# MedImmune

## Fundamentals of Project Management

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## Introduction

- Education:
  - B.Sc. Biology
  - M.Sc. Molecular Biology
  - D.Sc. Environmental Biotechnology (1993)
  - MBA (2002)
- Certification:
  - Project Management Professional (since 2005)
- Work Experience:
  - Environmental management various industries
  - Government project management NIH
  - Consultant for pharma, biotech & device companies
  - Managing of drug development teams



## What is a Project?

- A project is a temporary endeavor undertaken to produce a unique product or service
  - Temporary Definitive beginning and end
  - Unique New undertaking, unfamiliar ground

Almost everything we do in life sciences fits the definition of a project:

- Research projects
- Presentations
- Papers
- Lab setup



Project Management is the application of skills, knowledge, tools and techniques to meet the needs and expectations of stakeholders for a project.

The purpose of project management is **prediction** and **prevention**, NOT recognition and reaction.



## **Stakeholders?**

Any person or group with a vested interest in the outcome of a project or plan. Stakeholders can be internal or external to the project or organization.



- Your supervisor/mentor
- His/her supervisor/mentor, etc...
- Collaborators
- Sponsors
- Family



## Why Do We need Proper Project Management?







How the Analyst designed it



How the Programmer wrote it





How the project was documented



understood it

What operations installed



How the customer was billed



How it was supported



What the customer really needed



#### "Customer" Requirements satisfied/exceeded

#### **Completed within allocated time frame**

## Completed within allocated budget

#### Accepted by the "customer"

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## Elementary School Geometry - The sum of the angles in a triangle always equal 180 degrees

Change in one or more "angle(s)" of triple constraint will immediately affect the other.



- Scope Management
- Issue Management
- Cost Management
- Quality Management
- Communications Management
- Risk Management
- Change Control Management

**Remember** - The purpose of project management is **prediction** and **prevention**, NOT recognition and reaction. **Plan ahead!** 



## The definition and control of what *IS* and *IS NOT* included in the project.







- Issues are restraints to accomplishing the deliverables of the project.
- Typically identified throughout the project and logged and tracked through resolution.
- Issues usually impact the cost, time or quality of deliverables.



Cost management ensures that the project is completed within the approved budget and includes:

- Setting up a budget
- Tracking Resources people equipment materials





Quality Management ensures the project will meet the needs of the intended deliverable(s).



- Conformance to requirements Crosby
- Fitness for use Juran
- The totality of characteristics of an entity that bear on its ability to satisfy stated and implied need - ISO
- GxP in research, drug development and manufacturing.
- Adherence to institutional, regional, national and international regulations and guidelines.
- Adherence to publication and presentation guidelines.



Communication management ensures the timely and appropriate generation, collection, dissemination, and storage of project information.





Risk management ensures that risks are identified, a mitigation strategy (preferably a plan is in place, and risks are closely tracked and updated.

#### **Risk vs. Danger**

A danger is ever present whereas risk is the likelihood of that danger happening. Consider the following two statements:

A hungry tiger is dangerous.A hungry tiger is risky.

A hungry tiger is certainly dangerous, but it is only a risk if it is in your vicinity. It is very risky if it is in the same room as yourself!

#### **Conclusion: Do not let the tiger into your project !**



Change control management defines the following:

- Who has rights to request changes to the project scope.
- Who has rights to approve changes to the project scope.
- How changes to the project scope will be executed.

Scope Change – more/less work Changes in technical specifications Schedule changes Cest Cuality Scope

All changes require collaboration and buy in via the project sponsor's formal approval prior to implementation of the changes.







### **Role of the Project Manager**

#### Process **Responsibilities**

- Handle project issues
- Disseminating project information
- Mitigating project risk
- Quality
- Managing scope
- Metrics
- Managing the overall work plan

#### People **Responsibilities**

- Implementing standard processes
- Establishing leadership skills
- Setting expectations
- Team building
- Communicator skills



- Project Management Institute (PMI) www.pmi.org
- Pharma Specific Interest Group (PharmaSIG) - <u>www.pharmasig.org</u>
- Pharma Local Interest Group (PharmaLIG)
- Universities and colleges