New Drug Application (NDA)/ Biologics License Application (BLA) checklist

Bringing a new small molecule drug or biological product into the US?
You'll need either an NDA or BLA submission to secure FDA approval.

Only 12% of these products passing through clinical trials ever secure final approval. Use our step-by-step checklist for a confident, controlled and right-first-time submission that gets you to market!

First? Determine which route you'll follow

NDA 505(b)(1) → For brand-new novel drugs that have gone through full clinical trials

BLA 351(a) → For brand-new novel biological products that have gone through full clinical trials

NDA 505(b)(2) → For drugs where a similar predicate drug, already approved and on the market, can be used as a benchmark for proving safety and effectiveness

BLA 351(k) → For biological products where a biosimilar, already approved and on the market, can be used as a benchmark for proving safety and effectiveness

Submission ingredients

Cover letter	
☐	Introduction of your product and your company to the FDA
☐	Identified contact person(s)
☐	State/confirm any prior agreements/understandings with FDA
☐	Any other important information the FDA should be aware of

FDA Form 356h application form	
☐	Date of submission
☐	Name, address, contact details of applicant
☐	If re-submitting, amending or supplementing: NDA/BLA number and supplement number
☐	Proposed indication of product use

FDA Form 356h application form (continued)

☐	Submission type
☐	Reason for submission
☐	Establishment information: all sites related to product lifecycle, with FEI/MF/DMF/DUNS numbers and contact info
☐	Signature

Index

☐	Comprehensive index that references submission summary, technical sections and supporting information by volume/page number

Summary

☐	Clear sections and headings
☐	Supporting tables and graphics wherever possible
☐	Sufficient detail (comparable to medical/scientific journal level) to provide firm understanding of product and data
☐	No biased promotion of product
☐	Comprehensive and clear structure covering all application ingredients, reaching a concise and clear conclusion
☐	Separate summaries for each technical section
☐	Statement identifying pharmacologic class, intended use, clinical benefits and scientific rationale
☐	Proposed labeling text
☐	Non-US marketing history (if applicable)
☐	Conclusion with both pre-clinical and clinical risk/benefit and toxicity assessments
☐	Description of any post-clinical, post-approval studies to be conducted (with reasons)

Technical sections

☐	Chemistry, manufacturing and controls
☐	Non-clinical pharmacology and toxicology
☐	Human pharmacokinetics and bioavailability
☐	Microbiology
☐	Clinical data

Samples & labeling

☐	Label copies in .xml and .docx formats (4 draft or 12 final)
☐	3 copies of product/substance test information from chemistry, manufacturing and controls section
☐	Physical samples for dispatch when requested by FDA: 4 x product, 4 x substance used in product, 4 x reference standards or blanks for each FDA lab (2+ labs likely)

Case report forms & tabulations

☐	Case report tabulations of all studies
☐	Case report forms
☐	Readiness to send more within 30 days of request
☐	Meet with FDA pre-submission to ensure forms and tabulations are sufficient/formatted correctly

Patent information (for NDA 505(b)(2) predicate applications)

☐	Completed Form 3542a
☐	Patent number/certification for listed drugs, including expired

Claimed exclusivity

☐	If you believe your product is entitled to exclusivity, claim and prove for the following timeframes:
☐	351(k): 10 years
☐	Orphan drug: 7 years
☐	New chemical entity: 5 years
☐	GAIN: 5 years
☐	New clinical investigation: 3 years
☐	Pediatric: 6 months

Financial certification/disclosure statement

☐	Declare financial arrangements: Form 3455
☐	No arrangements to declare: Form 3454

Debarment certification

☐	Signed certification as follows: "[Company name] hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application."

