Position Summary

Quality Assurance Program Manager II

Purpose

Work independently under the direction of the CIBMTR Business Operations Program Director to oversee the CIBMTR Quality Assurance and Compliance Program to grow, maintain and monitor quality systems and processes that promotes an organizational culture of excellence; allow compliance with policies and regulations at the operational level; and are flexible to meet changing business and stakeholder needs.

Primary Functions

- Manages the development, implementation and continual evaluation of the CIBMTR quality management system.

- Works collaboratively with Quality Assurance and Compliance departments at both MCW and NMDP to support alignment of QA initiatives and responsibilities, maintain operational compliance with national/international regulations and institutional policies, and accreditation requirements of professional organizations.

- Collaborates in the management of a bi-campus program to monitor, report and resolve quality-related incidents. Collaborating with functional area leadership, ensure incident investigation, risk assessment and relevant corrective and preventive actions (CAPA) with effectiveness checks.

- Manages a bi-campus Document Control system to assure essential documents are current, appropriately reviewed and approved, consistently titled, archived when obsolete, and kept secure, confidential and traceable.

- Oversees the administration of a quality management electronic systems.

- Manages development of quality, compliance and process improvement training.

- Facilitates cross-functional quality improvement teams and process improvement initiatives.

- Manages internal and external audit processes.

- Manages supplier qualification processes when appropriate to assess compliance with quality standards and pertinent regulations.

- Conducts trend analysis and generation of quality reports.

- Advises and informs Senior Leadership and program stakeholders regarding quality and compliance issues that impact the CIBMTR.

- Serves as lead content expert from CIBMTR strategic quality initiatives and practices, and in support of building and sustaining a culture of quality and excellence.
• Coordinate in the development of program resources through literature searches, contact with outside programs, and review of funding opportunities.

• Participates on appropriate committees relevant to the advancement of the program and the profession or area of research.

• Maintain program timeline including tracking deadlines for program deliverables.

• Develop and manage program budget.

Knowledge – Skills – Abilities

Knowledge of technical, business, consultation, project management, and cultural awareness.

Customer focus, building trust, communication, critical thinking, and influencing skills.

Organizational Structure

Building: Clinical Cancer Center (CLCC)
Department: Center for International Blood & Marrow Transplant Research (CIBMTR)
Division:
Reports to (Title): CIBMTR Business Operations, Program Director
Direct Reports (Titles): Program Coordinators
Collaborates with (Titles): CIBMTR Milwaukee Management and Leadership, CIBMTR Minneapolis Management and Leadership

Specifications

Appropriate education and/or experience may be substituted on equivalent basis

Minimum Required Education: Bachelor’s degree

Minimum Required Experience: 8 years in a position with responsibilities for quality assurance activities within a regulated environment. Experience with International Conference on Harmonization Good Clinical Practice (ICH GCP) and Food and Drug Administration Good Manufacturing Process and Good Tissue Practice (FDA GMP and GTP). Experience with program management in a medical or educational environment preferred.

Preferred Education: 

Preferred Experience: Experience with program management in a medical or educational environment preferred.

Field:

Certification: CITI training required within 90 days of hire.

Classification

Grade Name 18
Full-Time Equivalent 1.0
FLSA Status Exempt
FLSA Test Administrative
Workweek Full-time role with expectations for coverage during core business hours
and flexibility required as necessary to accommodate business needs.

Job ID           263
Job Name         Manager
Position Category Professional Services

**Job Scope**

*Complexity* – requires sound judgment; leads difficult and involved planning of initiatives

*Impact* – errors may result in extensive damage; constant attention to accuracy required

*Autonomy* – individual responsible for completion of work; seeks supervision as appropriate

*Communication* – involved in frequent conflict resolution; communicates with senior leaders

*Responsibility* – influences others

*Confidentiality* – confidential information used frequently to make decisions

*Leadership* – prioritizes work of others or may provide supervision.

**Physical Requirements**
Work requires occasionally lifting moderate weight materials, standing, or walking continuously.

