Chapter 1

Pharmaceutical Management—Principles and Practice

Management (or **managing**) is the administration of an organization, whether it is a business, a not-for-profit organization, or government body. Management includes the activities of setting the strategy of an organization and coordinating the efforts of its employees (or of volunteers) to accomplish its objectives through the application of available resources, such as financial, natural, technological, and human resources. The term 'management' may also refer to those people who manage an organization—individually: **Managers**.

In profitable organizations, management's primary function is the satisfaction of a range of stakeholders. This typically involves making a profit (for the shareholders), creating valued products at a reasonable cost (for customers), and providing great employment opportunities for employees. In non-profit management, add the importance of keeping the faith of donors. In most models of management and governance, shareholders vote for the board of directors, and the board then hires senior management. Some organizations have experimented with other methods (such as employee-voting models) of selecting or reviewing managers, but this is rare.

"Pharmaceutical management is a discipline of management, which works with the health and chemical sciences and ensures the safe and secure use of pharmaceutical drugs".

Pharmaceutical management combines the study of basics of **pharmaceutical** sciences with **management** and marketing studies. It prepares your careers in **pharmaceutical** marketing, **management**, sales and other fields related to healthcare **industry**. "**Pharmaceutical Management** = **Pharmaceutical** Science + Business Strategies".

THE NATURE OF BUSINESS

1. **Human needs:** The starting point of any business is human needs. Human beings have physiological needs such as air, water; physical needs such as clothing, shelter, medicine and social needs such as love, affection, affiliation which needs to be fulfilled to live in a group. A higher order human has needs such as work satisfaction, self-achievement and self-realization. To satisfy these needs, he has to work and earn a decent living. When the higher level needs are satisfied, we call it a higher standard of living.

   Business contributes to human beings by providing work opportunity and satisfies his needs by making available goods and services. These goods and services are made available by a mechanism we call a market, a place where such goods and services are exchanged. The primary job of business is to provide goods and services which are required (and which may be required) by human beings.

2. **The concept of value:** Human beings have to pay value for goods and services. They must see worth paying value in the goods and services. If you do not require a haircut, even if a shop is available, you will not go for it. Business aims at increasing value of their goods and services.

   The mechanism through which we recognize value and pay for it is called price. Value and price need not be the same all the time. Value also depends upon the intensity of need, availability of goods and services and availability of money to pay for such services. Money is a common resource made available to people to receive and pay price. In barter transaction, instead of exchanging through medium of money, we do it through goods and services. However, money has now become an approved medium of exchange, and prices are being expressed in terms of money.

   Expressing more scientifically, we buy and sale value expressed in terms of money price. When we ask the price of, say, vegetables we ask in terms of money and decide its value for us. Thus value money and price are interrelated. Business may be defined as the exchange of value in terms of goods and services of consideration.

3. **The role of business:** Satisfaction of human needs is the basis of business. If there is no human need, business will fail to survive. The production of goods and services and its distribution is a business activity. Formerly, such activities which were paid for by the customers were described as business activity and those for which customer did not pay were called non-business activities. From the management point of view, it does not make any difference as to who pays. All activities which produce, and distribute goods and services, whether paid or not directly by customer, are business activities.

   Whether in public, private or social sector, all are business which exchange goods and services for value. In the public sector, may be paid goods service is by the Government, and in the social sector by someone as a charity. All these business activities need building organizations and, therefore, need management. The role of business is, therefore, exchanging goods and services for value, whether paid directly by customer or paid indirectly through Government or charitable funds.

4. **Business and economic development:** We are so much engrossed in the relation of business and profits that we neglect the major part it plays in economic development. It is found that countries that have a good business class contribute to development of a country. Business adds not only to the economic development but it renders social services making living more tolerable. Business involves value addition at every stage of working. It has to add value to make money. Thus, it is constantly looking for bettering its goods and services and converting its value to price. This it does by producing new goods and services, in terms of time and areas. Umbrellas are manufactured the whole year and then made available in rainy season. Business, make apples in Kashmir available in Mumbai by creating the need of packing services and transportation. Thus, business adds to utility and its value.

   Business locates human needs and then marches to service it through production and distribution of goods and services. Take a neighbourhood grocery store that collects many items from different sources, and then make it available at one place. Imagine what running around and cost would have been involved, if we had to go to manufacturer of these one by one to satisfy one's needs.

Another aspect we must appreciate is that each of the business activity provides employment. Increase in business leads, adds to increase in an organization, and increase in organizations needs increase in managerial personnel. Business requires resource mobilization such as money, people, equipment, etc. and thus works for developing these resources. Through mobilizing resources, it also adds to economic development.

CHARACTERISTICS OF BUSINESS

1. **Uncertainty and risks:** The ultimate success of business depends upon the customers who are willing to use their purchasing power to meet their needs, and competitive and alternating suppliers available in the market. Most of these factors are outside business organization and more directed by situational factors. This situation is further complicated by the fact that the supplier has to keep his products and serviceability ready to offer when an opportunity arises. It necessarily means that he has to act in anticipation of sales. It involves risk taking since he is not sure whether his goods will be sold or services will be accepted. Take the small business of a cobbler. He keeps his instruments ready along with leather pieces so that any time a customer walks in for shoe repair he gets a ready service. He invests in space, time, equipment and skills first and then he can expect to get some business. All these decisions, which he has taken to invest, may prove a risk and he may not get any return.

   Business is done with uncertainties and risks. Technological change, such as use of canvas shoes instead of leather ones, may not give him the same scope to repair. And with this change, his business may shrink. He can only forecast business but is never assured of its outcome.

2. **Minimizing uncertainties and risks:** Business will always try to minimize known uncertainties and risks. It does so by keeping to minimum the scale of operation. It has to find a scale of operation which will meet the cost and earn some excess to either grow business or act as insurance for uncertain future income. The scale of operation is not entirely a businessman's choice.

He has to see how a competitor is organized and may have to take decisions depending on the competitive scale of business operations. You will find big superstores and small neighbourhood shops dealing almost with identical goods or services. Thus, scale of business is a very important consideration in establishing and running business with minimum overheads.

You may find that bigger business companies may offer better scales of pay but they will also demand much hard and smart work. Business will always try to reduce impact of business overhead by getting it compensated through hard and smart work. An average businessman works longer hours, more days in a year. It needs more flexibility to face changing circumstances and demand and supply position in the market.

3. **Need for ownership and entrepreneurial characteristics:** Either an individual or a group must play a role of an owner in any business. This is the only way to safeguard continuance and growth of business. Decisions in business are such as what to exchange, at what price is to be exchanged and exchange price is to be recovered are very basic. This is not done only once but almost daily. Every day is different in business. Conditions change so fast that you have to take decisions in response to such changes and in fact have to forecast changes and proactively act on it. It is expected that they carry risks and uncertainties of business. The need to remain profitable all the time requires a calculating brain and capacity to view business in totality. We can compare this with what mothers feel about a child—a feeling of being a part of one body. Managers may leave the job, if conditions worsen, but owners cannot. They can only liquidate at a cost; that too as the last unpleasant act and a great social cost.

   To plan for business and its implementation, one has to go through so many hurdles that one requires a high achievement motivation and single purpose devotion (less emotional affiliation with people). This is truer when the business idea is new to the market. Such a person is a pioneer in the market and has to find his way-out as one does in trekking when one does not know the way. The entrepreneurial activity here is that of trying out a new business activity (not formerly established in the market).

In an established market when there is no enough possibilities for new entrant in similar business, he must come out with a new product or service, or a new concept in functioning business so that he can find an entry and later opportunity to grow. Entrepreneurs not only take a business risk but also a risk of introducing non-traditional product, service or business concept. One day we may find the market for mobile phone so competitive that we can sell mobile phones as in a vegetable market—in heaps and varieties to choose by customers on their own.

One who is a pioneer in a business is called an 'entrepreneur businessman' and the others who follow the same idea 'businessmen'.

In entrepreneurship, the innovative way of doing something stands first as a business proposition. Here not only business is done but the pioneering of a new avenue to do business is opened. It, in turn, gives the market another avenue for development. In Pune, one medical doctor established a hair cutting business and gave it a health angle instead of merely cutting hair. He can be termed an entrepreneur. Managing business is the purpose of management of business and managing an organization is a tool for implementing business.

The large scale American business pioneered the concept of blending business and management calling it business administration, leaving business concept and its development to owners of business. If business does not survive, administration cannot. Now business is competitive and if managers only administer without caring for business, both will have their last day. The worst is that business dictates the organization design and managers try to work within organization design. This has made 'business' and its management a part of overall management. We do not consider management as only 'administration' anymore.

What is Management?

