medpoint

MEDPOINT PROFESSIONAL SERVICES & CONSULTING

Helping clients ensure the safety and efficacy of their medical devices, diagnostics, drugs, and biologics.

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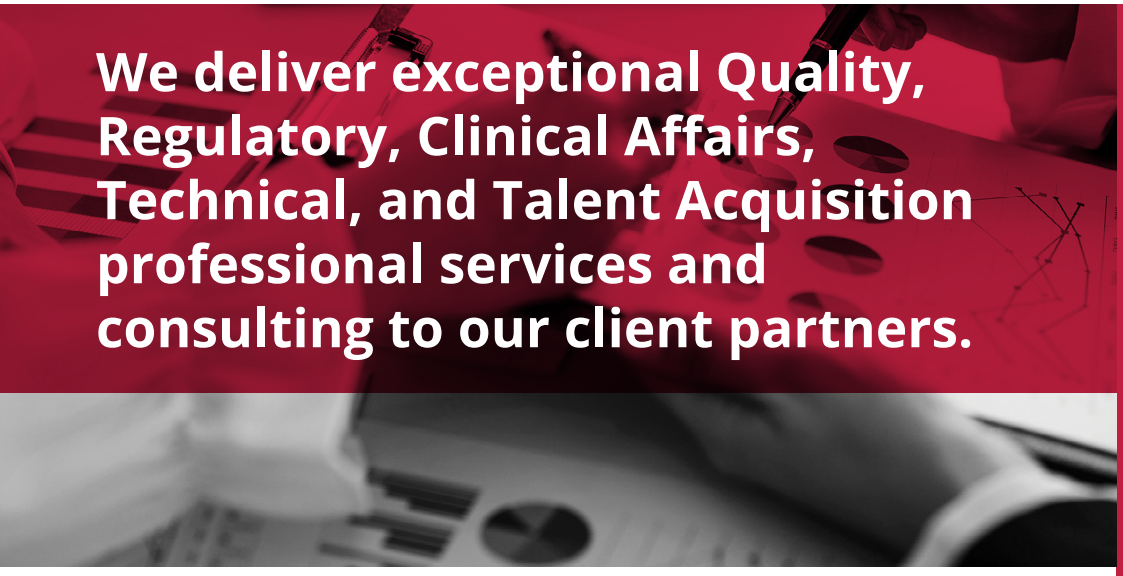

We deliver exceptional Quality, Regulatory, Clinical Affairs, Technical, and Talent Acquisition professional services and consulting to our client partners.

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QUALITY ASSURANCE CASE STUDIES

GLOBAL SUPPLIER QUALITY AUDIT PROGRAM CASE STUDY

Explore how Medpoint's turnkey global quality audit program ensures compliance across supply chains, leveraging a vast network of auditors, professional project management, and offering competitive pricing for diverse audit scenarios.

CLIENT BACKGROUND:

A leading Fortune 100 healthcare products manufacturer continues to rely on Medpoint's expertise for over 16 years to manage their global supplier quality audits, ensuring adherence to a long list of 21CFR and ISO regulatory standards.

OUR APPROACH:

Medpoint orchestrated a robust annual audit program, aligning client, supplier, and auditor interactions, and integrated a $3.4 billion acquisition into the client's quality compliance systems. The approach utilized dedicated coordinators, a lead auditor network covering 6 continents and 44 different languages, standardized observation grading, and review of supplier corrective action plans.

THE RESULT:

Through Medpoint's efforts, the client achieved an impressive 1,175 internal and supplier audits in 2022-2023, with report metrics exceeding goals of 90% right-first-pass and on-time delivery, demonstrating excellence in delivering comprehensive, efficient, and cost-effective audit programs.

SUPPLIER QUALITY AGREEMENT CASE STUDY

Discover how Medpoint led the development and amendment of over 100 Supplier Quality Agreements (SQAs) for a global leader in surgical and medical instruments.

