APCER LIFE SCIENCES
Together for better health

BROCHURE

Together for Documenting Results

Medical Writing Services

With the onset of new scientific discoveries and medical information, biopharma companies need to effectively disseminate key information to the industry stakeholders including regulators, patients, healthcare professionals etc. This information needs to be provided in standardized formats and tailored as per the good clinical practices (ICH-GCP) and other regulatory guidelines and policies.

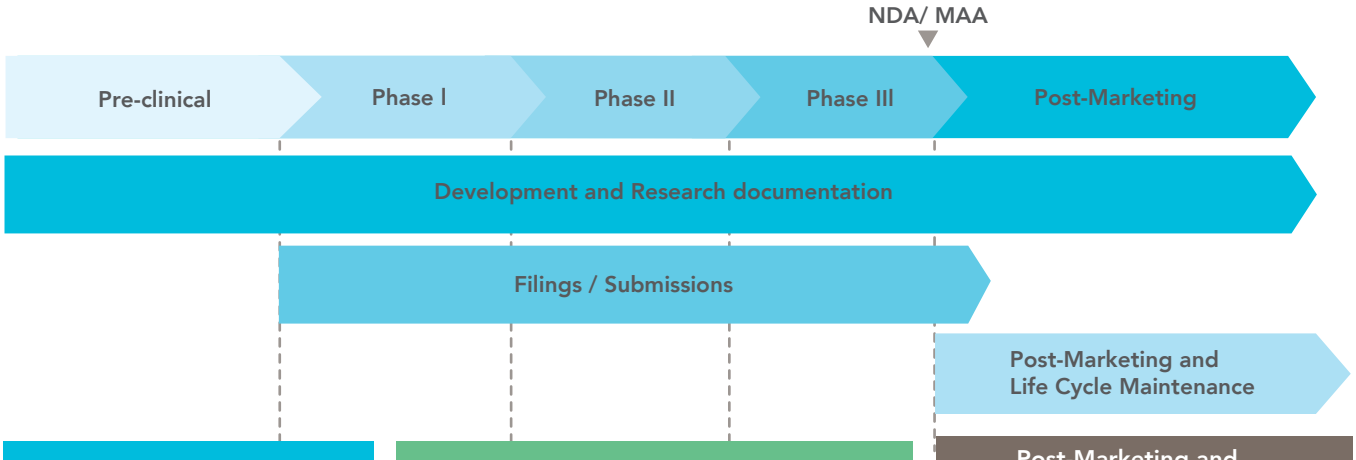
Biopharma companies are facing issues in producing high quality documents to meet increasing and changing regulatory requirements.

Key Documentation Challenges Faced by Pharmaceutical Companies

- Limited medical writing expertise & skills
- Lack of adherance to regulatory template
- Unable to scale up within constrained schedules
- Insufficient knowledge of guidelines and regulatory requirements
- Inefficient query management & review
- Lack of quality in submission ready documentation

Our team of highly qualified, dedicated and experienced Medical Writers help biopharma companies manage end-to-end high quality clinical and regulatory documents and scientific communications, throughout the drug lifecycle, across multiple therapeutic areas.

APCER's Medical Writing Services across the Drug Life Cycle



Development and Research

Clinical Protocols
- Early Phase/PhaseIIa
- Phase IIb/Phase III

Other Trial-related Documents
- Investigator Brochures
- Safety Narratives
- Informed Consent Documents
- Web synopses/Protocol registry Forms

Clinical Study Reports (Early Phase/IIa/IIb/III)
- Interim and Final CSRs
- Abbreviated CSRs and
- Synopses

Scientific Communications
- Congress deliverables
- Posters and Abstracts
- Product Monographs

Allied Services
- Pediatric Investigation Plan
- Orphan Drug Designation
- Medical Rationales
- Briefing Documents

Filings / Submissions

European Region Filings {Article 8,Article 10}
- CTD Summaries (Modules 2.6 and 2.7)
- CTD Overviews (Modules 2.4 and 2.5)
- Standalone COs and NCOs (Modules 2.4, 2.5)
- Labels (CCDS / SPC and PIL)
- Bioequivalence Studies (Protocols/ ICF/ CSRs)
- Briefing Documents

USFDA Filings {NDA (505b1),Hybrid (505b2), ANDA (505j)}
- ISS and ISE (Integrated analyses)
- CTD Summaries/ CTD Overviews
- Labels (Draft and updates of PI/ CCDS)
- Bioequivalence Studies (Protocols/ ICF/ CSRs)
- Briefing Documents
- Clinical and non-clinical modules for BLA

Australia (Category 1, 2, 3) and New Zealand (NMA, CMN) Filings
- CTD Summaries/ CTD Overviews
- Standalone Clinical Overviews
- Labels (Draft and updates of PI/CCDS)
- Labels (Draft and updates of PI/CCDS)