1. Management is the accomplishment of results through the efforts of other people. (*Lawrence A Appley)*

2. Management is the art of getting things done through and with the people in formally organised groups. (*Koontz H)*
3. Management is a process of planning, organising, actuating and controlling to determine and accomplish the objectives by the use of people and resources. *(Terry G.)*
4. Management is the process by which managers create, direct, maintain and operate purposive organisations through systematic, coordinated, cooperative human effort. *(Me Farland)*
5. It is the coordination of all resources through the process of planning, organising, directing and controlling in order to attain stated objectives. *(Sisk)*

What is an Organization?

a. Systematic arrangement of **people** brought together to accomplish some specific purpose.
b. Expressed in terms of **objectives or goals.**

IMPORTANCE OF MANAGEMENT

According to *Drucker*, management is the dynamic life-giving element in every organisation. It is the activating force that gets things done through people. Without management, an organisation is merely a collection of men, machines, money and material. In its absence, the resources of production remain resources and never become production. The importance of management can be understood from the following points.

i. **Optimum use of resources:** Management ensures optimum utilisation of resources by attempting to avoid wastage of all kinds. It helps in putting the resources to the best advantage within the limitations set by the organisation and its environment. A right climate is created for workers to put in their best and show superior performance.
ii. **Effective leadership and motivation:** In the absence of management, the working of an enterprise will become random and haphazard in nature. Employees feel a sense of security when they find a body of individuals working day and night for the continued growth of an organisation. Management

makes group effort more effective. It enables employees to move cooperatively and achieve goals in a coordinated manner. Management creates teamwork and motivates employees to work harder and better by providing necessary guidance, counselling and effective leadership.

iii. **Establishes sound industrial relations:** Management minimises industrial disputes and contributes to sound industrial relations in an undertaking. Industrial peace is an essential requirement for increasing productivity. To this end, managers try to strike a happy balance between the demands of employees and organisational requirements. They initiate prompt actions whenever workers express dissatisfaction over organisational rules, methods, procedures and reward systems.

iv. **Achievement of goals:** Management plays an important role in the achievement objectives of an organisation. Objectives can be achieved only when the human and non-human resources are combined in a proper way. Management is goal oriented. With a view to realise the predetermined goals, managers plan carefully, organise the resources properly, hire competent people and provide necessary guidance. They try to put everything on the right track. Thus, unnecessary deviations, overlapping efforts and waste motions are avoided. In the final analysis, all these help in realising goals with maximum **efficiency.**

FUNCTIONS OF MANAGEMENT

Managers are known by the work they do, the functions they perform. According to the functional approach, originated by *Henry Fayol*, in every organisation, managers perform certain basic functions in order to achieve results. These functions may be broadly classified into five categories (Fig. 1.1): Planning, organising, directing, staffing and controlling. Managers perform these functions within the limits established by the external environment and must consider the interests of such diverse groups as government, employees, unions, customers, shareholders, competitors and the public.

Fig. 1.1: Functions of management

Planning

Planning is the process of making decisions about future. It is the process of determining enterprise objectives and selecting future courses of actions necessary for their accomplishment. It is the process of deciding in advance what is to be done, when and where it is to be done, how it is to be done and by whom. Planning provides direction to enterprise activities. It helps managers cope with change. It enables managers to measure progress toward the objectives so that corrective action can be taken, if progress is not satisfactory. Planning is a fundamental function of management and all other functions of management are influenced by the planning progress.

Organising

Organising is concerned with the arrangement of an organisation's resources—people, materials, technology and finance in order to achieve enterprise objectives. It involves decisions about the division of work allocation of authority and responsibility and the coordination of tasks. The function increases in importance as a firm grows. A structure is created to cope with problems created by growth. Through this formal structure, the various work activities are defined, classified, arranged and coordinated. Thus, organising refers to certain dynamic aspects: What tasks are to be done? Who is to do them? How the tasks are to be grouped? Who is to report to whom? Where the decisions have to be made?

Staffing

Staffing is the function of employing suitable persons for the enterprise. It may be defined as an activity where people are recruited, selected, trained, developed, motivated and compensated for manning various positions. It includes not only the movement of individuals into an organisation, but also their movement through (promotion, job rotation, transfer) and out (termination, retirement) of the organisation. Staffing involves selection of the right man for right job. It has four important elements:

1. **Recruitment** may be defined as the process of attracting the maximum number of applications for a particular job.
2. **Selection** is the process of screening the candidates and choosing the best ones out of them.
3. **Training** involves imparting the necessary knowledge and skills required for the performance of a particular job.
4. **Compensation** is the price paid to the workers for the services rendered to the organisation.

Directing

The function of guiding and supervising the activities of subordinates is known as **directing**. According to *Dale*, direction is telling people what to do and seeing that they do it to the best of their ability. Acquiring physical and human assets and suitably placing them on jobs will not suffice, what is more important is that people must be directed towards organisational goals. This work involves four important elements:

1. **Leadership:** Leadership is the process of influencing the actions of a person or a group to attain desired objectives. A manager has to get the work done with and through people. The success of an organisation depends upon the quality of leadership shown by its managers.
2. **Motivation:** Motivation is the work a manager performs to inspire, encourage and impel people to take required action. It

is the process of stimulating people to take desired courses of action. In order to motivate employees, manager must provide a congenial working atmosphere coupled with attractive incentives.

3. **Communication:** Communication is the transfer of information and understanding from one person to another. It is a way of reaching others with ideas, facts, and thoughts. Significantly, communication always involves two people: A sender and a receiver. Effective communication is important in organisations because managers can accomplish very little without it.
4. **Supervision:** In getting the work done, it is not done enough for managers to tell the subordinates what they are required to do. They have also to watch and control and activities of the subordinates. Supervision is seeing that subordinates do their work and do it as directed. It involves overseeing the employees at work.

Controlling

The objective of **controlling** is to ensure that actions contribute to goal accomplishment. It helps in keeping the organisational activities on the right path and aligned with plans and goals. In controlling, performances are observed, measured and compared with what had been planned. If the measured performance is found wanting, the manager must find reasons and take corrective actions. If the performance is not found wanting, some planning decisions must be made, altering the original plans. If the controlling function is to be effective, it must be preceded by proper planning. Thus, controlling included four things:

1. Setting standards of performance,
2. Measuring actual performance,
3. Comparing actual performance against the standard, and
4. Taking corrective actions to ensure goal accomplishments.

Successful management involves active participation by managers in the above basic managerial functions. These functions are interrelated and most managers use a combination of the four simultaneously to solve the problems facing their companies. All management functions are related and interrelated to each other as shown in Fig. 1.2 (by the arrows).

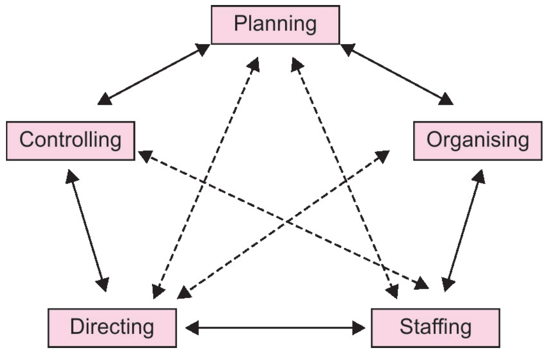


Fig. 1.2: Interrelated management functions

For theoretical purposes, it may be convenient to separate the management functions and study them independently but practically speaking, they defy such categorisations. They are highly inseparable. Each function blends into the other and each can be performed in any order or sequence, not necessarily in the order shown above, but tend to be performed (normally) in the planning, organising, leading and controlling sequence.

MANAGEMENT AS A PROFESSION

Now let us examine whether management meets the above criteria or not:

- **Well-defined body of knowledge:** Management has a well-defined body of knowledge that is generally valid in a variety of organisations and situations. Management literature has been continually growing. Many tools and techniques have been perfected over the years. Research and consultancy firms aid managerial thinking and practise nowadays. They produce a lot of data, aided at improving managerial decision-making.
- **Representative body:** As things stand now, there is no organisation or body of professionals whose membership is essential to become a manager. There is no organisation whose authority is recognised as final. In the case of lawyers, it is necessary to become a member of the Bar Council of India, in the case of doctors, in the Medical Council of India. However, such entry requirements do not exist in the field of management. In

fact, the entry into the field of management is not regulated. Further, no minimum qualification has so far been laid down for managers. There is also no licensing of managers. There are several management associations, however, offering training and research support to managerial work. But no such association enjoys the legal sanction to regulate the activities of managers throughout India.

- **Code of conduct:** There is no universal code of conduct. Although, certain trade associations and management associations (e.g. All India Management Association) have formulated ethical codes for managers working in particular industries, these have not been accepted totally.
- **Service motto:** In the absence of a regulating body (with legal sanction) and code of conduct, managers often indulge in practises aimed at maximising their personal wealth. The service motto stands thoroughly neglected. In recent years, however, this view of management is progressively changing. To survive in a competitive world, management has to reconcile the conflicting interests of the shareholders and workers on the one hand and meet the social obligations of business, on the other. They have to balance these conflicting interests while making profit.

Who are Managers?

Managers are the 'coordinators' and 'directors' in the organisation. They are the individuals charged with examining the workflow, coordinating efforts, meeting goals and providing leadership. In terms of authority, managers possess the right to command others in their areas of responsibility. Each manager reports to someone higher in the organisation in what constitutes a theoretical chain of command from the top to the bottom of the structure. Managers usually do not directly perform any of the workflow activities. They are there to direct, coordinate and assist the rank and file members who handle these functions. They are also the activating elements that provide leadership and rewards to get results.

