UW HEALTH JOB DESCRIPTION

Senior Cell Therapy Specialist - BMT

Job Code: 530018	**FLSA Status: Exempt**	**Mgt. Approval: B. Campbell**	**Date: November 2020**
Department: Bone Marrow Acquisition 210.1080.3036269		**HR Approval: J. Theisen**	**Date: November 2020**

JOB SUMMARY

The Senior Cell Therapy Specialist–BMT is responsible for producing the highest quality cell therapy products that comply with federal, industry and FACT standards and regulations by implementation, execution and oversight of highly complex laboratory procedures that directly impact a patient's health and safety. The Senior Specialist assures that the cellular therapy products released by the laboratory meet clinical and quality criteria for infusion in both the standard of care and clinical trial settings.

The Senior Cell Therapy Specialist-BMT brings forth the specialized scientific and technical knowledge critical to managing patient specific, therapeutic products. This position collaborates daily with clinical providers to make critical decisions resulting in the highest quality product that meet the patient's unique treatment plan while maximizing laboratory efficiency. This position works closely with the laboratory medical director to ensure that the cell processing procedures and techniques are compliant and meet applicable standards. The Senior Cell Therapy Specialist-BMT is also responsible for validating processes and equipment and for onboarding and executing the laboratory aspects of human clinical trials of novel cellular therapy products.

This position works in collaboration with the BMT team to build cross-functional relationships with physicians, faculty, nursing, clinical research and hospital facilities and operations staff. External collaborations include but are not limited to research and clinical staff at other medical centers, commercial research and development staff, technical and sales representatives and regulatory agencies.

A flexible schedule work schedule is required and is dependent on patient/donor conditions, product/sample availability and emergent situations as well as procedural modifications required to adapt to the variable nature of incoming cellular products/samples.

MAJOR RESPONSIBILITIES

Standard of Care and Clinical Trial Support

- Participate in all aspects of clinical trial activity from site selection through study end.
- Develop and validate the performance of new cell processing methodologies and technologies.
- Serve as a liaison to the Clinical Research Coordinators to coordinate research trials within the department. This includes workflow, communication with staff, billing, reporting, maintaining supply inventory and training. Communicate problems and concerns about the research trial with the appropriate staff.
- Implement new clinical trial cell processing documentation, communications and processing requirements. Verify external client databases are updated with product information.

Cellular Therapy Processing

- Perform therapeutic cell processing procedures consistently according to standard operating procedures including infusion of freshly collected stem cell products, cryopreservation, thawing/washing, and complex procedures such as CliniMACS cell selection/depletion and production of more than minimally manipulated products.
- Operates standard lab equipment required for the processing and characterization of HCT/P (Human Cellular and Tissue based products).
- Perform cell product labeling and processing including maintaining chain of custody and chain of identity, collaboration with the clinical team and product transport.
- Performs interpretation of test results including automated and manual cell counts, viability, flow cytometry, infectious disease marker panels and sterility testing.
- Performs validation procedures regarding establishment, optimization and change of SOP and use of equipment and reagents.
- Responsible for reproducibility and accuracy of data and analyses. Assists in the collation of data and report preparation.

Technical Leader

- Develop and validate new batch records, processing worksheets, and standard operating policies with changes in processing.
- Monitor the results of cell therapy processing and respond to problems.
- Assist with managerial oversight, duties scheduling, writing policies, submitting and responding to Patient Safety Network, troubleshooting quality assurance variance reports and reviewing results.
- Evaluate and make recommendations of new technology or process improvements.
- Accountable for the oversight of equipment and facility maintenance and performs advanced troubleshooting and problem-solving.
- Develop and maintain teaching / training materials, coordinate new employee orientation and annually evaluate employee competency.
- Oversee the inventory of supplies and reagents and apply principles of asset management.
- Assist with the purchasing functions (interact with purchasing and vendors, write specifications, research and evaluate equipment and products).

