

MODULE 1: Introduction to Pharmacy Administration and Management

MANAGEMENT

- Management is defined as an act of managing people and their work, for achieving a common goal by using the organization's resources.
- It creates an environment under which the manager and his subordinates can work together for the attainment of group objective.
- It is a group of people who use their skills and talent in running the complete system of the organization.

ADMINISTRATION

- Administration is a systematic process of administering the management of a business organization, an educational institution like school or college, government office or any nonprofit administration.
- The main function of administration is the formation of plans, policies, and procedures, setting up of goals and objectives enforcing rules and regulations, etc.

| Basis for comparison | MANAGEMENT | ADMINISTRATION |
|----------------------|---|---|
| Meaning | An organized way of managing people and things of a business organization | The process of administering an organization by a group of people |
| Authority | Middle and Lower Level | Top Level |
| Role | Makes decision under the boundaries set by the administration | Takes all the important decisions of the organization |
| Concerned with | Policy implementation | Policy Formation |
| Area of operation | It works under administration. | It has full control over the activities of the organization |
| Applicable to | Profit making organization, i.e. business organizations | Government officers, military, clubs, business enterprises, hospitals, religious & educational background |
| Decides | Who will do the work? And How will it be done? | What should be done? And when is should be done |
| Work | Putting plans and policies into action | Formulation of plants, framing policies and setting objectives |
| Focus on | Managing work | Making best possible allocation of limited resources |
| Key person | Manager | Administrator |
| Represents | Employees, who work for remuneration | Owners, who get a return on the capital invested by them |

| | | |
|------------|--------------------------------------|--|
| Represents | Employees, who work for remuneration | Owners, who get a return on the capital invested by them |
| Function | Executive and Governing | Legislative and Determinative |

NATURE OF ADMINISTRATION

- ✓ It is universal
- ✓ It is holistic
- ✓ It is continuous & ongoing process
- ✓ It is goal oriented
- ✓ It is social & human nature
- ✓ It is dynamic
- ✓ It is creative or innovative

HENRI FAYOL

- Henri Fayol is widely regarded as the father of modern management. Fayol was an engineer who worked his way up to become a manager of a mining company in France.
- Fayolism** was theory of management that analyzed and synthesized the role of management in organizations.
- Henri Fayol provided one of the most influential modern management concepts of his time. He is founder of the 14 Principles of management and the five functions of management.

HENRY FAYOL'S ADMINISTRATIVE THEORY OF PRINCIPLES OF MANAGEMENT

1. Division of Work
2. Authority and Responsibility
3. Discipline
4. Unity of Command
5. Unity of Direction
6. Subordination of Individual Interest to organizational interest
7. Remuneration of personnel
8. The Degree of Centralization
9. Scalar Chain of Command
10. Order
11. Equity
12. Stability of Tenure of Personnel
13. Initiative
14. Esprit de Corps (Team Spirit)

1. DIVISION OF WORK

- In practice, employees are specialized in different areas and they have different skills.
- Different levels of expertise can be distinguished within the knowledge areas.
- According to Henri Fayol
 - Specialization promotes efficiency of the workforce and increases productivity.
 - Specialization of the workforce increases their accuracy and speed.

2. AUTHORITY AND RESPONSIBILITY

- In order to get things done in an organization, management has the authority to give orders to the employees.
- With Authority comes Responsibility.
- According to Henri Fayol, the accompanying power or authority gives the management the right to give orders to the subordinates.
- The responsibility can be traced back from performance and it is therefore necessary to make agreements about this.

3. DISCIPLINE

- Discipline means respect for the rules and regulations of the organization.
- Discipline may be Self-discipline, or it may be Enforced discipline.
- The workers must respect the rules that run the organization.
- To establish discipline, good supervision and impartial judgment are needed.

4. UNITY OF COMMAND

- The management principle 'Unity of command' means that an individual employee should receive orders from one manager and that the employee is answerable to that manager.
- If tasks and related responsibilities are given to the employee by more than one manager, this may lead to confusion which may lead to possible conflicts for employees.
- By using this principle, the responsibility for mistakes can be established more easily.

5. UNITY OF DIRECTION

- One head and one plan for a group of activities with the same objective.
- All activities which have the same objective must be directed by one manager, and he must use one plan.
- For example, all marketing activities such as advertising, sales promotion, pricing policy, etc., must be directed by only one manager.

6. SUBORDINATION OF INDIVIDUAL INTEREST TO ORGANIZATIONAL INTEREST

- There are always all kinds of interests in an organization.
- In order to have an organization function well, Henri Fayol indicated that personal interests are subordinate to organization (ethics).
- The primary focus is on the organizational objectives and not on those of the individual.
- This applies to all levels of the entire organization, including the managers.

7. RENUMERATION OF PERSONNEL

- Motivation and productivity are close to one another as far as the smooth running of an organization is concerned.
- remuneration should be sufficient to keep employees motivated and productive.
- there are two types of remuneration namely **non-monetary** (a compliment, more responsibilities, credits) and **monetary** (compensation, bonus or other financial compensation).
- Ultimately, it is about rewarding the efforts that have been made.

8. CENTRALIZATION

- Management and authority for decision-making process must be properly balanced in an organization.
- This depends on the volume and size of an organization including its hierarchy.
- Centralization implies the concentration of decision making authority at the top management (executive board).
- Sharing of authorities for the decision-making process with lower levels (middle and lower management), is referred to as decentralization by Henri Fayol.
- Henri Fayol indicated that an organization should strive for a good balance in this.

9. SCALAR COMMAND

- Hierarchy presents itself in any given organization.
- This varies from senior management (executive board) to the lowest levels in the organization. .
- Henri Fayol 's "hierarchy" management principle states that there should be a clear line in the area of authority (from top to bottom and all managers at all levels).
- This can be seen as a type of management structure.
- Each employee can contact a manager or a superior in an emergency situation without challenging the hierarchy.

10. ORDER

- A place for everything and everything in its place' the right man in the right place.
- There should be an Order for material things and people in the organization.
- There must be an orderly placement of the resources such as Men and Women, Money, Materials, etc.
- Human and material resources must be in the right place at the right time.
- Misplacement will lead to misuse and disorder.

11. EQUITY

- The management principle of equity often occurs in the core values of an organization.
- According to Henri Fayol, employees must be treated kindly and equally.
- Equity is a combination of kindness and justice.
- It creates loyalty and devotion in the employees toward the organization. The equity principle suggests that the managers must be kind as well as equally fair to the subordinates.

12. STABILITY OF TENURE OF PERSONNEL

- An employee needs time to learn his job and to become efficient.
- The employees should have job security because instability leads to inefficiency. Successful firms usually had a stable group of employees.
- Management strives to minimize employee-turnover and to have the right staff in the right place.
- Focus areas such as frequent change of position and sufficient development must be managed well.

13. INITIATIVE

- Henri Fayol argued that with this management principle employees should be allowed to express new ideas.
- This encourages interest and involvement and creates added value for the company.
- Employee initiatives are a source of strength for the organization according to Henri Fayol.
- This encourages the employees to be involved and interested.
- It allows the subordinates to think out a plan and do what it takes to make it happen.

14. ESPIRIT DE CORPS OR TEAM SPIRIT

- The management should create unity, co-operation, and team spirit among the employees.
- Managers are responsible for the development of the workplace; individually and in the area of communication.
- Team spirit contributes to the development of the culture and creates an atmosphere of mutual trust and understanding.

FUNCTIONS OF MANAGEMENT

These five functions focus on the relationship between personnel and its management and they provide points of reference so that problems can be solved in a creative manner.

1. PLANNING

- Planning is looking ahead.
- According to Henri Fayol, drawing up a good plan of action is the hardest of the five functions of management.
- This requires an active participation of the entire organization.
- With respect to time and implementation, planning must be linked to and coordinated on different levels.
- Planning must take the organization's available resources and flexibility of personnel into consideration as this will guarantee continuity.

2. ORGANIZING

- An organization can only function well if it is well-organized.
- This means that there must be sufficient capital, staff and raw materials so that the organization can run smoothly and that it can build a good working structure.
- The organizational structure with a good division of functions and tasks is of crucial importance.
- When the number of functions increases, the organization will expand both horizontally and vertically.

3. COMMANDING

- Managers need to implement the plan.
- Leading people in a manner that achieves the goals of the organization requires proper allocation of resources and an effective support system.
- Requires exceptional interpersonal skills and the ability to motivate people.

4. COORDINATING

- The process of tying together all the organizational decisions, operations, activities and efforts to achieve unity of action for the accomplishment of organizational objectives.
- When all activities are harmonized, the organization will function better.
- Coordination therefore aims at stimulating motivation and discipline within the group dynamics. This requires clear communication and good leadership.

5. CONTROLLING

- Monitoring function that evaluates quality in all areas and detects potential or actual deviations from the plan, ensuring high-quality performance and satisfactory results while maintaining an orderly and problem-free environment.
- Controlling includes
 - Measurement of performance
 - Identification of deviations
 - Institution of corrective actions

MODULE 2: Organization

ORGANIZING

Is the process of classifying and categorizing personnel, establishing relationships among them and defining their authority and responsibilities.

Organizing is primarily focused on determining the functions of individual employees in an organization and how their individual efforts should be integrated to attain organizational objectives collectively.

THE FIVE MAIN STEPS OF ORGANIZING PROCESS

Step 1 - reflect on plans and objectives

Step 2 - establish major tasks

Step 3 - divide major tasks into subtasks

Step 4 - allocate resources and directives for subtasks

Step 5 - evaluate results of operationalizing the organizing strategy

FUNDAMENTALS OF ORGANIZING

1. The structure must reflect objectives and plans which act as the base of the organization's activities.
2. The structure must reflect authority given to top and middle management.
3. The structure should reflect the external environment to allow members of the group to contribute ideas and solutions and help people achieve objectives efficiently and effectively.

IMPORTANCE OF ORGANIZING

- Organizing is important in the overall management of an organization because it is the primary mechanism that managers use to implement the plans.
- It also provides the structure for how material and human resources are utilized in the organization.

METHOD OF ORGANIZING THE PHARMACY

- ✓ Defining the goals of the pharmacy
- ✓ Identifying and defining each task to be completed
- ✓ Grouping related tasks into specific job that can be assigned to an employee or a team of employees
- ✓ Grouping employees unto job units that are related in some manner
- ✓ Assigning a manager to each unit, providing him or her with the necessary authority and responsibility to ensure the completion of the tasks within the unit
- ✓ Arranging these units, relative to one another both horizontally and vertically and establish who reports to whom
- ✓ Establishing a control system for monitoring progress and achievements of each unit.

ORGANIZATION

- A group of individuals working to reach some common goal
- Organizations can be very small in numbers of personnel (fewer than 3) of very large (more than 5,000)
 - Personnel can include staff (e.g., ward clerk, technician, pharmacist, nurse, or physician) and management and administration (e.g., owner, president, vice president, manager, director, supervisor)

- Both staff and administrators are important to the overall functioning of any organization.

ORGANIZATION

- Pharmacists needs to understand not only the technical and professional aspects of their job (i.e. Dispensing, monitoring and counselling)
- They also must understand how the organization for which they work function and how people within them work.

ORGANIZATIONAL BEHAVIOR

- Systematic and scientific analysis of individuals, groups, and organizations.
- Its purpose is to understand, predict, and affect human behavior to improve performance of the individuals, which affects the functioning and success of the organizations in which they work.
- To be effective, managers must be able to understand why people in their organizations behave in certain ways. They must also be able to explain decisions and seek information from colleagues and employees even if turns out to be negative.
- Organizations exert control over their employees through rewards or sanctions to encourage fulfillment of organizational goals and objectives.

ORGANIZATION CULTURE

- Defined as the system of shared meaning held by members that distinguishes one organization from another.

CULTURE

- Refers to the understandings and belief regarding how "things are done around here".
- Once the culture is in place, practices within the organization act to maintain it by exposing employees to a set of similar experiences.
- "A strong culture is characterized by the organizations' core values being both intensely held and widely accepted.
- A weak culture is characterized by just the opposite-vagueness, ambiguity, and inconsistency.
- A strong culture will have a greater effect on the climate than a weak one because the high degree of sharedness and intensity creates an internal climate of high behavioral control.

ORGANIZATIONAL STRUCTURE

3 MAJOR ASPECTS

DIFFERENTIATION

Refers to the degree to which units are dissimilar.

FORMALIZATION

Refers to the degree to which jobs in the organization is standardized.

CENTRALIZATION

Refers to the extent to which decision making is concentrated at a single point in the organization.

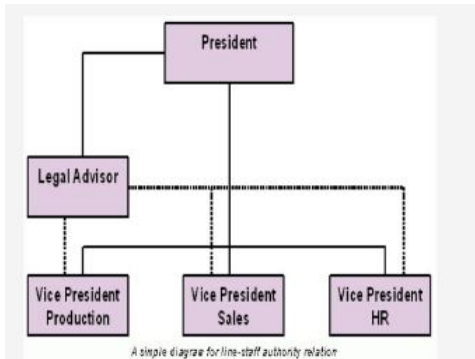
DIFFERENTIATION = Horizontal, Vertical, Spatial

HORIZONTAL DIFFERENTIATION

- This type of differentiation describes the differences among workers or units in an organization.
- This may include their education, type of training, and the tasks assigned to them.
Since pharmacies not only provide pharmacy services but also non pharmacy related items, all employees must be oriented on offering such services and items to the consumers.
- Horizontal differentiation may also refer to the multi-ownership of different firms from a variety of related industries.
For example, a health system can own several firms with different functions such as hospitals, health care and nursing facilities, and managed - care businesses.

VERTICAL DIFFERENTIATION

- Focuses on the differences in hierarchical positions.
- This involves "the chain of command" in an organization which is the number of levels between the top management or owner of the organization and the rest of the staff.
- Vertical differentiation typically is represented by what is known as an organization chart.
- An organizational chart is used to depict the relationships and the hierarchy of authority in an organization.
- The degree of authority and the number of staff vary depending on the size of the organization. The smaller the organization, the less positions of authority are present in the hierarchical structure. -
- Many independent community pharmacies started expanded, owners hired individuals to supervise out different this way. As pharmacies grew and areas or functions of the store. ?s owners branched out into running additional stores in various locations; more personnel were needed to run the day-to-day operations of the establishments.



