

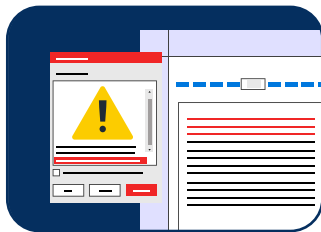
3 Costly Biotech Labeling & Documentation Errors That Delay Go-to-Market

And how to avoid them before your next submission



These 3 Mistakes Can Delay Your Product by Months

Especially for scaling biotechs preparing for a BLA, clinical trials, or commercial launch.



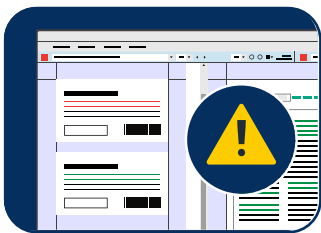
1. Unvalidated Proofreading of Regulatory Docs

✘ Mistake:

Manual review missed a decimal. Now the Health Authority requested clarification.

✔ Tip:

Use automated proofreading with 21 CFR Part 11-compliant audit trails and EMA Annex 11.



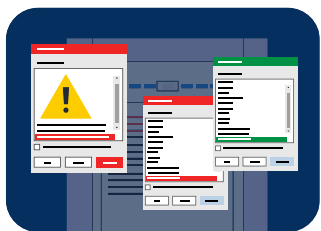
2. Label Mismatches Across Versions

✘ Mistake:

Artwork didn't match approved text. Rework delayed submission.

✔ Tip:

Align text and packaging review workflows using version control.



3. No Traceability for Label Changes

✘ Mistake:

Unable to show who approved what. Audit flagged for lack of traceability.

✔ Tip:

Implement a validated system that logs every change and check.

Avoid the Top 3 Go-to-Market Mistakes

Learn how biotech teams stay compliant, audit-ready, and efficient, without hiring more staff.

Connect with us



www.schlafenderhase.com

SCHLAFENDER HASE GMBH

St Martin Tower Franklinstr.

61-63 60486 Frankfurt

Phone: +49 69 244 481 0

Email: TVT@sh-p.com

SCHLAFENDER HASE INC.

245 First Street Suite 1800-103

Cambridge, MA 02142 USA,

02142-1292

Phone: +1 617 607 4900

Email: us@sh-p.com