

F R O S T & S U L L I V A N

2024 CUSTOMER VALUE LEADER

*IN THE GLOBAL
MEDICAL WRITING
INDUSTRY*

F R O S T & S U L L I V A N

2024 BEST
PRACTICES
AWARD

Sirco

Best Practices Criteria for World-Class Performance

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

AWARD CRITERIA	
<i>Business Impact</i>	<i>Customer Impact</i>
Financial Performance	Price/Performance Value
Customer Acquisition	Customer Purchase Experience
Operational Efficiency	Customer Ownership Experience
Growth Potential	Customer Service Experience
Human Capital	Brand Equity

Unlocking Growth in Medical Writing: Precision Medicine and Geopolitical Challenges

According to Frost & Sullivan analysts, the medical writing space is undergoing significant transformation, driven by two primary factors: the rise of personalized medicine and the impact of geopolitical changes. With healthcare increasingly moving towards precision medicine, medical writing must adapt to produce documentation tailored to individual patient characteristics. This shift requires specialized expertise in creating clinical trial protocols, consent forms, and regulatory documents that reflect the nuances of personalized treatments. Consequently, medical writers who can incorporate cutting-edge scientific developments and meet the specific regulatory demands of personalized therapies are in growing demand.

At the same time, geopolitical disruptions like Brexit introduce new complexities to medical writing, particularly in regulatory documentation. The regulatory divergence between the United Kingdom (UK) and the European Union (EU) necessitates compliance with two distinct systems, increasing the complexity of clinical trial submissions, product labeling, and marketing authorizations. This transformation presents challenges and opportunities, requiring medical writers that are adept at navigating these regulatory landscapes. Therefore, with expertise in UK and EU regulations can gain a competitive advantage by assisting pharmaceutical (pharma) and biotechnology (biotech) companies streamline their approval processes within this dual regulatory environment.

Alongside these strategic shifts, the medical writing market faces operational challenges, with competition from large, well-established agencies, particularly in markets like the UK, creating significant

barriers to entry. However, opportunities exist for smaller vendors, particularly those catering to mid-sized pharma companies that require versatile expertise across medical writing domains. The growing demand for writers experienced with the United States (US) Food and Drug Administration-regulated documents further complicates scaling efforts, as companies must balance the need for specialized knowledge with the logistics of expanding across global markets. Achieving a strong operational presence across multiple continents while maintaining onshore and offshore models is key for companies looking to differentiate themselves in this highly competitive space.

Within this context, Frost & Sullivan believes that SIRO Medical Writing Private Limited (SIRO), under the SIRO Clinpharm (Group), uniquely leverages its expertise and service to meet its market demands. The company is strategically placed to tap into new growth prospects, strengthening its position in the medical writing space.

Unmatched Expertise in Regulatory Writing, HEOR, Publication Services, and Drug Safety

Founded in 1996 and headquartered in Mumbai, India, the SIRO Clinpharm (Group) supports global drug development with expertise in Phase II through Phase IV clinical trials. SIRO, part of the group, offers specialized services across four key verticals: regulatory medical writing, health economics and outcomes research (HEOR) writing, publications, and drug safety and risk management. With over 25 years of experience, SIRO has successfully submitted more than 10,000 medical writing documents, serving over 20 global clients, including seven of the top 10 pharma companies. Its team of over 90 medical writers bring extensive knowledge across 20 therapeutic areas and 150 indications. The company has successfully cleared over 100 audits and inspections, conducted more than 300 clinical trials, and employs over 250 professionals.

Regulatory Medical Writing

SIRO offers comprehensive regulatory medical writing services across various therapeutic areas, with particular expertise in neuroscience and oncology, two of the most challenging fields. The company's specialized services cover multiple aspects of the regulatory documentation process, ensuring high compliance with industry standards like Standard Protocol Items: Recommendations for Interventional Trials Guidelines and International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Structure and Content of Clinical Study Reports (E3). SIRO excels in protocol development, including protocol amendments and utilizing the Common Protocol Template by TransCelerate, showcasing its ability to work across diverse client templates.

In informed consent documentation, SIRO drafts standard Informed Consent Forms and assent forms and ensures localization by translating documents into regional languages. Its Clinical Study Reports (CSR), compliant with ICH E3 guidelines, stand out for their thorough statistical analysis and interpretation, with the ability to include pharmacokinetic (PK) and pharmacodynamic (PD) results. A unique feature of the company's CSR offering is its "Review Panel," comprising medically qualified medical writers, ensuring that each document is reviewed with expert insight.

