URBEST Internship Opportunity

• Company, Agency, Office or Division hosting this Internship:
  URMC – Upstate Stem Cell cGMP Facility

• Title of Internship:
  cGMP Facility Operations, Manufacturing and Testing

• Description of the Internship:
  This internship is designed for individuals interested in learning about cGMP regulations and guidances for the production of materials for early-phase human clinical trials. The training will focus on the development of cGMP-compliant processes and analytical methods for the production and testing of clinical trial materials, including monoclonal antibodies and cell therapy products.

  The individual will learn how to work within a quality management system and become familiar with cGMP facility ongoing operations with respect to establishing and maintaining an environmental control program. The validation of facilities, equipment, processes and test methods will also be discussed. This training period may also provide the opportunity for hands-on work with existing project teams on the manufacture and testing of clinical-grade materials.

• Approximate length of time to be spent at this internship: (e.g., 2-4 weeks or 4-6 months)
  ~3 mos.

• Approximate number of hours to be spent on a recurring basis: (e.g., 40hrs/week or 3-5hrs/week)
  ~10 hrs/wk

• What is the goal of this internship opportunity for the trainee?
  The overall goal of this internship is to become familiar with cGMP regulations and guidances for the production of materials for early-phase human clinical trials.

• What are the objectives for the participant during the internship opportunity? (add more if needed)
  • Understand basic regulations FDA governing cGMP-compliant facilities.
  • Become familiar with the critical elements of a quality management system.
  • Develop an understanding of a comprehensive cGMP-compliant validation program.
  • Learn the techniques involved with environmental a facility environmental control program including cleaning and environmental monitoring.
  • Work with project team members to observe and/or assist in the manufacture and testing of clinical-grade materials.

• Will there be any formal training, coursework or examinations involved? If yes, please provide details:
  Formal, documented training in GMP procedures will be required. This may involve an “effectivity” check proving that the individual can perform the trained procedures correctly (i.e. gowning, cleaning, environmental monitoring).
• Responsibilities and duties of the intern:

The intern will be required to interact closely with USCGF staff ~10 hours each week which may include some evening or weekend work. These hours will vary depending on the ongoing activities.

• How will the participant be supervised throughout the internship? And how will they interact with their supervisor / mentor?

The intern will be supervised by one or members of the USCGF staff including the facility Director. Effective communication skills will be required as almost all learning interactions will be in a hands-on situation.

• Will there be any final project due from the intern at the completion of the internship opportunity? (e.g., summary memo, presentation, final paper)

Not applicable.

• How will the Intern be evaluated during the program? (e.g., progress reports, periodic reviews)

During the internship opportunity, the internship host and URBEST’s Tracey Baas will evaluate the intern using periodic monthly progress reports (what did they actually do). Each progress report will be written by the internship mentor and edited by the intern. The mentor and intern will then discuss the progress report, sign the document, and submit it to the URBEST office. Tracey will set up either a face-to-face meeting or a phone call with the mentor and intern, individually. The first progress report will be an “intake” document (when the student first arrives) and include goals and expectations for the internship. Following progress reports will address performance, achievement of goals, areas for further development and any other information that the mentor and intern deem important.

• How will the Intern be evaluated at the conclusion of the program? (e.g., final report)

At the end of the internship, URBEST’s Sarah Peyre or Tracey Baas will assess the intern, using a final reflection/analysis of the experience. The intern will write the analysis piece, connecting the internship experience to their professional development. They will highlight content knowledge, acquisition of skills and understanding of the workforce, self-assessment of their performance and identification of areas that they still need development. Tracey will set up a group meeting or conference call for a final debrief of both the mentor and the intern.

• If there is any additional information about your internship opportunity that you would like to provide, please include it here:

Not applicable.