the QA release folder. It takes about 15 minutes.	QA drive	Release checklist and summary
15	Review the file	Qualified Person	Receives the file by email and reviews the checklist, the certificate of analysis and the deviation status. Also confirms that the marketing authorisation and the manufacturing licence cover the batch. It takes 30 to 45 minutes.	Email, QA drive	File reviewed
16	Accept or send back	Qualified Person	If the QP is not satisfied (about 5% of batches), the file goes back to the reviewer with questions. Otherwise the QP continues.	Email	Questions, or go-ahead
17	Certify the batch	Qualified Person	Signs the batch certification register and records the usage decision in SAP QM. It takes about 10 minutes.	Certification register, SAP QM	Certified batch, usage decision
18	Status changes in SAP	Qualified Person	SAP changes the batch status from quarantine to unrestricted and sends an automatic message to the warehouse clerk.	SAP QM	Batch unrestricted
19	Move stock to saleable	Warehouse Clerk	Moves the stock to the saleable location, and the batch becomes available for dispatch. It takes about 10 minutes.	SAP MM	Batch available for dispatch
20	Archive the batch file	QA Batch Record Reviewer	Archives the batch record and the release file for retention. It takes about 10 minutes.	QA drive, archive	Archived file

7. Decision points and business rules

- Is the record complete at first look? No: return it to production the same day (step 4).
- Do new discrepancies appear after correction? Yes: the query loop repeats (step 8).
- Are all deviations linked to the batch closed? No: the batch waits until QA approves them (step 9).
- Is any result out of specification? Yes: open an OOS investigation and hold the batch (step 11).
- Is the packaging done outside? Yes: request the packaging record from the partner (step 12).
- Is the QP satisfied with the file? No: send it back to the reviewer with questions (step 16).

8. Exceptions

- Batch for urgent customer shipment (about 8%): QA moves the batch to the front of the review queue by email agreement with the QP.
- Missing sample result or late LIMS entry (about 7%): the release waits for QC.
- QP absent (about 5% of weeks): a second QP certifies after reading the full file.
- Batch rejected (about 1%): the stock is scrapped or reworked under change control.

9. Controls

- Only the QP can change a batch from quarantine to unrestricted in SAP, and this is a restricted authorisation.
- Segregation of duties: the reviewer and the QP are different people, and the person who executed a step does not review it.
- Certification follows EU GMP Annex 16 and the Austrian medicines law.
- GMP data integrity (ALCOA+): corrections are signed, dated and explained, and original records are never overwritten.
- The audit trail in SAP, LIMS and Veeva Vault QMS is reviewed as part of batch review.

10. Known issues today

- The paper record is scanned and then reviewed again on screen, so work is done twice.
- Query lists go by email, and the answers are hard to track.
- The reviewer checks QC, deviation and change status in three separate systems.
- Missing signatures account for most of the returns.
- QC results can arrive 5 to 10 working days after sampling, so release waits for them.

11. RACI matrix

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

Activity	Production	QA Reviewer	QC	Deviation Coord.	QP	Warehouse
Complete and hand over the batch record	A/R	I				
Review the record and raise queries	C	A/R			I	
Answer queries and correct the record	A/R	C				
Confirm deviations are closed	C	I		A/R	I	
Issue results and certificate of analysis		I	A/R		I	
Compile the release file		A/R	C	C	I	
Certify the batch		C	I	I	A/R	I
Move stock to saleable					A	R

12. KPIs

KPI	Definition	Target
Release lead time	Average working days from end of production to QP certification.	[set]
Right-first-time batch records	Share of batches where the record passes the first look and review without returns. Today about 90% pass the first look.	[set]
Review queries per batch	Average number of queries raised per batch record.	[set]
Batches waiting for deviation closure	Number of reviewed batches held because a linked deviation is still open.	[set]
QP review backlog	Number of batches waiting for QP review at the end of each week.	[set]

13. Revision history

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

Version	Date	Author	Change

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