Ownership Structure

Promedica International is a privately held corporation established in 1985. Corporate offices are located in Huntington Beach, California.

Professional Management

Organization

Promedica International runs projects using a team configuration. Project managers serve as our primary client contact. Each manager is responsible for project schedules, budgets, personnel and procedures. This configuration has provided the quality of service that is essential for our clients.

It is our practice to provide resumes of key team members for review and approval by our clients prior to their involvement in the project. This enables maximization of our resources to best suit client requirements.

Promedica International is committed to maintaining and updating the knowledge of its personnel. The company subscribes to industry-related educational publications, which are supplemented by electronic updates concerning newly issued FDA publications. Staff is regularly involved in medical and clinical/regulatory education meetings and employees belong to various professional organizations such as ACRP, DIA, RAPS, and OCRA.

Confidentiality

Execution of confidentiality agreements with our clients is standard policy for our services. We are forthright in disclosing potential conflicts with competing products to both existing and prospective clients. We have historically serviced competing products by organizing separate project teams, permitting services to proceed in a professional manner.

Financial Stability

Promedica International is a privately held multi-million dollar corporation. The management is pleased to provide a list of long-term references regarding payment history; however, does not disclose other financials.

Our careful review of clients and project validity prior to entering into contractual arrangements is an important component of our financial stability. The company has established criteria for reviewing new clients, and our standard billing practices are another important component of sound cash flow management. Clients make deposits prior to initiation of project activity and invoices are generated on a monthly basis.

TRACK RECORD

We have established service relationships with more than 100 clients and are pleased to provide a reference list of those who have agreed to be contacted.

Our management has 25+ years of experience with industry-leaders, mid-size companies, and "start-ups" in the medical device/diagnostic and pharmaceutical industries. This experience provides us with contacts in most medical specialties/therapeutic areas and gives us a first-hand understanding of our clients' business position. We have direct experience in the following areas:

– Cardiology
– Cardiovascular Surgery
– Clinical Laboratory Equipment and Instrumentation
– Cosmetic and Reconstructive Surgery
– Critical Care Medicine
– Dental
– General Surgery
– Home Health Care
– Nephrology
– Neurology
– Nutrition
– Obstetrics and Gynecology
– Ophthalmology and Optometry
– Oncology
– Orthopedics
– Otolaryngology

SPECIALIZATION

Promedica International provides a range of services related to the development, management and assessment of clinical studies. While there is no such thing as a "typical" project, services frequently requested are:

– Clinical study management and monitoring
– Data management and biostatistics
– Generation of clinical summary reports
– Good Clinical Practice (GCP) audits and training

EXPERIENCE WITH GCP, FDA AND OTHER NATIONAL AGENCY STANDARDS

Promedica International has conducted or audited numerous clinical investigations of medical products both in the US and Canada. Studies managed have involved up to 1,000 subjects and as many as 30 study sites and their associated IRBs/Ethics Committees.

We have managed "acute" studies, as well as studies involving long-term (3+ years) follow-up. As a result, we have experience with subject recruitment and retention programs that have assisted our clients in accomplishing aggressive FDA submission schedules.

The company has provided support for numerous FDA Bioresearch Monitoring audits, either as the ongoing monitoring organization, or as contracted to assist clients who performed their own study monitoring.

STANDARD OPERATING PROCEDURES (SOPS)

Our business operates according to an ISO-based Quality Management System, and maintains its own written Clinical and Regulatory SOPs. It is our policy that our clients review and approve project plans and SOPs at project initiation and on an as needed basis thereafter.

QUALITY ASSURANCE & AUDITING

The highest importance is placed on the quality of our work. Staff is trained intensively on each study protocol and secondary review is incorporated into our service. Formal internal quality assurance audits are conducted on a regular basis. Clients are encouraged to participate in our training and to audit our work regularly.

ADVERSE EVENT (AE) EVALUATION AND REPORTING

While our clients generally prefer to retain primary responsibility for serious or device-related AE evaluation and reporting to FDA, Promedica International may serve as the primary contact for AEs identified during studies. We work closely with our clients throughout AE investigations, and if requested, can develop reports for FDA and IRBs.

COMPANY INFRASTRUCTURE

Word and data processing are done on Novell and Windows NT server systems. Workstations are regularly assessed for performance upgrades to optimize data processing capabilities. Client data and information is securely stored on the network server where access requires a unique network login and password. Electronic files are regularly scanned for viruses. Backup tapes are generated regularly and stored at an off-site location. Additionally, we retain a service contract service for computer maintenance.

Each workstation has on-line capabilities to facilitate electronic communication with our clients and sites.

Promedica International's clinical study data management systems and procedures emphasize efficiency and accuracy in data storage and compilation. Customized study databases are compartmentalized and further password-protected, with access levels assigned based on employee clearance.

Registration Experience

Our consultants have experience with preparing 510(k)s, IDEs, PMAs, Device Establishment and Import/Export Registrations for review by FDA. The acceptance time for submissions varies based on client products and specific reviewing branches or organizations.

For more information, please contact:

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