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Executive Search

CDISC

Chief Standards Officer

Client Overview

Sterling Martin Associates has been retained by the Clinical Data Interchange Standards Consortium (CDISC) to search for ***Chief Standards Officer (CSO)***. This is a new position, and the incumbent will be a member of the senior leadership team. CDISC's headquarters are located in Austin, TX, but the CSO may be located anywhere in North America.

Founded in 1998 as a voluntary organization and formally chartered in 2000, CDISC is a 501(c)(3) global nonprofit, interdisciplinary organization that develops data standards to promote smarter clinical research and enable healthcare connections. CDISC's standards are downloaded in over 90 countries and are required for regulatory submissions to the U.S. Food and Drug Administration (FDA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA). CDISC's standards are also recommended by both China FDA and the EU European Medicines Agency. CDISC creates therapeutic-area data standards for more than 30 disease areas, advancing medical product development and research. Industry representation among CDISC's membership (~450 members based in 25 countries) is broad, with particular concentration among technology service providers, clinical research organizations, pharmaceutical companies, preeminent academic institutions, and regulatory agencies.

CDISC's mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of health care. CDISC's vision is to inform patient care and safety through higher quality medical research**.** These harmonized standards support seamless data sharing across studies, enabling cross-study comparisons and ready aggregation—yielding opportunities in the form of workflow efficiencies and the creation of large, high-quality datasets for disease modeling and biomarker qualification to stimulate the development of new therapies for patients.

CDISC's budget is in the $8M range, and the organization expects to grow over the next several years. Fourteen members of the 30-member staff are housed in the Austin, TX headquarters, and there is a well-developed technology infrastructure to support the remaining staff who work remotely. CDISC is governed by a 14-member Board of Directors, and a CDISC Advisory Council, made up of "Platinum Members," provides the Executive Committee and Board with recommendations and advice on a broad range of issues.

In 2017, the CDISC Board of Directors appointed David R. Bobbitt, MSc, MBA as President and CEO. The CSO will report to Mr. Bobbitt and serve as the second most senior executive in the organization.

For more information, please visit www.cdisc.org.

Chief Standards Officer (CSO)

Reporting directly to the President and CEO, the Chief Standards Officer (CSO) will have primary responsibility for defining and achieving the development and implementation of CDISC standards consistent with strategy defined by the CDISC President and CEO and Board of Directors. The CSO is a global leader and an "evangelist" for CDISC clinical standards, representing the organization and setting a global agenda within the clinical research space. S/he will have direct responsibility for the Director, Standards Development, and Director, Content Management, along with CDISC's Project Managers and Content Managers. S/he will be expected to garner the immediate respect of regulators (US FDA, Japan PMDA, China FDA and EU EMA) as well as leaders in the biopharmaceutical industry. Global professional experience is a priority for the position.

CDISC is a highly respected and successful organization that meets a critical global need. With the organization's growing membership base, dedicated staff and volunteers, and an accomplished senior leadership team, the position of CSO offers an exceptional opportunity for a unique individual. The successful candidate will step into an organization that is financially sound and has a well-regarded reputation, as well as the imperative to grow and extend its good work.

While many other standards development organizations have a Chief Technology Officer, to our knowledge this is the world's first Chief Standards Officer position among the leading standards development organizations. This commitment to building and sustaining first-in-class standards courses through all CDISC does.

Specific Duties & Responsibilities

Under the broad direction of the President and CEO, the CSO will assume the following duties and responsibilities:

