



HELPING DELIVER LIFE-CHANGING THERAPIES



PPD FUNCTIONAL SERVICE PARTNERSHIP (FSP) SOLUTIONS  
**MEDICAL WRITING**

# TRANSLATE COMPLEX SCIENTIFIC DATA INTO CLEAR AND COMPLIANT SCIENTIFIC STATEMENTS



Whether you are looking for a team of writers and reviewers to become an extension of your in-house team or need help filling a specialized gap in services, it's critical to find a partner you can rely on for customized medical writing solutions tailored to your unique needs.

Through comprehensive medical writing expertise available in a functional service partnership (FSP) model, **PPD FSP Medical Writing Solutions** helps biopharmaceutical, biotech, and medical device organizations translate complex scientific data into clear and compliant scientific statements. With a proven track record built from decades of experience, we provide the right talent and expertise to help our clients meet their timelines — while providing much-needed resource flexibility, reliability, and continuity.



## Proven track record

- **25+** years of experience
- **170+** pharma, government, and large and small biotech clients
- **400+** regulatory documents and **1,200** narratives delivered per year, on average
- Consistent achievement of **“excellence”** in KPI scores

# COMPREHENSIVE MEDICAL WRITING SOLUTIONS DELIVER THE BREADTH AND DEPTH OF EXPERTISE YOU NEED

Through reliable, high-quality medical writing services that leverage an extensive breadth and depth of therapeutic area and document expertise, our medical writing solutions provide the convenience of working with a single global partner for all your medical writing needs. Our professionals provide flexibility to quickly pivot based on program and regulatory requirements and support all facets of medical writing across the development lifecycle, including the following areas:

## Preclinical

- Investigational new drug (IND) modules
- Annual reports
- Investigator's brochures (IB)
- Briefing documents

## Phase I-III

- Protocols and informed consents
- IB updates
- Clinical study reports and narratives
- Briefing documents
- White papers

## Marketing Authorization Applications (MAA)

- New Drug Applications (NDA)
- Biologics License Applications (BLA)
- Agency responses

## Quality review

- A specialized service that ensures quality control and compliance for documents across the entire development lifecycle

## Patient-centric writing

- A dedicated service for patient-facing materials with appropriate messages, tone, and grade-level writing



# THE RIGHT TALENT, EXPERTISE, AND ENGAGEMENT MODELS FOR ACCURATE AND ON-TIME DELIVERABLES

Our experienced medical writers are problem-solvers who excel at producing documents that are scientifically accurate and fully compliant with regulations, industry best practices, and client standards.

Every engagement is customized to your requirements, from filling specialized gaps in services to providing a large team of writers and editors. Whether working within client or PPD technologies and systems, we provide dedicated resources aligned to your culture and values, and rapidly adjust resource levels as needed.

## Flexible Approach



- Partner to provide the best outsourcing model
- Flexibility to add staff to your workforce or bring your business in-house
- Customizable mix of processes, oversight, and systems — yours or ours
- Creative solutions to meet accelerated timelines and resourcing of drop-in work
- Innovative pricing models can accommodate various contract structures and be tailored to evolve over time

## Experienced Medical Writers



170+ writers, document reviewers, and compilers in 16 countries



More than 80% have Master's, PhD, PharmD, MD, or DVM



Diverse therapeutic backgrounds (including vaccines, rare diseases, oncology, and neuroscience)



Average 12+ years of experience

## Dedicated Teams



Consistent project teams to maximize efficiencies



Streamlined governance model with medical writing program managers and lead medical writers driving communications to maximize accountability



APoC (Asset Point of Contact) model: assign subject matter experts for knowledge and messaging consistency



Close partnerships across all levels for accountability and strategic support

# PROVEN KNOWLEDGE, EXPERIENCE, AND INFRASTRUCTURE TO MAXIMIZE SPEED, EFFICIENCY, AND VALUE

For every document we author, we leverage our proven knowledge and experience to identify the right resources, processes, and tools to meet timelines, achieve your objectives, and maximize speed, efficiency, and value. Examples include:

**Lean authoring** and focus on content reuse

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Customizable tools to **accelerate document development**

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Collaborative reviews with **Veeva RIM and PleaseReview<sup>®</sup>** software

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**PerfectIt<sup>®</sup>** proofreading software

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Dedicated **Process Improvement Lead**

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Automation options including fully **programmed and hybrid narratives** and programmed in-text tables

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**Medical Writing Program Manager** reduces client oversight

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EU clinical trials **regulation experts**

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Our global infrastructure also provides client-specific support for country, regional, and global deliverables with consistent worldwide standards of quality delivery. With experts in diverse locations spanning all time zones, our proven approach creates successful teams, encourages knowledge sharing, and produces productive interactions throughout the duration of our partnership.

**Flexible resource pool** of trained, sponsor-ready home-grown staff

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Staff in North America, Europe, Africa, and Asia-Pacific provide **24-hour coverage**

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Key roles in the **same time zones** as your functional and clinical teams



Talk with your account representative  
or visit [ppd.com/fsp-medical-writing](https://ppd.com/fsp-medical-writing) to learn more  
about how PPD FSP Medical Writing Solutions helps  
translate complex scientific data into clear and compliant  
scientific statements so you can meet your timelines.



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