Is Manager a Professional?

To answer this question, we have first to enumerate the distinguishing characteristics of a professional. We call an auditor, a pleader or a doctor a professional. The reason in that their practice is based on education received. Moreover, their conduct is governed by their professional association which has the right to terminate their profession, if they misbehave. Their profession is governed by their professional association. These we can call approved professions.

However, management training is not a condition to become a manager. Many managers may not be qualified in this sense. Managerial profession covers so many disciplines and sizes of organizations that one may find it difficult to standardize the profession. Efforts have been made in the directions but these have not been accepted. Thus, in the sense of legal sanctity and as a knowledge base, management is not standardized.

Even though people are being formally educated and given certification to this effect, it is not necessary that all these trained people can be called managers unless they manage and prove their skills. But professionalism which indicates pride, discipline and dedication to any work will always be there and managers will remain professional to that limit. We need not call ourselves professionals but can act as one. Let managers take pride as professionals without being recognized by law or any controlling professional body. They are to spread out and be varied, perform in all walks of life. Many of them prefer to get attached to specialized bodies such as those associated with materials, manpower, engineering, quality control than a very general body. Besides the fact that professional education is not necessarily a precondition to become a manager, management in a way can be said as liberal art—a profession in disguise.

MANAGERIAL ROLES (Fig. 1.3)

1. **Interpersonal roles:** Three interpersonal roles help the manager keep the organisation running smoothly. Managers play the *figurehead role* when they perform duties that are ceremonial and symbolic in nature. These include greeting the visitors, attending social functions involving their subordinates (like weddings, funerals), handing out merit certificates to workers showing promise, etc. The *leadership role* includes hiring, trainings, motivating and disciplining employees. Managers

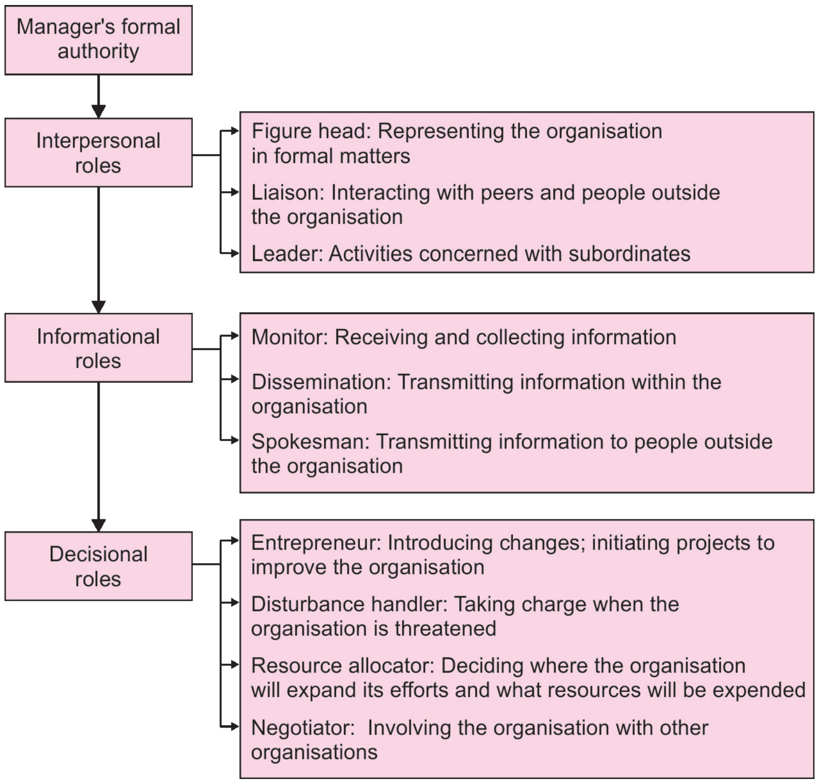


Fig. 1.3: Managerial roles

play the *liaison role* when they serve as a connecting link between their organisation and others or between their units and other organisational units. *Mintzberg* described this activity as contacting outsiders who provide the manager with information. Such activities like acknowledgements of mail, external board work, etc. are included in this category.

2. **Informational roles:** *Mintzberg* mentioned that *receiving and communicating information* are perhaps the most important aspects of a manager's job. In order to make the right decisions, managers need information from various sources. Typically, this activity is done through reading magazines and talking with others to learn about changes in the customers' tastes, competitors' moves and the like. *Mintzberg* called this the *monitor role*. In the *disseminator role*, the manager distributes

important information to subordinates that would otherwise be inaccessible to them. Managers also perform the *spokesperson role* when they represent the organisation to outsiders.

3. **Decisional roles:** There are four decision roles that the manager adopts. In the role of the *entrepreneur*, the manager tries to improve the unit. He initiates planned changes to adapt to environmental challenges. As *disturbance handlers*, managers respond to situations that are beyond their control such as strikes, shortages of materials, complaints, grievances, etc. In the role of a *resource allocator*, managers are responsible for allocating human, physical and monetary resources. As *negotiators*, managers not only mediate in internal conflicts but also carry out negotiations with other units to gain advantages for their own unit.

SKILLS OF AN EFFECTIVE MANAGER

An effective manager must possess certain skills in the areas of planning, organising, leading, controlling and decision-making in order to process activities that are presented to him from time-to-time.

LEVEL OF MANAGEMENT

All managers' positions involve performance of management functions (planning, organising, directing, staffing and controlling). But there are differences among managerial jobs. The differences arise because of the existence of various levels of managements in a typical organisation. The term '**levels of management'** refers to a line of demarcation between various managerial positions. In a large organisation, three levels of management are usually identified: (i) Top level management; (ii) Middle level management; and (iii) Lower level management. The functions performed by **top managers, middle managers**, and **lower level managers**, respectively may be briefly stated thus:

- **Top management**
  - Determines objectives and policies
  - Designs the basic operating and financial structure of an organisation.
  - Provides guidance and direction.

– Lays down standards of performance.
– Maintains good public relations.

Table 1.1: Skills of an effective manager

Planning skills	*Organising skills*	*Leading skills*	*Controlling skills*	*Decision-making skills*
Ability to think ahead Ability to forecast future trends	Ability to analyse and describe various organi-sational jobs.	Ability to see the big picture. Ability to communicate ideas effectively.	Ability to keep the activities on the desired paths. Ability to initiate corrective steps at the right time.	Ability to make good and timely decisions. Ability to devote on key, important and strategic issues.
Ability to state organisational objectives clearly and precisely	Ability to select, train, develop and maintain people in various jobs.	Ability to inspire people to do better.	Ability to ensure control measures without hurting the feelings of employees in a negative manner.	Ability to make right choices and pursue activities that enable the organisation to accomplish its purposes.
Ability to make choices that help in realising predetermined goals	Ability to define working relationships and authority flow properly.	Ability to inculcate a sense of collectivism in the employees and forcing them to work as a team.		Ability to commit funds to the best advantage.
Ability to set performance standards for measuring and implementing the plans.	Ability to get along with changing situations.	Ability to assess the situation and initiate the needed behaviour in an appropriate manner.		

- **Middle management**
  - Interprets and explains the policies framed by the top.
  - Issues detailed instructions.
  - Participates in operating decisions.
  - Trains other managers.
- **Lower management**
  - Plans day-to-day operations.
  - Assigns jobs to workers.
  - Provides supervision and control over work.
  - Arranges material tools and equipment.
  - Maintains discipline.

Point of distinction	*Top level management*	*Middle level management*	*Lower level management*
• Action focus	A small group of policymakers deciding the fate of an organisation.	Act as a connecting link between top and lower level people and manage activities of other managers.	These managers are in direct contact with employees.
• Representation	Chief Executive Officer, President, Chairman, Managing Director, etc.	Functional heads (marketing manager, personnel manager, etc.) and immediate subordinates.	Section head, supervisor, first-line manager, etc.
• Nature of work	They generally spend most of their time with peers, outsiders and to a lesser extent, subordinates. A top manager's schedule is typically hectic.	Middle managers, compared to supervisors, are far less physically active and far more involved in paperwork and meetings. Their job is less hectic, more reflective and more frustrating.	Generally physically active, experience frequent interruption, often shift back and forth between tasks and spend most of their time with subordinates and peers caring or monetary problems.

PLANNING IN PHARMACEUTICAL COMPANIES

Planning in pharmaceutical companies is the selection of short- and long-term objectives and the drawing up of tactical and strategic plans to achieve those objectives. Planning is both the organizational process of creating and maintaining a plan and the psychological process of thinking about the activities required to create a desired goal on some scale. Planning allows managers the opportunity to adjust to the environment instead of merely reacting to it. Planning increases the possibility of survival in business by actively anticipating and managing the risks that may occur in the future.