LINE VS STAFF AUTHORITY

Line Authority Function

- ✓ Solid lines represent direct reporting relationships important to the overall objectives of the organization.
- ✓ The right to command immediate subordinates in the chain of command Example: Vice president, directors, managers and staff.

Staff Authority Function

- ✓ Dashed line represent advisory position that supplement and support the line-authority positions.
- ✓ The right to advise but not command others. Example: chief personnel officer

LEVELS OF MANAGEMENT

Functions of the different levels of Management

| Top Management | Middle Management | Lower/ Operative Management |
|--|--|---|
| To establish objectives or goals | To prepare policies | Interpret & divide plans of the management into short-range operating plans |
| To make policies and frame plans | To prepare organizational set up in their own departments | Evaluate the performance of the workers |
| To set up organizational framework | To recruit and select suitable operative & supervisory staff | Report to the middle management |
| To assemble the resources of money, men, materials, machines and methods | To motivate personnel | Supervision of the workers |
| To establish effective control of the operations | To cooperate with other dept. for ensuring a smooth functioning of the entire organization | |
| To provide overall leadership to the enterprise | To assign activities, duties and responsibilities for timely implementation of plans | |
| | To make suitable recommendations to the top management for the better execution of plans and policies. | |

LEVELS OF MANAGEMENT

Examples of Positions in Different Management Levels

| Top Management | Middle Management | Lower/Operative Management |
|----------------------|---------------------------------|----------------------------|
| Owners/ Shareholders | Purchase manager | Supervisors |
| Board of Directors | Marketing manager | Sales officers |
| Chairman | Production manager | Account officers |
| Managing Director | Finance manager | |
| Chief executive | Divisional & Sectional Officers | |
| General manager | | |

SPATIAL DIFFERENTIATION

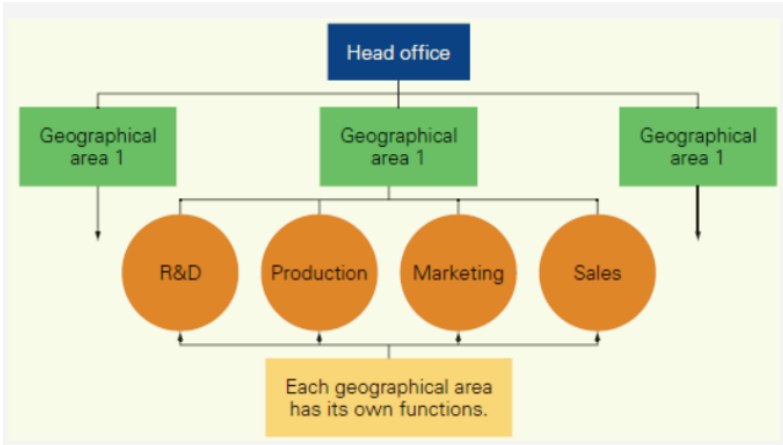
- The degree to which the location of an organization's unit is in one place or spread across several locations.
- As organizations spatially differentiate, more coordination between these units are necessary.
Independent Community Pharmacy
Have only one location that has all operations in one place

Chain Pharmacy

Can have multiple units spread across a city, state, or entire regions of the country.

- Also occurs when different departments are located in different areas.

Example: A pharmaceutical manufacturer may have its research and development departments in one city or state and the sales and marketing division in other areas of the country or the world.



FORMALIZATION

This organization emphasizes the maintenance of the structure.

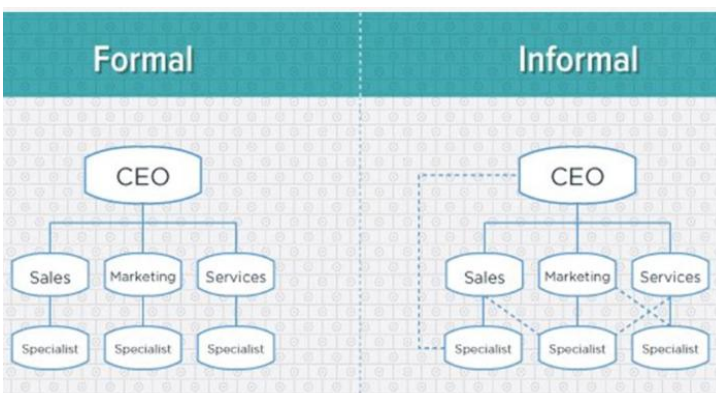
Maintenance involves:

Rules - degree of organizational control of employee behavior

Procedural Specification - defined techniques that organizational members must follow when dealing with specific situations.

Technical competence - the "universal" standards as defined by the organization and the extent of its use in selecting personnel and advancing processes

Impersonality - treatment of both members of the organization and individuals outside the organization regardless of their individual qualities.



Formal Organizational Structure

Formal Organization is an organization in which job of each member is clearly defined, whose authority, responsibility and accountability are fixed.

Informal Organizational Structure

Informal Organization is formed within the formal organization as a network of interpersonal relationship when people interact with each other.

CENTRALIZATION

- Refers to the concentration of decision-making power at a single point in the organization.
- The highest levels of management usually make most of the policy decisions in a centralized organization.
- The recent trend however, has been to **decentralize** decision-making and move it to lower levels of management and/or even to staff level employees.
Example: A hospital pharmacy that has several satellite pharmacies located throughout the hospital

DIVISION OF LABOR

- This can be observed in pharmacies where pharmacists are assigned with specific functions such as dispensing or caring for patients.
- Pharmacists can specialize in a particular field (geriatrics, pediatrics or disease states) ? It is expected to result in heightened efficiency in the utilization of specialized skills of individual employees.
- The disadvantage of dividing labor is that employees assigned with singular tasks will not develop skills sets and they may find the job monotonous.

PARITY OF AUTHORITY AND RESPONSIBILITY

- Responsibility for decisions cannot be passed on while the authority to make them can be shared and/ or given to others.
- Delegation of authority, however, is often not accomplished with smaller pharmacies. Owners who have gone into business to become bosses after developing and nurturing their pharmacies tend to be unwilling to share control with several other people.
- Even in companies where delegation is present, owners tend to centralize authority during difficult situations or when they feel that their employees are not performing well.

UNITY OF COMMAND

- This refers to the idea that an individual employee must report to only one supervisor or manager.

SPAN OF CONTROL

- This refers to the number of employees a manager can effectively control.

DEPARTMENTALIZATION

This refers to the categorization of individuals according to the specific tasks must perform. One of the advantages of having departments is that the individuals in one department share common vocabulary, training, and expertise.

ORGANIZATIONAL TEAMS

- ✓ One of the newest forms of organizational structure involves the establishment of teams.
- ✓ Teams in health care is not new
 - Teams of clinicians working together to provide care to patients in hospital and clinical setting.
 - Teams of pharmacists and technicians working together at a community pharmacy on a particular shift.
- ✓ As health care becomes more specialized, there will be increasing need for team structures to coordinate the work of individual specialists.

TEAM

Defined as a small number of people who are committed to a common purpose, who possess complimentary skills and who have agreed on specific performance goals for which team members hold themselves mutually accountable.

PHARMACIST'S ORGANIZATIONAL BEHAVIOURS

1. JOB SATISFACTION
2. ORGANIZATIONAL COMMITMENT
3. JOB STRESS
4. JOB TURNOVER

ORGANIZATIONAL TEAMS

| TYPES OF TEAM | DESCRIPTION |
|-------------------------|---|
| WORK TEAMS | <ul style="list-style-type: none"> ✓ Continuing work units responsible for producing goods or providing services. ✓ Usually directed by managers who makes most of the decisions on what is done, how it is done and who does it. |
| PARALLEL TEAMS | <ul style="list-style-type: none"> ✓ Draw members from different work units to perform functions that the regular organization is not equipped to perform well. ✓ Have limited authority and usually make recommendations to an individual higher up in the organizational hierarchy. ✓ Example: Quality improvement team in a health system. |
| PROJECT TEAMS | <ul style="list-style-type: none"> ✓ Produce one time output such as a new product or service. ✓ Usually draw their members from different units so that specialized expertise can be applied to the project at hand. ✓ When the project is completed, the member either return to their functional unit or move on to the next project. ✓ Example: New Drug Development Team |
| MANAGEMENT TEAMS | <ul style="list-style-type: none"> ✓ Coordinate and provide direction to units under their authority. ✓ Exist at the board of directors or trustee level, senior management level or department level. |

CHARACTERISTICS OF SUCCESSFUL TEAMS

| CHARACTERISTICS | DESCRIPTION |
|-------------------------------------|--|
| CLEAR GOALS | Allows everyone to understand the function and purpose of the team. |
| DEFINED ROLES | Allows everyone to understand why they are on the team and enables them to form clear individual and team-based goals. |
| OPEN AND CLEAR COMMUNICATION | Essential for team building and is based on effective listening. |
| EFFECTIVE DECISION MAKING | The team must be in agreement with the decisions that are reached through a consensus building process. |
| BALANCED PARTICIPATION | Ensures that all members are fully engaged. |
| VALUED DIVERSITY | Must recognize each members expertise and value variety of knowledge, skills and abilities. |
| MANAGED CONFLICT | All team members feel safe to freely state their points of view without fear of reprisal. |
| POSITIVE ATMOSPHERE | Requires a climate of trust be developed that requires team members to spend significant amount of time with each other. |
| COOPERATIVE RELATIONSHIPS | Team members need to recognize that they need one another's knowledge and skill to complete the task. |
| PARTICIPATIVE LEADERSHIP | Need to have leaders who are willing to share responsibility and recognition with the team. |

PHARMACIST'S ORGANIZATIONAL BEHAVIOURS

- ✓ Examining pharmacists' work-related attitudes and behaviors is important if an organization wants to improve the positive and decrease the negative actions of employees.
 - Increased absenteeism, tardiness, and counterproductive behaviors such as not completing work in a timely manner or theft will decrease organizational productivity and performance significantly.
- ✓ Economic consequence of decreasing profitability of the organization.
- ✓ An unhappy co-worker also can make the work environment unpleasant for other workers.
- ✓ Negative organizational attitudes also can compromise patient care.
- ✓ An unhappy or dissatisfied pharmacist may be less motivated to keep skills and knowledge levels current.
- ✓ Job dissatisfaction also has been found to be associated with an increased risk of medication errors.
- ✓ The physical and mental health of the pharmacists also can suffer, owing to the stress of working in an unappealing pharmacy environment with heavy workload.

1. JOB SATISFACTION

An emotional response or as a comparison between expectations and the perceived reality of the job as a whole.

STRONG PREDICTORS OF JOB SATISFACTION IN PHARMACY

- Performing more clinical or non distributive work activities.
- Higher levels of autonomy
- Recognition
- Ability utilization
- Good environmental conditions (e.g. Better work schedules, less workload, good workplace teamwork)
- Professional commitment
- Working in an independent pharmacy environment.

FACTORS ASSOCIATED WITH LESS SATISFACTION

- Being younger
- Male
- Non white
- In a staff position
- Working full-time
- High role stress
- Negative interpersonal interactions with either co-workers, management or patients.

2. ORGANIZATIONAL COMMITMENT

- Defined as both an emotional attachment and as accepting the organizations goal and values, putting forth effort, and wanting to maintain membership.
- Important because it is related to reduced job turn over intention for pharmacists.

Factors Enhancing Organizational Commitment for Health Care Professionals

1. Appropriate compensation and benefits
2. Have access to important organizational information
3. Resources to perform job
4. Opportunities for advancement within the organization.
5. Organizational support.

3. JOB STRESS

Factors the increases job stress.

- Role stress in the form of role conflict
- Role ambiguity
- role overload
- and work-home conflict increases job stress
- Job dissatisfaction

Stress that continues to be ignored can lead to a phenomenon known as burnout.

BURNOUT has been conceptualized as a problem confined to the individual however, growing evidence suggest that it is tied with the social environment of the workplace.

4. JOB TURNOVER

- One of the pressing concerns of organizations.
- Decreased productivity from voluntary turnover is very costly to an organization because less experienced workers must be used to replace the more experienced workers who leave.
 - Advertising, recruiting and training a replacement employee (monetary)
 - Lost productivity owing to the time spent bringing the new employee up to speed.

REASONS FOR CHAIN PHARMACISTS LEAVING THEIR JOBS

- Inflexible and long working hours
- Inadequate support personnel
- Job dissatisfaction
- Role stress
- Culture and climate factors
- Personal variables (children, race, age, education, major life event e.g. Getting married in family)

MODULE 3: Management Essentials for Pharmacists

Management

- ✓ The art of maximizing productivity by using developing people's talent while providing them with self-enrichment and opportunities for growth.
- ✓ Also concerned with the allocation and use of resources to accomplish task and achieve objectives.
- ✓ There is a shortage of pharmacist managers, so many career opportunities are available for those who are interested in pharmacy management.
- ✓ Paths to achieve a management career include formal education (management degree) and/or informal training through on-the-job experience.

Examples of Pharmacy Management Career Opportunities

| Setting | Managerial Roles |
|-------------------------|--|
| Academia | Dean, Assistant/Associate Dean, Director of Student Admissions, Director of Graduate Studies |
| Association Management | Manager, Senior Manager, Chief Executive Officer Director, Vice President |
| Community Pharmacy | Store Pharmacist, Pharmacy Manager, Regional Manager, Owner |
| Government | Chief of Regulatory Affairs, Clinical Reviewer |
| Health System | Operations Pharmacists, Director of Pharmacy, Clinical Coordinator |
| Long Term Care | Consultant Pharmacist, Pharmacist Manager |
| Pharmaceutical Industry | Sales manager, Marketing Manager, Director, Medical Science Liaison |

Essential Management Competencies

1. Knowledge of Organization Context and Environment
2. Human Resources Management
3. Communicating with impact
4. Organizing team meetings
5. Planning for contingencies, crisis and exit strategies
6. Managing time
7. Managing-up
8. Self Insight

Knowledge of Organizational Context and Environment

- **Effective Managers**
Understand the context in which their organizations exist, the organization's unique culture, and the industry and organization-specific knowledge required to get things done.
- **Effective Pharmacist Managers**
 - Utilize **formal and informal resources** to learn who is who, what matters, and how things work.
 - How do they obtain this knowledge?
Forge relationships with people throughout the organization, read corporate reports, and analyzed who is promoted and why, note which issues receive the most attention from leadership.

