Siro

2025 COMPANY OF THE YEAR

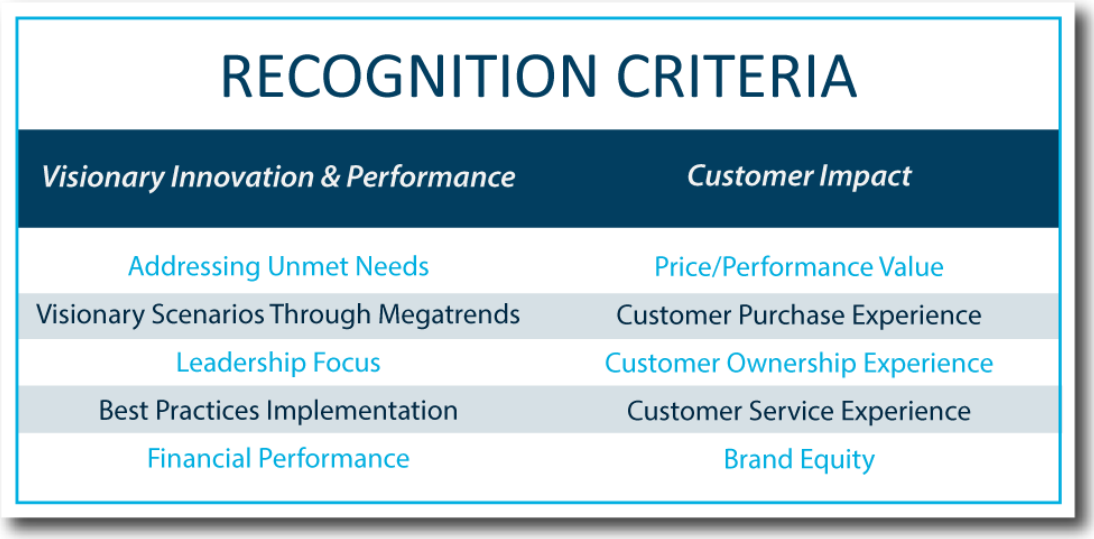
Driving impact across the customer value chain

RECOGNIZED FOR BEST PRACTICES IN THE GLOBAL MEDICAL WRITING INDUSTRY

FROST & SULLIVAN

Best Practices Criteria for World-class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each recognition category before determining the final recognition recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. SIRO MW excels in many of the criteria in the medical writing space.



The Medical Writing Sector: Transforming Complex Data into Clear Narratives

Medical writing is the essential discipline that underpins the communication of clinical and scientific information across the global healthcare landscape. Far from being a simple documentation task, it is a highly specialized function that translates complex research data, regulatory requirements, and medical concepts into clear, accurate, and compliant documents for various audiences, including regulatory authorities, physicians, and patients. Once confined to drafting clinical study reports, protocols, and investigator brochures, the field now encompasses a broader range of deliverables, including real-world evidence (RWE) analyses, health economics and outcomes research, plain-language summaries, and digital content tailored to diverse audiences. Market forces, such as escalating regulatory scrutiny, globalization of clinical development, and the proliferation of new therapeutic modalities (such as cell and gene therapies, digital health products), heighten the volume and complexity of medical-writing requirements.[1]

Over the past decade, the role of the medical writer has evolved from a support function to a strategic partnership in the development of drugs and medical devices. The primary challenge lies in understanding stringent, ever-changing regulatory frameworks established by bodies such as the United States (US) Food and Drug Administration (FDA) and the European Medicines Agency. Adherence to the comprehensive guidelines set by the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is non-negotiable, as even minor deviations in reporting can lead

[1] https://pmc.ncbi.nlm.nih.gov/articles/PMC3149406/

to significant delays in product approvals. Likewise, practitioners must navigate regulatory standards (such as ICH E6(R3), FDA guidance revisions), ensure quality assurance (QA) in line with Good Clinical Practice and Attributable, Legible, Contemporaneous, Original, Accurate, and Complete principles,[2,3] and support submissions that integrate real-world data, artificial intelligence (AI)-derived analyses, and patient-centric outputs. The technical complexity of modern medicine compounds this regulatory pressure, requiring writers to possess linguistic skills and a deep understanding of biostatistics, clinical trial design, and advanced life sciences. Resource constraints, including shortages of writers with therapeutic and regulatory expertise, intensify these challenges.

