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DANA-FARBER
CANCER INSTITUTE

Director
Operations Quality
Hematopoietic Stem Cell Transplant (HSCT) & Cellular Therapies

Dana-Farber Cancer Institute

Boston, MA

Leadership Profile

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Leadership Between

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Summary

Dana-Farber Cancer Institute (DFCI) is seeking a Director of Operations Quality for its Hematopoietic Stem Cell Transplant (HSCT) & Immune Effector Cell Therapy Programs (IEC). This is a mission critical and highly visible operational leadership role reporting into the nationally recognized Division of Stem Cell Transplantation and Cellular Therapies at the Institute. The combined programs are among the largest in the country and serve adult and pediatric patients and families of DFCI, Brigham & Women's Hospital, and Boston Children's Hospital. All three institutions are Harvard Medical School (HMS) teaching affiliates.

The Opportunity

The Director of Operations Quality for the Hematopoietic Stem Cell Transplant (HSCT) & Cellular Therapies Programs provides leadership and direction to ensure operational excellence across a broad range of activities and sites for two of the largest and most respected HSCT and Cellular Therapies programs in the U.S. Working collaboratively with faculty and staff to develop and implement strategies to achieve programmatic excellence, this position will rely on a deep understanding of clinical operations in a large and highly complex care delivery system to successfully build and socialize methods to optimize effective operations.

The Director will serve as a key leader for programmatic interests in overall operational effectiveness and innovative solutions that ensure patient safety, regulatory compliance, clinical templates, and electronic and other tools to support improvements in utilization and outcomes. The Director will also ensure the accuracy and reliability of documentation that supports clinical pathways, outcomes reporting and analytics, revenue integrity, business planning, and well-engineered day to day workflows. The Director will ensure positive and supportive interface with regulatory organizations and effective working relationships with commercial organizations to implement new products. The Director will also create and maintain programs to ensure staff readiness and training, and process improvements that support financial performance.

The Director will serve as a key consultant and provide guidance to other programmatic leads across sites of care, including inpatient and outpatient clinical operations, institutional facilities teams, clinical and cell processing laboratories, patient coordination, donor services, community-based care, referring physician relations, business analytics, financial planning and strategic planning. The Director reports to the Vice President for the HSCT & Cellular Therapies Service Line**.** The Director's team of 20 staff members includes quality assurance and improvement managers and specialists, outcomes reporting and program administrators, and an audit team.

The Dana-Farber Cancer Institute

The DFCI is a world leader in basic and clinical research, training and application of advanced diagnostic and treatment methods in the mission of conquering cancer, HIV/AIDS and related diseases. Founded in 1947 by Sidney Farber, MD, today DFCI employs nearly 5,000 people supporting more than 300,000 patient visits a year, is involved in some 700 clinical trials, and internationally renowned for its blending of research and clinical excellence. The Institute brings together exceptional professionals with the best technologies in a genuinely positive environment and provides compassionate and comprehensive care to children and adults. DFCI's expertise in these areas in the fight against cancer uniquely positions it to develop and test the next generation of cancer therapies in both the laboratory and the clinic. See www.danafarber.org

DFCI, a principal teaching affiliate of Harvard Medical School, is a founding member of the Dana-Farber/Harvard Cancer Center, an NIH comprehensive cancer center and a federally designated Center for AIDS Research. Providing advanced training in cancer treatment and research for an international faculty, the Institute conducts community-based programs in cancer prevention, detection and control throughout New England. DFCI is supported by the National Cancer Institute (where it continues to be one of the highest recipients of grant funding), as well as other institutes of the National Institutes of Health. It is also supported by numerous foundations and individuals, who contribute to the Institute's individual research and clinic programs or to the Jimmy Fund, the principal charity of the Institute, named for one of its pediatric patients.

DFCI and its two hospital partners have been recognized for their shared devotion to exceptional patient/family centered practices as reflected in successive ANCC Magnet Program designations and re-designations. DFCI faculty and staff share a deep commitment to the integration of innovation, science and caring practices. Together, they seek to advance academic adult and pediatric oncology care delivery, research, and educational missions to improve health and healthcare for DFCI oncology patients and families. DFCI is the only hospital ranked in the top four nationally by *U.S. News and World Report* in both adult and pediatric cancer care.

When ranked among 141 independent hospitals, DFCI placed fourth in receipt of NIH research awards, preceded only by Massachusetts General Hospital, Brigham and Women's Hospital and Boston Children's Hospital—all founding members of the consortium Dana-Farber/Harvard Cancer Center.

DFCI is equally committed to cancer research to advance knowledge of cancer causes and cures, as well as the psychosocial concerns and symptom management that enhance total care for patients. It supports a balance between research and care, with high standards for discovery and quality of care. This model is critical for making the most progress against this disease and for their mission.