CLIENT BACKGROUND:

The parent company was a surgical and medical instrument manufacturer selling in over 70 countries, with a total annual revenue of nearly $7 billion. The Client, consisting of two operating divisions, contacted Medpoint to assist in their upcoming spin-off into a standalone public company (NewCo). Medpoint was tasked with creating new Supplier Quality Agreements (SQAs) for over 100 suppliers transitioning to provide ongoing support to NewCo.

OUR APPROACH:

Medpoint broke down the project into six phases:

1. Initial consultation with the client's quality team.
2. Training on the client's electronic Quality Management System (eQMS).
3. Outreach to suppliers to define agreement terms.
4. Coordination of technical documentation.
5. Agreement execution by client and supplier.
6. Document control transfer of SQAs into the eQMS.

THE RESULT:

Medpoint successfully completed over 100 SQAs on behalf of the client, streamlining supplier transition during the spin-off. The SQA project allowed the client's quality team to concentrate on other mission critical initiatives including ongoing production demands. Medpoint competently and efficiently managed the complex aspects of the supplier quality agreement processes.

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REGULATORY AFFAIRS CASE STUDIES

PAI READINESS AND REMEDIATION CASE STUDY

Medpoint prepared a leading CDMO for FDA Pre-Approval Inspection, enhancing readiness across two manufacturing sites and the global regulatory organization.

CLIENT BACKGROUND:

A globally recognized Contract Development and Manufacturing Organization (CDMO) in the pharmaceutical sector, with multiple locations worldwide and over $5 billion in annual revenue, required assistance to prepare two key manufacturing sites and its global Quality & Regulatory organization for an upcoming US FDA Pre-Approval Inspection (PAI).

OUR APPROACH:

Medpoint provided an expert core team to rapidly assess risks and implement targeted remediation strategies. The project was divided into three phases: 1. Quality and Compliance Gap Assessment, 2. CAPA Program Implementation, and 3. SME/Audit Team Preparation including storyboarding. The team comprised specialists from various fields, including an ex-FDA Chemistry Team Leader, a Project Management CMC/Product Development QA/RA Expert, and others, highlighting a multidisciplinary approach to ensure comprehensive readiness.

THE RESULT:

The project duration was extended to five months, during which Medpoint guided the client through two FDA visits, improved documentation and process gaps, reviewed high-risk CAPA closures for effectiveness, identified SME needs for PAI, and prepared SMEs with storyboards for the FDA inspection. This extensive preparation and expert-driven approach led to an enhanced state of readiness for the PAI, demonstrating Medpoint's value in facilitating regulatory compliance and operational readiness.

CER LIFECYCLE MANAGEMENT CASE STUDY

Learn how Medpoint expertly managed the lifecycle of Clinical Evaluation Reports for a Fortune 500 Medical Device manufacturer, ensuring compliance with the Medical Device Regulation 2017/745.

CLIENT BACKGROUND:

A leading global Fortune 500 Medical Device manufacturer specializing in personal protection and surgical accessories with a presence in 400 locations worldwide faced a challenge. They needed to consolidate and update their Clinical Evaluation Reports (CER) across multiple divisions to comply with the Medical Device Regulation 2017/745. This regulation mandates yearly updates for CERs of high-risk devices and updates every two to five years for devices with lower-risk profiles.

OUR APPROACH:

Medpoint launched a project aimed at managing the revision lifecycle of CERs for CE Marking purposes. The project was structured into three phases:

1. Consolidation, benchmarking, and updating CER drafts.
2. Creation of a master revision schedule.
3. Yearly review and updates of CERs per the master schedule.

This proactive lifecycle management approach was designed to distribute the effort required for updating CERs over time, preventing excessive demand on the client's resources and budget and ensuring compliance with regulatory deadlines.

THE RESULT:

Medpoint successfully created a master CER revision schedule, enabling predictable and consistent resource utilization without overburdening the client. This schedule facilitated timely updates and annual reviews of CERs, ensuring the client remained compliant with the Medical Device Regulation 2017/745. This strategic approach not only streamlined the client's CER management process but also safeguarded their global operations against regulatory risks, demonstrating Medpoint's value in enhancing regulatory compliance and operational efficiency.

