MANAGEMENT PROCESSES DURING DRUG DEVELOPMENT: A SPECIAL REPORT ON RESEARCH & DEVELOPMENT IN CRO'S AND PHARMACEUTICAL COMPANIES

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ARTICLE INFO	ABSTRACT
Article history Received 14/11/2018 Available online 30/11/2018 **Keywords** Drug-Development Programs, Investigative New Drug (IND) Application, Product R&D, Quality Assurance/ Documentation.	The most successful new drug-development programs require competent, caring, people-oriented leaders at all levels. Overwhelming social science data show that this approach will optimize productivity, efficiency, and creativity, while fostering employee growth, enthusiasm, cooperation, and loyalty. Companies are organized differently; for example, the various engineering responsibilities may be in one or more departments. A brief description of typical functions follows: _ Synthetic chemistry synthesizes NCE candidates for pharmacological testing. _ Pharmacology examines the in vivo activity of the NCE in animals. Other involved departments/disciplines that are equally important as the above groups include Analytical Chemistry, Biochemistry, Biopharmaceutics/ Pharmacokinetics/Drug Metabolism, Chemical Pilot Plant, Experimental Engineering, Packaging Development, and Statistics. Additional significant contributors include Purchasing and Quality Assurance/ Documentation.

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INTRODUCTION

The most successful new drug-development programs require competent, caring, people-oriented leaders at all levels. Overwhelming social science data show that this approach will optimize productivity, efficiency, and creativity, while fostering employee growth, enthusiasm, cooperation, and loyalty.

THE DRUG DEVELOPMENT PROCESS

Before addressing the components of good management, here is a review of the basic new drug (new chemical entity or NCE) development process.

Brief Overview

The NCE works its way through the following groups before it can be marketed: Synthetic Chemistry, Pharmacology, Toxicology, Pathology, Regulatory Affairs, Investigative New Drug (IND) application, Product R & D, Clinical Research, Regulatory Affairs, New Drug Application (NDA), and Approval by government regulatory agency.

Additional Important Contributors

Other involved departments/disciplines that are equally important as the above groups include Analytical Chemistry, Biochemistry, Biopharmaceutics/ Pharmacokinetics/Drug Metabolism, Chemical Pilot Plant, Experimental Engineering, Packaging Development, and Statistics. Additional significant contributors include Purchasing and Quality Assurance/ Documentation.

Post-NDA Departments

After NDA approval, non-R&D functions—after being partially involved at various stages of NCE development—take over, including Chemical Manufacturing, Engineering, Marketing, Packaging, Pharmaceutical Manufacturing, Quality Control, and Sales.

Departmental Responsibilities

Companies are organized differently; for example, the various engineering responsibilities may be in one or more departments. A brief description of typical functions follows: _ Synthetic chemistry synthesizes NCE candidates for pharmacological testing. _ Pharmacology examines the in vivo activity of the NCE in animals.

1. For economic reasons, activity is determined in animals before safety, whereas in humans, preliminary safety studies need to come first. Toxicology determines the ''macro'' negative effects of the NCE in animals. Pathology examines the ''micro'' negative effects of the NCE in animals. Product R&D designs a simple, preliminary dosage form for initial clinical trials.

2. Additional dosage-form development is deferred until safety/activity experiments in humans show promise. Eventually, scale-up experiments are conducted in cooperation with Pharmaceutical Manufacturing.

Clinical research determines the safety and efficacy of the NCE in humans.

1. Phase I, Examines small-dose tolerance and safety in a limited number of young adult, usually male, volunteers.

2. Phase II, Involving hundreds of patients, investigates efficacy, dosage, and prominent side effects.

3. Phase III, Utilizing thousands of patients, broadens Phase II experiments and determines safety, efficacy, and marketability.

4. Phase IV, Conducted after regulatory approval and marketing, investigates additional medical uses.

Regulatory Affairs works closely with all relevant organizational units and is the primary contact with government regulatory agencies. Analytical Chemistry develops stability-indicating assays for NCEs and identifies/quantifies impurities; cooperates with Product R&D on product stability studies. Biochemistry determines, among other experiments, the cell-level effects of NCEs. Biopharmaceutics, Pharmacokinetics, and Drug Metabolism examines the absorption, distribution, metabolism, and elimination of NCEs Chemical Pilot Plant produces NCEs for R&D groups. Experimental Engineering helps design new processes and equipment. Packaging Development develops containers for new products with stability and consumer issues in mind.

Statistics is involved in planning and interpreting many R&D experiments. Purchasing works with R&D to ensure consistent, high-quality raw materials from vendors. Quality Assurance/Documentation monitors procedures and records to comply with governmentregulated

Good Laboratory and Manufacturing Practices. Chemical Manufacturing supplies the bulk NCE to Pharmaceutical Manufacturing. Engineering offers process/equipment services to post-NDA groups. Marketing, in cooperation with Sales and Advertising, determines the overall strategy for supplying NCE products to primary customers (physicians and other healthcare professionals). Packaging packages and labels manufactured drug products for sale. Pharmaceutical Manufacturing produces finished drug products for consumer use. Quality Control monitors the quality and stability of manufactured/marketed drug lots. Sales supplies products to customers.

