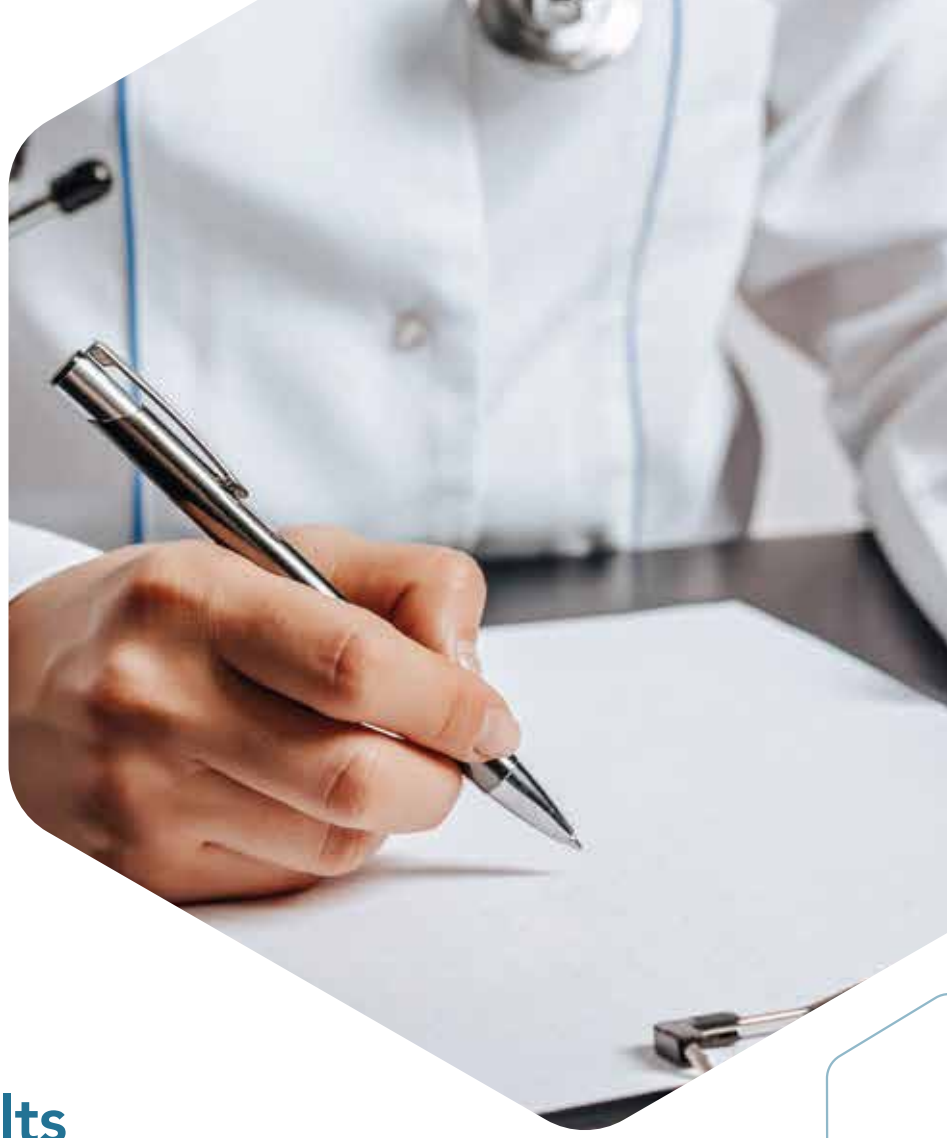
APCER LIFE SCIENCES
Together for better health



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.