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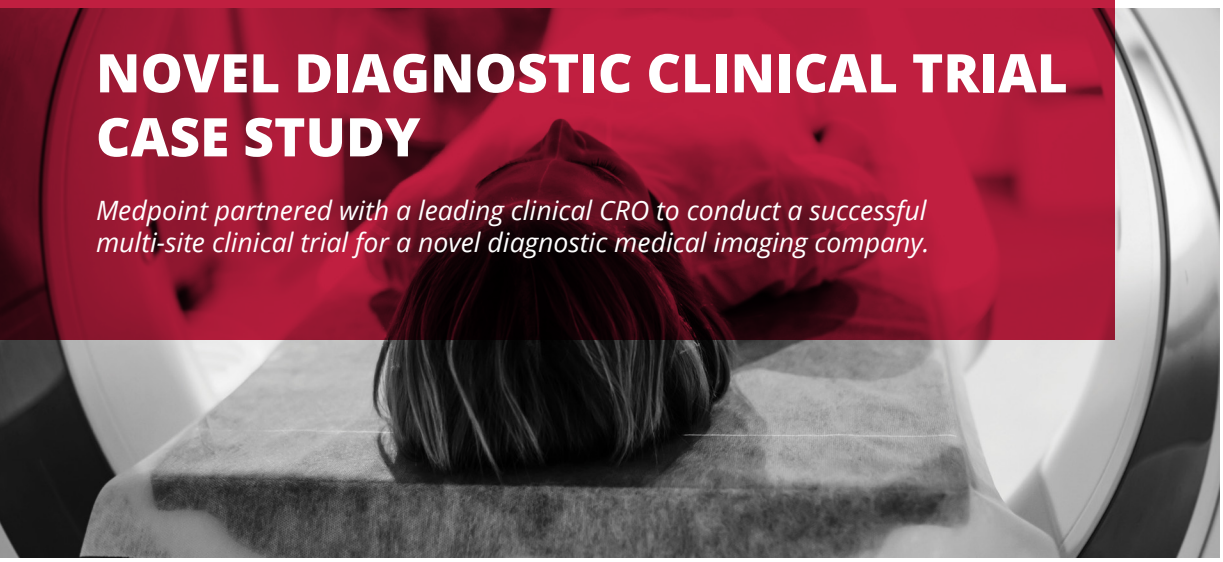
CLINICAL AFFAIRS CASE STUDIES



NOVEL DIAGNOSTIC CLINICAL TRIAL CASE STUDY

Medpoint partnered with a leading clinical CRO to conduct a successful multi-site clinical trial for a novel diagnostic medical imaging company.

CLIENT BACKGROUND:

An innovative medical imaging company developing a novel diagnostic instrument for the early detection and monitoring of chronic neurodegenerative diseases came to Medpoint seeking support for their clinical trial execution. The Client wanted to conduct the trial simultaneously across two countries and seven clinical sites.

OUR APPROACH:

Medpoint partnered with a leading clinical CRO to establish contracts with the clinical sites, train clinical staff on the novel diagnostic approach, manage enrollment, trial execution, and patient monitoring. The clinical trial targeted enrollment of 500 patients over an 18-month duration.

THE RESULT:

The clinical trial is scheduled to wrap up by Q1 2024, with the study intent to achieve FDA clearance and commercialization of the novel diagnostic approach. Medpoint and the partnering clinical CRO effectively managed the Client needs to ensure an efficient and successful trial implementation.

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TALENT ACQUISITION CASE STUDIES

Medpoint believes the heart of any successful organization lies in its people.

Our philosophy is a commitment to delivering exceptional talent acquisition services. We understand recruiting is not merely a transaction; it's a strategic partnership that shapes the future of your business.

OUR PHILOSOPHY IS BASED ON SIX PRINCIPLES:

Client-Centric Approach

We prioritize understanding the unique needs and goals of our clients. By aligning our strategies with your business objectives, we ensure every recruitment effort is a tailored solution crafted to elevate your workforce, and overall success.