Human Resources Management

- Most pharmacist managers are responsible for personnel management activities including:
 - Hiring
 - Motivating and Engaging
 - Establishing Goals
 - Providing feedback
 - Evaluating performance
 - Coaching
- Effective managers should surround themselves with talented people and develop those individuals into high-performing team members who can translate vision into reality.
- ✓ **Hiring Excellent People**
 - Organization success is most likely when a manager make wise choices about the people who join his or her pharmacy team
 - Hiring the right people is critical to a manager's success as the right employees are essential for executing projects and achieving results.
 - Search and hiring process
 - Most managers view these activities as a distraction from their "real work"
 - Hiring the wrong people waste valuable time (requires manager to address mistakes or bad behaviors)
- ✓ **Motivating and Engaging Employees**
 - Most believe that good managers have the ability to motivate employees, some suggested it is a **manager's job to avoid demotivating employees.**

EXPECTANCY THEORY

- Victor Vroom developed the expectancy theory
- "employee's likelihood of tackling a task is related to the **probability of the ability to complete it** and the **possible outcome or consequence** of doing so"
- Influenced by three factors – expectancy, valance and instrumentality

According to Vroom's Expectancy Theory, an Employee's Motivation is influenced by Three Factors:

EXPECTANCY- Does the employee believe he or she can achieve the task?

VALENCE - Does the employee believe that completing the task will be personally beneficial or that it will lead to unfortunate consequences?

INSTRUMENTALITY - What is the probability that completing the task will lead to the outcome desired by the individual?

- How can a pharmacist manager ensure their employees are engaged?
 - Although competitive and **equitable pay matters**, decades of research and hundreds of studies have demonstrated that while money can be a demotivator, **it rarely matters most to employees.**
 - Many pharmacists enter the profession because they are **interested in providing patient care.**

Examples of Nonmonetary Motivators

| Method | Description | Examples |
|--------------------------------------|---|--|
| RECOGNITION | Recognize people's achievements This lets people know their efforts are appreciated and facilitates work for future recognition | Publicly recognizing the technician or pharmacist who routinely provides excellent customer service. |
| CELEBRATION | Celebrate victories along the way. Celebrations do not have to be large scale- they can be as simple as tickets to a ball game or lunch coupons to a local restaurant | Organize a potluck luncheon with your staff. Everyone can participate in the celebration of their own achievements |
| COMPELLING MISSION | Create a mission that everyone adheres to. The best creation process incorporates everyone's input to develop a strong mission. | Seek input from your pharmacy staff and others to develop medication-use safety mission statement for the department. |
| BALANCE OF ACHIEVEMENT AND CHALLENGE | People want to accomplish their goals while still knowing there is room to grow. They need achievement as much as they need challenge | Involve your technician and pharmacists in the strategic planning of the department and organization. |
| INCREASED RESPONSIBILITY | One of the most often cited reasons for employees to put extra effort is having responsibility for results. When employees are allowed to make decisions and produce results on their own, they are more motivated to volunteer and go beyond the call of duty. | Create department report card, and let the staff choose the things they want to be measured on. Help them understand the important of each metric to the department. |

| | |
|--------------|--|
| BELONGING | Because these individuals find the social aspects of their job to be the most meaningful, you can motivate them by making them feel as if they are part of a larger group. Example: Arrange meetings where they can collaborate and share ideas, or assign them to project teams. |
| INDEPENDENCE | Provide clear goals and allow these employees to find the best way to produce results. When possible, offer them the flexibility to set their own hours and choose projects. |
| RESPECT | Recognize employees' contributions and acknowledge the value of their opinion. Give them time to express their perspective, and do not interrupt them while they are talking. Listen to them carefully and provide them with undivided attention when interacting. |
| EQUITY | Take care to be fair when making decisions about your staff's work schedules, job titles, scope of responsibilities, pay and benefits to ensure there are no hints of inequities. Explain you rationale for making decisions so that the employees will understand the process you used to make choices. |

What is the best way to determine what motivates your staff? Simply ask them

- **Establishing Goals and Performance Standards and Providing Feedback**

- ✓ **Establishing Goals and Performance Standard**

- Employees look to their managers to establish clear expectations regarding work performance and results, and they want to know which performance standards or outcome measures, including behaviors and metrics.
 - Employees are more likely to be engaged in their work **when they know what is expected of them.**

- **ORIENTATION PROGRAMS**

- Are helpful in demonstrating correct application of skills and explaining information systems and processes

- DO NOT explain which expectations an employee must meet and how performance is measured.

- **SMART GOALS**

- **SPECIFIC** - Well defined, clear to anyone who has basic knowledge of the project.

- **MEASURABLE** - Know whether the goal is obtainable and how far away completion is.

- **AGREED UPON** - Agreement with all the stakeholders on what the goal should be.

- **REALISTIC** - Within the availability of resources, knowledge, and time.

- **TIME BASED** - Enough time to achieve the goal

- Not too much time, which can affect project performance.

Factors Influencing Motivation

| Factors | Strategy |
|------------|--|
| ATTAINMENT | Motivate employees introducing new tasks that build on one another. Allow them to work toward both short and long term goals, thereby creating record of achievements. |
| POWER | Treat employees like in-house experts, and frequently ask them for advice, This will instantly plug employees into what makes them feel motivated because they will savor the chance to offer their opinions and see that you take them seriously. |

✓ Providing Performance Feedback

- All employees require regular communication about things that are working well and aspects of their performance that merit attention.
- It is not uncommon to hear employees say the only time they receive feedback is during their annual evaluation.
 - There should be an ongoing communication between managers and employees throughout the year.

Failing to provide feedback is a failure to manage.

FEEDBACK

- Serves as both a preventive and a corrective measure.
- A mechanism not only to help identify and develop solutions to potential work-related barriers or problems but also to **get assignments back on track when problem arise or when mistakes are made.**
- Critical aspect of managing employees and accomplishing desired results.

✓ Coaching for Success

- When employee performance is less than what it should be, and simple feedback is not enough to improve performance, employees may need more active support to be successful.

COACHING

- An **interactive process** through which managers and supervisors aim to enhance employee performance and capabilities.

Communicating with Impact

• COMMUNICATION

- One of the most important management competencies, it includes:
 - Sharing information through verbal means, body language, written documents and compelling presentations.
- Pharmacist managers who master communication have a unique ability to **connect with people to achieve organizational results.**
- **Effective communication** relies on two engaged parties who are both **focused on success.**
- Strong communicators understand the:

- FOUR BASIC ELEMENTS OF COMMUNICATION -

1. The sender
2. The receiver
3. The message
4. The environment

- Strong communication skills are especially important when there is a need to **negotiate with others, solve problems, or resolve conflicts.**

✓ Negotiating with Others

- In pharmacy setting, pharmacists and pharmacist manager may negotiate prices or delivery schedules with vendors, formularies with insurance with insurance companies, and schedules and duties with employees.

NEGOTIATION

- A voluntary attempt, through direct dialogue, to achieve goals or resolve conflicts that arise from competing needs, interest and objectives.

✓ Solving Problems and Managing Conflicts

- Managers with **strong negotiation skills** are typically better equipped to solve problems and manage conflict than those without these skills.
- **PROBLEM SOLVING STEPS:**
 1. Define the problem
 2. Analyze the problem
 3. Develop possible solutions to the problem
 4. Analyze proposed solutions
 5. Select the best solution given the environment and parties involved.
 6. Plan the next course of action (or, how you will implement the solution.
- In pharmacy setting, opportunities for conflict abound.
 - A patient may be angry about the cost of a medication or its side effects.
 - An employee may take issue with the way you have planned the week's schedule.
- **GUIDE ON MANAGING CONFLICTS**
 - Treat the other person with respect.
 - Define the conflict by determining the underlying interest.
 - Communicate understanding
 - Explore alternatives
 - Agree on the most workable solution
 - Document the agreed-upon resolution to make sure both parties understand and support the outcomes.
 - Conduct a post-negotiation evaluation

ORGANIZING TEAM MEETINGS

- Team meetings set the **tone for interactions with employees** and, for the first-time manager, serve as the true **management initiation.**
- Managers should create a supportive, nonthreatening atmosphere in team meetings.
 - Make everyone feel comfortable.
- Meetings should occur regularly to keep the team apprised of relevant information, events, and projects.

STRATEGIES TO PREPARE FOR A TEAM MEETING:

- Make a list of questions that employees may ask, including issues that individuals have already raised in one-on-one meetings.
- Managers should consider responses to each question, noting important points to express.
- Managers should also ask themselves:
 - What is the key message?
 - Which words or phrases will best convey the importance of the message?
 - What is the best format to communicate clearly and concisely.

STRATEGIES TO PREPARE FOR A TEAM MEETING:

If possible, managers should hold meetings in a conference room where everyone can sit together, and arrange the seats in a **circle so that all participants are positioned as peers.**

Planning for Contingencies, Crisis and Exit Strategies

- Effective managers are good planners who **manage their time well, establish reasonable budgets, deploy people appropriately, and prepare for contingencies.**
- Managers cannot possibly prevent all emergencies, but they can take steps to minimize surprises.
- **CONTINGENCY PLANNING**
 - Refers to the development of strategies to address possible future risks, problems, or undesirable situations that could have serious negative consequences for the organization.

STEPS IN CONTINGENCY

1. Identify potential risk or problem scenarios
 2. Set priorities and goals for these scenarios
 3. Identify a range of strategies to address the risks or problems
 4. Allocate resources and assign responsibilities for implementing strategies
 5. Decide when and how strategies should be implemented.
 6. Implement strategies as needed to achieve priorities and goals
 7. Evaluate strategies to determine if they are effective
- Having contingency plans in place is an important aspect of **crisis management.**
 - Example:
 - A pharmacy that faces the depletion of an important medication in its stock. A prepared manager and department would have a contingency plan in place for obtaining emergency supplies.
 - Resignation or extended leave of a highly trained employee. If there are no adequate numbers of trained back up technicians, there could be delay in services or the potential
 - The exit of a manager or leader from an organization may be considered a crisis-level event.
 - However, **well planned and executed exits** may ultimately benefit both the exiting individual and the organization.

EXIT STRATEGIES

- Are plans for leaving a position, investment, program, or business.
- Allows a person or entity to withdraw from a situation on a positive note.
- Should leave both parties well positioned to move forward to future achievements.
- May involve succession planning

SUCCESSION PLANNING

- Defined as identifying and developing or training other individuals who might **assume the individual's responsibilities** in the post-exit organization.
- **Assures continuity of work** within the organization during the transition period.

Managing Time

- Requires understanding one's workload, identifying priority tasks, staying organized, and remaining flexible in the face of emergent situations.

- Managers can employ several strategies to better manage their time such as:
 - Establishing priorities
 - Using to-do-list
 - Establishing meeting agendas
 - Using scheduling and organizational tools
Electronic calendars

• **DELEGATING**

- Effective delegating is one of the best time management skills a manager can develop.

- Delegation is most effective when managers:
 1. Entrust employees with job
 2. Give employees adequate freedom to get a job done (empowering employees)
 3. Provide employees with appropriate level of support to get job done well, including information, training and resource
 4. Hold employees accountable to produce desirable outcomes.

Delegation is most likely to lead to successful outcomes when the manager is willing to take these steps:

- Select qualified individuals
- Delegate tasks of significance
- Exhibit confidence
- Delegate the proper authority to complete task and convey accountability for completion
- Supervise according to employees follow-up style
- Give employees room to fail (and then hopefully succeed)
- Provide adequate directions and ensure the employee understands them
- Focus on outcomes rather than deadlines
- Treat employees like grown-ups
- Give praise and credit for a work well done.

Managing Up

- The process of **consciously working with your boss** to obtain the best possible results for you, your boss, and your organization.
- A method for developing a **positive and effective relationship** with the supervisor.
- A deliberate effort to bring **understanding and cooperation** to a relationship between individuals who often have different perspectives.

Areas on which you as a pharmacist or pharmacist manager should concentrate to build a solid relationship with your managers.

- Clarify roles and expectations so that both you and your manager understand you task, responsibilities, and priorities
- Know and adhere to your manager's work and communication styles to facilitate effective interactions.
- Provide your manager with necessary and complete information, all relevant news, and your concerns/ issues/ positions.
- Develop a trusting relationship
- Assist your manager in better managing his or her time,
- Provide your manager with sincerely positive comments and express appreciation
- Disagree with your manager tactfully, respectfully, and in private when you believe it is appropriate and in the best interest of the organization.

Managing Up Strategies

- Enhance the reputation of your manager
- Never criticize your manager to others
- Never "show up" or correct your manager when others are around
- Be nice to everyone in the department
- Always give credit where credit is due
- Never put others down
- Honour your commitments
- Present options to your manager
- Pay attention to details
- Find out how often and in what manner your manager wants to hear from you.
- Determine your manager's preferred communication style
- Remember your priorities
- Be a role model
- Serve as a resource
- Show initiative
- Communicate well
- Check your ego
- Seek advice and feedback
- Watch and learn
- Look professional
- Manage your own conflicts

Accurate Self-Insight

Just As Managing Your Boss Is Important, So Is Managing Yourself

- Regular request for feedback can reveal opportunities to *improve your own effectiveness*.
- A **360-degree feedback process** allows for information on performance to be received from all angles
 - Those who report to you
 - Your peers who work alongside you
 - Your manager

3 Ways To Solicit Employee Feedback Effectively

SEEK CASUAL ADVICE

By showing interest in employees' ideas and opinions, managers can increase employees' willingness to provide honest feedback and offer manager valuable insights.

FORMALIZE THE PROCESS

Ask employees to submit items of concern.

TRACE CHANGES IN BEHAVIOUR

Managers should be attentive to changes in employee behavior.

For example:

- Do employees smile and seem comfortable chatting with manager?
- Do they volunteer comments when they run into the manager in the hall?

MODULE 4: Introduction to Leadership

What is your concept of a leader?

“Leadership is not about titles, positions or flowcharts. It is about one life influencing another”>

- John C. Maxwell

“The leader leads and the boss drives”.

– Theodore Roosevelt

“Leadership concept is not a title. It is a behavior.

Live it.”

- Rolan Sharma

CORE CONCEPTS OF LEADERSHIP

Competence

- As leaders, we have to channel our energies to those arenas of leadership where we are most likely to excel.
- Working in the areas of our strengths is crucial to being effective.

