Project Management in Pharmaceutical Industry

Project Manager
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AGENDA

- Pharmaceutical R&D
- The R&D Business Processes
- Why Pharmaceutical Project Management?
- Project Management Basics
- Project Management Is About 6 “C”
- Needs From a Project manager
- Project Management in Pharma Research & Development

PHARMACEUTICAL R&D

- Pharmaceutical R&D is about the process of discovering, developing, and bringing to market new ethical drug products.

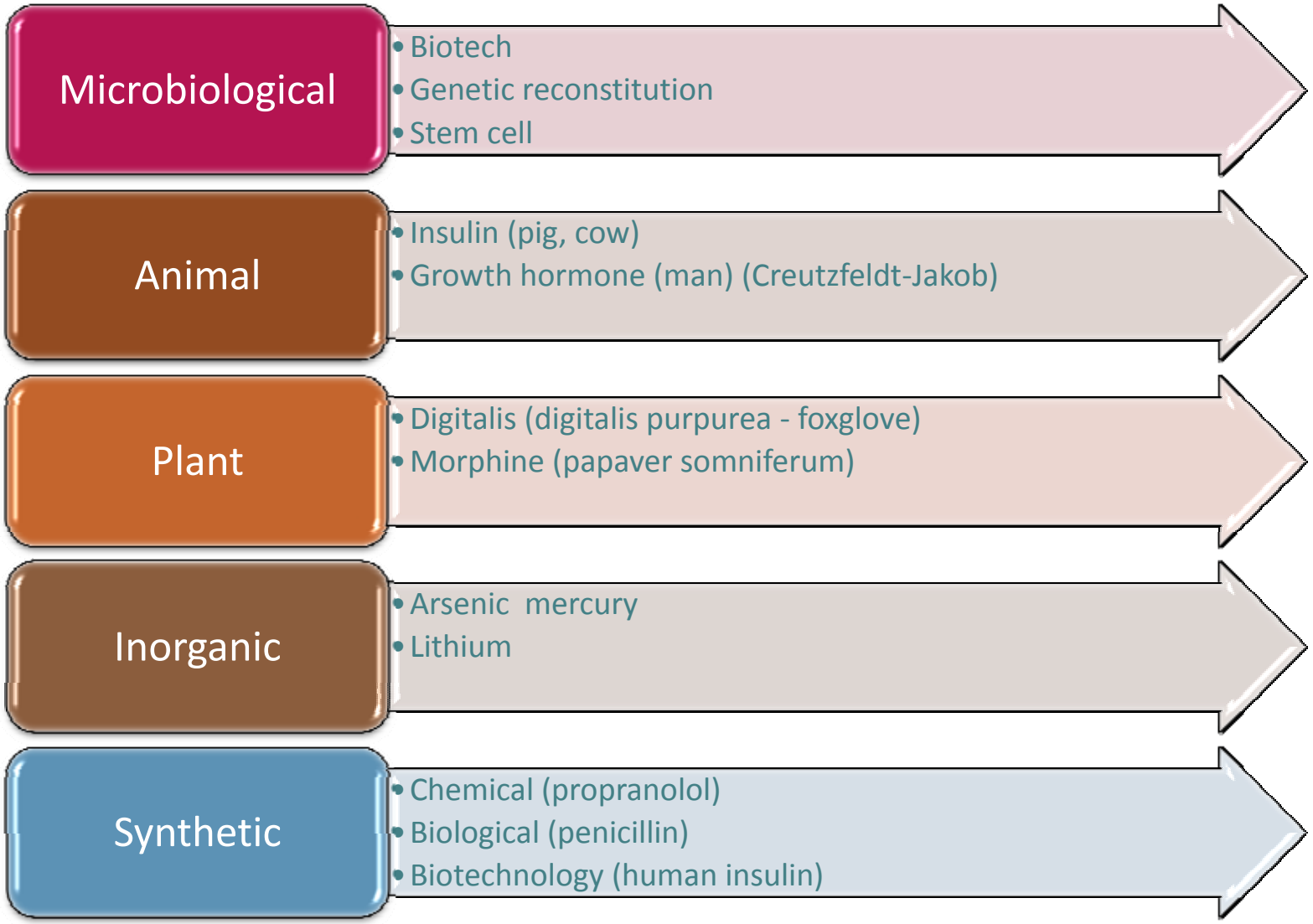
- Manufacturers in the pharmaceuticals industry turn out goods in five distinct areas;

  ✓ Ethical products
    - NCE
    - Generics
  ✓ Biotechnology products
  ✓ Generic products
  ✓ Diagnostics products
  ✓ Medical products

Why Are New Drugs Needed?

