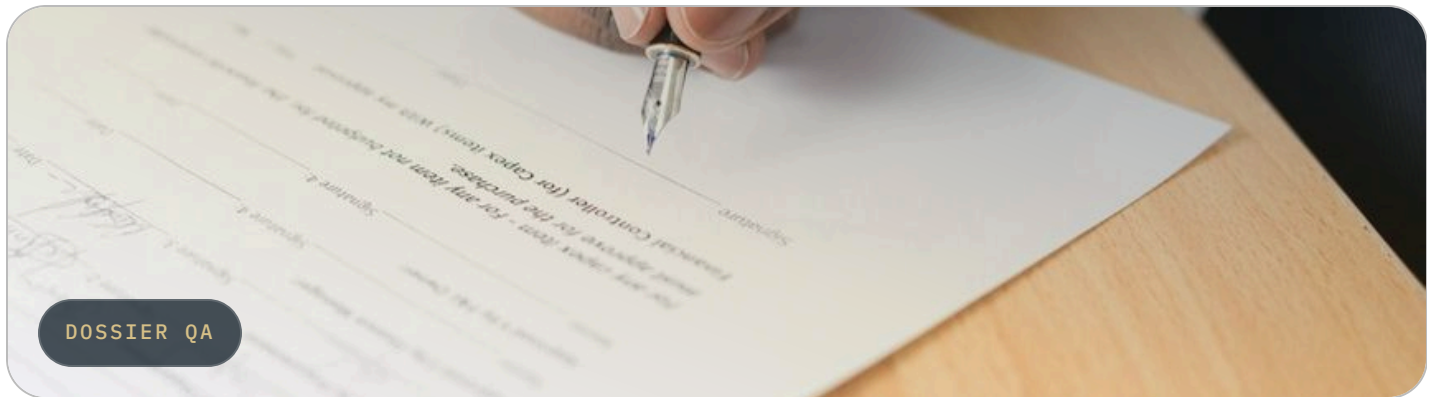


CTD dossier quality assurance checklist

The checklist we run before anything is filed. A dossier that clears every line below is not guaranteed a first-pass approval — but a dossier that does not will generate queries you could have prevented.



01 Administrative documents

- ✓ Cover letter
- ✓ Application form in Word and PDF
- ✓ Proof of payment
- ✓ Power of Attorney / LTR appointment letter
- ✓ PPB-issued GMP certificate
- ✓ Certificate of Pharmaceutical Product (COPP)
- ✓ Trademark clearance evidence

02 Module 1 — Regional requirements

- ✓ Product information
- ✓ Labelling
- ✓ Patient information leaflet
- ✓ Packaging artwork
- ✓ Naming compliance review

03 Module 2 — Summaries

- ✓ Quality Overall Summary in Word
- ✓ Non-clinical overview
- ✓ Clinical overview
- ✓ Bioequivalence summary (if applicable)

04 Module 3 — Quality

- ✓ API information (DMF)
- ✓ Manufacturing process
- ✓ Batch formula
- ✓ Specifications
- ✓ Validation reports
- ✓ Container closure system
- ✓ Stability data

05 Module 4 — Non-clinical

- ✓ Pharmacology
- ✓ Toxicology
- ✓ Safety studies

06 Module 5 — Clinical

- ✓ Clinical studies
- ✓ Bioequivalence reports
- ✓ Literature references

07 Special attachments

- ✓ Patient information leaflet
- ✓ Summary of Product Characteristics
- ✓ Primary and secondary pack shots
- ✓ Certificate of Analysis from a PPB-accredited lab
- ✓ Certificate of Pharmaceutical Product (COPP)
- ✓ PPB-issued GMP certificate
- ✓ Biowaiver application form and justification
- ✓ Certificate of Suitability (CEP)



Trademark clearance evidence is an administrative requirement. It sits alongside your COPP and GMP certificate — which means a naming conflict discovered at assessment costs you artwork, labelling, the patient information leaflet, and your place in the queue. Run clearance in parallel with dossier preparation, not after it.



Requirements vary by product category and change over time. Medical devices and IVDs follow the Common Submission Dossier Template rather than the CTD. **Confirm the current requirement set on PRIMS, or ask us to confirm it for your product.**

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