



CTD Quality Consulting

Helping our Pharma Clients Succeed

Training ♦ Consulting ♦ Management ♦ Writing

- * *Improve workflow efficiency in preparation of submissions*
- * *Accelerate drug development and approvals*
- * *The right resources to attract success*

CTD Quality Consulting is a drug development consulting firm specializing in quality medical writing and technical writing using CTD/eCTD (Common Technical Document, electronic submissions), efficient submission planning and life cycle management processes, and working as a submission team with the client, contractors, and partners from pre-IND to post-NDA. We assist our clients with regulatory and clinical strategy, authoring and reviewing, gap analysis, planning submission-ready documents, and regulatory project management with the submission and project teams. We specialize in assisting emerging companies establish these processes and get the expertise in-house or help set up contracting arrangements to meet times of high work volume in all areas of drug development: Regulatory, Clinical, QA/QC, R&D, Operations, etc.

CTD Quality Consulting has over 20 years experience with planning and preparing regulatory submissions and years of training on CTD/eCTD and GMP/GLP compliance with small molecules, biologics, and drug-device. We offer expert medical writing, regulatory, clinical, and chemistry, manufacturing, and controls (CMC) consulting. Our medical writers contribute significant understanding to the planning of clinical protocols and labeling (investigator brochure) as well as creating templates, authoring, and reviewing clinical study reports. Our extended team has expertise in all areas of drug development, including eCTD publishing.

We don't just help clients with our expert consulting, we train them and team with them to facilitate long-term success. Call CTD Quality Consulting at 978-356-0872 or email Michelle@ctdquality.com and we'll set up a time to evaluate your situation, free of charge.

Affordable, Targeted Training:

- *Building the CTD/eCTD from IND to NDA
- *Easing the Transition to eCTD for INDs and NDAs
- *Customized courses in all areas of drug development
- *CMC Submissions
- *GMP/GLP Compliance

What Our Clients Say:

“Excellent planning, communication, follow-up, and team leadership. Planning early with training and an established team process and expert resources has given us relief and efficiency along with quality.”