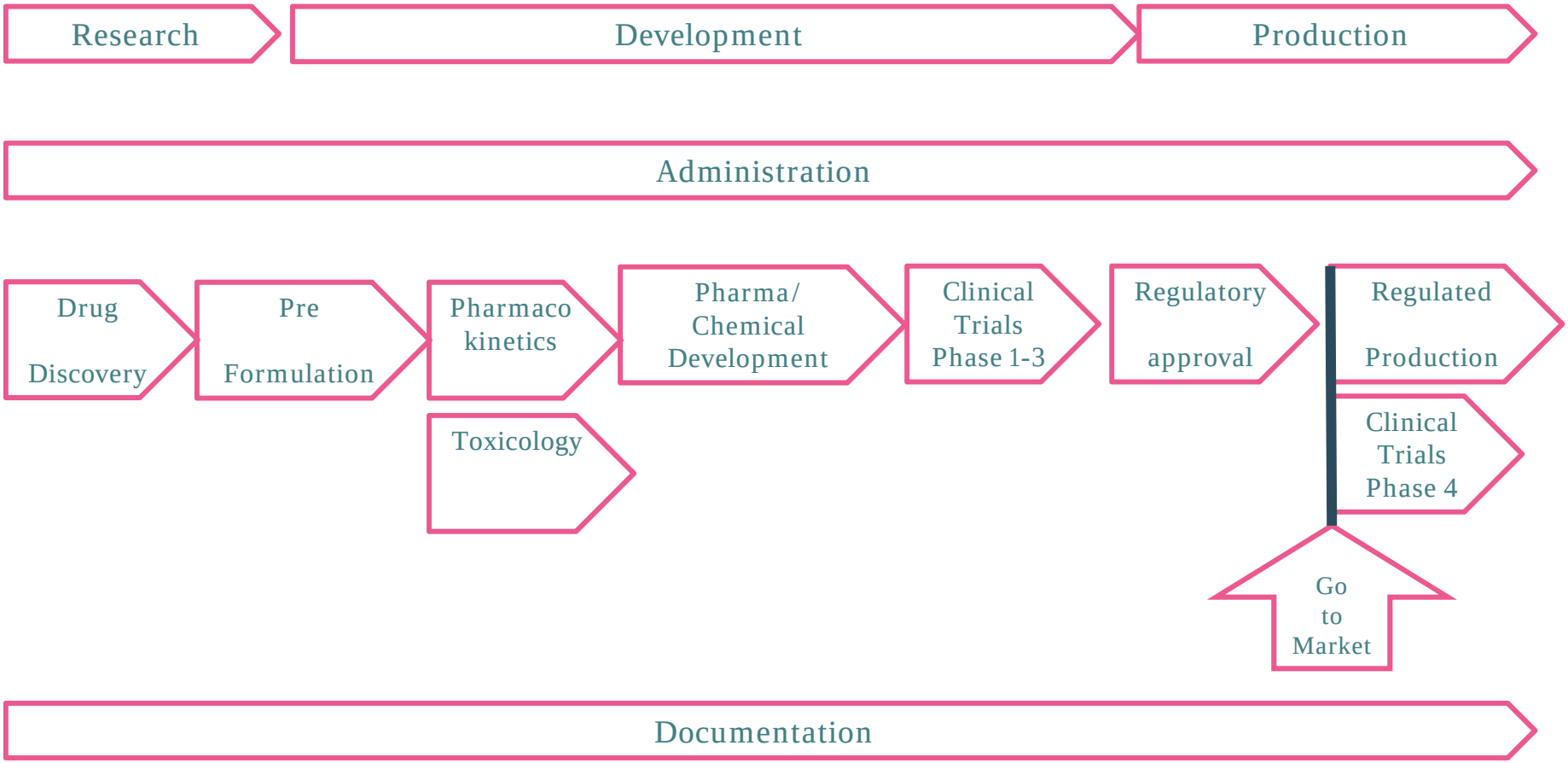
- Unmet medical need
- New diseases (BSE; AIDS, Alzheimer's; obesity)
- Low efficacy (Dementia, Cancer)
- Side effects (Antidepressants, Antipsychotics)
- Downstream health costs; (Alzheimer's; Spinal injury)
- Cost of therapy; (Viagra, Interleukins)
- Costs to individual/country; (Depression)
- Sustain industrial activity
- Patent expiry
- Comprehensive addressable to the disease - like diabetes or disease modification