To circumvent these hurdles, the industry is at a technological inflection point. The integration of AI and Natural Language Processing is revolutionizing the field by automating routine, time-intensive tasks. AI-powered platforms can now assist in generating initial drafts of clinical study reports (CSR), performing quality control (QC) checks for consistency, and conducting rapid literature reviews, enhancing efficiency and reducing the potential for human error.[4] Document management systems with audit-trail capabilities support compliance, while collaborative platforms and modular authoring frameworks accelerate version control and multi-stakeholder reviews. In parallel, peer review ecosystems, standard templates, and metadata-driven content reuse bolster quality, which also helps manage growing demand without compromising compliance.

> *"Operating independently as a 100% family-owned and self-funded enterprise, SIRO MW maintains agility in a market dominated by investor-backed firms, while continuously validating its leadership through measurable outcomes. It boasts a team of over 100 expert medical writers, covering more than 40 distinct document types and delivering projects across over 150 therapeutic indications on three continents."*
>
> ***Rabin Dhakal,***
> ***Best Practices Research Analyst***

While these technologies offer powerful tools to manage volume and complexity, they do not replace the quintessential need for human oversight. The critical thinking, ethical judgment, and strategic interpretation of an expert medical writer remain crucial to warrant the integrity and clarity of the final submission.

SIRO Medical Writing Private Limited (SIRO MW) leads in the medical writing spectrum with its ability to harmonize scientific expertise, regulatory acumen, and technological innovation. The company blends more than two decades of contract research organization-embedded medical writing experience with strong credentials in scientific publications, RWE communications, and regulatory documents.

Bridging Gaps Across the Medical Writing Value Chain

SIRO MW is a trusted partner across the global drug development ecosystem amid growing demands for precision, compliance, and scientific clarity in medical documentation. As part of the SIRO Group (originally founded in 1996 and incorporated in 2000), the company brings over two decades of focused expertise in medical writing, enabling pharmaceutical (pharma), biotechnology (biotech), and medical

[2] https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e6-r3-guideline-good-clinical-practice-gcp-step-5_en.pdf
[3] https://www.uhhospitals.org/-/media/files/for-clinicians/research/alcoac-documentation.pdf
[4] https://pmc.ncbi.nlm.nih.gov/articles/PMC12058053/

device companies to traverse increasingly complex regulatory, safety, and scientific communication requirements. Operating independently as a 100% family-owned and self-funded enterprise, SIRO MW maintains agility in a market dominated by investor-backed firms, while continuously validating its leadership through measurable outcomes. It boasts a team of over 100 expert medical writers, covering more than 40 distinct document types and delivering projects across over 150 therapeutic indications on three continents.[5] The company supports every phase of the drug lifecycle, including regulatory writing, clinical trial transparency, scientific publications, RWE, and patient-centered communications like plain language summaries. Its deep therapeutic knowledge, spanning areas such as oncology, neuroscience, and immunology, and a robust quality framework proven through more than 30 successful audits, makes it uniquely equipped to meet the industry's evolving content, compliance, and communication needs.

While many competitors scale through inorganic acquisitions, SIRO MW instead takes a vertical-centered, organically built approach, drawing on deep therapeutic expertise and process-driven innovation to cater to underserved client segments. This strategy enables the company to offer tailored, high-impact solutions across the drug development continuum (from regulatory filings to patient communications), empowering sponsors of all sizes to navigate operational, regulatory, and scientific challenges with agility and confidence.

