UW HEALTH JOB DESCRIPTION

Blood & Bone Marrow Transplant (BMT) Quality Coordinator

Job Code: 533001	**FLSA Status: Exempt**	**Mgt. Approval: B Campbell**	**Date: 6-17**
Department : Bone Marrow Acquisition 5325		**HR Approval: CMW**	**Date: 6-17**

JOB SUMMARY

The BMT Quality Coordinator is responsible for the development, maintenance, and ongoing activities of the clinical, collections, and laboratory quality programs of the UW Health Blood and Bone Marrow Transplant (BMT) Program.

The Quality Coordinator ensures :

- Compliance with all aspects of the BMT Program Quality System: the requirements, policies, procedures and practices as they relate to accreditation standards and regulated products administered for both standard of care and clinical research purposes. This includes quality management of the adult and pediatric: clinical programs, bone marrow harvest collections facility, apheresis collections facility, and the clinical hematopoietic cell processing laboratory.
- The program's Quality Management Plan facilitates high quality clinical care for adult and pediatric recipients and donors, through audits, assessments and reporting of process and outcome measures, quality improvement activities, and investigations including CAPA (corrective and preventative actions) and root cause analysis.
- All products released from the Clinical Hematopoietic Cell Processing Laboratory (CHCPL) comply with the Foundation for the Accreditation of Cellular Therapy (FACT) standards and applicable FDA regulations including good tissue practices (GTP) and good manufacturing practices (GMP).

MAJOR RESPONSIBILITIES

Quality Systems:

- Responsible for the implementation and maintenance of the Quality System in the clinical transplant setting, within the collections programs, and within a GTP/GMP cellular processing environment, supporting the collection, manufacturing, testing and release of clinical and investigational cell therapy products
- Ensure that clearly defined quality objectives and functional responsibilities are in place and followed Document Control:
- Responsible for the document control system, including maintenance of standard operating procedures and batch production records
- Responsible for records management including standard operating policies/procedures (SOP) and batch record issuance, records retention and archiving
- Ensure document change control and periodic review are facilitated and implemented in a timely manner

Training:

- Implement and maintain the required training programs, and conduct training of administrative, clinical, and technical staff as needed

Auditing:

- Audit production, facility and validation data, documents, log books and other records for completeness, correctness and compliance
- Perform internal and external compliance audits
- Ensure the BMT program is in a perpetually audit-ready state; participate in regulatory and accreditation agency inspections
- Ensure deviations are documented and investigated, and corrective and preventative actions are initiated, completed, and effective.
- Ensure change control is initiated, evaluated and implemented appropriately
- Participate in periodic internal programmatic reviews of performance and compliance to applicable standards

Regulatory:

- May assist clinical investigators with the FDA and IRB application submissions and query responses

Behaviors:

- Adhere to internal SOPs and applicable regulatory requirements; encourage and ensure compliance by others

ALL DUTIES AND REQUIREMENTS MUST BE PERFORMED CONSISTENT WITH THE UW HEALTH PERFORMANCE STANDARDS.

JOB REQUIREMENTS

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Education	Minimum	Bachelor's degree in the life sciences or an equivalent field of study required
	Preferred	Master's degree in the life sciences or an equivalent field of study preferred
Work Experience	Minimum	Three (3) years of experience in a Quality Assurance role within a regulated environment is required
	Preferred	Five (5) years of experience in a Quality Assurance role within a regulated clinical, blood or tissue banking, or manufacturing environment
Licenses & Certifications	Minimum	
	Preferred	
Required Skills, Knowledge, and Abilities		• Experience applying quality management/performance improvement and customer service approaches • In-depth knowledge of GMP and GTP, Quality System Regulations and other applicable regulatory requirements • Demonstrated ability to establish, implement and audit GMP/GTP Quality Systems in conformance to U.S federal standards • Expertise, skills, and knowledge of blood/bone marrow transplantation, apheresis, hematology/oncology, and cellular therapy clinical activities • Expertise in the requirements and expectations of human clinical studies conducted in compliance with good clinical practices (GCP). • In-depth knowledge of Foundation for the Accreditation of Cellular Therapies (FACT) and American Association of Blood Banks (AABB) accreditation standards • Experience assisting clinical investigators with Investigational New Drug (IND)/ Investigational Device Exemption (IDE) applications.

PHYSICAL REQUIREMENTS

Indicate the appropriate physical requirements of this job in the course of a shift. *Note: reasonable accommodations may be made available for individuals with disabilities to perform the essential functions of this position.*

	Physical Demand Level	**Occasional** Up to 33% of the time	**Frequent** 34%-66% of the time	**Constant** 67%-100% of the time
	Sedentary: Ability to lift up to 10 pounds maximum and occasionally lifting and/or carrying such articles as dockets, ledgers and small tools. Although a sedentary job is defined as one, which involves sitting, a certain amount of walking and standing is often necessary in carrying out job duties. Jobs are sedentary if walking and standing are required only occasionally and other sedentary criteria are met.	**Up to 10#**	**Negligible**	**Negligible**
	Light: Ability to lift up to 20 pounds maximum with frequent lifting and/or carrying of objects weighing up to 10 pounds. Even though the weight lifted may only be a negligible amount, a job is in this category when it requires walking or standing to a significant degree.	**Up to 20#**	**Up to 10#** or requires significant walking or standing, or requires pushing/pulling of arm/leg controls	**Negligible** or constant push/pull of items of negligible weight
X	**Medium:** Ability to lift up to 50 pounds maximum with frequent lifting/and or carrying objects weighing up to 25 pounds.	**20-50#**	**10-25#**	**Negligible-10#**
	Heavy: Ability to lift up to 100 pounds maximum with frequent lifting and/or carrying objects weighing up to 50 pounds.	**50-100#**	**25-50#**	**10-20#**
	Very Heavy: Ability to lift over 100 pounds with frequent lifting and/or carrying objects weighing over 50 pounds.	**Over 100#**	**Over 50#**	**Over 20#**
List any other physical requirements or bona fide occupational qualifications:				

Note: The purpose of this document is to describe the general nature and level of work performed by personnel so classified; it is not intended to serve as an inclusive list of all responsibilities associated with this position.