Lab Informatics Specialist

- Oversee the Laboratory Information System process including initiation, maintenance, validation and documentation.
- Coordinate the Laboratory Information System validation process for new programs or software changes to ensure accurate display of results and/or information.
- Perform periodic Laboratory Information System checks (e.g., calculation, patient data) or reviews and implement any necessary changes.
- Develop and maintain related standard operating policies and procedures.
- Participate in continuing education such as workshops, lectures, reading journal articles, etc.
- Annually validate product labeling software updates.

Quality Assurance Coordinator

- Oversee quality activities and programs including departmental procedure evaluations, quality control processes, materials, documentation and data analysis in accordance with lab policies and accreditation agencies.
- Collaborate with Quality Manager to develop and review the quality assurance plan with appropriate monitors. Assist with the summary of these monitors. Evaluate and assure on-going progress of performance improvement activities.
- In collaboration with the Quality Manager, develop and oversee a plan to assure continual accreditation readiness.
- Maintain annotated checklists in area(s) of expertise.
- Serve as consultant and coach for procedural validation studies.
- Participates in internal department and external client audits.

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

JOB REQUIREMENTS

Education	Minimum	Bachelor's degree in a Biological Science or Clinical Laboratory Science.
	Preferred	Master's degree in the life sciences, or equivalent experience in a related academic or industrial setting.
Work Experience	Minimum	Five years progressively responsible experience in a clinical laboratory sciences position, and/or cGMP aseptic manufacturing operations or other regulated environment.
	Preferred	Ten years progressively responsible experience in a clinical laboratory sciences position, and/or cGMP aseptic manufacturing operations or other regulated environment.
Licenses & Certifications	Minimum	
	Preferred	
Required Skills, Knowledge, and Abilities		• Extreme attention to detail and strong analytical ability are required to perform error-free cell processing to meet patient specific cell therapy product specifications and to ensure accuracy of data. • Advanced knowledge of cell processing and aseptic techniques, basic knowledge of immunology, cell biology, hematology and blood banking.

	• Experience operating in a regulated environment including familiarity with cGMP/cGTP standards, internal and external audits, and good documentation practices. • Familiarity with proper and safe operation and maintenance of basic and complex lab equipment including centrifuges, biosafety cabinets, LN_2 freezers and controlled rate freezers. • Experience with controlled documents including authoring and editing standard operating procedures, occurrence reports and validation protocols. • Experience with technical transfer and development of new laboratory processes and procedures. • Advanced MS Office skills including creating and modifying documents, using and programming spreadsheets and databases, and the ability to quickly adopt and use new software. • Effective time management and organizational skills; able to appropriately prioritize, delegate and/or execute multiple tasks simultaneously. • Strong interpersonal skills; ability to work independently and as a collaborative team member. • Familiarity with Continuous Quality Improvement concepts such as PDCA. • Ability to serve as both the technical leader in the cellular therapy laboratory and resource for BMT staff and management when questions or problems arise. • Strong understanding of the regulatory and quality requirements applicable to cellular therapy and deep knowledge of and the ability to embody good laboratory and good documentation practices. • Ability to motivate, coordinate and support team members to ensure cellular therapy products and daily lab operations meet the highest quality standards. • Problem-solving skills for very complex problems that may quickly arise and require investigation and initiative to reach a final resolution. • Process, apply and communicate specialized scientific and technical knowledge critical to managing irreplaceable products essential for patients' lives.

AGE SPECIFIC COMPETENCY (Clinical jobs only)

Identify age-specific competencies for direct and indirect patient care providers who regularly assess, manage and treat patients.

Instructions: Indicate the age groups of patients served either by direct or indirect patient care by checking the appropriate boxes below. Next,

X	Infants (Birth – 11 months)	**X**	Adolescent (13 – 19 years)
X	Toddlers (1 – 3 years)	**X**	Young Adult (20 – 40 years)
X	Preschool (4 – 5 years)	**X**	Middle Adult (41 – 65 years)
X	School Age (6 – 12 years)	**X**	Older Adult (Over 65 years)

JOB FUNCTIONS

Review the employee's job description and identify each essential function that is performed differently based on the age group of the patient.

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**
X	**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

	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#**
Other - list any other physical requirements or bona fide occupational qualifications not indicated above:				

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.