Submission format

☐	1 x archival copy: official, complete version, submitted by paper or eCTD
☐	1 x review copy: technical sections, plus application form and summary
☐	1 x field copy: physical version of review copy, with certification that it's a true representation of the archival copy, to be mailed to your nearest FDA district office

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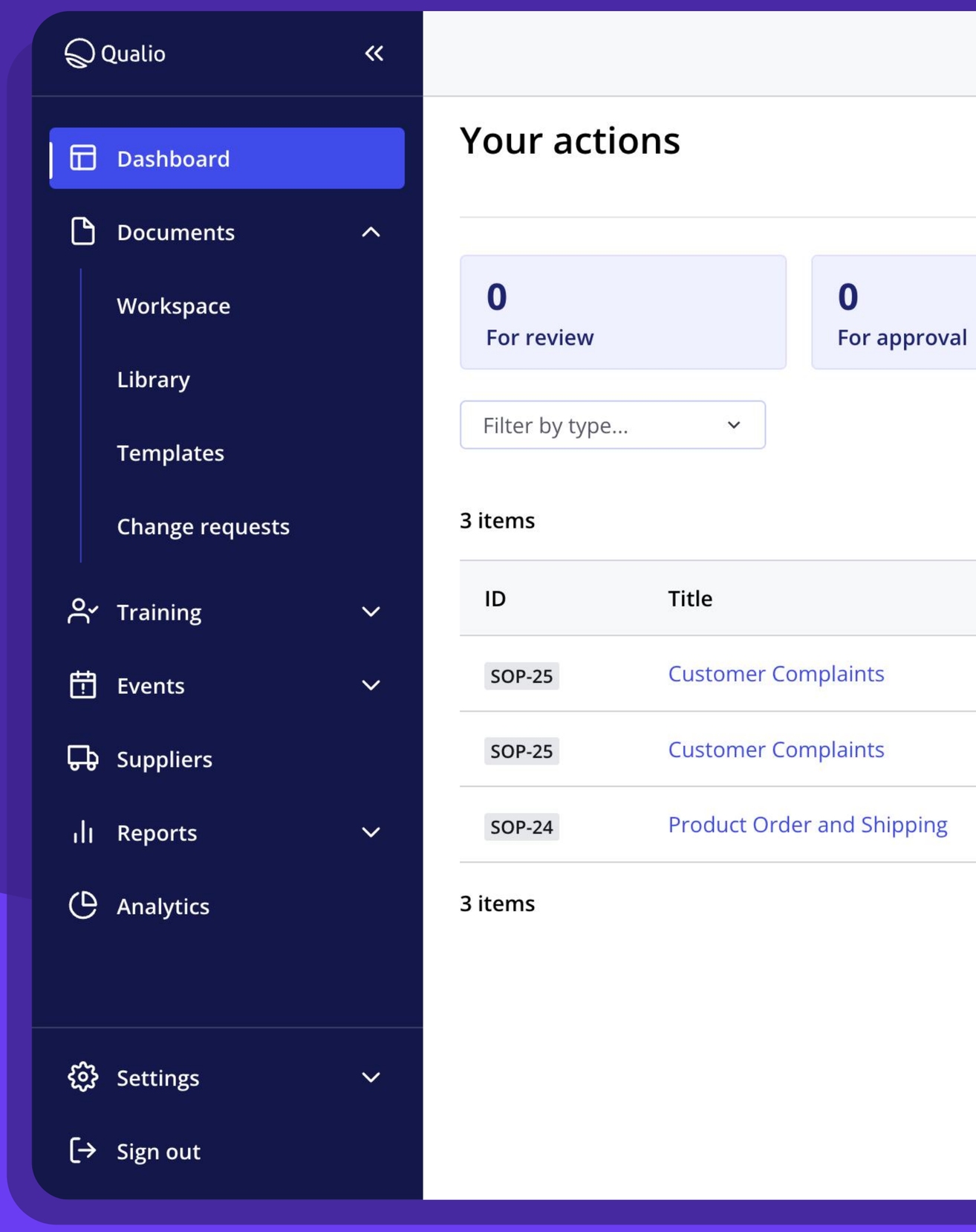

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