In addition, the company is proficient in creating Investigator's Brochures, ensuring alignment with Development Safety Update Reports (DSUR) and Clinical Trials Facilitation and Coordination Group guidelines. SIRO's publishing capabilities include collation, formatting, hyperlinking, and submission-ready

checks for regulatory documents, ensuring compliance with Electronic Common Technical Document standards using advanced tools like Indexing, Summarization, and Interlinking Toolbox and Technical Regulatory Support Writer. With a wealth of experience in oncology, neuroscience, immunology, infectious diseases, and growing expertise in cardiology, hematology, ophthalmology, and respiratory diseases, the company's regulatory medical writing services are robust and adaptable across various therapeutic areas.

HEOR Writing

SIRO's comprehensive HEOR writing service supports pharma companies in making data-driven decisions that optimize market strategies and ensure accessible, effective healthcare. The company's expertise spans real-world data collection and analysis, connecting with investigators and hospitals to generate prospective and retrospective data for healthcare evaluations. This capability allows SIRO to provide valuable insights into treatment effectiveness, patient outcomes, and healthcare economics.

Analysts at the company, with backgrounds in public health and epidemiology, apply advanced methodologies such as regression analysis, survival analysis, meta-analysis, and pharmacoeconomic modeling. SIRO's team of specialized writers focus on real-world evidence (RWE) and outcomes research, producing high-quality publications and excelling in value communications for global audiences.

The company's HEOR offerings include systematic literature reviews, economic modeling consulting, secondary data analysis, and reimbursement landscape analysis, which are crucial for informing market access and reimbursement strategies. SIRO's real-world research covers various studies, including patient registries, health records analytics, patient and physician surveys, and late-phase effectiveness studies. The company's commitment to global platforms, such as regular presentations at the International Society for Medical Publication Professionals and the International Society for Pharmacoeconomics and Outcomes Research conferences, highlights its expertise and influence in the field.

In communications, SIRO excels in creating global value dossiers, Academy of Managed Care Pharmacy dossiers, whitepapers, and systematic literature review reports. The company also offers training workshops, continuing medical education, and other educational programs to strengthen its clients' ability to effectively communicate the value of their products. Through this robust HEOR offering, SIRO plays a vital role in helping companies demonstrate the real-world value of their innovations.

Publications

SIRO provides a comprehensive range of publication services to communicate scientific research and clinical outcomes across various formats. The company's offerings include manuscripts (primary and secondary), abstracts, posters, slide decks, white papers, training modules, consensus guidelines, case reports. It also specializes in areas such as RWE and HEOR, while offering expertise in PK/PD modeling, population PK, meta-analyses, and review articles.

SIRO differentiates itself through several key strengths. Its in-house graphic design team enhances the visual presentation of publications, making complex data easily understandable and visually appealing. Publication management services ensure seamless coordination of projects from concept to completion. The company also prides itself on the expertise of its Certified Medical Publication Professional-certified

publication writers who uphold high standards of integrity and transparency in scientific communication. Additionally, SIRO's leadership is evident through its participation as faculty speakers at international publication forums, reinforcing its thought leadership and expertise.

With over 1,000 publication documents delivered and an impressive 98% acceptance rate, SIRO's track record speaks to its scientific writing and publishing excellence.¹ The company's writers have contributed more than 200 articles in top peer-reviewed journals, including prestigious publications such as Nature Review Neuroscience, Journal of Clinical Oncology, and Journal of the American Medical Association Psychiatry.

SIRO's team uses advanced tools like Online Virtual Information Database, Scopus, and Public/Publisher MEDLINE for research and EndNote for reference management, ensuring the highest quality of evidence-based publications. This expertise positions the company as a reliable partner for pharma companies seeking to publish in high-impact biomedical journals.

Drug Safety and Risk Management

SIRO's drug safety and risk management services encompass various pharmacovigilance aggregate reports across global regions, including the US, EU, Japan, China, and other Asia Pacific countries. With over a decade of experience, the company is a global leader in this field, known for its expertise in compiling and managing critical safety documents.

SIRO's key differentiators include its pioneering role in the submission of DSURs. The company was one of the first to submit a DSUR in 2011, shortly after the implementation of the International Conference on Harmonization E2F guidelines. Since then, SIRO has successfully submitted over 500 DSURs with no queries from health authorities, demonstrating its high standards in compliance and accuracy. The company is also recognized for its expertise in developing Risk Management Plans (RMP), particularly for the EU and core RMPs. Its specialized team ensures efficiency in authoring, technical review, and quality control for various regulatory submissions.

