



Batch Record Review & Release Kit

Batch record review checklist, error log, release tracker and annual product review starter.

What's inside

File	What it is / how to use it
01_Batch_Record_Review_Workbook.xlsx	Release tracker, GDP error log and APR data sheet.
02_Batch_Record_Review_Checklist.docx	QA review checklist.
03_Annual_Product_Review.docx	APR/PQR report template (21 CFR 211.180(e), navigation).

Templates, not regulatory advice. Public regulation text (e.g., 21 CFR, EU 2017/745, CDC/OSHA guidance) is summarized with sources named. ISO, IEC and AAMI standards are copyrighted; this kit paraphrases and cites clause numbers only, so buy the standards from their publishers. Confirm current requirements for your market, and use qualified regulatory support for submissions and compliance decisions.

GMP decisions (batch release, validation acceptance, OOS conclusions) belong to your quality unit. Confirm requirements against current 21 CFR 210/211, Part 11 and FDA/ICH guidance for your products.

About the author

Built by Matt Norman, US Navy veteran and former SpaceX Falcon 9 quality inspector and QA supervisor. (Not affiliated with or endorsed by SpaceX.) Norman Quality Tools is Veteran-Owned & Operated. Contains no SpaceX, government, or customer proprietary information; all example data is made up.

License

One company license: use and edit at all sites of the purchasing company. Do not resell or redistribute. Works with Word/Excel 2016+, Microsoft 365, LibreOffice; no macros. Norman Quality Tools (Veteran-Owned & Operated), 600 W Santa Ana Blvd, Ste 114-A3064, Santa Ana, CA 92701. Support: normanqualitytools.com/support.html

Batch Record Review & Release Kit v1, Rev A (2026-10). Independent guidance. Not affiliated with or endorsed by the U.S. FDA, EMA, ICH, PIC/S, ISPE, WHO, USP, SAE International, IAQG, ISO, or any current or former employer of the author. Standard clause numbers are for navigation only; buy standards from their publishers. Not legal advice; does not guarantee certification or approval. Templates, not regulatory advice. © 2026 Norman Quality Tools. All rights reserved. Licensed for use within the purchasing company; do not resell or redistribute.

Batch Record Review Checklist

Batch Record Review & Release Kit - Document 02 - Rev A (2026-10)

Product		Batch	
Reviewer		Date	

Check	OK	Note
Correct master record version issued		
All steps completed, signed, dated (and verified where required)		
Materials: lots, quantities, release status match		
Equipment IDs, cleaning status and calibration current		
In-process results within limits; out-of-range flagged		
Yields calculated and within limits; reconciliation done		
Labels issued, used, destroyed reconciled		
Deviations closed or assessed for this batch		
Lab results complete and approved		
GDP errors corrected properly		
Environmental monitoring acceptable for the period		

Role	Name	Signature	Date
Production review			
QA approval			

Template, not regulatory advice. Standards cited by clause number only; buy them from the publisher.