Regulatory Medical Writing

One of the most significant pain points for small and mid-sized pharma companies is managing the complexity of global regulatory documentation without large internal teams. SIRO MW addresses this challenge by offering end-to-end regulatory writing services, including investigational new drug applications and common technical document packages. It has developed over 5,000 regulatory documents, partnered with seven of the top 10 global pharma leaders, and operates across all therapeutic areas, reflecting its comprehensive capabilities.[6] The team's average seven years of experience, familiarity with Standard Protocol Items: Recommendations for Interventional Trials, ICH M11, and TransCelerate templates, and deep expertise in Development Safety Update Report (DSUR) and CSR compliance help sponsors accelerate timelines while ensuring high-quality and guideline-adherent submissions.[7]

Clinical Trial Transparency and Disclosure

With growing regulatory mandates around public disclosure, sponsors often struggle to operationalize transparency without overextending internal resources. SIRO MW addresses this unmet need with dedicated trial disclosure services, including document redaction, anonymization, and registry submissions. The company has posted hundreds of records with over 90% approval on first submission to ClinicalTrials.gov.[8] Leveraging Vizard, an AI-based redaction platform, SIRO MW automates up to 98% of

[5] https://www.siromw.com/

[6] https://www.siromw.com/regulatory-medical-writing

[7] Ibid.

[8] https://www.siromw.com/clinical-trial-transparency-and-disclosure

redaction workflows, reduces manual effort by 80%,[9] and delivers sevenfold faster risk scoring, boosting operational efficiency and regulatory alignment.

Scientific Publications and Medical Communications

SIRO MW recognizes that many organizations lack the expertise to translate complex data into high-impact publications. It fills this gap with strategic publication planning and content development services. With over 3,000 published documents and a 98% manuscript acceptance rate, the company supports publication in more than 200 peer-reviewed journals.[10] Its suite of scientific publication and communication solutions, including manuscripts, congress deliverables, medical communications, and patient lay summaries, enables clients to engage key opinion leaders and disseminate findings across stakeholder groups.

HEOR and RWE

As value-based healthcare models gain traction, the need for RWE and health economics and outcomes research (HEOR) support has become significant. SIRO MW's specialized HEOR and RWE writing services help clients develop dossiers and models that support health technology assessments, payer negotiations, and reimbursement applications. Its services span evidence synthesis, economic modeling, scientific communications, and analytics, providing clients with the strategic tools needed to secure market access and prove long-term product value.[11]

Drug Safety and Risk Management

The burden of pharmacovigilance documentation continues to grow, especially in global development programs. SIRO MW alleviates this challenge by offering a full suite of safety writing services, including Periodic Safety Update Reports, DSURs, and Risk Management Plans (RMP). Since authoring its first DSUR in 2011 (just 30 days after ICH E2F implementation), the company has delivered over 1,100 DSURs, 550 Periodic Benefit-risk Evaluation Reports, and more than 290 RMPs.[12] A dedicated safety writing team, robust standard operating procedures (SOP), and strict QC protocols ensure that submissions meet global compliance requirements and maintain patient safety throughout the product lifecycle.

Patient Narratives

SIRO MW's high-volume narrative writing service has delivered over 350,000 patient narratives across various health authority formats,[13] including independent data monitoring committee, real-time, and adjudication narratives. The company distinguishes its offerings through deep therapeutic specialization, including expertise in vaccines, rare diseases, and medical devices, and designs them to relieve client teams from labor-intensive tasks while ensuring submission-readiness.

Plain Language Summaries

[9] Ibid.

[10] https://www.siromw.com/scientific-publications-and-medical-communications

[11] https://www.siromw.com/health-economics-and-real-world-evidence-solutions

[12] https://www.siromw.com/drug-safety-and-risk-management

[13] https://www.siromw.com/patient-narratives

SIRO MW has invested in plain language summaries (PLS) capabilities, recognizing the need to communicate clinical outcomes to non-specialist audiences. The company delivers PLS that are compliant, jargon-free, and ethically sound, authored by trained writers and validated by lay reviewers. These summaries help sponsors meet their regulatory obligations and enhance transparency, boost public trust, and support patient engagement.

