URBEST Internship Opportunity

- **Company, Agency, Office or Division hosting this Internship**
  URMC, SMD, Research Quality & Compliance

- **Title of Internship**
  Quality and Compliance

- **Description of the Internship**
  This opportunity will be for a student or postdoc interested in Regulatory Quality and Compliance who would like to know how product safety, efficacy, and quality are implemented and maintained throughout the development process.

- **Approximate length of time to be spent at this internship: (eg. 2-4 weeks or 4-6 months)**
  4-6 months

- **Approximate number of hours to be spent on a recurring basis: (eg. 40hrs/week or 3-5hrs/week)**
  3-6 hrs/week

- **What is the goal of this Internship Opportunity for the trainee?**
  The goal of this internship is for the participant to obtain working, practical knowledge of the GxP regulations through learning and application of regulations to product development.

- **What are the objectives for the participant during the internship opportunity?**
  1. Learn the GxP regulations and understand their purpose(s)
  2. Define the purpose of a quality system
  3. Describe elements of a quality system
  4. Demonstrate understanding of the Quality and Compliance functions
  5. Analyze compliance of quality system records

- **Will there be any formal training, coursework or examinations involved?** Yes  
  If yes, please provide details
  There will be an initial 2 hour GMP classroom training as well as on the job skill/task training such as gowning for entry to the GMP facility.

- **Responsibilities and Duties of the Intern**
  The intern will be expected to work with his/her mentor at least 1-2 hours per week, attend a selection of quality system meetings, review and provide input on quality system documents and records, as well as provide input during meetings or other occasions, as applicable.

- **How will the participant be supervised throughout the internship? And how will they interact with their supervisor / mentor?**
  The participant will be supervised through regularly scheduled 1:1 meetings and interactions with their mentor. The intern and mentor will also engage during quality system meetings. When communication is needed and an in-person meeting is not possible, interaction may occur via phone or email.
• What will be any final project due from the intern at the completion of the internship? (e.g., summary memo, presentation, final paper)
  
The intern and mentor will determine, based on the scope of the project and work that the intern undertakes, that a final report is desirable.

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