Uncompromising Quality

We are dedicated to delivering nothing short of excellence. Our stringent quality standards, combined with a meticulous screening process, guarantee every candidate we present is not only qualified but possess the cultural fit necessary to thrive within your organization.

Ethical Conduct

Integrity is the cornerstone of our operations. We adhere to the highest ethical standards in every aspect of our work, ensuring transparency, honesty, and absolute confidentiality. Our commitment to ethical conduct builds trust with you, fostering enduring relationships.

Long-Term Partnerships

We don't view you as a one-time transaction but a long-term partner. Building enduring relationships allows us to gain a deep understanding of your evolving needs and contribute proactively to your success over time.

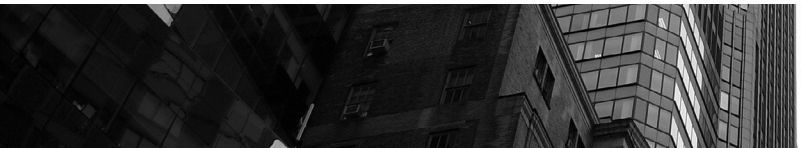
Measurable Impact

We believe in the power of measurable results. Our performance is not just about filling positions; it's about making a tangible impact with quick placements to have your team up and running faster, moving your company forward. We regularly evaluate and refine our strategies to ensure our efforts align with your key performance indicators.

Continuous Learning & Development

The recruitment landscape is ever evolving, and so are we. We invest in the continuous learning and development of our team to stay on top of industry trends, emerging technologies, and best practices. This commitment enables us to provide you with the insights and strategies that propel you ahead of the competition.

Medpoint's talent acquisition philosophy revolves around a relentless pursuit of excellence. We are not just recruiters; we are strategic partners committed to propelling you towards your goals by connecting you with the right talent at the right time.



TALENT ACQUISITION CASE STUDY 1

Preview Summary:

Medpoint's strategic recruitment delivered a perfect Technical Writer match for a major cold chain logistics company, enhancing their documentation process and team synergy.

Client Background:

A prominent cold chain logistics company serving the medical device and pharmaceutical sectors began its partnership with Medpoint in 2018, seeking a Technical Writer for their California team.

Our Approach:

Starting with a comprehensive needs assessment to align with the company culture and team, Medpoint conducted a targeted search across multiple channels, followed by a rigorous candidate screening to ensure technical proficiency and cultural fit.

The Result:

After a thorough search, screening, and interview process, Medpoint successfully identified and placed an ideal candidate for the Technical Writer position for the client with a time to fill of 42 days.

TALENT ACQUISITION CASE STUDY 2

Preview Summary:

Learn how Medpoint's recruitment expertise secured a Quality Assurance Manager for a global logistics subsidiary, ensuring quality system integrity and compliance.

Client Background:

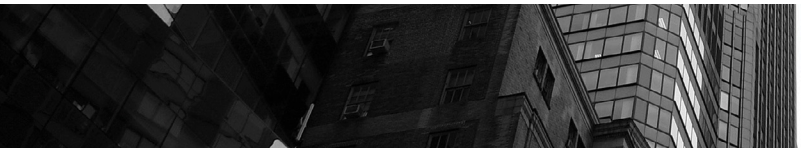
The subsidiary of a long-standing client required a Quality Assurance Manager for their Pennsylvania plant to oversee quality systems in line with ISO 9001:2015 standards.

Our Approach:

Through a thorough needs analysis and specialized candidate search, Medpoint pinpointed candidates who could fulfill the rigorous quality assurance expectations and contribute as business partners.

The Result:

The successful placement of a Quality Assurance Manager in 26 days fortified the client's commitment to excellence and regulatory adherence, further cementing Medpoint's reputation for delivering premium talent solutions.



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We strive to partner with medical device, pharmaceutical, and biotechnology companies to achieve and maintain global compliance in the areas of quality assurance, regulatory, and clinical affairs.

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SCAN TO CONTACT US