Courage

- It takes courage to pull together the talents on your team.
- It takes vision to say we are here at a point A, we want to get to point B.
- What is the plan to pull all this great talent together to create motion and momentum toward that?
- It takes courage to do this well and consistently.

Character

- You can lead without character and we all know some of those leaders, but you won't be a leader worth following.
- Character provides moral authority that is needed to bring together people and resources to move enterprise, a mission, a vision, project forward.

Clarity

- The hallmark of great leader is somebody who can lead with clarity in times of uncertainty.
- People are looking to leaders for guidance.

Coaching

- Without a coach, you'll never be as good as you could be.
- If your goal is to move further, faster than working with a coach will accelerate your leadership growth meaningfully.

LEADERSHIP

The process of influence in which one person is able to enlist the aid and support of others in accomplishing a common task, and the effectiveness of leaders is determined by both their level of influence and the outcomes of their decisions.

The true measure of leadership is influence- nothing more, nothing less. - John C. Maxwell

A leader is an individual ... who significantly affects the thoughts, feelings, and/or behaviors of a significant number of individuals. - Howard Gardner

True leadership is the ability to mobilize and inspire others; **it is not solely about a title or position.**

TYPES OF LEADERSHIP

1. Formal Leaders

- ✓ Have **formal power**
The right to hire and fire, transfer, demote or promote, and reward.
- ✓ Bestowed through **organizational authority**
- ✓ Often the result of a position held within the organization

2. Informal Leaders

- ✓ Earned through relationship and experience
- ✓ Rely on the creation and articulation of a compelling vision of the future.
- ✓ Without the power and authority granted to formal leaders.
- ✓ Have personal magnetism or charisma, expertise in their fields, a recognized history with the organization or the ability to inspire others.

THREE ORIGINS OF AUTHORITY according to Max Weber

1. TRADITIONAL AUTHORITY

- Associated custom or tradition (lines of royal succession]
- Modern setting- based on one's position or rank (e.g. Director, Chief, Dept. Head ...)

2. BUREAUCRATIC (Legal Rational) AUTHORITY

- Based on rules or established laws.
- Demonstrate their power by such tactics as enforcing rules, managing information, and requiring strict codes of organizational behavior.

3. CHARISMATIC AUTHORITY

- Based on how leaders use their powers of persuasion and sense of personal magnetism to acquire followers and, often, devotees.
- Tend to focus on transformation and use their personalities to make change.
Often possess no formal power or authority but rely on their magnetism and vision to get things done.

| | Traditional | Charismatic | Legal - Rational |
|------------------|---|--|---|
| Source of Power | Legitimized by long-standing custom | Based on a leader's personal qualities | Authority resides in the office not the person |
| Leadership Style | Historic Personality | Dynamic personality | Bureaucratic office |
| Example | Patriarchy (traditional positions of authority) | Napoleon, Jesus Christ, Mother Teresa, Martin Luther King, Jr. | U.S. presidency and congress Modern British parliament |

FIVE SOURCES OF POWER

In their 1959, "The Bases of Social Power," John French and Bertram Raven took a slightly different approach and suggested five sources of power.

1. REWARDED POWER

Based on a person's ability to provide material or non material inducements.

2. LEGITIMATE POWER

Derived from the follower's perception that a leader has a right to lead, make demands, and expect obedience from others.

3. EXPERT POWER

Based on individual knowledge and expertise.

4. REFERENT POWER

Steamed from a person's charm or appeal and a follower's desire to identify or emulate these characteristics.

5. COERCIVE POWER

Based on individual's ability to threaten or punish.

CHARACTERISTICS OF TRUE LEADERHSIP

✓ The ability to articulate a compelling vision for the future

- a compelling vision can attract and inspire others, increase commitment to organizational goals, provide purpose and meaning to work activities to future accomplishments, and promote change.
- The ability to create a compelling vision and garner widespread support to realize it is a critical leadership competency.

✓ Passion

- true leaders are absolutely committed to their vision and enjoy working toward it.
- This passion gives them energy to persist even during setbacks.

✓ Integrity

- Leaders know their strengths, are honest about their limitations, establish high standards, and are consistent in their approach.
- They honour their commitments, treat others with respect, and serve as role models.

✓ Encouragement of others

- Leaders understand the importance of engaging the collective talents of many people and facilitating teamwork and collaboration by creating an atmosphere of mutual trust and respect.
- They make it possible for people to be successful and recognize them for their accomplishments and contributions.

✓ Curiosity and daring

- leaders are not afraid to challenge the status quo and are willing to take risks to effect important change.
- They are not afraid to make mistakes in pursuing their goals and use adversity to prepare for future opportunities.

LEADERSHIP STYLE

• Autocratic

- ✓ make decisions independently, without engaging or consulting others
- ✓ works Well in crisis situations
- ✓ Does not typically engage the thinking or talent of others

Characteristics

- Little or no input from other group members
- Leaders make all the decisions
- Group leaders dictate all the processes and the methods
- No interference of group members in decision making
- Work tends to be highly rigid and structured
- Rules are important and clearly outlined

• Democratic (Participative)

- ✓ value fair process and tend to give all members of the organization an opportunity to weigh in with their preferences and recommendations.
- ✓ excel in engaging others, but their commitment to collecting input and establishing buy-in can sometimes be inefficient.

Pros

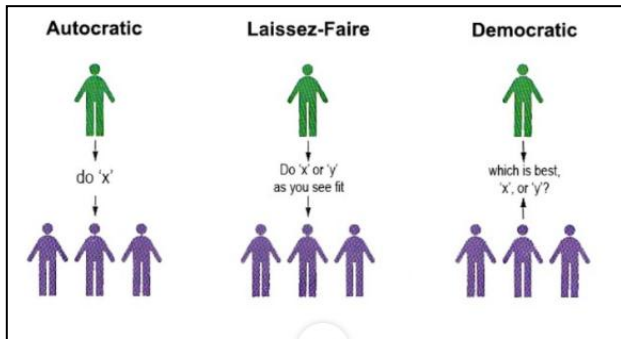
- Allows follower to have a say in decision
- Creates a collaborative workplace

Cons

- The leader depends on the knowledge of the followers
- Collaboration takes time

- **Laissez-Fair (Delegative)**

- ✓ provide critical resources and information but tend to **provide little direction**.
- ✓ Works well with **highly competent and independent individuals**
- ✓ May cause some people to feel abandoned or ignored.
 - freedom for followers to make decisions
 - group members expected to solve problems on their own



- ✓ Listens & understands that it is not about them
- ✓ view their role as being in service to others, meeting needs of those they lead, helping them to grow by building individual capacity and a sense of community.
- ✓ Believe that attending to the needs of employees or followers will enable them to achieve their full potential and when potential is fully realized, the organization will benefit.
- ✓ Focuses too much on developing others and not enough on setting direction to get things done.

- **Transformational (Visionary)**



- ✓ believe that social and spiritual values can be employed to raise employees to even higher levels of performance and motivation.
- ✓ Tend to be **"idea" people**
- ✓ May need **help attending to the details of their plans**
- ✓ Their passion can **exhaust others**

- **Affiliative**

Pros

- Creates a Positive Workplace
- Provides positive feedback

Cons

- Allow under-performers to go unchecked
- Ineffective when faced with complex challenges
- ✓ masters at forging relationships with others and can be especially effective at building productive teams.
- ✓ Effective at using the power of networks and connections to accomplish goals.
- ✓ They find it difficult to deliver bad news that may disappoint others, including feedback about underperformance.

- **Servant**

- ✓ Sees leadership as an opportunity to serve others
- ✓ Shares power & control to drive engagement
- ✓ Measures success through growth and development

MODULE 5: Leadership Essentials for Pharmacist

LEADER

An individual who affects the thoughts, feelings and behavior of number of individuals

- ✓ There is a difference between holding a leadership position and being a leader
- ✓ There is a difference between having power or authority that is earned and having power or authority that is bestowed.

FOUR PRIMARY FACTORS OF LEADERS

Leader – must have an understanding of who you are, what you know and what you can do

Follower – different people require different styles of leadership

Communication – you lead through two way communication. What and how you communicate builds or harms the relationship between you and your follower

Situation – all situations are different. You must use your judgment to decide the best course of action and the leadership style needed for each situation.

VARIOUS FORCES THAT AFFECT THESE FOUR FACTORS

- Your relationship with your seniors
- The skills of your followers
- The informal leaders within your organization
- How your organization is organized

ELEVEN PRINCIPLES OF LEADERSHIP

1. Know yourself and seek self improvement
2. Be Technically Proficient
3. Seek Responsibility and Take Responsibility for your Actions
4. Make Sound and Timely Decisions
5. Set the Examples
6. Know Your People and Look Out for your Well Being
7. Keep your workers informed
8. Develop a sense of responsibility, in your words
9. Ensure that tasks are understood, supervised and accomplished
10. Train as a team
11. Use the Full Capabilities of Your Organization

TWO MOST IMPORTANT KEYS TO EFFECTIVE LEADERSHIP

- ✓ **TRUST AND CONFIDENCE** in top leadership is the single most reliable predictor of employee satisfaction in an organization.
 - ✓ **EFFECTIVE COMMUNICATION** by leadership in three critical areas are the key to winning organizational trust and confidence
- Helping employees understand the company's **overall business strategy**.
 - Helping employees understand **how they contribute** to achieving key business objectives.

BUENO, M.

- Sharing information with employees on both **how the company is doing and how an employee's own division is doing**.

EXAMPLES OF OPPORTUNITIES RESULTING IN LEADERSHIP POSITIONS

- Lead pharmacist who is asked to assume some leadership responsibilities after his or her manager or director **leaves the organization suddenly**.
- Pharmacist who is seen as an **advocate for patient care** and is subsequently asked to **lead a new clinical expansion**.
- Pharmacist who shared an **innovative idea** with a colleague and is then asked to present this idea to others.
- Pharmacist who is known for **managing and solving complex problems**.
- Pharmacist who is frequently asked to present at Pharmacy and Therapeutics and other high profile medical staff meetings.
- Pharmacist team members whom other team members admire.
- Pharmacist whose knowledge and intelligence impress many and who is often asked to present his or her work to others.

COMMON BEHAVIORS AND TRAITS OF EFFECTIVE PHARMACIST LEADERS

| BEHAVIORS | |
|----------------------------------|-----------------------------|
| Acts assertively | Innovates |
| Admits mistakes | Listens |
| Challenges status quo | Makes others feel Important |
| Communicates well | Negotiates successfully |
| Delegates, entrusts and empowers | Provides good direction |
| Demonstrates integrity | Resolves conflict |
| Encourages | Stays involved |

| TRAITS | |
|--------------------|-----------------|
| Competent | Intelligent |
| Cooperative | Optimistic |
| Credible | Passionate |
| Decisive | Persuasive |
| Diplomatic | Responsive |
| Emotionally stable | Systems thinker |
| Innovative | Visionary |

TRAITS OF PHARMACY PROFESSIONALISM

- Accountability for actions, decisions and work efforts
- Knowledge and skills of pharmacy profession
- Commitment to improving the skills and knowledge of both self and others

- Ethically sound decision making
- Creativity and innovative thinking
- Pride in pharmacy profession
- Covenantal relationship with patients
- Service orientation

DEVELOPING YOUR LEADERSHIP POTENTIAL

- **Pursue leadership roles within community organizations**
 - ✓ community organizations provide volunteers with opportunities to pursue and build skills that would not normally be possible with one's employer.
 - ✓ help build marketing, financial and persuasiveness competencies
- **Volunteer for leadership roles within your professional associations**
 - ✓ recruiting corporate partners for a pharmacy conference or leading program planning for a local, state, regional, national, or international association will give you an opportunity to meet new people and network, acquire new skills and learn about how professional organizations works.
 - ✓ hone communication, persuasion and negotiation skills
- **Find one or more mentors**
 - ✓ The best mentors maybe individuals outside your management chain
 - ✓ mentors can support leadership development by opening doors and expanding networks and by providing feedback about issues ranging from style and presence to approaches to managing conflict
- **Ask for difficult assignments**
 - ✓ challenging assignments encourage growth and can result in organizational recognition.
 - ✓ Once you have been successful with one project, you will likely be called on to work on another.
 - ✓ it will expand your knowledge and experience base, provide you with opportunities to try new things, and increase your connections with others.
- **Stay Informed**
 - ✓ A solid grasp of the context in which one works is required for strategic thinking.
 - ✓ use different ways to learn more about your profession and the trends affecting it.
- **Observe others**
 - ✓ Pay attention to the traits and behaviours of leaders you admire.
 - ✓ You can learn a great deal by studying role models.

- **Read about Leaders**
 - ✓ Read stories of leaders and learn about the techniques they employ, the words they use, and the behaviours they exhibit.
- **Take Leadership test and inventories**
 - ✓ Leadership style assessment tools.
 - ✓ The more you understand your personal strengths and interests, the better you will be positioned to develop a leadership style that feels right for you.
- **Do not wait to be ready**
 - ✓ We all need stretch assignments, so do not wait to be fully proficient tackling assignments.
 - ✓ Act with confidence and be ready to ask others for support in the event you need it

MENTORING ROLES

| Elements | Description of mentor's activities/responsibilities |
|--------------------------------------|---|
| SPONSORSHIP | Opens doors that otherwise be closed |
| COACHING | Teaches and provide feedback |
| PROTECTION | upports the protege and/or acts as a buffer. |
| CHALLENGE | Encourages new ways of thinking and acting, and pushes the protege to stretch his or her abilities. |
| EXPOSURE & VISIBILITY | Steers the protege into assignments that make him or her known to top management, |
| ROLE MODELING | Demonstrates the kind of behaviours, attitudes, and values that lead to success |
| COUNSELLING | Helps the protege with difficult professional dilemmas |
| ACCEPTANCE & CONFIRMATION | Supports the protege and shows respect |
| FRIENDSHIP | Demonstrate personal caring that goes beyond business requirements. |

COMPETENCIES FOR PHARMACIST LEADERS AND MANAGERS

ACCURATE SELF INSIGHT

- demonstrating an awareness of your own strengths and development needs, as well as the effect on your own behaviour to others

Key actions:

- ✓ inviting feedback, performing self assessment, understanding impact.

BUILDING BUSINESS RELATIONSHIP

- using appropriate interpersonal styles and communication methods to work effectively with business partners.