SIRO's early adoption of aggregate reports, utilizing a Day Minus 90 strategy for timely submissions, demonstrates its commitment to innovation. Its extensive experience covers a broad spectrum of document types, including Periodic Benefit-Risk Evaluation Reports, Periodic Safety Update Reports, DSURs, regional periodic reports, Post-Marketing Adverse Drug Experience Reports, Annual Clinical Outcome reports, and periodic Suspected Unexpected Serious Adverse Reactions Line Listings. The company also manages European Public Assessment Reports. Furthermore, SIRO employs a dedicated team of experts proficient across all major therapeutic areas, with scientific reviews of aggregate reports conducted by specialized physicians. This extensive expertise ensures that the company remains at the forefront of drug safety and risk management, providing reliable and timely support to its clients.

Frost & Sullivan is impressed by SIRO's comprehensive and high-impact services across its core offerings. The company's regulatory medical writing demonstrates exceptional compliance and expertise, particularly in neuroscience and oncology, while advanced methodologies and significant contributions to global platforms highlight its HEOR writing capabilities. SIRO's robust publication services, marked by a

¹ SIRO, "Publications - SIRO: Leader in Global Medical Writing," SIRO, November 16, 2022, <https://siroclinpharm.co.uk/publications/>.

high acceptance rate, contributions to prestigious journals, and pioneering role in drug safety and risk management with a history of successful submissions, underscores its leadership and excellence in the pharma and biotech industries.

Driving Value through Expertise and Flexibility: SIRO's Approach to Client Success

SIRO emphasizes talent acquisition and operational excellence, employing a dual strategy of attracting top-tier professionals with extensive experience in global contract research organizations and pharma and investing in junior hires through structured training programs. This balanced approach ensures a scalable model that blends high-level expertise with developing a skilled workforce. Additionally, the company promotes horizontal growth by encouraging staff to work across various documents and clients, enhancing their experience and job satisfaction.

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- Ojaswi Rana
Best Practices Research Analyst

SIRO prioritizes rigorous adherence to Standard Operating Procedures (SOP), which guide the quality and timeliness of their deliverables. The company maintains a dedicated quality control team to review documents and ensure they meet high standards before they reach clients. In addition, key account managers provide a single point of contact, overseeing ongoing projects, addressing concerns proactively, and facilitating business development. These resources streamline communication and strengthen client relationships, contributing to improved satisfaction.

For new clients, SIRO offers a personalized approach, customizing proposals and pricing structures to meet specific needs, rather than relying on generic solutions. For ongoing clients, the company conducts

regular governance meetings involving senior management to gather feedback, address concerns, and discuss future plans. Additionally, feedback forms post-submission assess communication, quality, and overall performance, allowing SIRO to continuously improve its services.

The company emphasizes value through a flexible, client-focused approach, prioritizing tailored solutions over price alone. By adapting to various business models, including functional service provider, time-and-materials, and transactional frameworks, SIRO meets the diverse needs of its clients. It also offers volume-based discounts and long-term partnership options, delivering added value through sustained relationships rather than short-term cost savings.

Frost & Sullivan commends SIRO for its exemplary talent acquisition and operational excellence strategies. The company's commitment to rigorous SOP adherence, a dedicated quality control team, and personalized client interactions, bolstered by key account managers and tailored solutions, demonstrates its ability to deliver exceptional value and satisfaction while adapting to diverse client needs and business models.

Strategic Expansion and Sustainability: SIRO's Comprehensive Approach to Growth

SIRO has achieved notable success, evidenced by a high repeat business rate of 90% to 95%, reflecting strong client satisfaction and loyalty.² The company maintains relationships with approximately 20 to 25 unique clients across eight to 10 countries. In 2023, SIRO onboarded about six new accounts and experienced 15% to 20% annual revenue growth.³ Impressively, the company retains all existing clients, with nearly 100% of new clients engaging in subsequent projects, underscoring its consistent ability to meet and exceed client expectations.⁴

Branding

SIRO focuses on establishing a solid market presence and enhancing its professional reputation. In the UK, the company began by setting up a dedicated business development team to build credibility and engage directly with potential clients. Word-of-mouth referrals and direct client interactions facilitated further

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- Ojaswi Rana
Best Practices Research Analyst

growth as it penetrated initial accounts. SIRO is also revamping its website to reflect an updated and professional image, alongside increasing its visibility through social media marketing.