Long-range Planning vs. Short-range Planning

Long-range planning	*Point of distinction*	*Short-range meaning*
5 years or more	Time factor	Up to one year
Mission, long-term goals and strategies	Deals with	Current operations of an organisation
Organisation's linkage with external factors	Primary focus	Linkage with various parts of an organisation
Demand changes in the structure, resource allocation	Impact	Operates within the existing structure and resources
It goes too far into the future, the risk and uncertainty level is high	Uncertainty	The time horizon is limited and the risk associated with uncertainty level is low
Top management	Prepared by	Lower level executives

Planning Process/Steps

- **Perception of opportunities:** It is preliminary look at all possible opportunities and the ability to see them clearly and completely.
- **Establishing objectives:** At this stage major organizational and unit objectives are set.
- **Planning premises:** The condition under which the planning activities will be undertaken.

External: PESTL. Internal—capital, labour, raw material, machinery, etc.

- **Identification of alternatives:** Based on the organizational objective and planning premises, various alternatives can be identified, e.g. taking over another organization.
- **Evaluation of alternatives:** Various alternatives feasible can also be considered.
- **Choice of alternatives:** Choosing the alternative which fit the organization.
- **Formulation of supporting plans:** After formulating the basic plans, various plans are derived so as to support the main plan, e.g. buying raw material, recruiting, training.
- **Establishing sequence of activities:**
  - After formulating basic plans and derivative plans, the sequence of activity is determined so that the plans are put into action.

Corporate Planning Process

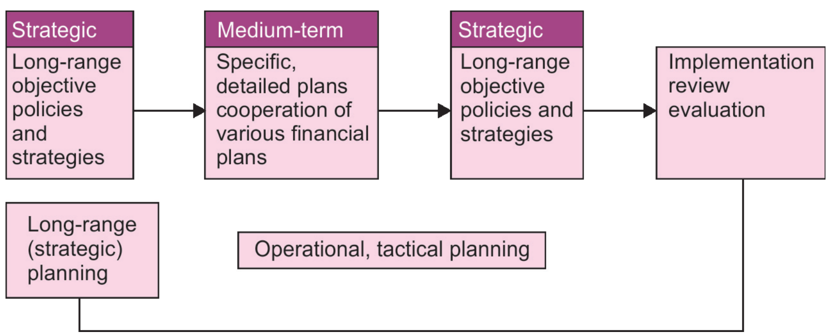


Fig. 1.4: Corporate planning process

Strategic Planning

- **Hayes and Wheelwright:** Strategic planning is the "planning that is long-term, wide ranging and critical to organisational success, in terms of the costs of the resources it affects and the outcomes it envisions."
- **Harvey:** Strategic planning is long-range planning that focuses on the organisation, as a whole. Managers consider the organisation as a total unit and ask themselves what must be done in the long run to attain organisational goals. The most successful managers are those who are able to encourage innovative strategic thinking within the organisations (Pearson).

Characteristics of Strategic and Operational Plans

Feature	*Strategic (long range)*	*Operational (short-range)*
Time horizon	5 years of more	Under 1 year
Purpose	Adapt to external environment based on internal strengths	Implement internal goals
Activity controlled	Total institutional performance	Internal tasks and operations
Decision range	Relatively enduring	Short term
Organisational level involved	Top management	Middle and lower management
Basis for planning	Primarily judgemental	Exact data and standards used
Predictability	Uncertain	Highly certain
Anticipated accuracy	Within 25 percent	Within 2 or 3 percent
Management functions involved	Planning and forecasting dominant	Control primarily
Management control of outcomes	Slight; contingency plans required	Almost complete; single option plans used

Comparison between Strategic Planning and Operational Planning

Strategic (long-range) plans	*Intermediate (tactical) plans*	*Operational (short-range) plans*
Long-range plan	Intermediate plan	Short-range plan
Time frame: 3 or more years	Time frame: 2–3 years	Time frame: 1 year
Top management responsibility	Performed by manager at middle level	Done usually at lower levels
Concerned with road objectives of the organisation	Concerned with integrating the work of various departments in the organisation	Covers day-to-day operations; implements internal goals
Focus on planning and forecasting	Focus on coordination	Focus on control primarily

Steps of Sales and Operations Planning

The basic components of the Sales and Operations Planning (SOP) in the pharmaceutical industry are the commercial plan, the production plan (often called the industrial plan so as not to confuse it with the production program), coherence of these two plans, decisions and arbitrations, validation by the company of the resulting plans.

The major phases leaders

- Sales and marketing management (sales forecasts and commercial action plans),
- Industrial management and the purchasing department,
- Supply chain manager (who is often also the owner or facilitator of the process),
- The president, to manage arbitrations, coherence with strategic plans, validation,
- Responsible for the sales and operations planning process in the pharmaceutical industry.

However, the other functions of the company such as finance, studies/R&D/product development and HR will be involved in the process.

Update of the Commercial Plan

The sales and marketing department analyzes the sales over the past month: Differences between actual orders and forecasts, indicators change. It collects forecasts: Market forecasts, customer forecasts, forecasts from sales managers. It lists the significant sales and marketing actions (promotions, etc.) and organizes these data: Updates the sales forecasts and the sales action plan.

Update of the Industrial Plan

The industrial and purchasing department and the logistics or supply chain department analyze industrial plan over the past month: Differences between actual and planned production, indicators change. They collect manufacturing data: Nomenclatures, load profiles, capacity evolutions (industrial projects such as new equipment, taking into account the actual capacities demonstrated by the tools, shutdown and maintenance plans, staff changes and leave, etc.) internally as well as externally (suppliers).

These two directions take into account the updating of sales plan and simulate the updating of the industrial plan allowing to respect it. They calculate global capacity by applying load profiles of production families, and update strategic or critical supply and sub-contracting requirements. They highlight variations in different management areas (firm/flexible/free), prepare adaptation scenarios and note the associated issues with these changes, the impacts of different scenarios and important changes.

The sales and operations planning in the pharmaceutical industry in relation to other planning levels: The sales and operations planning in the pharmaceutical industry is the planning level above the PMP (production master program). He plans further and with less detail.

Preparation Meetings

The process facilitator, the commercial and marketing, industrial and purchasing departments meet as much as necessary in various meetings and consult the other actors. They review the data relevance especially those concerning variations and hard points. They consider scenarios of resources adaptation (means of production, outsourcing, schedules, hiring, etc.) and demand adaptation scenarios (promotions, commercial action plan). They examine the impacts of different scenarios (financial, suppliers, etc.). Finally, they validate the hypothesis with the various functions of the company (financial management, studies/R&D/product development, HR).

Useful documents are circulated at the end of these meetings to allow arbitration and validation in industrial and commercial meetings in the commercial industry. They can describe several scenarios with the associated risks and their feasibility.

SOP Meeting

If enough prepared, it is a decision meeting (for example, between two scenarios). It allows issuing within 24 hours of a IPC understood by all, validated and manageable. This facilitates the updating of other schedules (PMP, supply, etc.) and the realization, as requested, of actions to adapt capacities and commercial actions. The participants are:

- **The main actors of the IPC:** The President, heads of commercial, industrial, purchasing, logistics, and the IPC manager,
- **Other departments:** Studies/R & D (partially), financial (HR)
- The person in charge of the PMP.

Typical agenda of the IPC meeting (duration 2h)

- **Review of the action list of the previous IPC:** Achievement and relevance.
- General information by the President (economic info, long-term perspectives).
- **Performance analysis:** Review of customer service indicators, IPC performance indicators (expected/realized production) and critical constraints.
- Review of market, economy, competition and company evolution assumptions (strengths and weaknesses).
- **Family by family analysis:** Performance of the last month, commercial and industrial plans, possible proposals, President decision (often we will not list invariants to be limited to singular points: Variations and alternatives requiring a decision).
- Update on new products.
- Update on projects that may impact production (works, new software packages, etc.).
- Summary of decisions.

After the executive meeting of the Sales and Operations Planning in the pharmaceutical industry:

- Immediate circulation of the report (it is a list of decisions which can be validated by the President at the end of the meeting).

- Diffusion within 24 hours of the validated SOP plan.
- Taken into account in the PMP.

ORGANISING IN PHARMACEUTICAL COMPANIES

After different level of planning pharmaceutical companies undergo the process of organizing by establishing the orderly use of resources by assigning and coordinating tasks. The organisation process transforms preparation into reality through the purposeful deployment of people and resources within a decision-making framework known as organisational structure. Organizing like planning must be carefully worked out and applied. This process involves determining what endeavour is needed to accomplish the goal, assigning those tasks to individuals, and arranging those individuals in a decision-making framework. The end result of this process is an "Organisation"—a whole consisting of unified parts acting in harmony to execute tasks to achieve goals, both effectively and efficiently.

A properly implemented organizing process should result in a work environment where all team members are aware of their responsibilities. Organisational process consists of five steps, namely 1. Job design, 2. Departmentalization, 3. Delegation, 4. Span of control/management, 5. Chain of command.

Approaches to Organizational Design

Pharmaceutical companies make choices about how to group people together to perform their endeavour. Five common approaches—functional, divisional, team, matrix and networking help pharma managers to determine departmental grouping or organisational structure. Different structures are given below.