Key actions:

- ✓ Establishing shared goals
- ✓ Collaboratively developing solutions
- ✓ Influencing action

BUILDING ORGANIZATIONAL TALENT

- Attracting, developing, and retaining talented individuals
- creating a learning environment that ensures associates realize their highest potential

Key actions:

- ✓ Diagnosing capability and developmental needs.
- ✓ Creating a learning culture
- ✓ Demonstrating advocacy for diversity

CHANGE LEADERSHIP

- Continuously seeking opportunities for innovative approaches to organizational problems and opportunities.

Key actions:

- ✓ Recognizing opportunities
- ✓ Valuing sound approaches
- ✓ Addressing resistance to change
- ✓ Managing complexity, contradictions, and driving toward improvement

COMMUNICATING WITH IMPACT

- Expressing thoughts, feelings and ideas in a clear, succinct, and compelling manner in both individual and group situations
- Adjusting language to capture the attention of the audience

Key actions:

- ✓ Delivering clear message
- ✓ Presenting with impact
- ✓ Creating clear written communications
- ✓ Adjusting to the audience
- ✓ Ensuring understanding

CUSTOMER FOCUS

- Cultivating strategic customer relationships and ensuring that the customer perspective is the driving force behind all value added business activities.

Key actions:

- ✓ Seeking to understand customers
- ✓ Educating customers
- ✓ Maintaining trust
- ✓ Acting to meet customer needs and concerns
- ✓ Recognizing customer service issues

DRIVING FOR RESULTS

- setting high goals or personal and group accomplishments
- Measuring progress towards goals

Key actions:

- ✓ Targeting opportunities
- ✓ Establishing and reaching for goals
- ✓ Stay focused
- ✓ Evaluate performance

ESTABLISHING STRATEGIC DIRECTION

- establishing and committing to a long-range course of action to achieve a strategic goal or vision

Key actions:

- ✓ Gathering and organizing information
- ✓ Analyzing data
- ✓ Evaluating and selecting strategies
- ✓ Executing plans

EXECUTIVE PRESENCE

- conveying an image that is consistent with the organization's values
- demonstrating qualities, traits and demeanor that command leadership respect

Key actions:

- ✓ Advocating for the organization
- ✓ Managing stress
- ✓ Creating impact
- ✓ Exhibiting flexibility and adaptability

LEADING THROUGH VISION AND VALUES

- keeping the organization's vision at the forefront of decision making and action.

Key actions:

- ✓ Communicating the importance of vision and values
- ✓ Moving others to action
- ✓ Modelling vision and values
- ✓ Rewarding others who display vision and values

MANAGING DIVERSITY

- creating and maintaining an environment that naturally enables all participants to contribute their full potential in pursuit of organizational objectives

Key actions:

- ✓ Creating an equitable work environment
- ✓ Ensuring inclusivity of policies
- ✓ Recognizing diversity as an organizational asset
- ✓ Setting standards of behaviour based on respect and dignity.

OPERATIONAL DECISION MAKING

- Relating and comparing data on operational effectiveness from different sources
- Securing relevant information and identifying key issues, key people and cause-effect relationships from a base of information.

Key actions:

- ✓ Seeking and organizing information
- ✓ Analyzing data
- ✓ Developing and considering alternatives
- ✓ Gaining commitments
- ✓ Demonstrate decisiveness and action

ORGANIZATIONAL ACUMEN

- Understanding and using economic, financial, and industry data accurately to diagnose business strengths and weaknesses; identifying key issues; and developing strategies and plans

Key actions:

- ✓ Analyzing, integrating and understanding the application of financial strategies and systems

PROCESS IMPROVEMENT

- Acting to improve existing conditions and processes

Key actions:

- ✓ Assessing opportunities
- ✓ Determining causes
- ✓ Targeting and implementing improvements

PROFESSIONAL OR INDUSTRY KNOWLEDGE

- Having a satisfactory level of technical and professional skill or knowledge in position-related areas.
- Keeping up with the current developments and trends in areas of expertise.

Key actions:

- ✓ Engaging in continuous learning
- ✓ Applying state-of the art technology and concepts
- ✓ Developing and maintaining industry awareness

MODULE 6: Pharmacy Regulation

Republic Act 10918

An Act Regulating and Modernizing the Practice of Pharmacy in the Philippines, Repealing for the Purpose Republic Act Numbered Five Thousand Nine Hundred Twenty One (R.A. 5921), otherwise known as the Pharmacy Law.

Passed into Law: **July 21, 2016**

RA 10918

Section 1. Title. – This Act shall be known as the "**Philippine Pharmacy Act**".

Section 2. Statement of Policy. - The State recognizes the vital role of pharmacists in the delivery of quality health care services through the provision of safe, effective, and quality pharmaceutical products, pharmaceutical care, drug information, patient medication counseling, and health promotion. The pharmacists' professional services shall, therefore, be promoted as an indispensable component of the total health care system to ensure the physical well-being of the Filipinos.

Hence, **the State shall develop and nurture competent, productive, morally upright, and well-rounded pharmacists** whose standards of professional practice and service shall be excellent and globally competitive through regulatory measures, programs, and activities that promote and sustain their continuing professional development.

Section 3. Objectives. –

This Act provides for and shall govern the:

- Standardization and regulation of pharmacy education;
- Administration of licensure examination, registration, and licensing of pharmacists;
- Supervision, control, and regulation of the practice of pharmacy in the Philippines;
- Development and enhancement of professional competence of pharmacists through continuing professional development, research, and other related activities; and
- Integration of the pharmacy profession.

Section 4. Scope of the Practice of Pharmacy.

- A person is deemed to be practicing pharmacy, within the meaning of this Act, when with or without a fee, salary, percentage or other rewards, paid or given directly or indirectly, shall:

- Prepare, compound or manufacture, preserve, store, distribute, procure, sell, or dispense, or both, any pharmaceutical product or its raw materials; or
- Render services, such as clinical pharmacy services, drug information services, regulatory services, pharmaceutical marketing, medication management, or whenever the expertise and technical knowledge of the pharmacist is required; or
- Engage in teaching scientific, technical, or professional pharmacy courses in a school or college of pharmacy; or
- (d) Dispense pharmaceutical products in situations where supervision of dispensing of pharmaceutical products is required; or
- Chemical, biological or microbiological analyses and assay of pharmaceutical products, food/dietary supplements, health supplements, and cosmetics; or
- Physico-chemical analyses for medical devices used in aid of administration of pharmaceutical products; or

- Administration of adult vaccines as approved by the Food and Drug Administration (FDA): Provided, That they shall undergo the training on the safe administration of adult vaccines and management of adverse event following immunization (AEFI) for pharmacists and hold a certificate of training issued by an institution duly accredited by the Professional Regulation Commission (PRC); Provided, further, That the safe administration of vaccines be part of the higher education curriculum for pharmacists; or
- Conduct or undertake scientific research in all aspects involving pharmaceutical products and health care; or
- Provide other services where pharmaceutical knowledge is required.

Section 5. Definition of Terms. - As used in this Act:

- Accredited professional organization (APO)** refers to the duly integrated and accredited professional organization of registered and licensed pharmacists, of which there shall be only one (1), as prescribed under Section 41, Article V of this Act;
- Adult vaccines** refer to cervical cancer, flu (influenza), pneumococcal, other pre-exposure prophylactic vaccines to be administered to patients aged eighteen (18) years and above, and such other vaccines as may be defined by the Department of Health (DOH) in an administrative issuance;
- Brand name** refers to the proprietary name given by the manufacturer to distinguish its product from those of competitors;
- Continuing professional development (CPD)** refers to the inculcation of advanced knowledge, skills, and ethical values in a post-licensure specialized or in an inter- or multidisciplinary field of study for assimilation into professional practice, self-directed research, and/or lifelong learning;
- Cosmetics** refer to a substance or preparation intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odor, and/or protecting the body or keeping them in good condition
- Dispensing** refers to the sum of processes performed by a pharmacist from reading, validating, and interpreting prescriptions; preparing; packaging; labeling; record keeping; dose calculations; and counseling or giving information, in relation to the sale or transfer of pharmaceutical products, with or without a prescription or medication order;
- Drugs** refer to pharmaceutical products that pertain to chemical compounds or biological substances, other than food, intended for use in the treatment, prevention, or diagnosis of disease in humans or animals
- Food/Dietary supplements** refer to processed food products intended to supplement the diet that bears or contains one (1) or more of the following dietary ingredients: vitamins, minerals, herbs, or other botanicals, amino acids, and dietary substances to increase the total daily intake in amounts conforming to the latest Philippine-recommended energy and nutrient intakes or internationally agreed minimum daily requirements
- Generic name** refers to the scientifically and internationally recognized name of the active ingredients
- Medical device** refers to any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or

related article intended by the manufacturer to be used alone, or in combination, for human beings, for one (1) or more of the specific purposes of: diagnosis, prevention, monitoring, treatment, or alleviation of disease; diagnosis, monitoring, treatment, or alleviation of or compensation for an injury; investigation, replacement, modification or support of the anatomy of a physiological process; supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body.

- **Over-the-counter (OTC)** medicines refer to medicines used for symptomatic relief of minor ailments and which may be dispensed without a prescription;
- **Pharmaceutical establishments** refer to entities licensed by appropriate government agencies, and which are involved in the manufacture, importation, exportation, repacking, and distribution of pharmaceutical products to pharmaceutical outlets;
- **Pharmaceutical outlets** refer to entities licensed by appropriate government agencies, and which are involved in compounding and/or dispensing and selling of pharmaceutical products directly to patients or end-users;
- **Pharmacist** refers to a health professional who has been registered and issued a valid Certificate of Registration (COR) and Professional Identification Card (PIC) by the PRC and the Professional Regulatory Board of Pharmacy;

Section 20. Issuance of Certificate of Registration and Professional Identification Card. –

A COR as a pharmacist shall be issued to those who passed the licensure examination, subject to compliance with the registration requirements and payment of the prescribed fees.

- The COR shall bear
- the registration number
- the date of its issuance
- and the signatures of the Chairperson of the PRC and the members of the Board
- stamped with the official seals of the PRC and of the Board certifying that the person named therein is entitled to the practice of the profession, with all the privileges appurtenant thereto.

Professional Identification

A PIC bearing the registration number and dates of its issuance and expiry, duly signed by the Chairperson of the PRC, shall likewise be issued to every registrant, upon payment of the prescribed fees.

The PIC shall be renewed every three (3) years, upon presentation of the Certificate of Good Standing (COGS) from the APO and proof of completion of the CPD requirements.

Section 26. Affixing RPh After a Registered Pharmacist's Name.

- Only duly registered and licensed pharmacists shall have the right to affix to one's name, the title "Registered Pharmacist" or "RPh".

Section 29. Display of Certificate of Registration.

- It shall be the duty of every pharmacist engaged in the practice, whether in private or under the employ of another, to display the original copy of one's COR in a prominent and conspicuous place in the drug establishment in which one is employed in a professional capacity as pharmacist.

Section. 31. Pharmacist Requirement.

- Establishments/ outlets which are required to employ and/or retain and maintain the professional services of duly registered and licensed pharmacists shall be classified as follows;

Category A - Pharmaceutical establishment/outlets where the direct and immediate control and supervision of a pharmacist is required. Example - Drugstores, Hospitals, Manufacturing, etc.

Category B - Pharmaceutical establishment/outlets where the supervision and oversight of a pharmacist is required under pertinent provisions of the law. Example - Convenience stores and 4th, 5th and 6th class municipalities

Multiple RONPD Supervision (FDA Circular 2014 - 028) Retail Outlet for Non Prescription Drugs

1. Pharmacists required to dedicate a minimum of 2 hours a week of physical presence
2. The location of RONPD must be within the same LGU within each region
3. The distance between two RONPD must not exceed 25 km in distance
4. All other RONPDs supervise by a single pharmacist must be within a circumferential area when plotted between the two farthest RONPDs
5. A maximum of fifteen (15) RONPDs is allowed to be supervised by a single pharmacist

Section. 38. Requirements for the Opening and Operation of Retail Pharmaceutical Outlet or Establishment.

- The opening of a retail pharmaceutical outlet or establishment shall be subject to requirements provided for in this Act and the rules and regulations prescribed by the FDA.

Section. 39. Handling of Pharmaceutical Products by Persons Other Than a Pharmacist.

- For the purpose of this section, persons handling pharmaceutical products, other than the pharmacist, which shall include pharmacy owners who are non-pharmacists, medical representatives or professional service representatives, pharmacy support personnel, pharmacy technicians, pharmacy assistants, pharmacy aides, persons who assist pharmacists in any part of a pharmacy operation, or any other person performing functions involved in the handling of pharmaceutical products, shall be duly certified by appropriate government agencies after undergoing an accredited training program.

Section 40. Administration of Adult Vaccines.

- In addition to the requirement provided in Section 4, paragraph (g) of this Act, licensed and trained pharmacist who shall administer adult vaccines shall ensure that the vaccine to be administered shall have a doctor's prescription which is not more than seven (7) days old and submit a monthly vaccination report and AEFI report to DOH regional offices using the prescribed form.

GENERAL REQUIREMENTS FOR ISSUANCE OF LTO

LICENSE TO OPERATE (LTO)

A License to Operate or LTO is a license which must be secured by an establishment in order to operate prior to engaging in the manufacture, importation, exportation, sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of food, drugs, cosmetics, health products, and other medical products and devices.