DFCI is a financially strong organization. It invests in cancer research and care by generating a consistent operating margin, earning a return on its endowment, and through generous philanthropy. DFCI has a strong balance sheet with a $1 billion endowment, $2 billion in assets and $1.3 billion in net assets supporting its "A" credit rating. While the healthcare industry is challenged, DFCI as a specialty cancer center is in a stronger relative financial position than most of the industry.

The organization budgets a 1.5 percent margin annually and has a demonstrated record of achieving or exceeding that margin for the last five years. Revenue growth in pharmacy has been strong, driven by the introduction of revolutionary cancer treatments that are helping patients with improved outcomes. DFCI projects continued strength within three primary focus areas of clinical care, research and philanthropy.

The HSCT and Cellular Therapies Program

The stem cell transplantation programs at Dana-Farber/Brigham and Women's Cancer Center and Boston Children's are among the largest and most experienced programs in the world. These programs combine major basic, translational, and clinical research programs to continuously improve and provide new therapies for patients. It is the dominant program in the region, and cares for significant national and international patients as well. These programs have performed more than 11,500 transplants for the treatment of blood cancers and related disorders since they began in 1972, originally as a joint program. The quality assurance operation, outcomes data repositories, and associated analytics resources to support research and treatment advances are heavily invested in by Dana-Farber Cancer Institute and provide key resources for the programs, contributing to successful advancement of therapies and research. The programs have tracked and provided valuable data to the Center for International Blood &

Marrow Transplant Research (CIBMTR) since its inception and consistently exceed expected outcomes set by the CIBMTR. The center specific outcomes have been recognized as among the best in the United States.

The HSCT and IEC therapies programs evaluate more than 1000 patients/year. Currently performing approximately 500 adult and 140 pediatric transplants annually and 150 CAR T procedures annually in the fast-growing IEC program. There are more than forty (40) credentialed physicians, with many holding leadership roles in national organizations and playing key editorial contributor roles for the most cited journals in the field. The research enterprise and the facilities are equally robust and are considered the national benchmarks among NIH Cancer Centers. The research is cutting edge, novel, and pioneering and includes major multicenter efforts that drive the most efficacious tools, techniques, and therapies. The programs are served by an all new (opened in August 2018), state of the art, 34,000 sq. ft. cellular processing and manufacturing laboratory. Inpatients are cared for in specialized, state of the art facilities, with high-efficiency particulate air (HEPA) filtered rooms.

CAR-T volume has grown quickly in 2018 and has become a major component of the adult DF/BWCC cellular therapies enterprise. CAR-T is expected to comprise 15 to 20 percent of total cell therapies volume next year.

The Position: Director of Operations Quality

The Director of Operations Quality (the Director) reports to the Vice President, HSCT & Cellular Therapy Service Line Operations. S/he leads a team of 20 staff members, including quality assurance and improvement managers and specialists, outcomes reporting and program administrators, and an audit team for both adult and pediatric programs. The Director will oversee a dedicated operating budget for quality operations with support from the Division's financial analyst for day to day financial transactions.

The Director is a key member of the clinical leadership team working closely with the Medical Directors and executives providing consultation and guidance relative to quality assurance and operational effectiveness. The Director will provide advisory and informational support to administrative leadership and other institutional executives and officials across the sites of care relative to transplant and cellular therapy operations quality and will play a leading role in informing and educating all staff involved with cellular therapies across the organizations as needed regarding standards and operational methods necessary to comply with such standards.

The Director is responsible for overseeing and managing the transplant and cell therapies quality management program, serving as the quality officer for these services and licenses, ensuring regulatory compliance methodology and documentation, continuous quality and process improvement, outcomes reporting, patient safety safeguards, and global education across the organizations. The Director ensures full integration of the program's quality systems with the organizations' patient safety and risk management enterprises and serves as the key quality contact for the program for other leaders in the institution. The Director will oversee the program's clinical outcomes data enterprise, including reporting to the national repository, meeting regulatory requirements for data quality, and working with the organization's analytics program to ensure reliable data consolidation for broad utilization for research, quality improvement and business purposes. She/he is expected to lead and support quality research and improvement initiatives internally and as a representative of the organization for national or multi-site quality projects. It is important to note that Dana-Farber is presently implementing an all new data repository application to support case management, outcomes and reporting to the CIBMTR, with go-live scheduled for March 2019. The quality staff are heavily involved in this critically important implementation that is simultaneously revising many workflows and communication pathways.

