IGEMs/HERC Project Status Report
Idaho Infrastructure Proposal
Final Progress Report
August, 31st 2018

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

Executive Summary:

Over the course of this grant 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 completed include:

1). Complete measurement and qualification methods for verifying activity of the sample and cleanliness of the clean room. Purchase and implement a clean room particle counter.

2). Complete required documents listing for API certification

3). Complete process run tracking and documentation system.

4). Hire an FDA qualified consultant (cGMP) to work with us to complete the large array of specifications.

5). Completed over 50 specifications, quality documents, templates, forms and associated materials.

During this period, one of our customers, Clarity Pharmaceutical, completed validation using our product and we have begun shipping product to them for early phase human trials taking place in Australia (as of 8/2018).

PROJECT STATUS REPORT ACTIVITIES

This is the Final 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 validation 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. In the first half, we implemented a log-book process recording system in partial fulfillment of our project run tracking system (item 4 above).

During 1H FY18, we worked closely with Clarity to define the required Q7 quality system required by the FDA. An RFQ (as opposed to an RFP) was generated with significant feedback from ISU's purchasing department in Q2, FY18 and an FDA consultant was selected (cGMP Consulting).

During 2H FY18, we hired a 20 hour/week student to work with us and the consultant, cGMP Consulting, to complete a very large number of specifications and systems as required by the FDA. Here is a partial list of the completed specification set:

(1) Overall Quality Manual defining the required processes and methods for developing and maintaining control of the final product.
(2) 29 Standard Operating procedures including procedures for controlling documents, writing specifications, operating the process, purchasing and accepting materials and running and controlling the equipment.
(3) 14 Material specifications defining each component of the process and the acceptance criteria.
(4) 14 Forms and Templates for everything from completing specifications to calibrations and data tracking.
(5) Completed a rough draft of a Validation Master Plan.

In addition to all of this work, we completed over 20 runs for shipments to various customers supporting their research to develop treatments for 3 different cancers.

Also, ISU was awarded a patent in June, 2018 for our process to make ^{67}Cu.

FINANCIAL Summary for the Program:

		Actual	Final
	Budget	Spend	Balance
Salaries	5,500.00	8,127.46	(2,627.46)
Irregular Help	3,441.00	2,986.50	454.50
Fringe	2,721.00	3,664.49	(943.49)
Total Personnel Costs	**11,662.00**	**14,778.45**	**(3,116.45)**
Materials and Supplies	3,121.00		3,121.00
Consultant Costs	34,000.00	33,999.49	0.51
Capital	1,017.00	1,017.00	-
Totals	**49,800.00**	**49,794.94**	**5.06**

The budget above represents our revised budget approved in 2H, 2018. We spent significantly more money on labor, including our student hire, to complete the large number of specifications. The redistribution of funds came from our material and supply budget. We essentially completely spent our funds in this program.

Conclusions

Attaining API cGMP approval for the copper 67 process is a huge task that will take an additional year or more from the conclusion of this grant. However, these funds were instrumental in generating the capability in house to continue the work. The value of achieving API status for our product is extremely significant. Our product has potential for treatment of several cancers and plans are progressing quickly to begin trials in the US with several institutions. Among the cancers that may start trials in 2019 are Neuro Blastoma, Neuro Endocrine Tumors, Prostate Cancer and Meningioma.

We appreciate the support of the HERC in continuing this very important work!

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