Sources Of Drugs

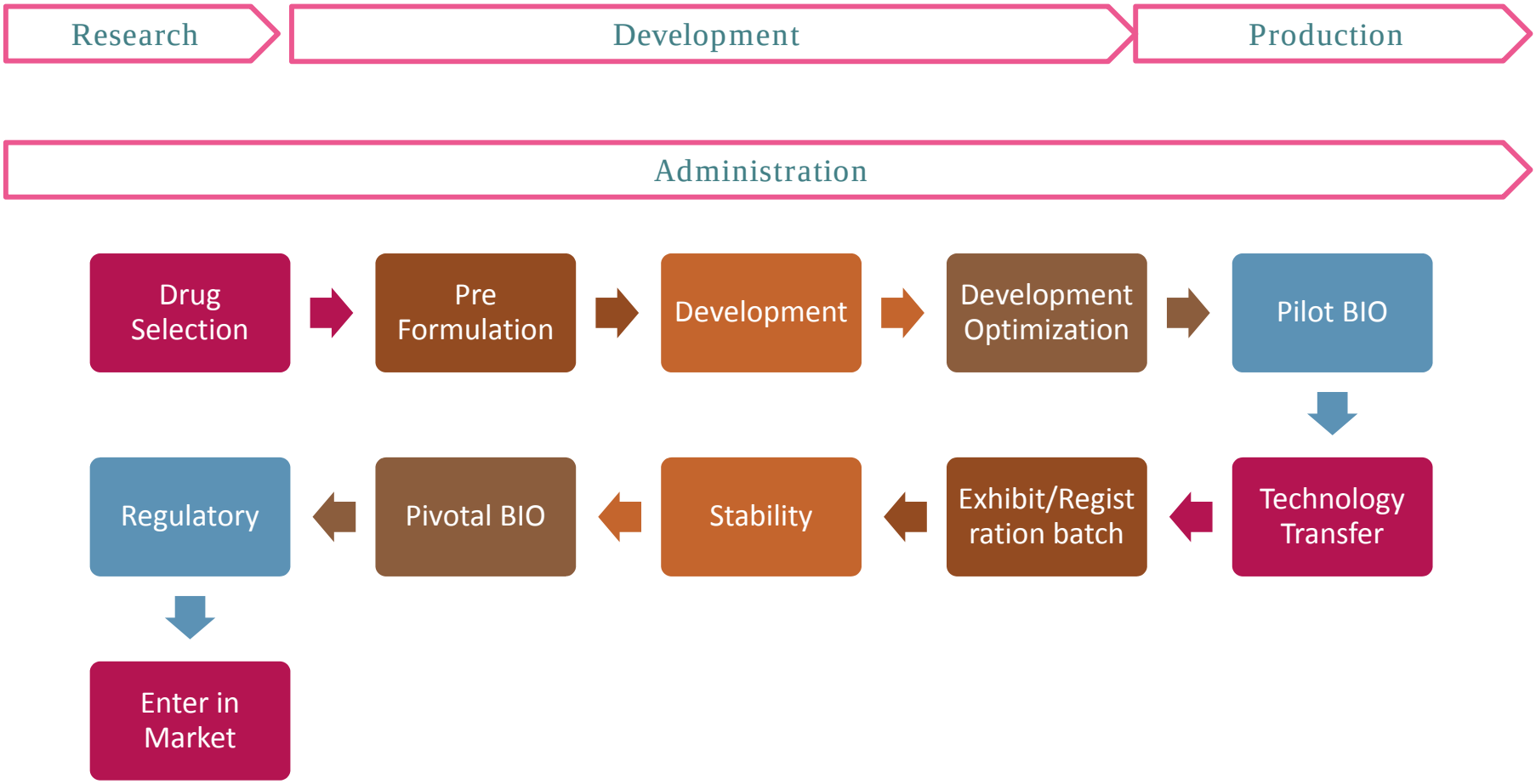


Drug Discovery/Development Process

The R&D Business Processes In The Pharma Industry - NCE



The R&D Business Processes In The Pharma Industry - Generics



From Bench To Bedside

- A medicine progresses ‘from bench to bedside’ over a period of many years —from initial development in the laboratory, through clinical testing, licensing, promotion to doctor and patient, and final prescription.