Working closely with clinical staff, duties include: oversight of the development, updating and dissemination of standard operating procedures for clinical practices that fall under regulatory control; monitoring and reporting on stem cell transplantation and other cell therapy clinical key indicators; performing and managing responses to clinical process audits; and managing planned and unplanned deviation reporting and trend analysis. Directing the efforts of three quality managers and a quality assurance team, the Director will oversee the coordination of FACT, FDA, JC, AABB, and other relevant compliance reporting and reaccreditation and inspection readiness requiring a full understanding of all relevant quality standards, ensuring that all regulatory and internal outcomes driven operating procedures are implemented and tracked. The Director will support clinical leadership in the development of treatment plans, consents, and forms as needed to ensure structured clinical practices. The Director will appropriately direct and support the quality managers or personally participate contemporaneously in deviation and adverse event documentation and assessment and play a lead role in subsequent root cause analysis and corrective action.

The Director will play a lead role in the development of uniform training standards, procedures and documentation of competencies for all staff engaged in the coordination and care of transplant and cell therapy patients and donors. The Director organizes, plans and moderates various committee meetings and presents and ensures quality outcomes implementation as needed.

The Candidate Profile

The strongest candidate will be an experienced operational leader, who has worked in academic medical centers or complex scientific enterprise. S/he will continue to cultivate a culture of teamwork and collaboration. The best candidate will be a good listener and gifted communicator with staff and colleagues at all levels and practice settings. S/he will possess and apply EQ to work effectively with physicians, nurses, and leaders across the Institute and Hospital partners. The Director will promote and contribute to operational effectiveness, innovations in safety and quality operations, and improved business process flows.

Qualifications, Experience, and Professional Leadership Attributes will include:

- A bachelor's degree is required plus a minimum of 8 years of experience in a role of management responsibility in a clinical operations setting that includes some experience working with quality management and regulatory affairs. A relevant higher or professional degree is highly preferred. Previous experience is preferred in an oncology clinical setting, blood bank/hematology system, stem cell transplant or cell therapies program or other relevant setting. Demonstrated ability and success in ensuring compliance with all internal quality and safety policies, procedures and guidelines, state and federal regulations, and regulatory agencies.
- Ability to deftly balance competing operational priorities, guide the team, and rapidly resolve clinical and operational safety and quality challenges.
- Knowledge of FACT, FDA, AABB, and JC regulations is strongly preferred.
- Ability to be a respected and recognized voice of the operations quality team for the HSTC and IEC programs with external organizations, including regulatory agencies, professional associations, and national safety and quality collaboratives.

- Conceptual understanding of clinical databases for overseeing outcomes reporting and analysis and other regulatory reporting, for organizing information in a useful manner.
- Competence or ability to gain competence in the use of institutional clinical information and health record systems.
- A background involving financial planning and performance, and business analytics is strongly preferred to enable rational development of operational models that support both quality and efficient resource utilization.
- Demonstrated ability to supervise and ensure training and preparation of staff working as a team to perform within complex workflows and to lead staff through challenging change management and quality improvement implementation
- Experience leading the development and implementation of effective and appropriate communication plans, such as for disseminating process, system or rule changes across a large and multidisciplinary staff.
- A strong interest in mentoring staff and promoting staff professional development, training, effective organizational working relationships and advancement.
- In conjunction with the Vice President, the Director will establish an overall staffing and retention strategy to support departmental goals and initiatives, and to achieve and maintain a high level of clinical and client service.
- The ability to initiate and navigate honest conversations with staff and colleagues at all levels, including an ability to express perspectives counter to prevailing thought via informed reasoning.
- The ability to be creative and innovative in developing solutions to the many challenges in complex care faced by academic medical centers and their referring provider systems.

Critical Success Factors

The Director will encounter both opportunities and challenges in his/her role. Specific priorities for the new leader in the first 12-24 months:

- Develop formal and informal networks and collaborative working relationships across the Service Line, with other units of the associated clinical programs and Nursing leadership.
- Assess the efficiency and effectiveness of regulatory readiness and quality operations and identify and implement one or two major improvements.
- Model accountability, effective collaboration, project management skills, and resilience to unite a broad range of stakeholders.
- Ensure that problems that are identified are recorded and solutions decided upon in conjunction with faculty, leadership, colleagues and staff are implemented in the desired time frame.

Compensation

An attractive compensation package will be constructed that is competitive and commensurate with the background and experience of the selected candidate.

For More Information

Referrals and nominations are welcomed. Interested parties please send a letter of interest and resume to DFCI.DirOpsQualityTransplant2257@ZurickDavis.com. For questions and additional information, please contact **Janet Clifford** (janet.clifford@zurickdavis.com) or **Jacqueline Rosenthal** at **781.938.1975.** All communication with **ZurickDavis** will remain confidential.

Dana-Farber Cancer Institute is an equal opportunity employer and affirms the right of every qualified applicant to receive consideration for employment without regard to race, color, religion, sex, gender identity or expression, national origin, sexual orientation, genetic information, disability, age, ancestry, military service, protected veteran status, or other groups as protected by law.