Rutgers University iJOBS
Successful Management of Life Science Projects
Case Study – October 23, 2019

Case Study Project #1: **New Product Development of Next Generation Point of Care (POC) Device**

Project Description: IVDx is a manufacturer of a point of care coagulation (POC) system. IVDx has just acquired a small company that markets a blood gas & electrolyte (BGE) POC system. IVDx wants to develop a next generation microfluidic POC device combining these 2 systems into a single platform, including assays, software and external quality controls. The 2 R&D groups are expected to work together. Each group has their own of doing things, and don't see eye-to-eye on the vision for this new device or the project.

Stakeholders:

- R&D: Develop and test the new system
- Regulatory: Provide US & international design input requirements for new product development from applicable Regulations & Standards
- Quality: Provide requirements for and conduct finished good quality control & assurance
- Manufacturing: Produce these devices including traceability, labeling and packaging and perform required in-process testing
- Technical/Customer Support: Provide requirements for customer technical support, order fulfillment including supply chain. Requires training to support the device.
- Marketing: Provides "Voice of the Customer", i.e., design input requirements, sales forecast projections, minimum margin requirements.

Exercises:

- **Exercise 1** - Project Charter Inputs: Using the Project Charter template as a guide, determine a brief list of a few inputs the PM should use to create a charter for this project.
- **Exercise 2** - Stakeholders: Using the Stakeholder RACI Matrix template as a guide, determine how the PM should categorize the project's stakeholders and if there are others not addressed in the list above. How should the PM work with the cross-functional team – also considering the R&D interaction issues - and conduct overall communications for the project?
- **Exercise 3** - Risk: Develop a brief list of a few key areas requiring risk management planning, using the Risk Analysis template as a guide.

Rutgers University iJOBS
Successful Management of Life Science Projects
Case Study – October 23, 2019

Case Study Project #2: **Brain Imaging Center**

Project Description: Rutgers University was awarded a $2million grant from National Science Foundation (NSF), to setup a brain imaging center with a Magnetic Resonance Imaging (MRI) technology to aid Rutgers researchers to understand the brain.

Stakeholders:

Newark Rutgers Psychology and Neuroscience departments as well as surrounding institutions with the emphasis on understanding the human and animal brain.

- Regulatory: US requirement such as FDA and local guidelines such as IRB
- Safety: Safety requirements for a high field magnetic device
- Manufacturers and Devices: Satisfy stakeholders' needs of such a center
- Technical/Training: Processes to use the system, acquire data, and use data.
- Marketing: Promote use of the center and acquire funding to run the center.

Exercises:

- **Exercise 1** - Project Charter Inputs: Using the Project Charter template as a guide, determine a brief list of a few inputs the PM should use to create a charter for this project.
- **Exercise 2** - Stakeholders: Using the Stakeholder RACI Matrix template as a guide, determine how the PM should categorize the project's stakeholders and if there are others not addressed in the list above. How should the PM work with the cross-functional team?
- **Exercise 3** - Risk: Develop a brief list of a few key areas requiring risk management planning, using the Risk Analysis template as a guide.