FDA E SERVICES PORTAL

The Food and Drug Administration (FDA), in its commitment to provide stakeholders with streamlined and improved government services, has issued FDA Circular No. 2020-030 on 16 October 2020 as implementing guideline in the application for License to Operate (LTO) of Drug NonManufacturing Establishments in the eServices Portal System: eservices.fda.gov.ph

The ePortal System shall remain online for Drug Establishments with on-going/inprocess LTO applications and Drug Manufacturer LTO applications

APPLICATION REQUIREMENTS - Initial Application

- A. Accomplished e-Application Form with Declaration of undertaking (eservices.fda.gov.ph)
- B. Proof of Business Name Registration (in pdf, 2MB maximum file size) shall be submitted in any of the following:
 - For single proprietorship, the Certificate of Business Registration issued by the **Department of Trade and Industry (DTI)**
 - For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the **Securities and Exchange Commission (SEC)** with complete Articles of Incorporation.
 - For Cooperative, the Certificate of Registration issued by the **Cooperative Development Authority (CDA)** and Articles of Cooperation; or
 - For Government Owned or Controlled Corporation, the law creating the establishment, if with the original charter, or its Certificate of Registration issued by the **Securities and Exchange Commission (SEC)** and Articles of Incorporation, if without original charter.
- C. If the Business or establishment is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g. Mayor's Permit, Barangay Business, Permit Clearance)
- D. For Drug Trader, proof of income (in pdf, 2MB maximum file size) such as the latest audited Financial Statement with Balance Sheet (In pdf) shall be submitted. This is to verify the capitalization of the establishment to their corresponding application fees. For newly established companies that have no Financial Statement yet, duly notarized Statement/Certification of Initial Capitalization must be submitted.
- E. Payment of Fees based on the latest FDA issuance.
- F. Additional Documents for Drug Establishments that maybe further request shall be presented to FDA specifically to all drug inspectorates during inspection, including the Risk Management Plan (RMP).

APPLICATION REQUIREMENTS - Renewal Application

- A. Accomplished e-Application Form with Declaration of Undertaking; and
- B. Payment of Fees based on the latest FDA issuance.

APPLICATION REQUIREMENTS - Variation Application

- A. Accomplished e-Application Form with Declaration of Undertaking;
- B. Documentary requirements depending on the type of variation or circumstances of the establishment or product as shown in the table below: and
- C. Payment of Fees based on the latest FDA issuance.

PRE-ASSESSMENT

1. An FDA evaluator/assessor shall conduct pre-assessment on the submitted application and documentary requirements with regards to their completeness and correctness. Applications with incomplete or incorrect data entry and document submissions shall not be accepted and the application will not proceed to the next step of the process.
2. The Pre-assessment of applications shall be done within the prescribed working days and office hours of the FDA.
3. The FDA shall inform the applicant through the registered email address the result of the pre-assessment. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number through email indicating the fees to be paid. If the application did not pass the pre-assessment step, the FDA shall notify the reasons for non-acceptance e.g. deficiencies found and prompt the applicant to apply again through the eservices Portal.

PAYMENT OF FEES

1. Payment of the total application fee as indicated in the Order of Payment (OP) maybe done through **Over-the-counter (OTC) payment at FDAC, Land Bank of the Philippines (LBP) branches, or online payment thru Bancnet (including LBP bills payment)**, based on the existing FDA issuances. Always indicate the Reference Number reflected in the OP.
2. Once the payment is made, the payment channel - LBP or Bancnet will send a transaction report to FDA which usually takes a minimum of two (2) days. Upon receipt of the report, the Cashier Section checks the details and posts the payment in the eservices Portal if payment is made in full. Posting of payment may take a maximum of two (2) days, depending on the volume of paid applications received.
3. Incomplete payment (amount paid is less than that of OP amount) will not be posted until the full amount as indicated in OP is settled. This also means that the application will not proceed to the next step of the process.
4. **Applicants will receive a system-generated message through the registered email address on the status of the payment made once posted or need further settlement. If full payment is made, email will contain Acknowledgment Receipt, otherwise, a notification on payment deficiency.**

PAYMENT OF FEES

- ✓ Initial Application - PHP 2,020
- ✓ Renewal Application - PHP 3,030
- ✓ Variation Application - PHP 510

APPROVAL OF THE APPLICATION

1. The veracity of the application and compliance with all relevant FDA requirements and standards shall be checked.
2. For emphasis, the grounds for disapproval of LTO application may be any of the following, as stated in AO No. 2020-0017:
 - a. the documentary requirements submitted show that the establishment does not meet the required technical requirements and/or appropriate standards:
 - b. absence of physical office upon inspection, without permission or approval from FDA;

- c. the applicant made misrepresentations, false entries, withhold relevant data contrary to the provisions of the law or appropriate standards;
 - d. the owner has violated any of the terms and conditions of its license; and
 - e. such other analogous grounds or causes as determined by the FDA.
3. If the application is approved, the FDA shall send the LTO to the registered email address of the applicant. If the application is disapproved, the FDA shall inform the applicant through its registered email address of the reason such action on the application.

RELEASE OF LTO

1. The applicant shall receive the LTO in their registered email address and may also be accessed through the FDA eservices Portal.
2. Upon receipt of the LTO, the establishments shall print the LTO on a standard A4 size (21 cm x 29.7 cm) paper, on full-colored page and in portrait orientation. It shall be positioned on the most conspicuous place within the business establishments.
3. A QR Code verifier shall be included in the LTO as basis of legitimacy of the document.
4. For Variation, the applied variation shall automatically be reflected on the LTO: an updated LTO shall be provided to the email address.

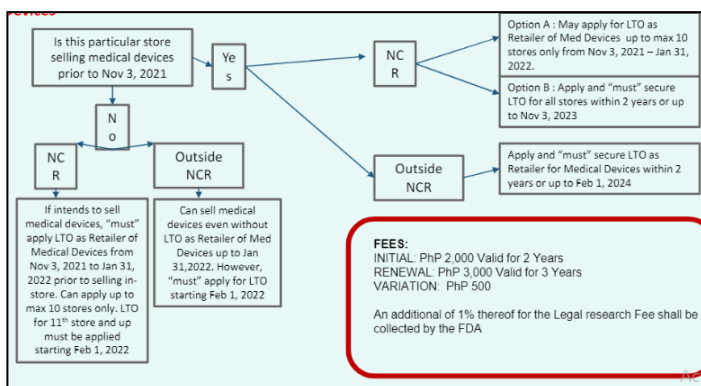
RELEASING OF LTO 2 - 3 Weeks

VALIDITY Initial LTO - 2 Years Renewal LTO - 3 Years

This LTO shall be renewed within **90 days** before its expiration, upon compliance with relevant laws, rules and regulations and the payment of fees. This LTO may be suspended, cancelled or revoked by this Office for cause if found violating RA 9711 and related issuances.

- o Operating without a license is prohibited
- o Likewise, existing licenses that were not renewed after one hundred twenty (120) days from the date of expiration will be automatically canceled by the FDA.
- o Not only that, but the company will automatically be delisted from the FDA's list of licensed establishments, so be sure to renew on time

Flowchart on when to apply for LTO as Retailer of Medical Devices



Seminars and Trainings that Pharmacists Should Attend

| Training/ Seminar Title | Program Description | Tentative Duration | Target Participants | Registration Fee |
|------------------------------------|---|--------------------|---|------------------|
| Licensing Seminar for Drug Outlets | The program provides a procedural discussion on the licensing application process and regulatory requirements for drug outlets. | 4 hours | Drug outlet owners, Pharmacists, Pharmacy Assistants and Other external stakeholders. | Free |

- The FDA Academy may include additional program as the need arises or as determined by the FDA
- Other seminars with CPD Units for PRC license renewal (15 CPD Units)
- Other seminars relevant to work

STANDARD OPERATION PROCEDURE

- ✓ Standard Operating Procedure (SOP) according to FDA Philippines is a document that describes "how to perform" various routine operations that contains step by step instructions.
- ✓ It is written by the individuals who perform the operation and who share some aspects of the operation.
- ✓ SOP is needed to guide personnel when and why to perform a task, and what is the scope of the task.
- ✓ The SOP must undergo series of reviews and approvals before it can be imposed.

The following are the main content of SOP

OBJECTIVE

- describes purpose of the goal and aim.

SCOPE

- up to what extent can be the task performed

RESPONSIBILITY

- who can be involved in performing the task.

PROCEDURE

- the step by step action of doing a task

QUALITY RECORDS

- how to do records and uphold them

FORMS

- to where the records are written (Optional)

END OF DOCUMENT

- can be used to place additional information and rationale

LIST OF STANDARD OPERATING PROCEDURES

- o Pharmacovigilance
- o Procurement of Stocks
- o Dispensing of pharmaceutical products
- o Storage of stocks including temperature monitoring & retention of monitoring records.
- o Cold chain management (if with vaccines & biological) WHO Handling complaints
- o Handling product recall
- o Handling returned products from customers
- o Destruction/disposal of pharmaceutical products (expired, damaged, unusable stocks)
- o Sanitation program indicating the frequency of cleaning and the methods to be used
- o Program for pest control
- o Reporting of Adverse Drug Reactions/ Events
- o Extemporaneous Compounding

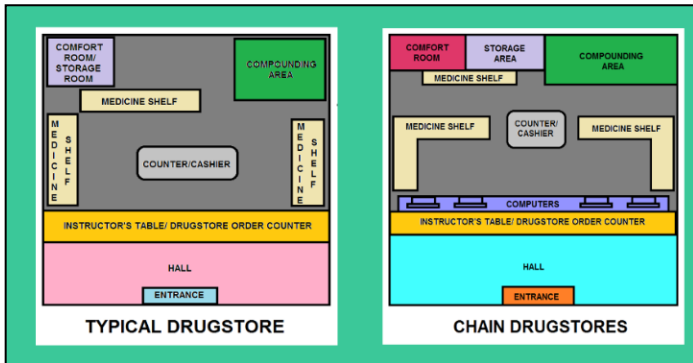
RISK MANAGEMENT PLAN (RMP)

RMP is defined as a set of health product vigilance activities and interventions designed to identify characterize, prevent or minimize risks to health products and the assessment of effectiveness of those interventions

| Risk Management Plan Format | |
|-----------------------------|---|
| Sec. A | Introduction |
| | 1. Internal Environment |
| | 2. Risk Management Approach |
| | 3. Risk Management Objectives |
| | 4. Data Lock Point |
| Sec. B | Risk Identification |
| | 1. Risk Universe |
| | 2. Risk Assessment |
| | 3. Summary Risk Register |
| | 4. Unknown Risks |
| Sec. C | Risk Minimization |
| | 1. Routine Risk Minimization |
| | 2. Additional Risk Minimization |
| | 3. Justification for Identified Risks without Minimization Activities |
| Sec. D | Risk Communication |
| | 1. Internal Communication |
| | 2. Communication to FDA |
| | 3. Communication to Consumers and Healthcare Professionals |
| | 4. Communication to Other Stakeholders |
| Sec. E | Risk Monitoring and Management Evaluation |
| | 1. Routine Evaluation |
| | 2. Additional Evaluation |

- Area/size of Pharmacy should be 15. sq meter at least
- Availability of Reference Materials PNF, Philippine Practice Standards for Pharmacists
- Record books - Prescription Book, Senior Citizen's book, PWD book.
- Menu Card (Generics, MDRP, GMAP) Generic Dispensing Flow Chart
- Dispensing materials and equipments - pill counting tray, graduated cylinder, labels
- Copies of pertinent laws and regulations

PHYSICAL SET UP OF A PHARMACY



MODULE 7: Ethics in Management

ETHICS

- An area of study that deals with **ideas about what is good and bad behavior and with moral duty and obligation**
- The rules and principles that define **right and wrong conduct**

Management Ethics

- Is the study of standards of **business behavior which promote human welfare and the good.**
- A **set of principles and rules** dictated by the upper management that define what is right and what is wrong in an organization.
- It is a **guideline** that helps direct a lower manager's decision in the scope of his or her job when a **conflict of values is presented.**

1. IMMORAL MANAGEMENT

- It implies lack of ethical practices followed by managers. Managers want to maximize profits even if it is at the cost of legal standards or concern for employees.

2. MORAL MANAGEMENT

1. According to moral management ethics, managers aim to maximize profits within the confines of ethical values and principles. They conform to professional and legal standards of conduct. The guiding principle in moral management ethics is "Is this action, decision, or behavior fair to us and all parties involved?"

3. AMORAL MANAGEMENT

2. This type of management ethics lies between moral and immoral management ethics. Managers respond to personal and legal ethics only if they are required to do so; otherwise there is lack of ethical perception and awareness.

TWO TYPES OF AMORAL MANAGEMENT

a. Intentional:

Managers deliberately avoid ethical practices in business decisions because they think ethics should be followed in non-business activities.

b. Unintentional:

Managers do not deliberately avoid ethical practices but unintentionally they make decisions whose moral implications are not taken into consideration.

ETHICAL BEHAVIORS

1. Honesty

In all their dealings, ethical executives are honest and truthful.

2. Integrity

Ethical executives show personal honesty and courage. They are principled, trustworthy and upright.

3. Trustworthiness

Ethical executives are worthy of faith.

4. Fairness

Ethical treat people equally with tolerance and acceptance of diversity.

5. Kindness

Ethical executives are loving, compassionate, generous and kind.

6. Respect

They treat all people, regardless of sex, race or national origin, with equal respect and dignity.

7. Lawful

Ethical managers follow rules and regulations in their company operations.

8. Excellence

They actively aspire to improve their competence in all areas.

9. Leadership

Ethical employees strive to be positive role models as leaders.

10. Responsible

They consider and accept responsibility for their choices and actions

IMPROVING ETHICAL BEHAVIOR

- Hire individuals with high ethical standards
- Establish codes of ethics and decision rules
- Lead by example
- Provide ethics training
- Conduct social audits
- Provide support for individuals facing ethical dilemmas

FORCES SHAPING

ETHICAL DECISION MAKING IN ORGANIZATIONS

PERSONAL ETHICS

- Beliefs & Values
- Moral Development
- Ethical Framework

ORGANIZATIONAL CULTURE

- Rituals
- Slogans
- Symbols
- History

ORGANIZATIONAL SYSTEM

- Structure
- Policies
- Code of Ethics
- Reward System

Is decision/behavior ethical & socially responsible?

ETHICS IN PHARMACY

ETHICS

- A branch of philosophy that poses four fundamental questions:
 1. What are the source, meaning, and justification of ethical claim?
 2. What kinds of acts are right?
 3. How do rules apply to specific situations?
 4. What ought to be done in specific situations?

APPLIED ETHICS

- Takes the tools and concepts of ethics and applies them to practical issues such as those encountered in health care, in general, and in pharmacy management and leadership, in particular.

THREE CONCERNS OF ETHICS

The basic concerns of ethics that are particularly important in health care are:

1. Respect for persons and human dignity.
2. Well-developed justification for ethical decisions.
3. Recognition of the multiple and competing demands of the moral life.

