



INDIVUMED, a company based in Hamburg, Germany, is an integrated oncology company that leverages its bio repository of human tissue samples with its diagnostic laboratory to develop individual cancer therapies. INDIVUMED maintains a bio bank of tissues and annotated data from more than 30,000 patients and will integrate its unique bio banking standards at a clinical Partner Site to jointly create a platform that offers extraordinary opportunities for clinical research focused on tumor biology.

INDIVUMED has partnered with different Clinical Sites to collect samples from consenting patients who are already undergoing surgical tumor resections or lesions causing tumor development. Upon resection, a portion of the tissue, blood or urine remaining beyond what is required to make a clinical diagnosis will be banked at the Clinical Partner Site. Another portion will be banked by INDIVUMED, which will analyze the tissue to be used in the development and, eventually, application of targeted therapies for cancer patients. Under the supervision of the Chief Medical Officer, the Training and Quality Assurance Specialist will be act as a subject matter expert for collection of tissue and lab operations, and responsible for the effective training of lab associates at clinical partner sites.

To support our team in the United States we are seeking an experienced

## **Training and Quality Assurance Specialist (m/f)**

This position reports directly to INDIVUMED Chief Medical Officer.

### **MAJOR DUTIES AND RESPONSIBILITIES**

The Training and Quality Assurance Specialist will be a subject matter expert and deploy this knowledge to the laboratory staff at a new clinical site, by training staff for tissue procurement (the collection of clinically annotated human specimen for the IRB-approved tissue bio-banking project at the lab site), routine collection of a comprehensive set of biological specimens (tissue, blood, and urine), and on how to compile and complete clinical data from patients undergoing cancer-related surgeries at the site. In addition, the Training and Quality Assurance Specialist will train the staff on processing of liquid, formalin-fixed and paraffin-embedded tissue and related data tracking/documentation as well as for laboratory hygiene and biologic sample shipment/release.

Additional responsibilities include working closely with the clinical teams (surgeons, anesthesiologists, nurses, etc.) at (Clinical Partner Site) and the sponsor.

More specifically the incumbent will need to be a subject matter expert and proficient to train others in the following tasks, and consequently do periodic follow-up quality assurance checks at all clinical partner sites:

- Screen patients based upon enrollment criteria and obtain informed consent from said patients.
- Attend surgeries and/or biopsies to collect tissue.
- Work with Pathology Assistant and Pathologist to obtain, dissect and process the biobank portion of the surgical specimens at surgical pathology and/or biopsy procedure suites.
- Transport surgical specimens between operating room and surgical pathology.
- Transport fixed specimens to the laboratory to further processing and storage in liquid nitrogen and ultra-low freezer.
- Participate in formalin-fixed, paraffin-embedded tissue preparation
- Conduct in-person interviews with consented patients throughout the hospital
- Review patient clinical records, blood work, and other clinical data.
- Collect follow-up data
- Complete and finalize patient case report form and transfer those to Indivumed for data verification.
- Ship/release samples to Indivumed and (Clinical Partner Site) Tissue Governing Board or Investigators.
- Receive liquid tissue (whole blood/urine) from the collection team.
- Process blood and urine samples into respective into respective research products such as plasma, serum, PBMC, urine supernatants, and sediments
- Receive formalin-fixed tissue from the clinical collection team and work with histopathology on paraffin-embedded block preparation. This may require participation in formalin-fixed and paraffin-embedded tissue in ultra-low, -80 freezers, paraffin cabinets, liquid nitrogen freezers, and sample tracking software systems
- Scan, store, register and track liquid, formalin-fixed and paraffin-embedded tissue in ultra-low -80 freezers, paraffin cabinets, liquid nitrogen freezers and sample tracking software systems



- Maintain laboratory hygiene such as biologic waste handling, disposal and reusable disinfection and autoclaving
- Handle hazardous chemicals: dry ice, formalin, disinfectant solutions, liquid nitrogen, etc., Category B materials
- Review patient clinical records, blood work, and related medical data as needed
- Shipment and release of biologic materials to Indivumed and (Clinical Partner Site)
- Prepare blood and urine collection and storage case kits.
- Perform on-site quality assurance checks to ensure compliance with Indivumed SOP's.
- Retrain in problem areas identified during quality assurance checks.

#### **SKILLS AND ABILITIES:**

- Understanding of basic anatomy and pathology.
- Knowledge of laboratory procedures or oncologic specialties is a plus.
- Must be fluent in Microsoft Office applications including Word, Excel, and Access.

#### **EDUCATION AND/OR EXPERIENCE:**

- Master's Degree in Biological Sciences, Life Sciences, or science-related field, or Registered Nurse (RN), training as a pathology assistant, or in nursing or medicine, or such a professional degree or equivalent master/doctorate would be preferable. Bachelor's degree in above mentioned field with a 5-year equivalent professional experience will be acceptable.
- Experience within a hospital setting (i.e., physician and patient interaction) is favored.
- HIPAA and Human Subjects training.
- Oncology research experience is a plus.

#### **WORKING CONDITIONS/PHYSICAL DEMANDS:**

- Work is performed in a laboratory environment, the Operating Room, surgical pathology.
- Exposure to chemicals and hazardous materials such as dry ice, formalin, and liquid nitrogen.
- Standing for long periods of time.
- Extended overnight travel to clinical partner sites during the start-up/training phase.
- Some overnight travel required during the quality assurance audits at the clinical partner sites.

#### **EEO STATEMENT:**

- Our company is committed to equal employment opportunity. We will not discriminate against applicants for employment on any legally-recognized bases ("protected class") including, but not limited to: race, color, religion, genetic information, national origin, sex, pregnancy, childbirth, or related medical conditions, age, disability, citizenship status, uniform service member status, or any other protected class under federal, state, or local law.

**Note:** *The specific statements shown in each section of this description are not intended to be all-inclusive. They represent typical elements considered necessary to successfully perform the job.*

Would you like to contribute to the success of our company? Please apply online via [curtis@indivumed.com](mailto:curtis@indivumed.com) and include your salary expectations and current notice period.

We are looking forward to receiving your application!

For more information about INDIVUMED please also visit our website [www.indivumed.com](http://www.indivumed.com).

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