Simplified Functional Structure

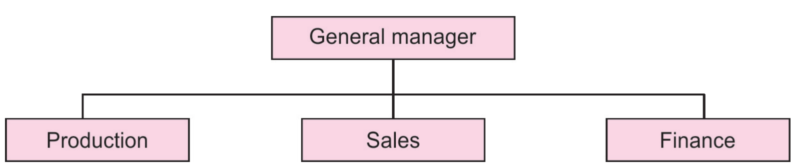


Fig. 1.5: Simplified functional structure

Departmentation by Product

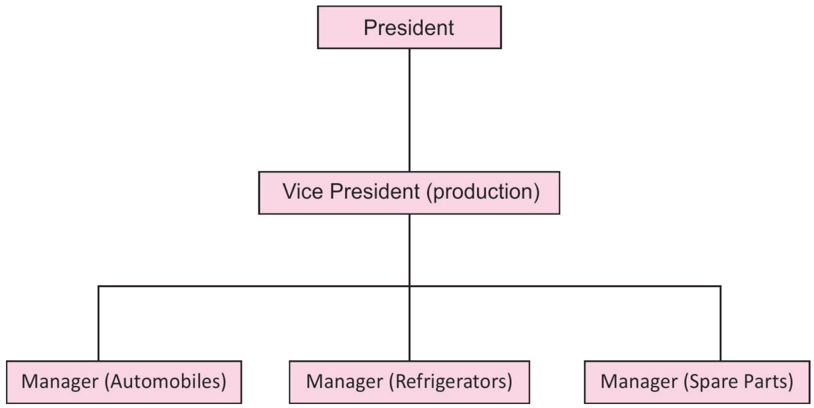


Fig. 1.6: Departmentation by product

Departmentation by Territory

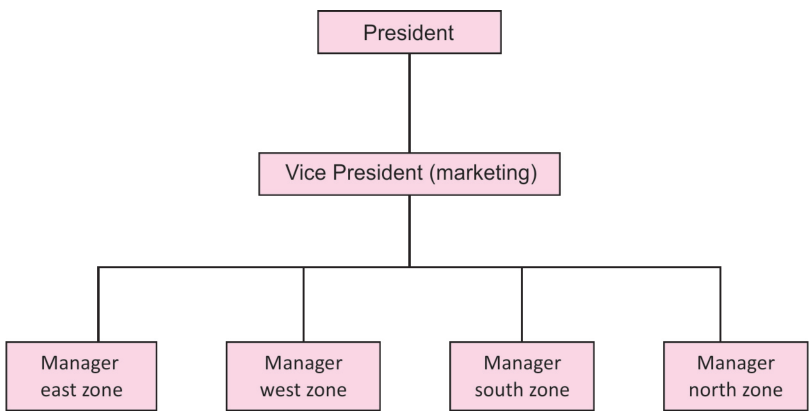


Fig. 1.7: Departmentation by territory

Departmentation by Customer

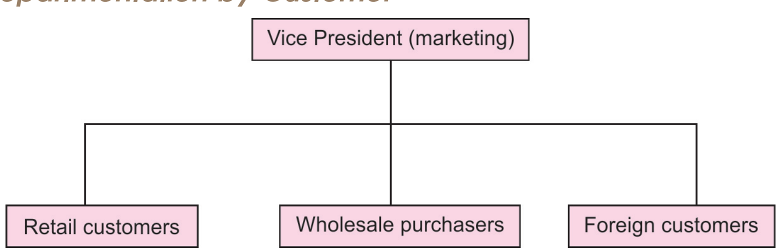


Fig. 1.8: Departmentation by customer

Project Form of Organisation

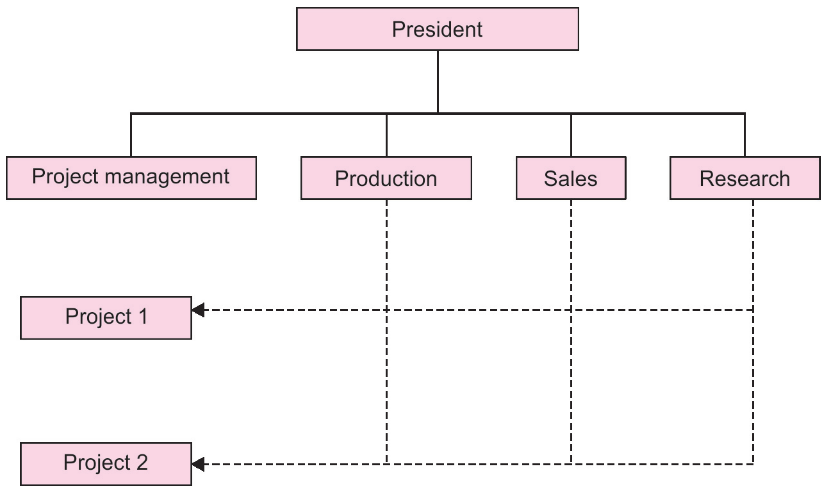


Fig. 1.9: Project form of organisation

Matrix Structure

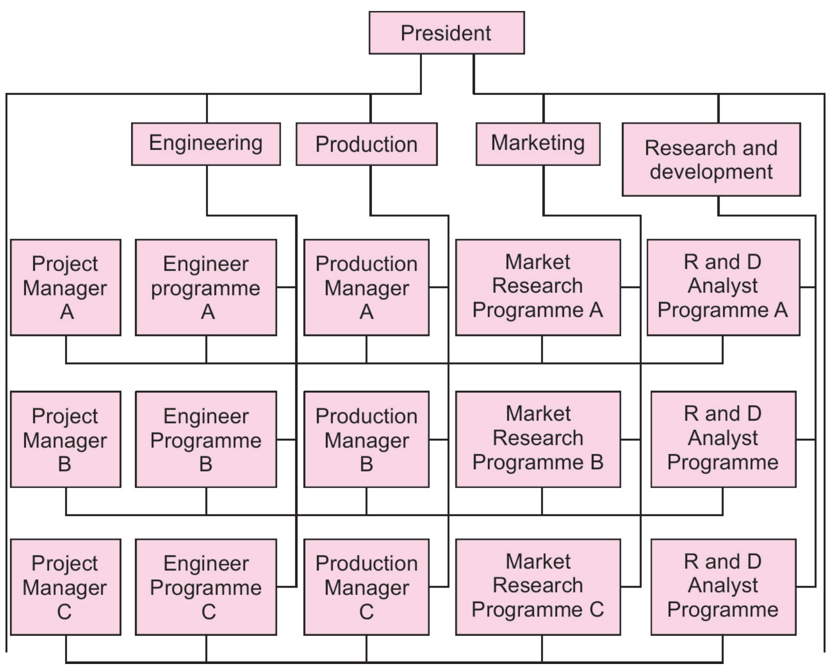


Fig. 1.10: Matrix structure

Pharmaceutical Companies—Typical Organization Chart

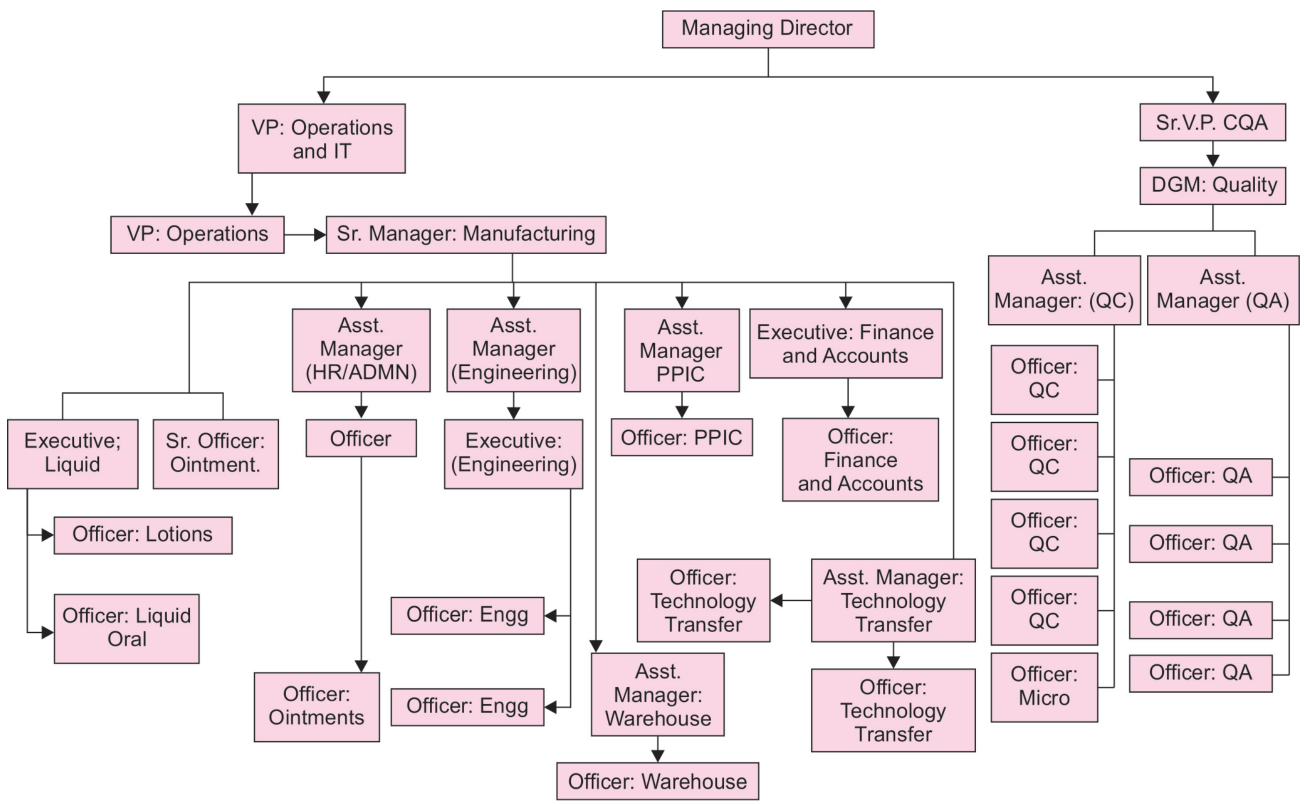
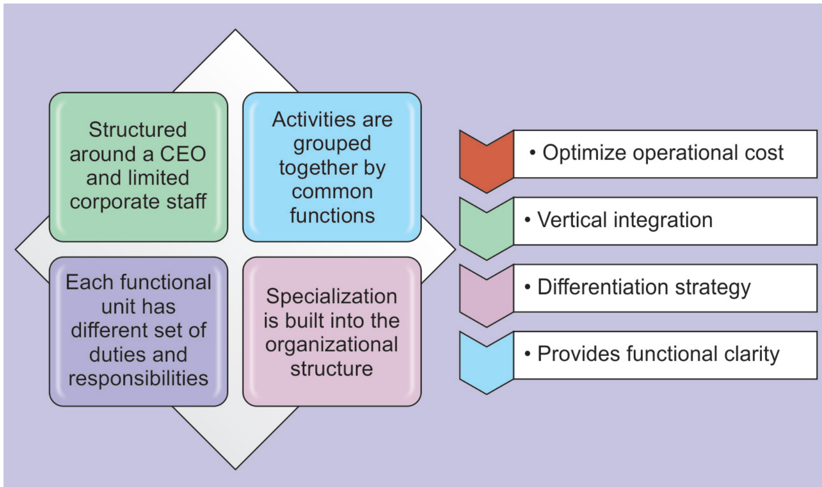
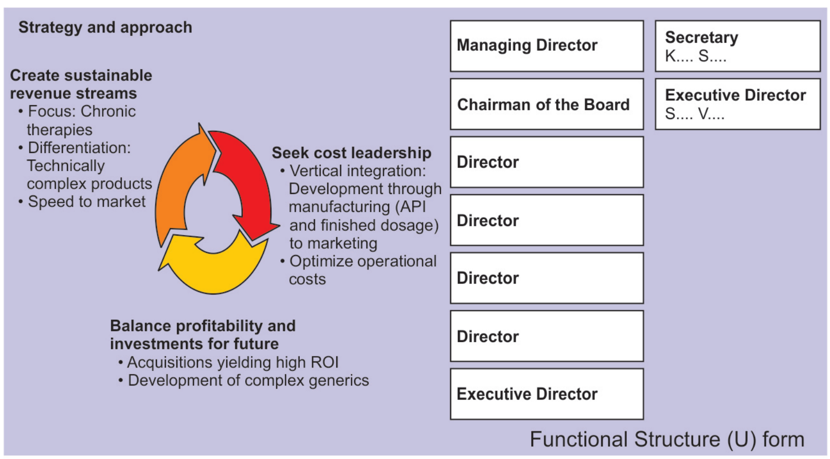


Fig. 1.11: Typical organisational chart of pharma companies

Modern Structure—Functional Unitary Structure





Sun Pharmaceutical Industries Limited

Fig. 1.12: Functional unitary structure

MAJOR DEPARTMENTS IN PHARMACEUTICAL COMPANIES

Pharmaceutical companies handle the research, production and delivery of pharmaceutical drugs to healthcare service providers (physicians, pharmacies, hospitals, etc.) and consumers. Pharmaceutical products must go through extensive research and testing (i.e. Research and Development), as well as follow regulations and obtain approval from government entities such as the Food and Drug Administration (FDA) before the products can reach its targeted market. Once products have been approved for large-scale distribution, pharmaceutical companies scale-up manufacturing and align themselves with intermediaries to sell the drug through various channels (direct-to-consumer or through distribution channels such as pharmacies and hospitals).

Research and Development

The Research and Development function is responsible for creating new medications and installing them in the disease-fighting arsenal of physicians. The process begins with "discovery," during which time researchers identify new candidates from a large library of chemical compounds. Thousands of such candidates are selected using modern computerized tools. After the candidates have been selected, they are tested for their ability to move through the body and interact with the desired pathology. Researchers then optimize the candidates by altering their chemical structures to increase their medicinal effects and to decrease their side effects. A phase of tests determines whether the drug is safe enough for human testing. By the end of these steps, only a handful of candidate drugs will remain. These are entered into clinical trials, which is the final and longest step.

Clinical Trials

The testing phase of a new drug is a lengthy and expensive part of research and development. The Food and Drug Administration (FDA) demands that candidate pharmaceuticals pass through a three-phase process of human trials to demonstrate safety and baseline efficacy. The first two phases involve only small sample groups of test patients. The third phase involves a sample size of thousands of patients and carries huge costs. Generally, phase III trials need to demonstrate that a drug meets the necessary efficacy requirements with a 95 percent statistical certainty.

Drug Discovery

Drug discovery is the process by which new disease or sickness-fighting compounds are screened and identified. This is the first step in new drug development. During this phase, compounds are identified and tested using criteria such as efficacy, stability and bioavailability.

New Drug Approval