RESPECT FOR PERSONS AND HUMAN DIGNITY

- Human dignity means that humans possess an absolute, intrinsic worth.
- Respect refers to:
 - Individual such as patients, but also pharmacists should be respected for **their capacity to make autonomous (self-determined) decisions.**
 - The requirement to **protect those with diminished ability to make their own decisions.**
- Patients who possess the capacity to make **informed decisions** should be able to do so without interference.
- As pharmacists we should respect our patients for their differences and ability to be involved in their healthcare decisions.

WELL DEVELOPED JUSTIFICATION FOR ETHICAL DECISIONS

The second basic concern of ethics is justification, or the "why" of ethics

- Pharmacist can developed a possible course of action to resolve an ethical problem but often find it **challenging to explain the rationale for their choices.**
- Ethics involves carefully considering **reasons for a particular actions** so that pharmacists can "act with conviction of conscience"

- Examples of ethical situations that involve pharmacists and pharmacist managers may include how they respond to requests to justify dispensing emergency contraceptives and other controversial agents.

RECOGNITION OF THE MULTIPLE AND COMPETING DEMANDS OF THE MORAL LIFE

We need to be aware that we have many duties or obligations in our lives.

- Healthcare professionals must juggle patient needs, professional responsibilities, and personal duties to family and friends each day.
- We cannot meet all of the needs that we are called on to meet, so **we make choices throughout the day.**
- Some of our choices are conscious and some are not.
- We should strive to be **aware of the values that influence these choices**, especially in relation to maintaining professional competency.

CONTEXT OF MANAGEMENT AND ORGANIZATIONAL ETHICS

- Problems in healthcare ethics, regardless of the specific health discipline, addresses the interpersonal level of ethics
 - An ethical conflict between two moral agents or competent adults: pharmacist and a patient.
 - The pharmacist, in such cases, must **determine what is the right thing to do for and with a particular patient.**
 - With pharmacist manager, the focus is no longer solely on patients, but on other several other things, including the people who report to the manager

By sharing ethical concerns with others, we may also determine several "right" answers or different paths to reach an ethical conclusion."

- **Primary objective of organizational ethics**
 - **Overall good or benefit of the organization** which includes individuals within the organization, such as patients, healthcare professionals and other staff.
 - Organizational ethics must also attend to the good of the society, as organizations are part of the larger community.
- Principles and tools of ethics that are important at the interpersonal level - **respect for autonomy, are not relevant at the organizational level.**
- Principles such as **justice or nonmaleficence** become more salient at the organizational level.

Sample Case Scenario:

An error occurs in preparing and dispensing a certain drug product in pharmacy

As a pharmacist-manager what will you do?

- Medication errors of organizational, not individual, ethics
- Treating the error as an isolated event by questioning the pharmacist responsible is not enough.
- The approach called for here involves institutional systems and structure.
- With a focus on the organizational level, care should be taken to ensure the well being of all those affected by errors, including patients, family members and healthcare professionals.
- This means institutionalizing consistent, fair and effective methods to identify and resolve systemic causes of errors.

CONTEXT OF MANAGEMENT AND ORGANIZATIONAL ETHICS

- *Pharmacist and pharmacist managers must also respond to societal-level concerns.*
 - External compliance with the law and regulatory bodies.
 - Fair and equitable distribution of healthcare resources based on patient and society needs.

EVALUATION OF ETHICAL PHARMACY SITUATIONS

RECOGNIZE A PHARMACY ETHICAL ISSUE

1. Could this pharmacy-related situation be damaging to someone or to some group? Does this decision involve a choice between a good and bad alternative?
2. Is this issue about more than what is legal or what is most efficient? If so, how?
3. What are the relevant facts of the case? What facts are known? Can I learn more about the situation? Do I know enough to make a decision?
4. What individual and groups have an important stake in the outcome? Are some concerns more important? Why?
5. What are the options for acting? Have all the relevant persons and groups been consulted.

EVALUATE ALTERNATIVE ACTIONS

6. Evaluate the options by asking the following questions.
 - Which option will produce the most good and cause the least harm?
 - Which option best respect the rights of the stakeholders?
 - Which option treats people equally or proportionately?
 - Which options best serves the community as a whole, not just some members?
 - Which option leads me to act as the sort of person I want to be?

MAKE A DECISION AND TEST IT

7. Considering all these approaches, which option best addresses the pharmacy situation?
8. If I told someone respect, which option I have chosen, what would they say?

ACT AND REFLECT ON THE OUTCOME

9. How can my decision be implemented with the greatest care and attention to the concerns of all stakeholders?
10. How did my decision turn out, and what have I learned

APPROACHES TO ETHICS

Four Ways People Approach Ethics?

- The **PRINCIPLE APPROACH**, in which decisions are made according to a principle such as the Ten Commandments or the Golden Rule
- The **CONSEQUENCE APPROACH**, in which decisions are made according to their likely outcomes
- The **VIRTUE/CHARACTER APPROACH**, in which decisions are made according to the decision makers' view of his or her responsibilities
- The **moral sentiment approach**, in which decisions are made according to the decision maker's feelings

PRINCIPLES IN PHARMACY ETHICS

| ETHICAL PRINCIPLE | DEFINITION | PHARMACIST/PATIENT EXAMPLE |
|---------------------|--|---|
| AUTONOMY | Ability to make decisions without controlling interference | Pharmacist can individualize drug information for a specific patient during a counselling session. |
| BENEFICIENCE | Obligation to help other people | Patient can choose not to take prescribed medication. Pharmacists provides accurate and up-to-date patient education on the management of asthma or diabetes. |
| FIDELITY | Obligation to keep promises | Pharmacist is trusted to keep a patient's medical information confidential |

| ETHICAL PRINCIPLE | DEFINITION | PHARMACIST/ PATIENT EXAMPLE |
|-------------------|--|--|
| JUSTICE | Ability to be right and fair within reason | Pharmacist provides medications for costs determined by patients insurance status. |
| NONMALEFICENCE | Obligation to avoid harming other people | Pharmacist must refuse to fill prescription for penicillin in a patient with a history of a type 1 hypersensitivity reaction to penicillin |

CODE OF ETHICS

- A code of ethics is a guide of principles designed to help professionals conduct business honestly and with integrity.
- A code of ethics document may:
 - outline the mission and values of the business or organization
 - how professionals are supposed to approach problems
 - the ethical principles based on the organization's core values
 - The standards to which the professional is held.
- A code of ethics also referred to as an "ethical code," may encompass areas such as business ethics, a code of professional practice and an employee code of conduct.

Professional Regulatory Board of Pharmacy
Resolution No. 23
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RESOLUTION PROMULGATING AND PRESCRIBING THE CODE OF
ETHICS FOR PHARMACISTS IN THE PHILIPPINES
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CODE OF ETHICS FOR PHARMACISTS IN THE PHILIPPINES

FOCUS AREA: The Pharmacist's Patients and Clients

1. **A pharmacist places the health and well-being of the individual and the community at the center of professional practice.**

Interpretation: A pharmacist commits to help individual and community to improve self-care and to maintain good health, prevent illness and make the best use of medications. A pharmacist establishes therapeutic relationship to gain trust and confidence of the clients.

2. **A pharmacist respects the autonomy and rights of the patient and recognizes cultural differences.**

Interpretation: A pharmacist promotes self-care, decision making in health and rights pertaining to choice of treatment, according to personal, gender, cultural and racial differences.

3. **A pharmacist cares for each individual with competence and compassion.**

Interpretation: A pharmacist provides pharmaceutical care and assists patients and clients with compassion.

FOCUS AREA: The Pharmacy Profession

1. **A pharmacist acts with honesty, integrity and professionalism in her/his relationship with patients, carers and other stakeholders in healthcare.**

Interpretation: A pharmacist builds a trusting relationship with patients, carers, and other healthcare professionals with appropriate actions and behaviors; commits to transparency and accountability in all dealing.

2. **A pharmacist abides by regulatory requirements, scientific principles, professional practice and ethical standards:**

Interpretation: A pharmacist is responsible for his/her actions and faces consequences when regulatory and scientific standards are not met.

3. **A pharmacist is committed to lifelong learning to enhance professional competence.**

Interpretation: A pharmacist ensures that his/her knowledge and skills are continuously updated and upgraded.

4. **A pharmacist demonstrates commitment to the development and enhancement of the profession**

Interpretation: A pharmacist takes leadership roles and involvement in initiatives and programs that are critical to the demands of the profession as it continuously evolves.

FOCUS AREA: Other Health Professionals

1. **A pharmacist respects and collaborates with other healthcare professionals and colleagues to achieve optimal treatment outcomes for their patients and ensures continuum of care**

Interpretation: A pharmacist exercises professionalism, diplomacy and tact at all times and recognizes the individual contributions and differences of the members of the team in the patient's continuum of care.

FOCUS AREA: The Society

1. **A pharmacist in coordination with the government and nongovernment organizations, actively participates in the formulation and implementation of health care policies, standards and programs designed for the benefit of society.**

Interpretation: A pharmacist takes part in the formulation and development of health policies and standards relevant to the practice of the profession and its proper implementation

2. **A pharmacist advocates equitable distribution of health resources, health promotion, disease prevention and wellness**

Interpretation: A pharmacist makes available essential medicines and provides cheaper quality alternatives at all times when appropriate, conducts public health education on rational and responsible use of medicines and promotes healthier communities

MODULE 8: Introduction to Standard Operating Procedure

What are SOP's

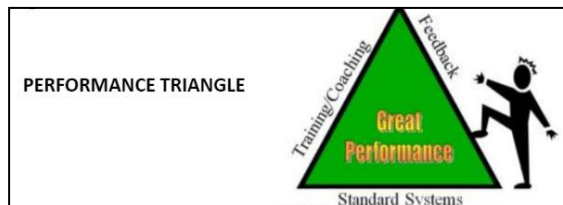
- A standard operating procedure (SOP) is a set of written instructions that document a routine or repetitive activity which is followed by employees in an organization.
- The development and use of SOPs are an **integral part** of a successful quality system.
- It provides information to perform a job **properly**, and **consistently in order to achieve predetermined specification and quality end result**.
- A document that describes how to perform" various routine operations that contains step by step instructions (*FDA Philippines*).
- It is written by the individuals who perform the operation and who share some aspects of the operation.

Importance of SOPs

- SOP is guide personnel "when" and "why" they should perform a task, and "what" is the scope of the task.
- The SOP must undergo series of reviews approvals before it can be imposed. Individuals who can be knowledgeable to review the procedure and who can be higher up in the hierarchy of the department are the possible reviewers and can approve the tentative manual.
- Standard operating procedures are essential to maintain:
 - **CONSISTENCY**
 - Helps to maintain the level of services offered and therefore maintains good pharmaceutical practice at all times
 - **ACCURACY**
 - Ensure that the services are offered with the highest level of attention, care and due diligence to guarantee safety of the patient and confidence of both the patient and the health worker.
 - **RELIABILITY**
 - Ensures that the outlined processes are dependable to achieve outcomes
 - **VALIDITY**
 - To legalise processes within the pharmacy.

Roles of SOPs in the Community Pharmacy

- **Standardized systems**- must ensure consistent work is done and that performance is clear and fair.
 - SOPs help to create consistency in work, they are the foundation for high performance.
- **Training and coaching**- essential to give people the opportunity to understand clearly and perform at their best.
 - SOPs help to guide training and coaching and ensure that people are doing tasks the same way.
- **Feedback**- critical to continual improvement of systems and motivation of employees.
 - Feedback gives direction about how an individual, group/team, or procedure is performing.
 - SOPs are important for fair feedback as otherwise different people might have had different information.



- Through SOPs, service delivery in the pharmacy will be **CONSISTENT**.
 - Patients should be served and counselled in the same way irrespective of whether attended to Pharmacist A or Pharmacist B.
 - Medicines should be ordered on schedule, received, distributed and dispensed in the **required standards**.

Who is responsible to make SOP?

Usually the **Pharmacist** is tasked to make it and reserved the right to create according to the operations that he/she seems to be applicable to his workplace.

How do you create an SOP?

1. First you need to think of the important functions and tasks in your pharmacy other than the basic contents that required by FDA Philippines.
2. The language of your SOP should be clear, Use language that can be easily understood. You may use Filipino or other native dialects to reach those who cannot understand English much. Be considerate; remember that almost all the tasks and operations are performed by employees that may not be eloquent enough to understand the manual in English.

Parts of the SOP

- **OBJECTIVE**
 - describes purpose of the goal and aim.
- **SCOPE**
 - up to what extent can be the task performed
- **RESPONSIBILITY**
 - who can be involved in performing the task.
- **PROCEDURE**
 - the step by step action of doing a task
- **QUALITY RECORDS**
 - how to do records and uphold them
- **FORMS**
 - to where the records are written (Optional)
- **END OF DOCUMENT**
 - can be used to place additional information and rationale

SAMPLE

The image shows a sample form for a Standard Operating Procedure. At the top, it says 'STANDARD OPERATING PROCEDURE' and 'Document No.' with a box for 'Revision No: 1' and 'Page of'. Below this is a 'Revision History' table with columns for 'Revision', 'Prepared by', 'Reviewed by', and 'Approved by'. There is a table for 'Issue No.' and 'Effective Date'. Below that is a 'REFERENCES' table with columns for 'Document No.' and 'Title No.'. The main body of the form lists seven sections: 1. OBJECTIVE, 2. SCOPE, 3. RESPONSIBILITY, 4. PROCEDURE, 5. QUALITY RECORDS, 6. FORMS, and 7. END OF DOCUMENT. A scroll-down arrow is visible at the bottom right of the form.

- The writer, reviewer and editor must affix their sign over their names when completed.
- Should be reviewed regularly and kept up to date.
- A system of revision should be clear before any reform is made.
- All documentation should be made available on request of competent authorities, if possible, all personnel encompassed are given a copy which become their personal guide.
- Records should be made at the time each operation is performed so that in such a way all the significant activities are traceable.
- All records must be readily retrievable, stored and retained.