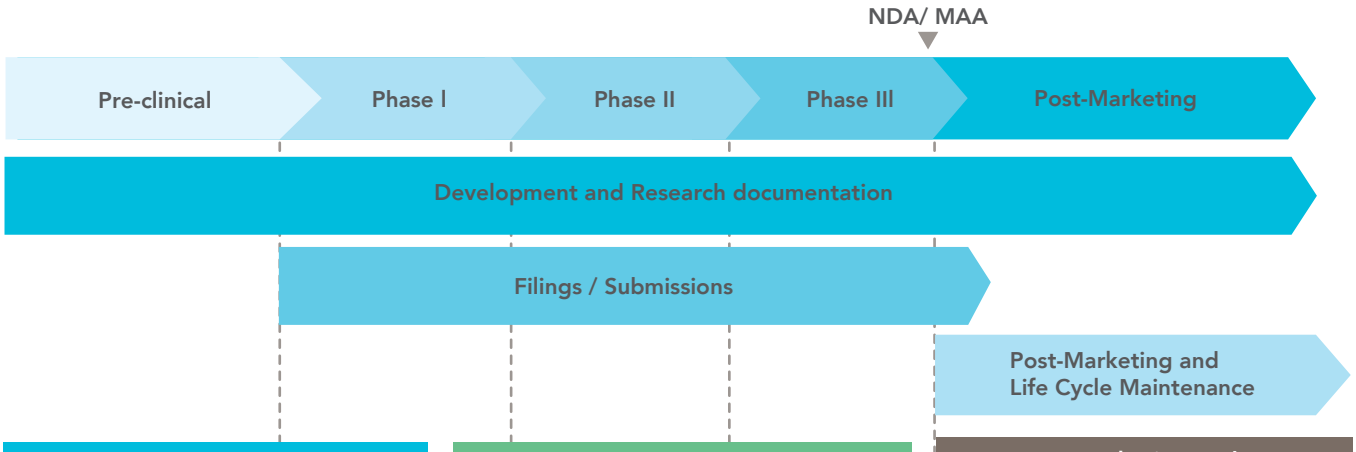
Majority of the companies are facing issues in producing high-quality documents to meet the increasing and changing regulatory requirements.

Key Documentation Challenges Faced by Pharmaceutical Companies

- Limited medical writing expertise & skills to present complex scientific data and concepts
- Insufficient knowledge of guidelines and regulatory requirements
- Unable to scale up within constrained schedules
- Quality issues such as inconsistency and inaccuracy leading to delay and rework

To ensure smooth progress of your drug development program toward successful regulatory approval, we craft flawless clinical, regulatory, and scientific documents in an end-to-end process that meets the strictest standards and navigate regulatory hurdles with unmatched efficiency. Our team of highly qualified, dedicated, and experienced medical writing experts have a deep understanding across diverse therapeutic areas.

APCER's Medical Writing Services across the Drug Life Cycle



Development and Research

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

Clinical Study Reports (Early Phase/IIa/IIb/III)
- Full CSRs
- Abbreviated CSRs
- Synoptic CSRs

Other Trial-related Documents
- Investigator Brochures
- Safety Narratives
- Informed Consent Documents

Regulatory Documents
- Briefing Document
- Investigational New Drug Application
- Annual Reports
- Drug Designations
- Pediatric Safety Plan

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

Filings / Submissions

For Innovator Companies
- CTD Summaries & Overviews
- ISS and ISE (integrated analyses)
- Labels (drafts and updates)
- Reference Safety Information (RSI)

For Generic Companies
- CTD Summaries (Modules 2.6 and 2.7)
- CTD Overviews (Modules 2.4 and 2.5)
- Standalone COs and NCOs (Modules 2.4 and 2.5)
- Labels (SPC and PIL; PI and Medication Guide)
- CCDS
- Bioequivalence Studies (Protocols/ICF/CSRs)

Scientific Writing
- Congress Materials: Posters and Abstracts
- Manuscripts

Post-Marketing and Life Cycle Maintenance

Post-Marketing Commitments
- Protocols and Reports for Phase IV PMS studies: Observational studies (RWE), Investigator-initiated studies

Product Life Cycle Maintenance
- Variation Filings (Label updates, Clinical Expert Statements, CCDS)
- Renewals (Clinical and non-clinical documentation)
- NDA/ANDA Annual Reports