Through its deep vertical integration, technology-enabled workflows, and patient- and science-centric approach, SIRO MW bridges industry gaps that others overlook. Frost & Sullivan is impressed by the company's ability to build tailored, scalable, and high-quality solutions, which transform unmet client needs into strategic growth opportunities across the entire medical writing spectrum.

Embedding Process Discipline and Scientific Rigor in the Medical Writing Domain

SIRO MW demonstrates the best industry-leading practices by embedding structured processes, quality systems, and scalable engagement models across its service delivery operations. The crux of the company's delivery engine is its specialized medical review team, composed of highly qualified postdoctoral professionals, including PhDs and MBBS graduates. This expert team is responsible for reviews and oversights that go beyond surface-level checks, strengthening the medical and scientific integrity of every document produced. This layer of medical validation is a key differentiator in ensuring that SIRO MW's deliverables withstand global regulatory scrutiny.

In parallel, SIRO MW's institutionalized multi-layered QC framework integrates structured, template-based checks for scientific accuracy, data integrity, and formatting compliance. This approach goes beyond ad hoc corrections to deliver a repeatable and scalable QA model, enabling reliable operation even in high-volume environments. The company also recognizes the importance of domain expertise as a quality enabler. To this end, it has instituted therapeutic area–specific training, ensuring that writers are scientifically proficient and deeply familiar with the nuances of individual therapeutic verticals. This domain-specific focus results in documents that reflect clinical insight and contextual relevance.

SIRO MW takes a process-first approach to address emerging regulatory mandates such as PLS. Rather than offering this as a reactive service, the company builds internal lexicons, standardizes readability metrics, and structures workflows to simplify complex scientific data into public-facing summaries. SIRO MW helps clients establish internal processes for lay summaries in addition to delivering the content, guaranteeing compliance and transparency.

SIRO MW displays best-in-class practices in its adaptive client engagement models, including transactional (project-based), functional service provider, and hybrid models. Its operational agility aligns with varied outsourcing strategies, ensuring seamless integration with client workflows and greater delivery efficiency.

Frost & Sullivan commends SIRO MW's ability to align medical expertise, quality discipline, and client-centric operating models, which represents a rigorous implementation of best practices in the global medical writing landscape.

Leadership Focus

Strategic Expansion and Integrated Engagement

SIRO MW establishes a formidable leadership position by executing horizontal and vertical account growth strategies that transform single-project engagements into long-term strategic partnerships. Once engaged by a department within a global pharma organization, the company capitalizes on its profound scientific understanding and continuity to expand seamlessly across departments that handle the same molecule or therapeutic area. This integrated approach enables SIRO MW to move beyond initial engagements (such as protocol development) to add significant value in later-stage deliverables, including CSRs, publications, and lay summaries. In essence, the company's comprehensive grasp of client molecules and data serves as an effective gateway to deeper, more expansive collaborations.

> *"SIRO MW brings validated domain expertise in high-complexity therapeutic verticals such as oncology, neuroscience, and rare neurological conditions like myasthenia gravis and schizophrenia. The company's growing footprint in emerging areas such as gastroenterology, diabetes, respiratory diseases, and medical devices reflects its dedication to broadening value across new markets."*
>
> ***- Unmesh Lal,***
> ***Vice President,***
> ***Growth Opportunity Analytics***

Global Footprint and Robust Governance

SIRO MW enhances its onshore-offshore model to bolster market dominance. It has established a United Kingdom-based headquarters with 10 operational personnel that help boost its credibility and client-facing capabilities in Europe. This onshore presence complements a robust offshore delivery hub in India, enabling cost efficiencies without compromising quality. Further expanding its reach, the company has built a geographically distributed sales team spanning the US, Europe, and India, which supports real-time client engagement, enhances cultural alignment, and ensures responsive service in key life sciences markets.