The R&D Business Processes In The Pharma Industry - NCE

- Identifying active ingredients
  - ✓ Medical chemistry
    - Here, natural substances or known chemical substances are systematically modified to increase their effectiveness,
    - reduce their side-effects, or increase their therapeutic value in treating diseases. The medical chemistry and pharmacology areas work closely together.
  - ✓ Screening
    - A large number of substances are investigated in one or more tests in order to identify a new active molecule
  - ✓ Rational drug design
    - The idea behind this method is to tailor-make a molecule that will interact with known and well-researched biological systems in the desired way.

The R&D Business Processes In The Pharma Industry - NCE

- Development

  When a research substance demonstrates a desired pharmacological effect, and a decision is made to pass it on to development.

  ✓Preformulation

  - The first step is to determine the substances chemical and physical properties. Procedures must be found to produce sufficient quantities of the substance with the required purity for the subsequent development steps.

The R&D Business Processes In The Pharma Industry - NCE

✓Pharmacokinetics

- The effects of the substance on living organisms are investigated with the help of animal experiments. These make it possible to effectively assess toxicological data and to obtain information about the effects of the substance on the human body.

✓Toxicology

- Both animal and non-animal tests are used to assess whether a substance is safe for use by humans. These include studies on acute toxicity, chronic toxicity, mutagenicity, fertility, and carcinogenicity.

The R&D Business Processes In The Pharma Industry - NCE

- Pharmaceutical and chemical development
  - ✓Pharmaceutical and chemical development
    - The active-ingredient synthesis developed in the laboratory is then scaled up for production, and the final formulation of the new product is developed. If the scale up is too large to accomplish straight away, an interim step is included. This interim step can be used to produce clinical samples before the final scale-up prior to market launch.

The R&D Business Processes In The Pharma Industry - NCE

- Clinical trials

  Once the pharmacokinetic and toxicological investigations have provided the necessary information about whether a substance is effective and safe for use by humans, a risk/benefit analysis is carried out and a decision is then made about whether to use the substance on humans.

  The central objective is to achieve an improvement in the treatment of disease.

The R&D Business Processes In The Pharma Industry - NCE

✓ Phase I

- The new substance is administered to healthy, volunteer test subjects or to selected patients with particular indications, such as cancer or Aids. This first clinical study provides information about the substances pharmacological effects, side-effects, pharmacokinetics, bio-availability, and drug interaction. Based on these results, which take about 8 - 18 months to gather, the initial dosage and dosage interval for patients are determined. At the end of Phase I, a decision is made about whether to continue or terminate the clinical trials for the substance.

The R&D Business Processes In The Pharma Industry - NCE

✓Phase II

- This phase involves patients with target indications, and aims to gather data on pharmacological effects, therapeutic effects, correct dosage, and pharmacokinetics, and information about chronic application. In this phase too, a decision is made about whether to continue or terminate the study. This second phase usually lasts between 18 and 36 months.

THE R&D BUSINESS PROCESSES IN THE PHARMA INDUSTRY - NCE

✓Phase III

- Patients with the target indication receive the preparation under normal medical conditions. The number of patients involved ranges from 200 to 4,000. Based on this broad scope of application, the compound is tested for its efficacy and side-effects on people of different ages, sex, lifestyle, and ethnic origin (various countries). The nature and frequency of side-effects are recorded, interaction with other medicaments is observed, and a comparison is made with standard therapy. This phase, lasting between 20 and 46 months, leads to a decision about whether to apply for regulatory approval or whether to terminate the project.

THE R&D BUSINESS PROCESSES IN THE PHARMA INDUSTRY - NCE

✓Phase IV

- Phase IV begins when the compound has been approved. It involves clarifying the side-effects noted in relatively large numbers of patients, investigating interactions with other drugs, and examining the long-term effects. New areas of application may also be identified for a compound during this phase.

