



PILOT PLANT SCALE UP TECHNIQUES



Dr C Suryaprakash Reddy

Professor of Pharmaceutics

Annamacharya College of Pharmacy (Autonomous)

Rajampet, AP, India

Syllabus

UNIT-I

10 Hours

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

Introduction

The **Pilot plant** is a Hybrid Development facility and Manufacturing unit, which integrates followings:

- Development
- Early development activities
- Clinical supply manufacture
- Technology evaluation
- Scale up and
- Transfer to production sites

“Defined as a part of the pharmaceutical industry where a lab scale formula is transformed into a viable product by the development of liable practical procedure for manufacture.”

Introduction

- **Plant:** It is place where the 5 M's like Money, Material, Man, Method and Machine are brought together for the manufacturing of the products.
- A **pilot plant** can also be defined as the pre-commercial production system which includes new production technology and produces small volumes of new technology-based products (Fig 1).
- **Scale-up** is the process of increasing the batch size or a procedure for applying the same process to different output volumes.

Introduction

The Pilot plant studies must include;

- Current Good Manufacturing Practices (cGMP) environment,
- Highly trained and skilled staffs,
- Equipment support,
- Facility of through and close examination of the formula.

Introduction

The factors that must be determine for successful product scale up are;

- The requirements
- Training
- The reporting relationships
- Responsibility of personnel
- ❖ The pilot plant, production and process control must be evaluated, validated and finalized during the scale up
- ❖ The pilot plant plays an important role in the technology evaluation, scale up and transfer activities of new products.

Introduction

Pilot plant scale up activities:

- Technical aspects of process development
- Technical aspects of scale up
- Organization responsibility
- Determination of responsibility of technology transfer team
- Technology transfer documentation
- FDA pre-approval inspection preparation

Introduction

Major technical aspects

- Identification of critical components
- Control of critical components
- Identification of formulation variables
- Control of formulation variables
- Simulating the pilot plant equipment with manufacturing areas equipment
- Identification of critical process parameters
- Identification of operating ranges for the pilot plant equipment
- Collection of data of Product and process

Introduction

Objectives of Pilot Plant Scale Up

- Avoidance of the problems associated with the scale-up
- Production and process controls guidelines preparation
- To identify the critical features of the process
- Preparation and providing of Master Manufacturing Formula for manufacturing
- Evaluation and Validation for process and equipment
- Examination of the formula to assess the batch stability

Introduction

Significance of Pilot Plant

- Standardization of formulae.
- Review of range of relevant processing equipment.
- Optimization and control of production rate.
- Information on infrastructure of equipment during the scale up batches.
- Information of batches physical space required for equipment.
- Identification of critical features to maintain quality of a product.
- Appropriate records and reports to support GMP.

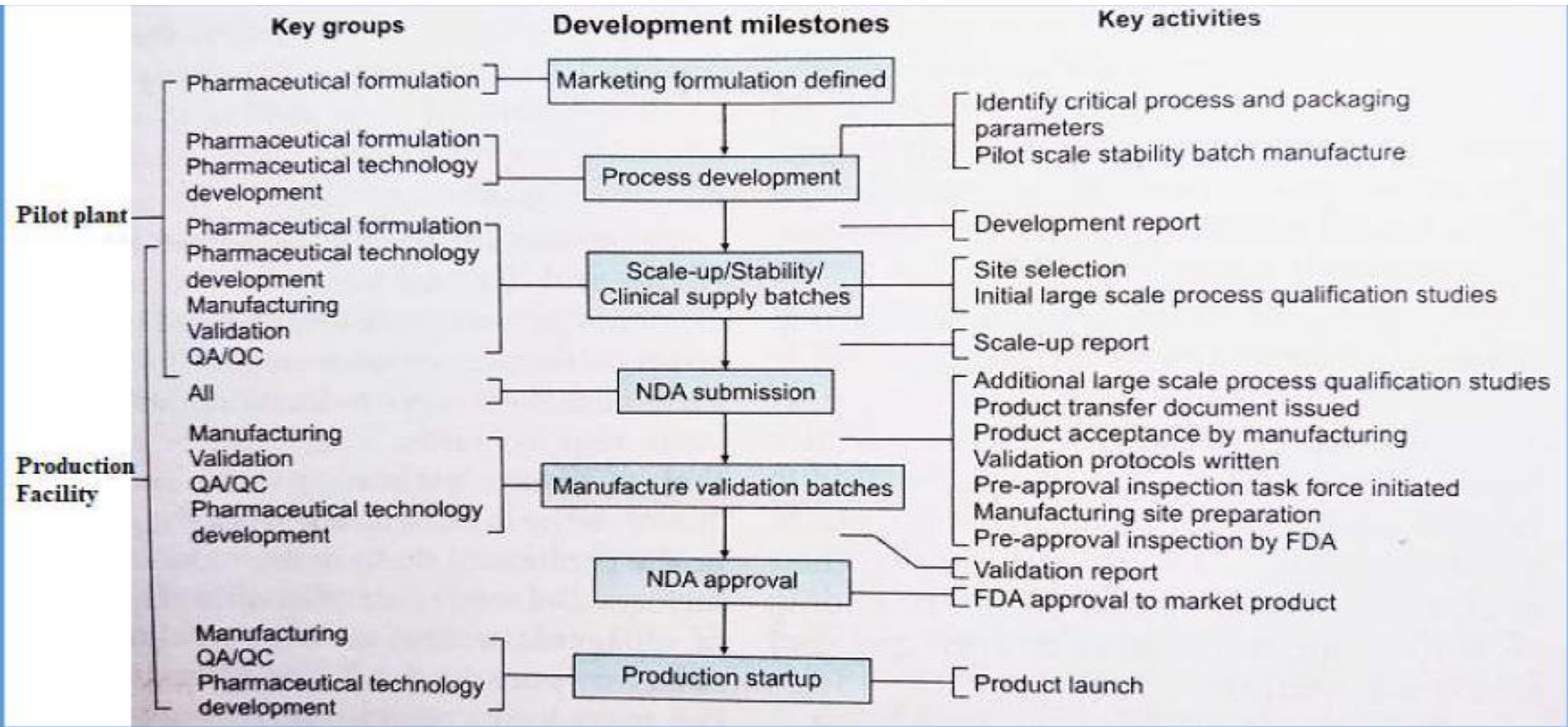


Fig 1. The layout of the relationship between different activities during technology transfers from the pilot plant to the production facility