- Provide executive leadership to the development and implementation of clinical standards in the CDISC strategy and operational plans. Build peer relationships with leadership in the biopharmaceutical, biotechnology, Contract Research Organizations (CROs), and related industries as well as government entities with deep connections to regulated research.
- Describe, maintain, and update a technical vision for clinical standards, positioning CDISC as the global organizational leader in clinical standards. Work closely with the Board of Directors, stakeholders and opinion leaders to keep this vision fresh and in the regular conversation of key stakeholders.
- Build a culture that meets the needs of regulators, CDISC members, partners, clinical researchers, and ultimately patients so that CDISC standards are broadly accepted and utilized.
- Serve as a visible spokesperson and champion for CDISC with key stakeholders, including clinical, research, and technical audiences. Serve as an expert speaker at conferences and symposia. Support the President & CEO to ensure CDISC delivers on its commitments.
- Build and support a high-performing team of experts in clinical standards, content management, and project management to support CDISC's strategic plan. Motivate and support career development of subordinates.
- Ensure consistency across CDISC standards and work in collaboration with outside partners to support implementation of CDISC standards in a variety of settings.
- Motivate and lead a diverse team of volunteers, ensuring clear and reasonable expectations for volunteers while best utilizing their special skills and knowledge in the development and implementation of CDISC standards.
- Ensure that all projects and partnerships achieve results on time and within budget. Establish and maintain new critical partnerships.
- Support organizational revenue through membership, business development, and sales, as necessary, to ensure the sustainability of the CDISC standards.
- Ensure integration of standards efforts with the CDISC Educational programs.
- Serve on appropriate boards, colloquia, and committees, both internally and externally, to ensure CDISC visibility and respect in critical spheres of influence.
- Actively participate as a member of CDISC's Executive Team (ET), including providing clear, accurate, and timely information; listening attentively; engaging other ET members and supporting their projects; promoting inter-departmental harmony; and supporting full execution of the organization's Strategic Plan in all departments.
- Lead CDISC efforts to evaluate the efficacy of developing and managing a CDISC certification.
- Ensure timely and accurate reporting of departmental hours; billing (A/P and A/R); and results on Strategic Plan Goals. Ensure departmental adherence to CDISC Travel Policy.
- In all activities and communications, represent CDISC professionally and demonstrate loyalty to the organization.

Ideal Background & Experience | Qualities & Characteristics

All candidates will be expected to embrace CDISC's mission and will have a deep understanding of and experience with standards development and implementation. In addition, qualified candidates will be expected to present the following background and experience, qualities and characteristics:

- Minimum of MS/MBA degree in a technical/computer science field; PhD or MD degree preferred.
- Minimum of 15 years of experience in a relevant field, with a minimum of 10 years of management experience in a virtual, multi-location, and/or international environment.
- Minimum of 10 years of experience working in the global clinical research environment (pharmaceutical and academic), with knowledge of relevant regulations, standards, and information technology.
- Global leadership experience required. Experience living or working outside North America strongly preferred.
- Demonstrated leadership skills: ability to manage, motivate, and integrate committees and teams to achieve their mission and objectives
- Expertise in the areas of computer science, IT architectures, model-driven architecture, UML modeling, XML, and medical informatics.
- Knowledge of standards development processes and the global standards landscape for research and healthcare.
- Expertise in standards development, preferably in the medical/healthcare field.
- In-depth knowledge of and direct implementation experience with CDISC standards for clinical trial and submission use cases – a plus.
- Strong emotional intelligence.
- Ability to understand and relate to different cultures, i.e., culturally sensitive.
- Ability to work effectively with diverse audiences and personalities and diffuse difficult situations with tact and diplomacy.
- Sense of humor and ability to bring out a sense of humor in others.
- Comfortable with ambiguity.
- Fluency in a language in addition to English preferred. Preference for Japanese, Chinese, German, or French.
- Excellent interpersonal, problem solving, organizational, negotiation, decision making, oral/written communications, consensus-building and meeting facilitation skills.

Some travel (up to 50%) is required, much of that international. Monthly travel to Austin and/or Washington, DC required.

Compensation and Benefits

CDISC offers competitive compensation with an attractive benefit package including healthcare and 401k matching.

To apply, please send a cover letter and current résumé (Microsoft Word® format preferred) to cdisc@smartinsearch.com. *A well-crafted cover letter outlining how your background and experience relate to the position is considered an important part of the candidate review process.* All applications will be acknowledged.

CDISC is an Equal Opportunity Employer, committed to diversity in the workplace. **For more information, please contact:**

Sterling Martin Associates
1025 Connecticut Avenue | Suite 1000
Washington, DC 20036
www.smartinsearch.com

David S. Martin | Managing Partner
cdisc@smartinsearch.com

Tricia Bork Canavan | Search Consultant
cdisc@smartinsearch.com

No phone calls, please.