New drug approval from various regulatory bodies (such as the FDA) is the next step in bringing a drug to market, following a successful round of clinical trials. The regulators review rigorous statistical analysis and test results produced during the clinical trial phases. Some drugs may be "fast-tracked" if they treat a serious condition that does not currently have many viable treatment options. After a new drug has been approved, it is ready to move into the manufacturing process.

Post-Approval Research and Monitoring

During post-approval research and monitoring, pharmaceutical companies continue to collect data on the efficacy and use of a drug after it is approved and manufactured. They monitor factors such as safety, long-term side effects and potential secondary uses for the drug. Continued research can identify additional clinical value (new methods of delivery, combination of treatments, new uses, patient targeting, etc.) for drugs that have already been approved.

Pharmaceutical Manufacturing

The pharmaceutical manufacturing function is responsible for producing drugs on an industrial scale following testing (clinical trials) and regulatory approval. The process of manufacturing pharmaceutical products includes many unique components, including chromatography, milling, coating, granulation and pressing. Other facets of the pharmaceutical production process, such as batch integrity testing, quality assurance and facility maintenance, are common to other manufacturing operations. In some cases, pharmaceutical manufacturing groups may produce active pharmaceutical ingredients (APIs), while other manufacturers might purchase APIs in bulk from a third party and prepare them for consumption by adding certain compounds, binders and/or fillers.

Pharmaceutical Distribution

The distribution function within the pharmaceuticals industry is responsible for supplying drugs to pharmacies, hospitals and other healthcare facilities. In most cases, drug distribution is carried out by third parties that link manufacturers (pharmaceutical companies) with retailers (pharmacy and hospital networks).

Product Education and Compliance

The product compliance function is responsible for the final licensing of a drug (after clinical trials) and the subsequent labeling, education and information management related to that product. They ensure that products are labeled in accordance with requirements set forth by the Food and Drug Administration (FDA) and fact-check marketing/promotional materials that are used to market the drug to physicians and potential patients. In some cases, the product compliance group may audit company operations (manufacturing, drug testing, etc.) to ensure that all operations are in compliance with industry regulations.

Patient Assistance Programs (PAPs)

Patient Assistance Programs (PAPs) are initiatives funded by pharmaceutical companies to distribute free or reduced-rate medicines to people with low to moderate income or who are underinsured. The eligibility requirements for these programs may vary; some programs demand that the patient be uninsured, while others require that certain income levels are met. PAPs have been in existence since the 1990s, and have helped roughly 7 million patients since 2005, according to statistics kept by the Partnership for Prescription Assistance.

STAFFING IN PHARMACEUTICAL COMPANIES

"The management of staffing involves managing the organisation structure through proper and effective selection, appraisal and development of personnel to fill the roles designed into the structure"—Koonts and O' Donell.

