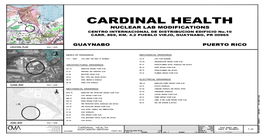
Enhancements to Cardinal Health NPS Lab to USP-787 Standards



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Abstract

As the world develops and populations expand, new diseases arise at an exponential rate. This research is based on employing new modifications to NPS (Nuclear Pharmacy Services) Laboratory at Cardinal Health, Inc. (Guaynabo, Puerto Rico) in order to provide facilities with the necessary enhancements to comply and provide quality products to clients and patients in the island. The primary purpose of this project is to increase the facilities capabilities in management of radioactive materials used for patient's medical solutions, increasing the cleanroom compliance under federal regulations, reducing costs in the process and provide a high-quality product without compromising safety. Current federal regulations require pharmaceutical and biopharmaceutical manufacturers to follow a specific quantity of particles in their cleanroom process stated as ISO 8 or 7 cleanroom standards. The actual project development plan is to bring this facility into these standards no later than December, 1st 2019.

Background

A Nuclear Pharmacy is involved in the preparation and handling of medical products based on radioactive materials a principal component to treat specific diseases (i.e. Alzheimer's disease, etc.). There are two types of nuclear pharmacy environments: Institutional which works directly with hospital/medical center elaboration in site. The second is a centralized commercial pharmacy which prepares products and delivers them to distinct medical institutions (i.e Cardinal Health, Inc.). This institution which intends to bring new products for fabrication and distribution around the world will be a center for new technology and innovation in Puerto Rico.

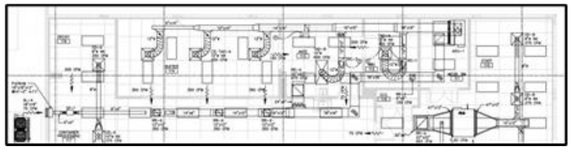


Figure #1
Actual HVAC Layout (NHPS) Area

Problem Statement

The pharmaceutical industry is evolving every day with new advancements and technology development. The current process requires rigorous supervision to control cleanliness and standards procedures in order to comply with federal regulations. Cardinal Health 120, Inc. is a manufacturer & distributor of medical devices industry located in Guaynabo, Puerto Rico. The purpose of this research is to include all information required to integrate necessary modifications to facilities in order to comply with new USP-787 requirements. Total budget allocated for this project is $150,936.77 which is projected to return investment in 12 months period time.

Literature Review

A Nuclear lab, also called in the core as a radio pharmacy, consists in the management and creation of radioactive medical solutions for treating diseases or conditions that require a specific treatment: hyperthyroidism, thyroid cancer, lymphomas and some types of targeted cancer (United States Nuclear Regulatory Commission, 2017). The majority of these products are in the form of capsules, injections, aerosols, etc. At this time in Puerto Rico, there are only two nuclear pharmacies that support patients around the island: Cardinal Health PR 120, Inc. (Guaynabo, P.R.) and Lantheus Mi Radiopharmaceuticals, Inc. (San Juan, P.R.). Cardinal Health PR 120, Inc. was established at Guaynabo, Puerto Rico in 1951. Currently from that date, it has consistently served over 1,500 customers including hospitals, pharmacies, physicians, and other healthcare providers with over 20,000 products from over 1,000 supply sources. (Cardinal Health, Inc., 2019).