**Risk Potential**
Little or no exposure to hazards such as dust, fumes, or extreme temperatures, airborne or blood borne pathogens, extreme temperatures, or allergens.

**Sensory Acuity**
Ability to detect and translate speech or other communication required. May occasionally require the ability to distinguish colors and perceive relative distances between objects.

**Work Environment**
Occasional exposure to dust, noise, temperature changes, or contact with water or other liquids. Work is performed in an environmentally controlled environment.

**Performance Dimensions**

*Collegiality*
Exhibit confidentiality, honesty, and actions that build trust and strengthen relationships. Listen to others and effectively communicate in a clear and concise manner through written and verbal communication. Demonstrate respect and commitment to the values of diversity and equity; seek out and incorporate diverse perspectives into decision making.

*Excellence and Creativity*
Exhibit initiative and ingenuity by taking ownership of tasks to proactively improve services, avoid problems, or develop opportunities. Generate novel and valuable ideas to impact institutional missions. Identify and implement new methods to increase efficiency and quality.

*Education and Development*
Displays an ongoing commitment to continuous learning and self-improvement in one's area of responsibility. Actively seek out mentorship and learning opportunities that can be applied to current and future work activities. Develop and maintain professional affiliations. Participate in design, development, and/or evaluation of instructional materials, methods, courses, or programs.

*Agility and Judgment*
Remain flexible and versatile in rapidly changing environment and adapt quickly to changing circumstances.
Change behavioral style or method of approach when necessary to achieve a goal. Make timely and sound decisions based on analysis of information, experience, and logic. Show reliability and accountability in the successful completion of all work.

**Stewardship and Institutional Citizenship**
Support transformational change to achieve institutional vision and strategies. Be an active and thoughtful participant in institutional initiatives, meetings, and committee work. Conserve resources and use in an efficient and cost-effective manner across all institutional missions. Look for ways to improve and promote quality within area of influence.

**Disclaimers**

**Background Check**
Employment in this position may be contingent upon successfully completing a background and criminal history check, caregiver background check in accordance with the Wisconsin Caregiver Background Check Law, physical examination, and/or driving record check.

**Equal Opportunity Employer**
The Medical College of Wisconsin (MCW) is an Equal Opportunity Employer. We are committed to fostering a diverse community of outstanding faculty, staff, and students, as well as ensuring equal educational opportunity, employment, and access to services, programs, and activities, without regard to an individual's race, color, national origin, religion, age, disability, sex, gender identity/expression, sexual orientation, marital status, pregnancy, predisposing genetic characteristic, or military status. Employees, students, applicants or other members of the MCW community (including but not limited to vendors, visitors, and guests) may not be subjected to harassment that is prohibited by law or treated adversely or retaliated against based upon a protected characteristic.

**Diversity and Inclusion**
The Medical College of Wisconsin (MCW) is committed to creating an inclusive and welcoming workplace that includes individuals with diverse backgrounds and experiences. We believe that embracing human differences is critical to realize our vision of a healthier world, and we recognize that a healthy and thriving community starts from within. We strive to integrate our human and social differences into MCW's functioning, strategies and culture to create a diverse and equitable workplace. If you believe embracing individuality and working together makes us stronger, then MCW is the place for you. People of color, women, LGBTQIA+, veterans and persons with disabilities are encouraged to apply.

**Confidentiality**
Employees that have access to MCW, affiliate, subsidiary, or student data or Protected Health Information (PI), or research protected information are obligated to protect the confidentiality and proper use and access of this information in order to prevent loss, misuse, unauthorized access, unnecessary identification, or security breaches.

**Completeness**
This job description is not an employment contract and the Medical College of Wisconsin may modify this document at any time. This document is intended to indicate the types of tasks and levels of skill, effort, and responsibility required by positions assigned this title. This information shall not be construed as a declaration of the specific duties and responsibilities of any particular position. It is not intended to limit or modify the right of any supervisor to assign, direct, and control the work of direct reports. The functions described are not to be interpreted as exclusive or all-inclusive of the various functions performed.