

# FDA eCopy Submission Checklist – Format, Folder Structure & Compliance

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## Basic File Structure & Format

- Single root-level folder without subfolders
- All documents in searchable PDF format
- No executable files, external links, or compressed folders
- File names under 64 characters with no special characters

## Required Elements

- Signed Cover letter in PDF
- Table of Contents in each PDF
- Signed Truthful & Accuracy Statement (Only for 510(k) submission)

## Validation & Submission

- Validated using FDA eCopy Validation Tool
- Files successfully transferred to CD/DVD/Flash Drive
- Shipped to FDA's Document Control Center
- Confirmation received from FDA (if applicable)