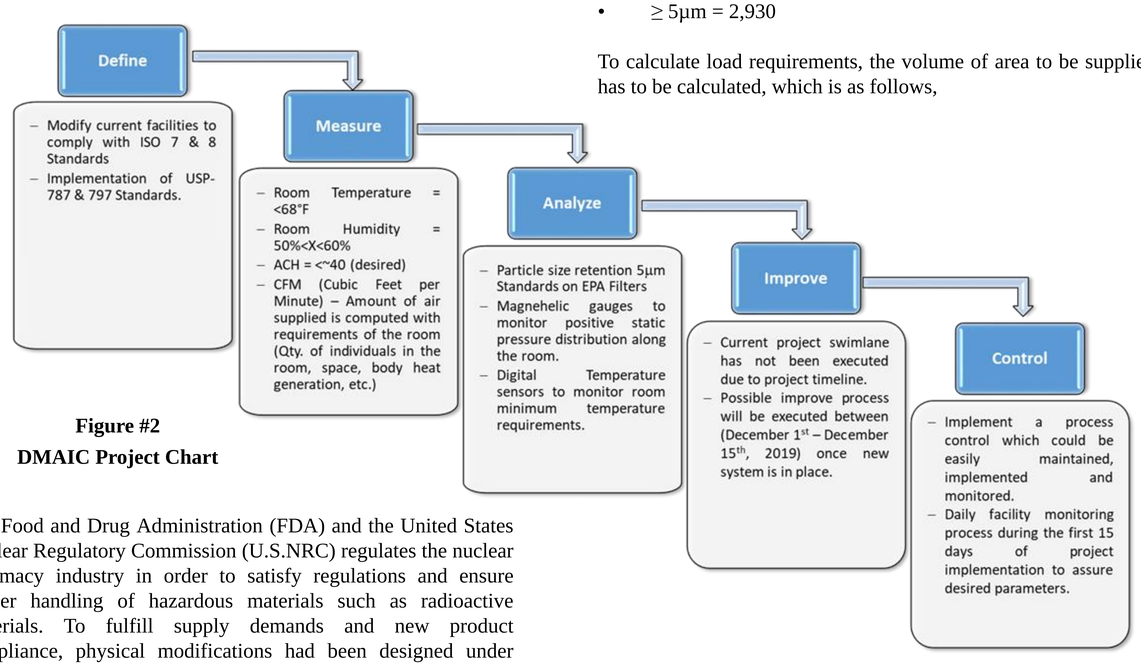


Figure #2
DMAIC Project Chart

The Food and Drug Administration (FDA) and the United States Nuclear Regulatory Commission (U.S.NRC) regulates the nuclear pharmacy industry in order to satisfy regulations and ensure proper handling of hazardous materials such as radioactive materials. To fulfill supply demands and new product compliance, physical modifications had been designed under CAR (Capital Acquisition Request) to facilities in order to comply with ISO 7 or 8 and USP-787 Standards.

Methodology

Controlled environments consist in a specific group of variables to be monitored in order to ensure product quality and federal regulations compliance. However, in order to establish a process that is well documented and simple to follow, a DMAIC diagram was performed to illustrate the data gathering, analysis and process implementation.

On December 1st, 2019 project execution will be developed with current regulations and process agreed under project CAR: CAH-PR NPHS. In order to satisfy these requirements, parameters will be monitored such as (i.e. room temperature, static pressure differential across rooms, humidity, particle size, etc.

Results and Discussion

This section presents the results of the research, the analysis of the data including the most important statistical analyses performed, and discusses the implications of these results regarding the research objectives. It must include only the results relevant to the research and how the conclusions were reached.

In order to successfully create a HVAC system that satisfies an ISO7 or ISO8 nuclear lab federal regulation requirement, the following criteria or methodology was implemented. For the purpose of this project, some of the equipment and structure was re-utilized according to CAR and requirements permitted.
ISO 7 Particle Size Requirements:

- ≥ 0.5µm = 352,000
- ≥ 1 µm = 83,200
- ≥ 5µm = 2,930

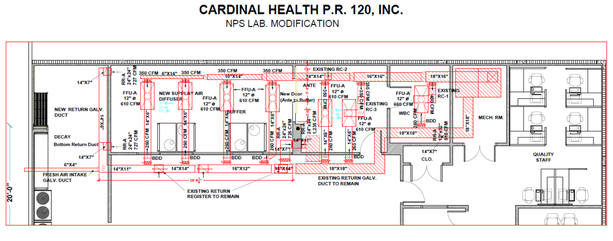
To calculate load requirements, the volume of area to be supplied has to be calculated, which is as follows,

$$Q = mc\Delta t = mc(T_2 - T_1), \quad (1)$$

$$Room_{Area} = Room_{Width}\, x\, Room_{Length} \quad (2)$$

$$Room_{Volume} = Room_{Area}\,(ft^2) * Height\,(ft^2) \quad (3)$$

$$\text{Required CFM} = \frac{\text{Volume of } Room * \text{ACH}}{60\ minutes} \quad (4)$$



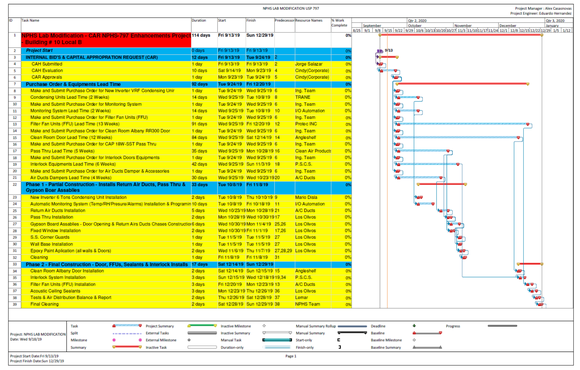


Figure #3
Project Timeline (Gantt Chart)

Conclusions

Cardinal Health, Inc. as one of two facilities in the island that provides services for radioactive materials in the pharmaceutical controlled environment, which this project has expanded its capacity and provided a new market that could reach new products to elevate company market cap and support local economy. As a process verification, HVAC system reached desired specifications required.

Future Work

As an mechanical/aerospace engineer, the exploration of new technology in the additive manufacturing and CMC's (Ceramic Matrix Composites) field is major step looking forward to. In order to advance in the new growing technologies we need to create new ways to manufacture parts more precise, robust and low cost to thrive. This concept could be incorporated into HVAC Design of the future for a green capability perspective.

Acknowledgements

Extension of gratitude to all professors and advisors who made this project successful. Moreover, to Cardinal Health, Inc. for giving this opportunity to develop and exert my skills into the optimization and contribute to the evolution of their facilities as one of the most advanced and unique on the island. To my advisor, Dr. Rafael Salgado Mangual, who provided guidance and understanding to produce a successful execution of this project. To my first mentor, Prof. Rafael Nieves, who provided a clear path that aligned my engineering judgment and knowledge to the accomplishment of this project. And most of all, to God and my family who provided the courage and guided my path continuously with their unconditional support & thoughtfulness.

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