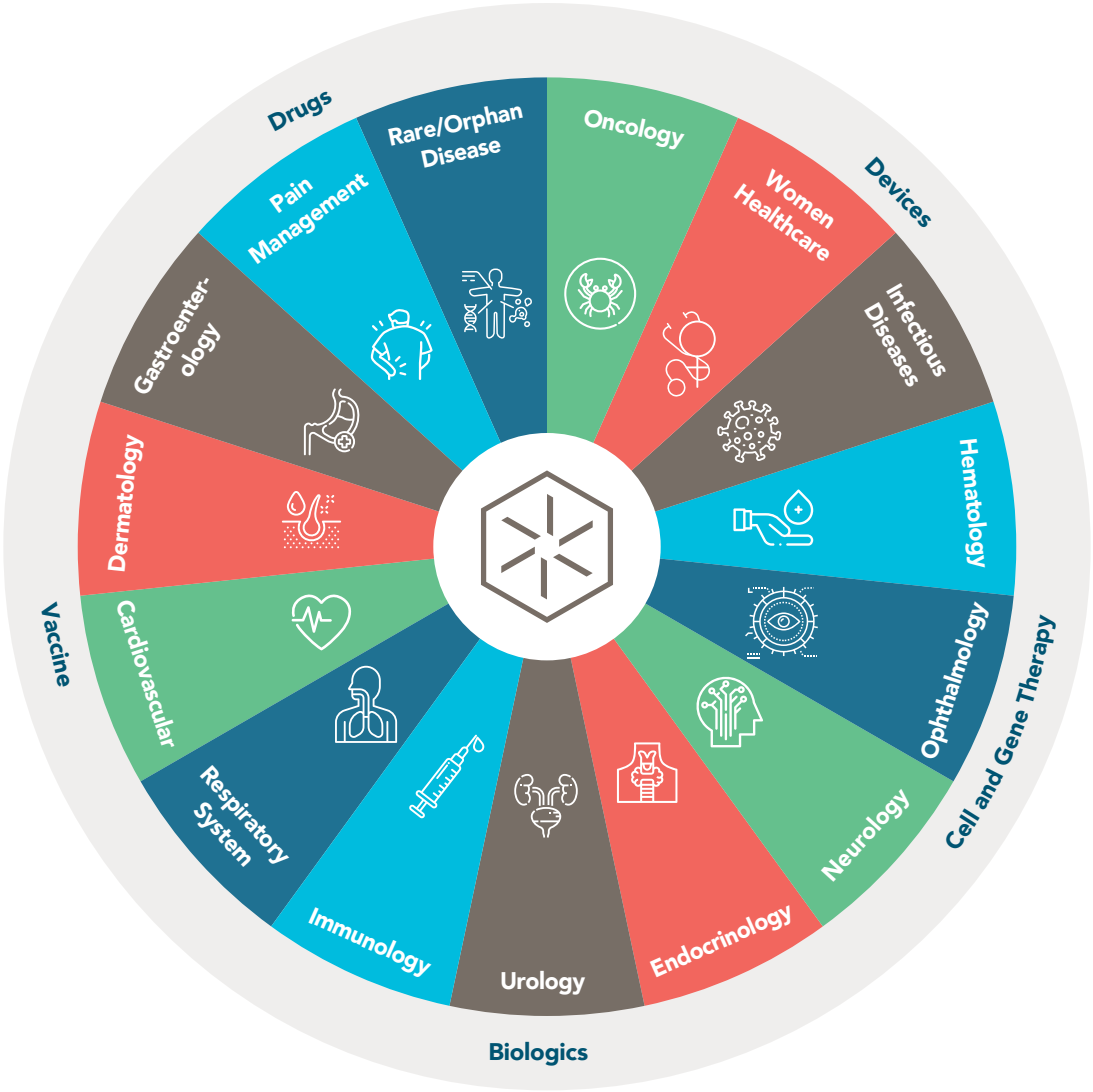
Scientific Communications
- Manuscripts and Review articles
- Slide Decks/Newsletters/LBL/Infographics/E mailers
- Posters and Abstracts
- Educational material and Website Content

Allied Services
- Training and Training Manuals
- SOPs
- SRLs

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

COs=Clinical Overviews
CSR: Clinical study report
NCOs: Non-clinical
CTD: Common Technical Document
SPC: Summary of product characteristics
ISS: Integrated summary of safety
ISE: Integrated summary of efficacy
PI: Prescribing information
RWE: Real-world evidence
ANDA: Abbreviated new drug application
ICF=Informed Consent Forms
PMS=Post-Marketing Surveillance
PIL: Patient information leaflet
LBL: Leave behind leaflet
CCDS=Company Core Data Sheet
NDA= New Drug Application
MAA= Marketing Authorization Application
SOP: Standard Operating Procedure
SRL: standard response letter

Extensive Experience across Therapeutic Areas



The APCER Advantage

One-stop-solution for Medical Writing services supporting across all phases of product life cycle

To keep abreast of the ever changing regulatory landscape with wide-ranging global regulatory experience from EU, USFDA, Health Canada, TGA, etc. through our **customized and fully compliant services**

Robust two-step review process, 100% quality check and a "first-time-right" approach to produce high-quality documents, thereby reducing the review time of clients

Impeccable quality delivered through an experienced team comprising physicians and subject matter experts (SMEs) with extensive therapeutic area expertise coupled with deep scientific knowledge

End-to-end Solutions through Integrated Regulatory Services

Specialized services on need basis and engagement with consultants/SMEs

A dedicated team of copyeditors and typesetters to perform a check on language, grammar, and style and ensuring e-submission readiness.

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 27001:2022, 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) 79 6677 8600

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