QA
BIOTECH
CONSULTANCY

Audit-ready?

The 10 most common GMP deficiencies in pharmaceutical companies - and how to avoid them.
A practical guide from QA Biotech Consultancy -
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Why audits fail - and how to do it better

GMP inspections and internal audits are a critical milestone for biotech and ATMP companies. Nevertheless, experience shows that even highly innovative companies regularly fail due to avoidable deficiencies.

This compact guide shows you the ten most common mistakes made in GMP practice - based on over 20 years of QA experience. With clear recommendations and an audit self-check to help you identify gaps at an early stage.

The 10 most common GMP deficiencies - and how to avoid them:

✗ **Missing or outdated SOPs**
✓ **Solution:** Establish a document management system, schedule regular SOP reviews.

✗ **Insufficiently trained employees**
✓ **Solution:** Document GxP training plans and provide regular proof of participation.

✗ **Untraceable batch releases**
✓ **Solution:** Standardize and document QP release processes; establish double check.

✗ **Incomplete CAPA processes**
✓ **Solution:** Every deviation must go through a documented CAPA cycle with root cause analysis.

✗ **Gaps in data integrity**
✓ **Solution:** Establish ALCOA principles (Attributable, Legible, Contemporaneous, Original, Accurate) as a standard.

✗ **Non-validated processes or devices**
✓ **Solution:** Implement qualification and validation plans for all critical systems (URS, IQ, OQ, PQ).

✗ **Lack of traceability of source materials**
✓ **Solution:** Implement complete supplier qualification and incoming goods inspection.

✗ **No clear allocation of roles in QA/QP**
✓ **Solution:** Clearly define responsibilities in QMS and organization chart, define deputy regulations.

✗ **Incomplete audit trails or reports**
✓ **Solution:** Use electronic systems with audit trail function and check regularly.

✗ **No preparation for inspections**
✓ **Solution:** Carry out regular mock inspections with external QA support.

Self-check: Are you audit-ready?

- ☐ Is there an up-to-date training status for all GxP employees?
- ☐ Is your QMS fully documented and up to date?
- ☐ Was the last mock inspection carried out - including follow-up?
- ☐ Are your processes and systems validated (IQ/OQ/PQ)?
- ☐ Is the QP release documented, traceable and GMP-compliant?

If you are unsure about any of these questions, it is worth taking an external look!

About us

QA Biotech Consultancy
Dr. Gabriela-Nadja Huetz

With over 20 years of experience as a Qualified Person, GxP auditor and QA consultant, I support pharma, biotech and ATMP companies throughout Europe in ensuring regulatory compliance. Whether audits, mock inspections or QMS set-up - we accompany you on the way to audit security.