THE R&D BUSINESS PROCESSES IN THE PHARMA INDUSTRY - NCE

- Regulatory approval
  - ✓ Application:
    - Once Phases 1 to 3 of the clinical trial for a new substance have been completed successfully, the company can apply for regulatory approval.
  - ✓ Documentation:
    - The documents required for the application are prepared on an ongoing basis throughout the development process, which means that only the results of Phase 3 need to be added at this stage.
  - ✓ Submission:
    - When the application documents are complete, they are sent to the responsible authority. The application process can take anything from 9 to 26 months, depending on the authority concerned and the quality of the application documents.

THE R&D BUSINESS PROCESSES IN THE PHARMA INDUSTRY - NCE

- Market launch
  - ✓ Introduction to Market:
    - Once regulatory approval has been issued, the next goal is to bring the new compound to market as quickly as possible. With this goal in mind, companies begin manufacturing the compound and preparing their marketing activities before they actually receive approval, so that market launch can begin the instant approval arrives.

- Post-launch
  - ✓ Analysis of New drug formations:
    - Once the new compound is on the market, another series of steps begins. These include Phase IV of clinical testing, developing new forms in which to administer the drug, and marketing. And, if this has not already happened, the compound is now scaled up for production in a normal manufacturing environment.

ADMINISTRATION

- Project management embraces the entire project procedure, from active-ingredient discovery to compound development. It plans the entire R&D process, monitors execution, and evaluates the results. At the same time, it plans dates, defines milestones and resources, and sets the budget.

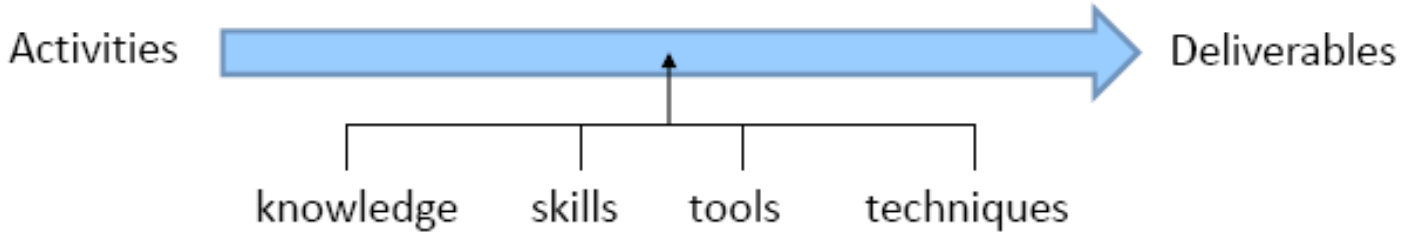
Why Pharmaceutical Project Management

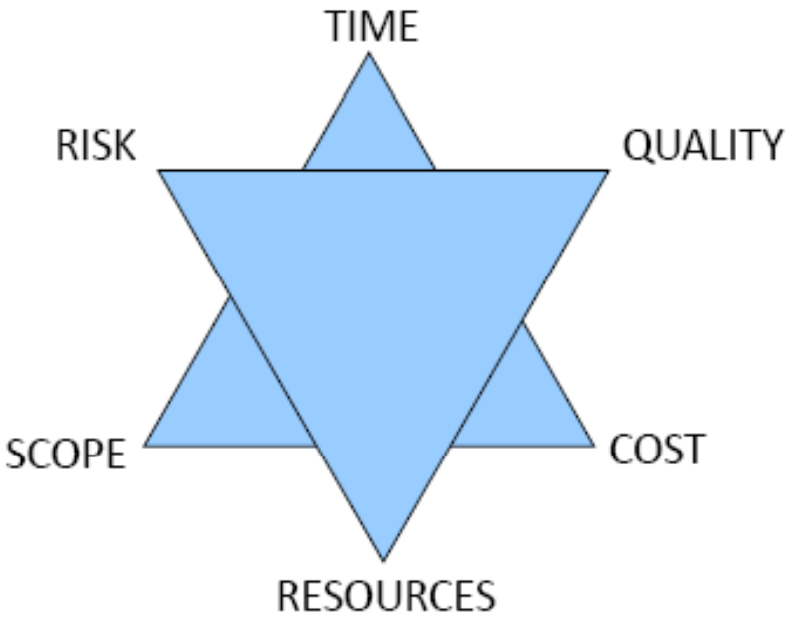
- The course of drug development is unpredictable and therefore it is critical to have realistic expectations for any given project.