SIRO strategically positions medical writers in the UK to maintain a robust operational presence. This local staffing helps the company navigate any regulatory or logistical changes resulting from geopolitical changes, such as Brexit. Furthermore, the company’s active participation in various industry events, from small roundtables to large global conferences, ensures that it remains engaged with key stakeholders and continues to build strong relationships within the UK and the broader European market. This proactive approach helps SIRO stay influential and adaptable in

the evolving post-Brexit landscape.

The company’s commitment to sustainability is a core aspect of its brand, highlighted by its Silver Medal from EcoVadis and active involvement in the Science Based Targets initiative to reduce greenhouse gas emissions. Achieving a ranking in the 82nd percentile on EcoVadis, SIRO is a global leader in sustainable practices, aligning with the values of pharma companies that prioritize environmental responsibility in their vendor selection. Its ongoing enhancements in ethics, procurement, and labor practices, alongside its rigorous adherence to global standards, reinforce its reputation further as a trusted and forward-thinking partner in the industry.

² Frost & Sullivan’s Interview with SIRO Clinpharm, (August 29, 2024).

³ Ibid.

⁴ Ibid.

Growth Potential

SIRO is enhancing its onshore-offshore model, which integrates robust operations in the UK, Europe, and the US with a strong offshore team in India. By reinforcing its physical presence onshore, the company aims to build greater trust and reliability in the market while expanding its business development and operational capabilities. Additionally, SIRO is establishing a board of advisors to guide its growth in medical writing and emerging fields like artificial intelligence. This strategic move supports ongoing development and adaptation.

While the company is not currently looking to expand its onshore presence beyond the UK, it is increasing its business development efforts across Europe. In India, SIRO leverages its established reputation to offer employees diverse growth opportunities, ensuring a dynamic work environment that encourages horizontal and vertical career advancement. This approach helps retain talent and drives continued growth and innovation.

Frost & Sullivan believes SIRO's impressive repeat business rate and robust year-on-year revenue growth highlight the company's exceptional client satisfaction and consistent ability to exceed expectations. SIRO's strategic focus on enhancing its market presence, commitment to sustainability, and proactive engagement in industry events further solidifies its position as a forward-thinking leader, well-equipped for sustained growth and adaptation in an evolving global landscape.

Conclusion

Effective customer-centric strategies are key to maintaining a market position as long as the approach is sincere, and the implementation is efficient. SIRO Medical Writing Private Limited (SIRO), a subsidiary of the SIRO Clinpharm (Group), integrates customer-focused strategies and demonstrates exemplary implementation of best practices. For instance, the company's comprehensive medical writing services deliver significant value by providing tailored documentation that enhances regulatory submissions and accelerates time-to-market for pharmaceuticals. Additionally, SIRO's customer-centric approach is evident through its personalized client engagement, which includes assigning dedicated account managers to ensure seamless communication and address specific needs. Moreover, the company's commitment to ongoing feedback and continuous improvement helps refine its offerings, ensuring that clients receive the most relevant and effective solutions.

SIRO exemplifies its solid brand presence through strategic expansion in the United Kingdom, where it has built a dedicated business development team and actively participates in industry events to enhance its credibility and visibility. Looking ahead, the company supports its growth prospects by continuously improving its onshore-offshore model, strengthening its presence in key markets like the United States and Europe, and leveraging its well-established offshore team in India. This approach fosters trust and reliability while driving its long-term expansion and innovation.

With its strong overall performance, SIRO earns Frost & Sullivan's 2024 Global Customer Value Leadership Award in the medical writing industry.

What You Need to Know about the Customer Value Leadership Recognition

Frost & Sullivan's Customer Value Leadership Award recognizes the company that offers products or services customers find superior for the overall price, performance, and quality.

Best Practices Award Analysis

For the Customer Value Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Business Impact

Financial Performance: Strong overall financial performance is achieved in terms of revenues, revenue growth, operating margin, and other key financial metrics

Customer Acquisition: Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

Operational Efficiency: Company staff performs assigned tasks productively, quickly, and to a high-quality standard

Growth Potential: Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

Human Capital: Commitment to quality and to customers characterize the company culture, which in turn enhances employee morale and retention

Customer Impact

Price/Performance Value: Products or services provide the best value for the price compared to similar market offerings

Customer Purchase Experience: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

Customer Ownership Experience: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

Customer Service Experience: Customer service is accessible, fast, stress-free, and high quality

Brand Equity: Customers perceive the brand positively and exhibit high brand loyalty