UAE Submissions
- CTD Summaries/ CTD Overviews
- Standalone Clinical and Non-clinical Overviews
- Labels (Draft and updates of PI/CCDS)

Post-Marketing and Life Cycle Maintenance

Post-Marketing Commitments
- Protocols and CSRs for Phase IV PMS studies
- EU Risk Minimization programs (PASS Protocols and Annual reports, Educational material for Prescribers and Patients)
- US FDA REMS Protocols, surveys and Annual reports

Product Life Cycle Maintenance
- Variation Filings (Label updates, Clinical Expert Statements, CCDS)
- Renewals (Clinical and non-clinical documentation)
- Safety reports: PBRER, PADER, RMP

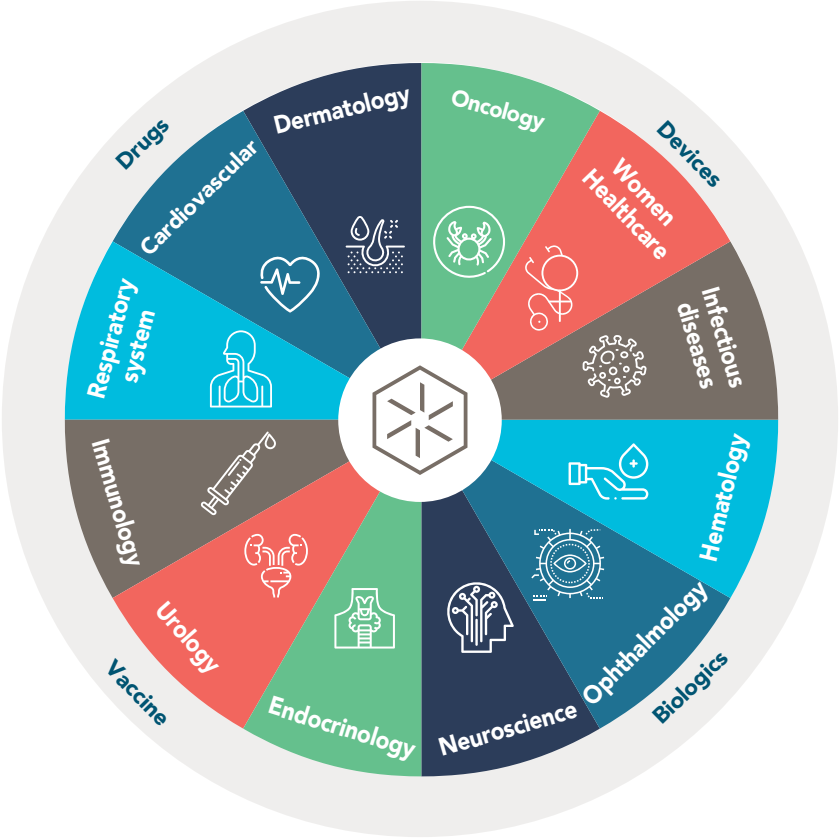
Scientific Communications
- Manuscripts and Review articles
- Slide Decks
- Posters and Abstracts
- Educational material and Website Content

Allied Services
- Training Manuals
- SOPs
- Translation Services

APCER LIFE SCIENCES
A reliable partner to help you navigate the path through drug development, licensing, marketing and life cycle maintenance

COs=Clinical Overviews
NCOs=Non-clinical Overviews
CCDS=Company Core Data Sheet
ISS=Integrated Summary of Safety
ISE=Integrated Summary of Efficacy
PI=Prescribing Information
ICF=Informed Consent Forms
PMS=Post-Marketing Surveillance
NMA= New Medicines Application
CMN= Changed Medicine Notification
NDA= New Drug Application
MAA= Marketing Authorization Application

Extensive Experience across Therapeutic Areas



The APCER Advantage

Experienced team comprising of physicians and subject matter experts (SMEs) with extensive therapeutic area expertise coupled with deep scientific knowledge

Customized services to meet ever-changing regulatory landscape with wide-ranging global regulatory experience from EU, USFDA, TGA, Medsafe, GCC, ASEAN

Robust 2-step review process, 100% quality check to produce high quality documents, thereby reducing review time of clients

Strong clinical writing expertise across all phases of drug development

Integrated Pharmacovigilance and Regulatory Submission processes to provide end-to-end services

Engagement with consultants/SMEs for specialized services on need basis

TESTIMONIALS

> **“APCER Life Sciences was instrumental in our success in meeting these important Clinical Trial Disclosure compliance deadlines.”**
>
> -Head,
> Clinical Trial Transparency

> **“They are cost competetive and very, very dependable, and that is why they keep getting more and more work.”**
>
> -Regional Head,
> Global Medical Writing

APCER LIFE SCIENCES

Together for better health
Part of APC Group

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2013, and ISO 27701:2019 certified company.

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (+91) 11 4650 0802

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