IGEMs/HERC Project Status Report
Idaho Infrastructure Proposal
Semi-Annual Progress Report
December, 18th 2017

Proposal No.	**AHRC42**
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Name of Institution:	**Idaho State University/ Idaho Accelerator Center**
Project Title:	**Infrastructure to support Active Pharmaceutical Ingredient designation for ^{67}Cu.**

Executive Summary:

During the first half of the FY17 work was executed on key quality indices as required by FDA guidelines for Active Pharmaceutical Ingredient cGMP processing " *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, Guidance for Industry*." The items worked on were:

1). Measurement and qualification methods for verifying activity of the sample and cleanliness of the clean room

2). Required documents listing for API certification

3). Process run tracking and documentation

4). RFQ for submission to FDA certification consultants.

A small portion of the budget, $1017, was spend on a used cleanroom particle monitor so routine measurements during processing can be taken.

PROJECT STATUS REPORT ACTIVITIES PLANNED

This is the semi-annual status report for FY 2018 for the IGEMs funded project Infrastructure to support Active Pharmaceutical Ingredient designation for 67Cu. The project proposal listed the following major project activities:

1). Complete an RFP to established FDA API consulting companies (Q1, FY18)
2). Select a student (Q1, FY 18)

3). Complete the high level QA and SOP documents (Q2, FY18)
4). Complete the run tracking system and begin equipment qualification runs. Order capital equipment if required. (Q3, FY18)
5). If possible, draft Validation Master Plan (Q4, FY18)

PROJECT STATUS REPORT – Activity Review

The first half of FY18 was marked by an increase in required shipments by our partner, Clarity Pharmaceutical. Clarity is rapidly pursuing human trial experiments in calendar year 2018 and several key shipments supported their pre-trial animal and quality certification experiments. This required us to delay bringing on an FDA API consultant and instead do work directly on the process to improve quality control systems. In that regard, one piece of capital was acquired, a particle counter, so that clean room cleanliness could be recorded for each process run. In addition, an extensive calibration project was performed to verify activity of each run shipped. This involved work with NIST traceable sources, our HPGe detector and an inexpensive ion-chamber that we acquired for dose level analysis and calibration with the customer. Over the last 5 months we have implemented a log-book process recording system in partial fulfillment of our project run tracking system (item 4 above). Only the PI and radiochemist have been involved in the 1H FY18.

During 1H FY18, we worked closely with Clarity to define the required Q7 quality systems we will require of the future FDA consultant. An RFQ (as opposed to an RFP) has been generated with significant feedback from ISU's purchasing department in Q2, FY18 (instead of the planned Q1 FY18) which is out for bid. We expect to have the consultant on board early in calendar year 2018.

The second half of this project will involve the selection of the FDA consultant, hiring of a student, writing documents, create a VMP and performing validation experiments. Our customers will do their initial API audits in 2018.

FINANCIAL Summary FY 2018 to date

As of 12/5/17	**HERC IGEM**
Budget	49,800
Spent	4,288
Remaining	45,512

We have deliberately underspent our grant funds during the first half of the year as we anticipated much higher activity during the second half of the project.

Spend categories to date are $3271 salary support for the radiochemist and $1017 for capital. The spend will increase dramatically as the consultant is brought on for work ($35,000) and a student is hired in 2H FY18 and the burn rate will increase to meet the budget projection.

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