Main functions of staffing are:

1. Manpower planning
2. Development of manpower

3. Fixing employment standards
4. Approaching the right sources
5. Selection
6. Placement
7. Training

Classification and Span of Workforce

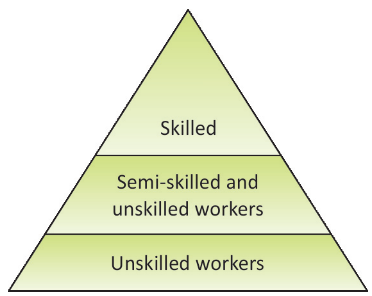


Fig. 1.13: Classification of workforce

Staffing procedure: The following elements are involved in staffing process/procedure (Fig. 1.14).

Sources of Recruitment

Sources of recruitment can be broadly divided into: 1. Internal sources; 2. External sources (Fig. 1.15).

E-RECRUITMENT

Today, "E-Recruitment" or otherwise called "Online recruitment" is a buzzwords in staffing process. This is a technology-based recruitment process. Websites such as "naukri.com" facilitate recruitment process. Besides using sources of service providers such as Monster, career builder.com, indeed, simply hired, glassdoor.com, AOL jobs, Snagjob.com, job.com, BEYOND.com, etc., individual organisations also create their own websites to recruit people, to different positions vacant in the firm. They advertise job positions in www and job seekers send their applications flashed on the site through e-mail.

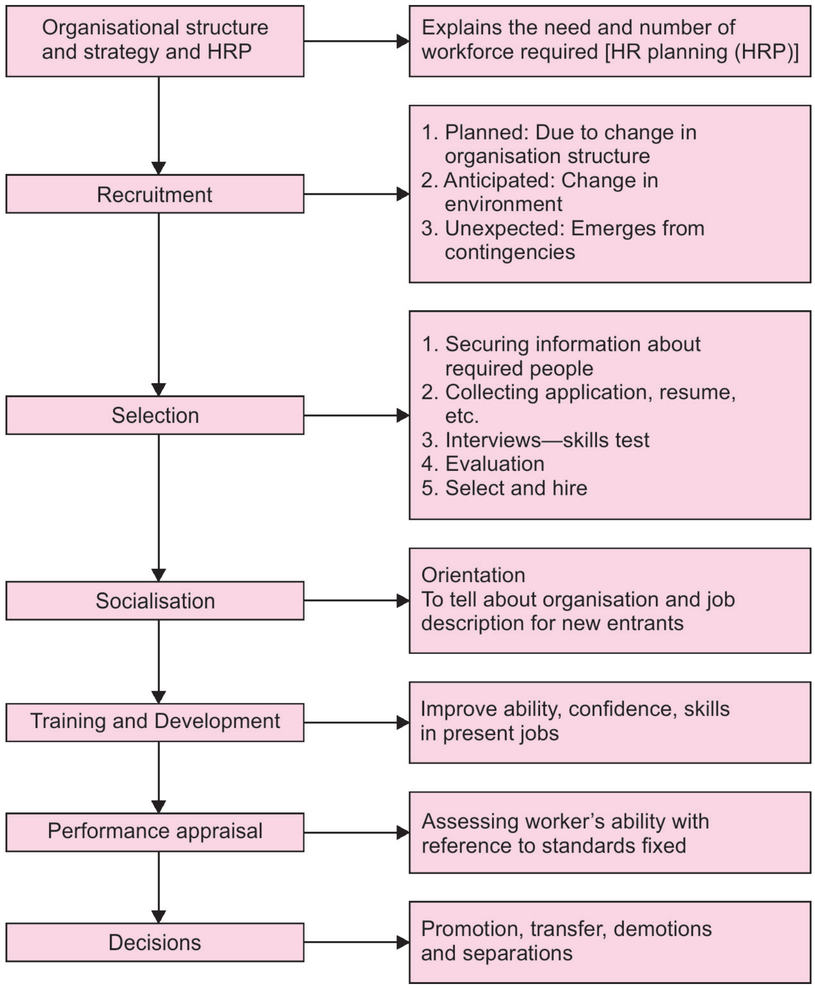


Fig. 1.14: Staffing process/procedure

There are two types of e-recruitment that a firm can select. (i) Job portals, which facilitate companies to post the job specifications on these portals and also they can search on these portals for suitable resumes posted on the sites which corresponds with job specification of the company, and (ii) Creating own portal for recruitment on the company's own site. Database for different job specifications can be developed on the company's site and can fill the vacancies as and when they are created.

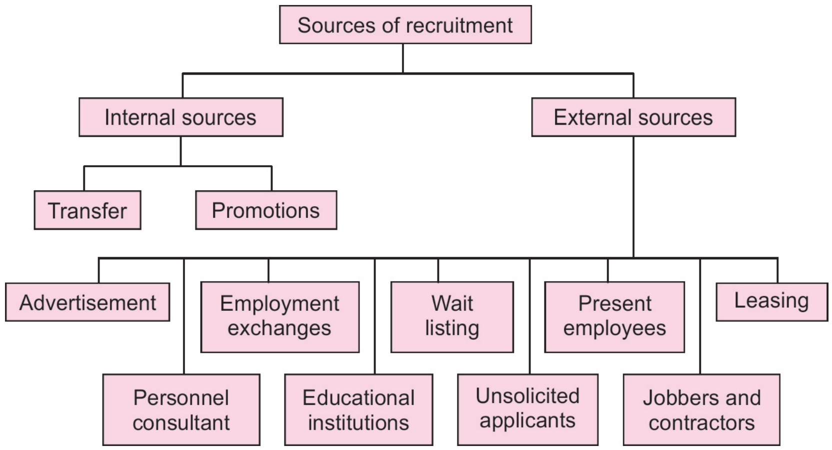


Fig. 1.15: Sources of recruitment

Job portals provide opportunity to job seekers to send resume to their portals and they are classified as per job description and create classified database to facilitate employers to get suitable men to their jobs. Job sites provide 24 × 7 service.

Pharmaceutical Job Titles

1. **Top management job titles:** Chief Executive Officer (CEO), Chief Operating Officer (COO), Chief Financial Officer (CFO), Chief Medical Officer (CMO).
2. **Research and development job titles:** Research Scientist, Clinical Research Specialist, Research Assistant, Clinical Research Scientist.
3. **Clinical trials job titles:** Research Investigator, Clinical Trials Research Associate, Clinical Research Coordinator, Clinical Cell Therapy Tech.
4. **Drug discovery job titles:** Drug Discovery Scientist, Immunology Scientific Investigator, Research Scientist.
5. **New drug approval job titles:** Regulatory Specialist, Regulatory Affairs Associate, Clinical Regulatory Associate.
6. **Post-approval research and monitoring job titles:** Clinical Research Monitor, Clinical Research Protocol Monitor, Post-Approval Compliance Monitoring Specialist.

7. **Pharmaceutical manufacturing job titles:** Production Chemist, Pharmaceutical Process Engineer, Pharmaceutical Manufacturing Engineer, Biotech Production Specialist.
8. **Pharmaceutical distribution job titles:** Quality Assurance Specialist, Warehouse Material Handler, Distribution Technician.
9. **Product education and compliance job titles:** Medical Information Specialist, Product Compliant Specialist, Medical Writer, Medical Editor, Clinical Operations Document Specialist.
10. **Patient assistance programs (PAPS) job titles:** Financial Assistance Representative, Patient Assistance Counselor, Patient Assistance Coordinator, Patient Advocate.

Typical Incentive Compensation Plans in Pharma Companies

Traditionally, pharmaceutical companies have attempted to attract and retain high-performing sales staff by offering exceptionally competitive total compensation packages. In recent years, companies have balanced this goal with budgetary constraints by devising variable pay schemes which account for a larger percentage of compensation.

Currently, the industry emphasis is shifting visibly from recruitment to retention activities. In order to combat the costly effects of voluntary attrition among sales representatives (estimated by the Hay Group to be $100,000 per individual), pharmaceutical companies must now ensure that their existing sales force remains productive, motivated, and committed by developing and refining strategic incentive and reward programs.

In addition, recent industry data regarding the labor market for sales staff indicates that hiring activity in the industry has stabilized after years of rapid expansion. If this trend continues, it will result in an overall decrease in the total number of new sales representatives hired within the next five years. In this environment, pharmaceutical firms must engage in an ongoing process of adjusting variable pay practices to ensure that retention goals are aligned with other critical business objectives.

The following structural features are visible among incentive programs in general:

- **Combination plans:** Some firms tend to use incentive structures that incorporate multiple performance metrics, a trend that is visible across functions and product.

- **Criteria weightings:** Companies that operate an incentive structure based on multiple metrics typically establish weighting systems that reflect the relative importance the firm places on certain desired behaviors. While incentive compensation schemes at profiled companies attempt to motivate sales performance, reward and recognition programs generally aim to reinforce exceptional sales force achievement.

This briefly highlights the following features of these programs:

- **Visibility and prestige:** Most companies attribute an exceptional degree of prestige, and
- Visibility associated with their top-tier reward and recognition programs,
- **Variety of recognition schemes:** The majority of firms offer multiple recognition schemes for different representatives,
- **Monetary and non-monetary rewards:** Most firms use non-monetary rewards, usually paid vacations, as part of their reward and recognition schemes,
- **Behavior-based rewards:** To varying degrees, companies may incorporate behaviors as well as sales goal attainment into reward and recognition schemes,

Evaluation and revision of variable compensation at firms may be characterized as a four-step process involving the following components.