Basic Components of Writing and Effective SOP

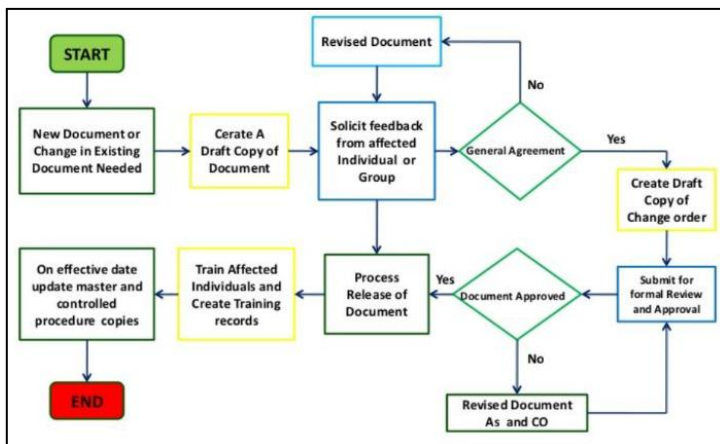
- Quickly touching on the basics, the purpose of these step-by-step instructions for performing operations, is ensuring that personnel perform operations correctly and consistently to achieve a quality outcome through uniform performance.
- With this goal in mind, here are a few best practices for writing SOPs based around common problems.
- Writing procedures from the end user's perspective
- Always remember that SOPs should be written from a purely practical perspective from the point-of-view from those who will actually use them.

10 Reasons for Writing SOP's

1. To provide people with all the safety, health, environment and operational information necessary to perform a job properly.
2. To ensure that production operations are performed consistently to **maintain quality control of processes and products.**
3. To ensure that **processes continue uninterrupted and are completed on a prescribe schedule.**
4. To ensure that **no failures occur** in the manufacturing and other processes that would harm anyone in the surrounding community.
5. To ensure that approved procedures are followed in **compliance with company and government regulations**
6. To serve as **training document** for teaching users about the process for which the SOP was written.
7. To **serve as a checklist for co-workers** who observe job performance to reinforce proper performance.
8. To **serve as checklist** for auditors.
9. To serve as an **historical record** of the how, why and when of steps in an existing process so there is a factual basis for revising those steps when a process or equipment are changed.
10. To serve as an explanation of steps in a process so they can be **reviewed in accident investigations.**

SOP PROCESS AND GUIDELINES IN WRITING SOPS

Flow diagram for SOP preparation and implementation



SOP Preparation

- The organization should have a procedure for determining **what procedure or processes need to be documented.**
 - SOP should be written by individuals knowledgeable with the **activity and the organizations internal structure**
 - **Subject-matter experts** who actually perform the work or use the process.
 - **Team approach** can be followed, especially multitasked processes where the experiences of a number of individuals are critical, which also promotes "buy in" from potential users of the SOP.

- SOPs should be written with **sufficient detail** so that someone with limited experience or knowledge of the procedure, but with a basic understanding, **can successfully reproduce the procedure when unsupervised.**
 - Experience requirement for performing an activity should be noted in the section on personnel qualifications.
 - FOR EXAMPLE: If a basic chemistry or biological course experience or additional trainings is required, that requirement should be indicated.

Review and Approval

- **SOPs should be reviewed (validated) by one or more individuals** with appropriate training and experience with the process.
- It is essentially helpful if draft SOPs are actually **tested by individuals other than the original writer before the SOPs are finalized.**
- The finalized SOPs **should be approved** as described in the organization's Quality Management Plan or its own SOP for preparation of SOPs.
 - The immediate supervisor, such as the section or branch chief, and the organization's quality assurance officer review and approve each SOP.
 - Signature approval indicates that an SOP has been both reviewed and approved by management.

Frequency of Revisions and Review

- SOPs need to remain **current** to be useful.
- Whenever procedures are changed, SOPs should be **updated and re-approved.**
- **SOPs should be also reviewed on a periodic basis e.g.** Every 1-2 years, to ensure that the policies and procedures remain current an appropriate, or to determine whether the SOPs are even needed.
- The **review date should be added** to each SOP that has been reviewed.
- If an SOP describes a process that is no longer followed, **it should be withdrawn from the current file and archived.**

Checklists

- Many activities use checklist to ensure that **steps are followed in order.**
- Checklists are also used to **document completed actions.**
- **Detailed checklists are prepared specifically for a given activity.**
- Remember that the **checklist is not the SOP, but a part of the SOP.**

Document Control

- Each organization should **develop a numbering system to systematically identify and label their SOPs and the document control** should be described in its Quality Management Plan.
 - Each page of an SOP should have control documentation notation.
 - The revision and date are very useful in identifying the SOP in use when reviewing historical data and is critical when the need for evidentiary records is involved and when the activity is being reviewed.
 - When the number of pages is indicated, the user can **quickly check if the SOP is complete.**
 - Generally this type of document control notation is located in the upper right-hand corner of each document page following the title page.

SOP Document Tracking And Archival

- The organization should maintain a master list of all SOPs.
- The file or database should indicate the SOP number, version number, date of issuance, title, author, status, organizational division, branch, section, and any historical information regarding past versions.
 - The **QA manager** is generally the individual responsible for maintaining a file listing all current quality-related SOPs used within the organization.
 - Note that this list may be used also when audits are being considered **or when questions are raised as to practices being followed within the organization.**

MODULE 9: Designing SOPs

Presentation of SOPs

- The best SOP format is one that, given the situation, does the best job accurately transmitting the necessary information and facilitating consistent implementation of the SOP.
- A SOP can be presented in different formats:
 - Simple steps
 - Hierarchical Steps
 - Graphic Format
 - Flowchart Format
 - Annotated Pictures

1. Simple Steps

- These are easy to write and follow and work well for short, simple, straightforward tasks.
- It is used in processes that are fairly repetitive with very limited decision making.

| ADVANTAGES | DISADVANTAGES |
|---|---|
| Easy to write Easy to follow Logical flow | Lack of detail Tend s to get long if detail is included Keeps all steps at same level Does not handle decisions well |

Example:

Procedure for dispensing ARV tablets or capsules:

1. Issue whole packs where possible;
2. If necessary, count out desired number of units using a spatula or knife on counting tray or clean sheet of paper. Avoid touching medicine product with hands, as contamination may result;
3. Recount number of units before packing into the container;
4. Select the appropriate pre-printed label for the ARV preparation to be dispensed. Add the following information and label the package:
 - Quantity
 - Batch No.
 - Expiry date
 - Times at which the medicine is to be taken
 - Patient's name
 - Date
5. Follow standard pharmacy operating procedures to countercheck the product to make sure that package and labelling contain the correct medicine, strength, quantity, dosage form, and directions for use.

2. Hierarchal Steps

- Hierarchal steps is an extension of the simple steps format.
- This format works better for tasks that require additional detail of sub-steps within each primary step.
- It allows the use of easy-to-read steps for experienced users while including more detailed sub steps as well.

| ADVANTAGES | DISADVANTAGES |
|---|--------------------------------|
| Easy to write Easy to follow Logical flow Handles details very well Allows different level of steps | Does not handle decisions well |

Example:

Stocktaking SOP

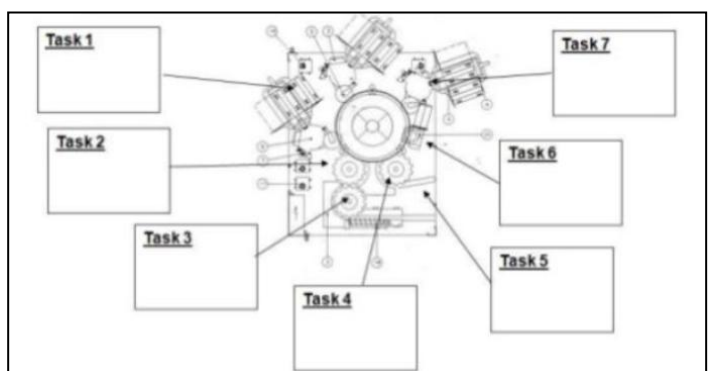
1. Prepare for the stocktaking:
 - Schedule the day and time when stocktaking will be done;
2. Assign staff to conduct the stocktaking;
3. Organize the storeroom;
 - Arrange products according to FEFO;
 - Make sure open cartons, boxes are visible;
 - Separate damaged or expired products.
4. Count the usable products;
 - Count products according to their dispensing units;
 - If you have a bottle that contains individual capsules or tablets, estimate the quantity. If a bottle of 1,000 capsules is 2/3 full, then estimate 650 or 700 capsules. If you have a one-litre bottle of syrup that is 3/4 full, then estimate 0.5 litres;
 - Update the stock keeping records. (The stock keeping record is the Tally Card);
 - Write the date the stocktaking is done and the word "Stocktaking" in the Issued/Received column of the tally card;
 - Write the quantity of the product that you count during stocktaking;
 - The Stock on Hand quantity listed on the Tally Card should match the quantity that you have counted;
5. Take action based on the results of the stocktaking.
 - If the number of products counted during stocktaking does not match the quantity listed on the Tally Card, update the Tally Card balance by adding or subtracting the excess or missing quantities in the appropriate column in the Tally Card;
 - If expired or damaged products are found, dispose of them following established procedures. Subtract the quantity from the Tally Card balance and update the current balance.

3. Graphic Format

- works well for tasks where activities must be done in a specific order and where an easy to follow reminder at the job site is useful.
- breaks long processes into shorter sub processes that consist of only a few steps.
- workers can learn several short sub processes more easily than one long procedure

| ADVANTAGES | DISADVANTAGES |
|---|--------------------------------|
| Easy to write Easy to follow Logical flow Handles long procedures well | Does not handle decisions well |

Example:

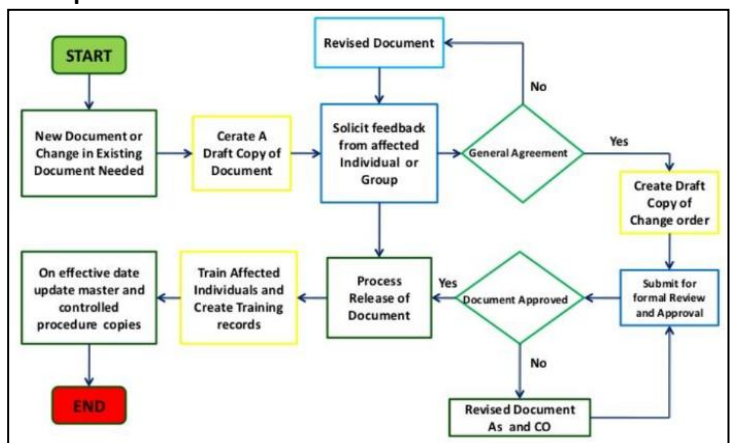


4. Flowchart Format

- A graphic way to present the logical steps in a decision making process.
- provides an easy to follow mechanism for walking through a series of logical decisions and the steps that should be taken as a result.

| ADVANTAGES | DISADVANTAGES |
|---|---------------------------|
| Easy to follow Logical flow Handles decisions very well | More difficult to prepare |

Example:



5. Annotated Pictures

- this format works well for people who cannot read or where a language barrier exists
- pictures can dramatically reduce the need for written explanations
- helps to shorten complex and detailed SOPs



Choice of Format

Which is the best format?

- It is the one that, given the situation, does the best job of accurately transmitting the necessary information and facilitating consistent implementation of the SOP.
- The following considerations will influence the choice of the format:

- The scope and complexity of the SOP
- The people who will use the format and how the SOP will be used
- How the SOP will be used

✓ SCOPE AND COMPLEXITY OF THE SOP

- How many decisions will the user need to make during the procedure?
- How many steps and sub-steps are in the procedure?
 - Routine procedures that are short and require few decisions can be written using simple steps format.
 - Long procedures consisting of more than ten steps, with few decisions, should be written in hierarchal steps format or in a graphic format.
 - Procedures that require many decisions should be in flowchart format.

✓ THE PEOPLE WHO WILL USE

- If they are visual learners, perhaps a series of **pictures or a flowchart will work best.**
- Physical limitations, such as poor eyesight, may necessitate large clear print or bright pictures and plenty of light such as **annotated format.**

✓ HOW THE SOP WILL BE USED

- Depending on the intended use at the time, the SOP may be written or presented differently to be more effective.
 - As a reference manual- more explanatory detail
 - Used for basic training- less detail may be desirable
 - Used for in-depth follow up training or retraining more detail useful
 - As an on-the-job reminder- less detailed overview that is readily accessible

Compliance Monitoring

- It is important to monitor the compliance with SOPs, otherwise the development and implementation of SOPs was useless.

MONITORING COMPLIANCE CAN BE DONE BY:

1. Monitoring if the SOP is being used
2. Periodic review of the SOP
3. Need to evaluate if SOP is contributing to improved service delivery

SUMMARY: Developing & Implementing SOPs

1. **PLAN FOR RESULTS**- start with business goal in mind
2. **FIRST DRAFT**- select a format, there will be revisions, and perfection will come later
3. **INTERNAL REVIEW**- ask each team member to review and comment and revise the procedure if necessary
4. **EXTERNAL REVIEW**- do the same for technical teams

5. **TESTING**- have someone perform each step exactly as in the procedure, while writer watches- revise anything that causes hesitation or confusion.
6. **POST**- Make a final draft and post in workplaces and central master SOP file.
7. **TRAIN**- train, or re-train everyone involved to follow the procedure.

SOPs to be Prepared

| PROVISIONS | REFERENCES | Y e s | N o | / | N A | REMARKS |
|---|------------------------------|-------------|--------|---|--------|---------|
| STANDARD OPERATING PROCEDURES (should be completed, approved, signed (as required) and dated by an appropriate authorized person(s) and should not be changed without the necessary authorization) | | | | | | |
| Pharmacovigilance | FC 2014-025 II A (4) | ✓ | | | | |
| Procurement of stocks | WHO Annex5 8.5 | ✓ | | | | |
| Dispensing of pharmaceutical products | AO 63 S. 1989 | ✓ | | | | |
| Storage of stocks including temperature monitoring & retention of monitoring records | WHO Annex5 14.14 | ✓ | | | | |
| Cold chain management (if with cold-chain) | WHO Annex9 TRS901 4.17 | ✓ | | | | |
| Handling complaints | WHO Annex5 16.1 | ✓ | | | | |
| Handling product recall | WHO Annex5 17.1-17.6 | ✓ | | | | |
| Handling returned products from customers | WHO Annex9 TRS908 6.1-6.3 | ✓ | | | | |
| Handling expired, damaged pharmaceutical products | WHO Annex9 TRS908 5.13, 5.18 | ✓ | | | | |
| Sanitation program indicating the frequency of cleaning and the methods to be used | WHO Annex9 TRS908 4.4 | ✓ | | | | |
| Pest control | | ✓ | | | | |

Activate