Moreover, SIRO MW is embarking on a strategic governance initiative by forming a board of advisors dedicated to steering growth in its core medical writing domain and emerging sectors such as AI. This forward-thinking move underlines a dedication to continuous innovation, process optimization, and market adaptation.

By leveraging its in-depth scientific expertise, expanding its operational footprint, and adopting a proactive, consultative approach to client relationships, SIRO MW transforms isolated projects into enduring, high-value partnerships. Frost & Sullivan praises this approach and firmly believes that the company's leadership focus advances its market position and sets the stage for sustained future growth.

Flexible Delivery Models Offering High Return on Investment and Operational Efficiency

SIRO MW tailors its service delivery models to the specific operational realities of emerging biotech and large pharma enterprises. Recognizing the constrained resources of small to mid-size pharma and biotech companies, many of which lack in-house medical writing and QC functions, the company offers a dedicated resource model. In this model, SIRO MW provides clients with highly skilled writers on a monthly billing basis, allowing them to maintain project management oversight while outsourcing the execution and QA aspects to itself. This model provides a cost-effective and agile alternative to building internal writing teams, enabling clients to scale without incurring the overhead of full-time staff or managing complex internal workflows.

For large, global pharma companies, SIRO MW deploys an integrated resource model, embedding its professionals directly into client systems and SOPs while still retaining responsibility for project and line management. This transactional model is deliverable-based, enabling enterprise clients to optimize cost structures, improve delivery timelines, and maintain compliance with internal governance without sacrificing control or quality. The ability to shift between these two delivery models demonstrates the company's operational agility and commitment to maximizing return on investment for a diverse client base.

Furthermore, the company's emphasis on hiring top-tier professionals from global contract research organizations and pharma companies, complemented by a strong internal talent development pipeline, guarantees high-quality deliverables at a competitive cost. Its hybrid workforce strategy, combining seasoned experts and rigorously trained junior talent, supports scalability, cost efficiency, and consistent output across multiple therapeutic areas.

Crucially, SIRO MW brings validated domain expertise in high-complexity therapeutic verticals such as oncology, neuroscience, and rare neurological conditions like myasthenia gravis and schizophrenia. The company's growing footprint in emerging areas such as gastroenterology, diabetes, respiratory diseases, and medical devices reflects its dedication to broadening value across new markets. SIRO MW leverages proven performance in scientifically rigorous domains, improving its credibility and justifying premium engagement terms.

In sum, SIRO MW's customizable engagement models, strategic workforce composition, and deep scientific specialization offer compelling economic and operational value.

Prioritizing Stability, Compliance, and Long-term Value through Customer-centric Engagement

SIRO MW's high-touch engagement, deep therapeutic area expertise, and operational agility help it earn client trust and long-term loyalty. Rather than embracing high-risk, third-party AI integrations that may compromise data integrity or regulatory compliance, the company maintains a conservative yet deliberate approach: prioritizing client data security, ownership, and control. This customer-centric philosophy aligns closely with the sensitive nature of medical writing, where confidentiality and precision are non-negotiable.

SIRO MW's nearly 100% repeat business rate is a powerful testament to its unwavering service quality.[14] Every multi-project client has returned for further collaboration, reflecting the company's ability to deliver consistent value across various phases of the drug development lifecycle. The average client engagement spans three to four years, with many partnerships extending beyond, establishing SIRO MW's reputation for reliability and sustained service performance.[15]

The company highlights exceptional customer experiences through strategically executed client engagements:

- In a high-complexity Phase II ophthalmology trial, SIRO MW delivered a CSR that required interpretation of over 500 tables, listings, and figures, far beyond the standard range. The

[14] Frost & Sullivan's Final Discussion Call with SIRO (July 15, 2025)

[15] Ibid.

team's solution includes therapeutic area orientation from a medical affairs Doctor of Medicine, structured collaboration with sponsor stakeholders, and its proprietary "Review Panel" process. This internal QA mechanism, where seasoned medical writers collectively refine the draft, ensures robust and polished deliverables, enhancing client confidence from the outset.[16]