- There are inherent difficulties in running a drug development successfully and the larger the project the more numerous potential problems can be.

- Accounting for the factors that can stand in the way of a project's success and being able to take an objective view of the strategies required is a demanding, but necessary task.

PROJECT MANAGEMENT BASICS





PROJECT MANAGEMENT

- Project management is a complex undertaking, with many stages and processes. It should follow the full business lifecycle, from definition and justification of the project, through to delivering demonstrable benefits for the business.

- Project management is the obedience of planning, organizing, and managing resources to bring about the successful completion of specific project goals and objectives.

- Project management is bringing cross-functional team members together to achieve a common goal.

WHAT COMPANIES WANT FROM PROJECT MANAGEMENT?

- Cost-effective planning, execution and monitoring of projects
- Optimized business processes and resources; fewer routine activities;
- Faster project procedures
- Also they want to be able to compare various different projects in order to identify at a glance which ones to press ahead with.

PROJECT MANAGEMENT IS ABOUT 6 "C"

- Concept
- Clarity
- Consensus
- Commitment
- Control
- Confirmation

6 "C" of Project Management

- Concept - High level ideas about the project
  - ✓ Project proposal
    - A brief about scope of project

- Clarity - Requirements elicitation, and analysis. Defining the requirements and then documenting them or implementing them into a system that can track changes and act as a control point.
  - ✓ Project Execution plan
    - System to draw a road map of the Project execution
  - ✓ Project status update
    - System to track and communicate project status which includes variance system and assignable route-causes systems

6 "C" of Project Management

- Consensus - Socialization and approvals.
  - ✓Project kick off meeting + Project status update meeting
    - One on one discussion on each challenges phased to avail a quick and reliable solution

- Commitment - Addressing requirements in the solution design and allocating resources to build the solution.
  - ✓Pre formulation/Formulation development
    - Guided by experts to avail a non-infringement development

6 "C" of Project Management

- Control - Control process applied to requirements; understanding the impact of changes (and possibly making sure the developers stay focused on the requirements while building the solution.)
  - ✓Analytical development

- Confirmation – Confirming designs in testing and implementation.
  - ✓ Tech transfer

OPERATIVE STRUCTURES

- Project definition : to describe project goals in general terms.

- Work breakdown structure : The WBS is the hierarchical model of the tasks to be performed in the project. It provides a clear overview of the project by:
  - ✓ Forming the basis for organizing and coordinating the project
  - ✓ Showing the work, time and costs involved in the project.
  - ✓ The WBS also forms the basis for subsequent planning steps, such as planning dates and costs, and allocating the budget.

Operative Structures

- Network : The main components of a network are activities and relationships. Through the activities in a network, you can represent the people, capacities, dates, materials, production resources/tools, and services that you need for the various tasks in your project. Depending on the task concerned, you can create different types of activity:

  ✓Internally processed activities
  ✓Externally processed activities
  ✓General costs activities

OPERATIVE STRUCTURES

- Milestones : Milestones are events of particular significance in a project or that trigger predefined functions. You can assign milestones to both activities and WBS elements. In the Project System, milestones are used:

  ✓To trigger predefined milestone functions, such as workflows

  ✓To carry out progress analyses

  ✓To determine dates in the billing plan for sales orders

Needs From a Project manager

Hard Skill

- Science
- Drug Development Understanding
- Line Function Comprehension
- Tools
  - ✓ Planning
  - ✓ Risk
  - ✓ Financial

Soft Skill

- Leadership
- Matrix Management
- Energy
- Drive
- Passion
- Influencing
- Negotiation
- Communication
- Facilitation
- Proactive
- Strategic Thinking

PROJECT MANAGEMENT IN PHARMA RESEARCH & DEVELOPMENT

- Bring 3 E's to Project:
  - ✓ Efficient, Economic , Elite

- One of the main factors to influence the success of a pharmaceuticals company is its efficiency in bringing new products to market.

- The faster market maturity is gained for a product, the greater the market lead.

- The success rate for developing new compounds is about 1:6,000. In other words, of 6,000 newly synthesized substances, only one will meet the requirements for a new product in terms of its effectiveness and safety for use in drugs.