- **Underlying business objectives:** Motivating sales staff to achieve volume and share growth is the most commonly-cited business purpose behind most types of variable compensation.
- **Feedback:** Firms gather feedback on their variable compensation programs through questionnaires, surveys, focus groups, interviews, and informal dialogue between managers and representatives.
- **Evaluation:** Many firms cite the difficulty of accurately gauging the efficacy of variable compensation due to the complexity of the factors that may affect individual sales performance.
- **Review and revision:** The majority of firms engage in an annual review of their incentive, reward, and recognition schemes and regularly make adjustments.

DIRECTING IN PHARMACEUTICAL COMPANIES

Once the organisational plans have been laid down, the structure being designed, and competent people brought in to fill various positions in organisation, direction starts. It is through that managers in pharmaceutical companies get the work done through people. It consists of

1. Issuing orders and instructions by a superior to his subordinates (communication).
2. Guiding, advising and helping subordinates in the proper method of work (leadership).
3. Motivating them to achieve goals by providing incentives, good working environment, etc. (motivation).
4. Supervising subordinates to ensure compliance with plans (supervision).

According to Koontz and O'Donnell directing includes all the above activities which a manager undertakes to influence the actions of his subordinates and achieve goals. It is the process of guiding, inspiring, supervising and commanding subordinates towards the accomplishments of goals.

Supervisors/managers: The functions mentioned above under Directing are undertaken by supervisors of managers. He should be good at human skills, technical skills and conceptual skills. He would be a good leader, organiser, planner and decision maker. A manager tries to integrate individual aspirations and organizational requirements. The focus is on developing employee capabilities and task-related skills so that he is able to meet the problems head on and accomplish effectively. The manager acts as a coach, a counsellor and facilitator.

CONTROLLING IN PHARMACEUTICAL COMPANIES

Organizational control in pharma companies is the process of assigning, evaluating and regulating resources on an ongoing basis to accomplish and organization’s goals. Through controlling function pharma companies achieve the following purposes:

1. Control makes preparation effective
2. Control makes sure that organizational activities are consistent

3. Execution and revision of plans
4. Bring order and discipline
5. Promotes coordination
6. Cope with uncertainty and change

Control Process

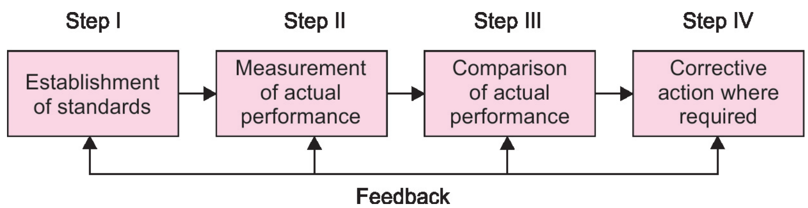


Fig. 1.16: Control process

Types of Control

Depending on the time at which control is applied, controls are of three types: (i) Feedback control, (ii) concurrent control, and (iii) feedforward control.

1. **Feedback control (historical or post-control):** It is the process of gathering information about a completed activity, evaluating the information and taking steps to improve similar activities in the future. Feedback control enables managers to use information on past performance to bring future performances into line with planned objectives. Critics of feedback control argue that it is like closing the gate after the horse is gone. Because corrective action is taken after the fact, costs tend to pile up quickly while problems and deviations persist. On the positive side, feedback control tests the quality and validity of standards. Standards that prove impossible to reach should be made more reasonable those that prove too easy need to be toughened.
2. **Concurrent control:** It is also called 'real time' control. Concurrent control techniques immediately consider any problem and analyse it to take necessary and corrective steps before any major damage is done Control chart is an example of this control. Concurrent controls are also known by another name 'steering controls' and occur while an activity is taking

place. The navigator of an aircraft who adjusts the aircraft's movements is an example of concurrent control. When you ride a bicycle, you must adjust your steering constantly, depending on the turns in the road, obstacles, changes in the terrain to keep your vehicle upright and move toward your destination.

3. **Predictive or feedforward control:** Here, the control system anticipates problems that the management encounters in future. Cash budget is an example of this type where the finance manager is in a position to estimate the next year's flow of cash. If there is a shortage of funds in a particular month, he can arrange for bank loan or some alternative. Predictive control is also frequently termed 'feedforward control'. Predictive control attempts to anticipate problems or deviations from the standard, in advance of their occurrence. It is, thus, a more aggressive, proactive approach to control, allowing corrective action to be taken ahead of the occurrence of the problem. One notable characteristic of feedforward control is that it anticipates problems and permits action to be taken before a problem occurs.

ROLE OF QUALITY CONTROL DEPT. IN PHARMA COMPANIES

Quality control department functions for assuring the quality of all the batches manufactured, at every stage of manufacturing/ processing drug products. This is achieved by performing the functions of QC system for the following areas:

1. Sampling, inspection and testing as per specifications of raw material for release or rejection and its documentation.
2. Sampling, inspection and testing as per specifications of packaging material for release or rejection and its documentation.
3. Sampling, inspection and testing as per specifications of in-process product for release or rejection for further processing or reprocessing and its documentation.
4. Sampling, inspection and testing as per specifications of final productions for release or rejection for further processing or re-processing and its documentation.
5. Release or rejection of every batch of drug products for distribution and sale.

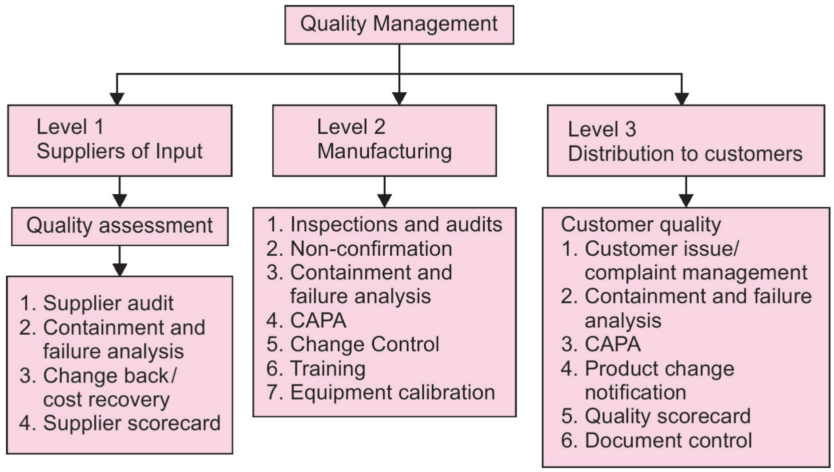


Fig. 1.17: Quality management levels and functions at each level

6. Stability testing and evaluation of shelf-life of products.
7. Microbiological analysis of raw material, finished products, water and environmental bio-burden monitoring.
8. Analytical investigation for complaints and product recalls
9. Analytical support for evaluating the change control proposals and systems.
10. Out of specification investigations for laboratory results.
11. Investigation of deviations in the analysis.
12. Analysis of returned products (salvage and disposal).
13. Internal quality system audits and quality review.
14. Analysis for control of non-conforming products.
15. Reference standards, working standards, solution preparations.

To achieve the objectives of quality control, functions of the department can be classified as follows:

1. To plan and manage all the activities of the quality control department. To assure the quality of all products manufactured by the company.
2. To co-ordinate with manufacturing department in controlling their process and products at every stage of manufacturing to meet the established specifications through testing, auditing and reporting.

3. To co-ordinate for development for specifications, the analytical procedure in coordination with Quality Assurance Dept. and R&D.
4. To review the adequacy and relevance of specifications, the analytical procedure in coordination with Quality Assurance Dept. and R&D.
5. To coordinate technical audits of the Quality Control Laboratory to determine the analytical quality systems are yielding the highest quality information and to ensure that the analytical instrumentation is functioning properly and calibration and servicing is as per schedule.
6. To be responsible for the quality control functions and records, which shall include: Maintenance of quality control records, control samples of raw materials and drug products each batch manufactured, records of release, quarantine or rejection of components and finished products, containers, closures and labels based on quality control test results, routines "good laboratory practices auditing" of the control process, and related areas.
7. To suggest and organize training programs for the development of technical and administrative skills of all the employees to meet with cGLP regulations on the continuous basis, which shall be done by co-ordination with Plant and Quality Heads.
8. To establish guidelines and procedures on cGMP and good laboratory practice—standard operating procedures of overall quality control activities. Protocols related to method/process/cleaning/analytical method validation, etc.
9. To evaluate the change control suggestions for overall reviews of non-conformances, failure investigations, analyzing the quality trends, investigations of market complaints, batch failure investigations, deviations, verifications of change control procedures updating the specifications test procedures, manufacturing processes, etc.
10. Validation of analytical test procedures, specifications, standard operating procedures (both pharmacopoeial and in-house).
11. To follow the reporting system to the Corporate Quality Head on the daily/weekly/monthly basis as per the standard procedure (Reporting System).