- For a top two global pharma client's American Society of Clinical Oncology (ASCO) and ASCO-Genitourinary congress submissions, SIRO MW demonstrates unmatched responsiveness and contingency management. Amid shifting datasets, late-stage changes, and rigid character limits, the team deployed flexible writer support across time zones, coordinated seamlessly with internal and external stakeholders, and executed high-stakes deliverables under pressure.[17]
- In an RWE publication project, SIRO MW supports a client's market access strategy by disseminating unbranded disease awareness content to stakeholders. The company's writing team facilitates strategic publication planning and ensures scientific rigor by aligning closely with statisticians to validate methodologies and data interpretations, culminating in the submission of over 10 impactful publications.[18]

Across all touchpoints, SIRO MW's customer service model transcends transactional engagement. It creates a collaborative, compliant, and high-performance environment that addresses each client's evolving needs. The result is a service experience that is accessible, responsive, and embedded in clients' success journeys.

Strengthening Global Brand Recognition through Strategic Partnerships and Client Trust

SIRO MW cultivates robust brand equity through consistent global visibility, targeted client alignment, and long-term relationship-building. The company positions itself as a trusted partner in the medical writing industry, particularly among regulated markets such as the US, Europe, and Asia-Pacific. With 90% to 95% of its revenue derived from outside India, SIRO MW roots its brand credibility in international client trust.[19]

A cornerstone of SIRO MW's brand-building strategy is its proactive presence at global industry conferences. Participating in approximately 15 to 18 events annually, across domains such as medical writing, functional service provision, and technology, the company maximizes brand visibility and drives client engagement.[20] SIRO MW does not limit itself to passive participation; it frequently takes on active roles as a sponsor, exhibitor, or thought leader through speaker sessions. These activities support brand awareness and generate tangible commercial impact.

[16] https://www.siromw.com/case-studies/c/csr-authoring-for-a-new-indication
[17] https://www.siromw.com/case-studies/c/asco-deliverables-landmark-publication
[18] https://www.siromw.com/case-studies/c/as-a-part-of-market-access-strategy
[19] Frost & Sullivan's Final Discussion Call with SIRO (July 15, 2025)
[20] Ibid.

Furthermore, amidst ongoing vendor consolidation in the life sciences sector, the company successfully retains and elevates its status with multiple large pharma clients through recent vendor refresh cycles.

Today, clients view SIRO MW as an operational service provider and a strategic partner, an upgrade that signals trust, consistent quality, and deeper integration into their long-term goals.

The company's commitment to Environmental, Social, and Governance (ESG) practices also enhances its brand perception. By earning a bronze medal from EcoVadis in 2025 and aligning with the Science Based Targets initiative, SIRO MW demonstrates a clear alignment with evolving client expectations and industry mandates. This forward-looking stance, supported by external validation and transparent, measurable ESG efforts, strengthens its brand's credibility, particularly among clients with increasingly stringent ESG procurement criteria.

Frost & Sullivan admires SIRO MW for combining global engagement, client partnership, and ESG leadership, fostering high brand recall and loyalty in the medical writing landscape.

Conclusion

SIRO Medical Writing Private Limited (SIRO MW) leads with purpose, precision, and performance in the evolving medical writing landscape. Through its deep therapeutic knowledge, robust regulatory expertise, and organically scaled operations, the company delivers exceptional value across the drug development continuum. SIROW MW prioritizes scientific rigor and quality assurance through a specialized review team and multi-layered quality control processes, ensuring that every deliverable meets the highest standards of accuracy, compliance, and clarity. The company's adaptive service models, strong talent pipeline, and operational scalability set it apart in the medical writing industry. Additionally, SIRO MW's global conference strategy, thoughtful brand positioning, and commitment to Environmental, Social, and Governance elevate its market reputation while reinforcing trust with international stakeholders.

With its strong overall performance, SIRO MW earns Frost & Sullivan's 2025 Global Company of the Year Recognition in the medical writing industry.