Departmental Interactions

It's important for managers and laboratory workers to meet with colleagues from other departments to learn about interrelations and interdependencies and to use that knowledge to ensure mutual understanding, respect, support, and cooperation. Here are examples:

Sales & All R&D groups-

R&D managers and laboratory workers should be encouraged to spend a day or two (one-on-one) with a salesperson ''on the road,'' for two primary reasons:

1. R&D individuals can observe firsthand the results of their labors.

2. Salespersons can learn important, relevant scientific facts about what they are selling and can directly inform the R&D person about problems their customers experience.

Synthetic chemistry & Biopharmaceutics-

Oral absorption data can help lead synthetic chemists in the most promising directions for NCE variations.

Synthetic chemistry & Product R&D-

Formulators usually prefer the most water-soluble form of an NCE; this can conflict with Synthetic Chemistry and Chemical Manufacturing's interest in high yields.

Biopharmaceutics & Pharmacology-

Interactional benefits go both ways, but Biopharmaceutics can help pharmacologists determine whether lackluster potency is attributable to inherent inactivity or poor oral absorption.

Product R&D & Toxicology-

True event: Product R&D helped Toxicology determine that the apparent intestinal irritation of an orally administered NCE was caused not by the drug, but by the ''innocuous'' solvent (glycerin).

Analytical chemistry & Quality control-

Analytical Chemistry develops stability-indicating assays for R&D, then transfers them to Quality Control when the product is marketed. Too often these groups are at loggerheads concerning what is an adequate, efficient assay procedure for the NCE.
Management's mutual respect and cooperation, plus voluntary temporary interdepartmental transfers, canusually minimize these difficulties.

Pharmaceutical manufacturing & Product R&D-

1. These two groups need to interact at the appropriate stages in new drug development (especially scale-up) to ensure that a dependable, highquality product can be consistently and economically manufactured.

2. Hands-on Manufacturing employees may feel most comfortable interacting with R&D scientists at the B.S./Associate degree level rather than at the Ph.D. level.

3. Product R&D laboratory workers at all educational levels should spend their first month or two in Pharmaceutical Manufacturing—working hands-on rather than just observing.

Marketing & All R&D groups-
True event:

A Marketing executive was touring R&D laboratories and asked a key synthetic chemist working on antibacterials what she thought was the most important quality in an antibiotic after therapeutic activity. She replied, ''lack of bacterial resistance.'' When the executive emphasized that Marketing was most concerned about lack of side effects, the scientist said, ''No one ever told me that.''

Quality assurance and documentation & All R&D groups-

Quality Assurance and Documentation should be thought of—and think of itself and operate accordingly—as helpful and supportive, not punitive.

Experimental engineering/product R&D & Pharmaceutical manufacturing-

True events:1. Experimental engineering and Product R&D developed a computer-controlled automatic lyophilization process that was then transferred to Pharmaceutical Manufacturing.

2. Air-suspension particle/tablet coating and electronic monitoring of Pharmaceutical Manufacturing's tablet presses improved product quality and manufacturing efficiency.

DEVELOPING LINE-EXTENSION PRODUCTS

Once the first NCE product has been approved by the government regulatory agency, additional products (Product Line Extensions, or PLEs) are often developed. Requests for PLEs usually come from Marketing and Sales, but ideas can come from any employee/department, particularly from Product R&D. Regulatory approval of most PLEs is less demanding than for NCEs, e.g., there are fewer safety and clinical experiments.

SUCCESSFUL MANAGEMENT OF DRUG DEVELOPMENT

Successful management consists of a series of thoughts, attitudes, feelings, and skilled practices, not simply (and counter productively) an ''I-am-the-boss-so-do-what-Isay'' culture.

Characteristics of a Fertile R&D Work Environment

Psychiatrist Abraham Maslow (1) emphasizes that managers should not be sculptors (molding/forcing/ shaping workers) but farmers who create a fertile work environment wherein all employees can learn, grow, and do their best. R&D managers can optimize group spirit, cohesiveness, innovation, and performance by looking at the team as a circle (in which everyone has a significant contribution to make), and not as the usual organizational pyramid with the boss at the top.

Here are characteristics of a fertile R&D work environment, starting with six cornerstones.

- Ethics—This is noted first for obvious reasons._ Empathy—Empathy is the key to proper treatment of hands-on workers, e.g., managers should ask themselves how they would want their boss to treat them.
- Respect—Feeling respected (valued) as a unique person and as a contributor to group success is as important as anything in the workplace.
- Trust—This is an identical twin to respect. Without mutual trust, two or more people cannot survive a joint effort. The manager's genuine trust of employees as well intentioned, responsible adults is crucial to an efficient, productive work atmosphere.
- Caring—Managers need to have a genuine concern for employees' personal and professional well-being.
- Communication—Keeping employees informed fosters feelings of importance and ''being in on things.'' Managers who listen carefully and inform abundantly will soon be surrounded by good communicators.
- Sense of Purpose—The manager and group members need to know how their department fits into the R&D division.
- Commitment—Everyone has a strong commitment to the long-term health of the division and to harmonized company, R&D, group, and personal goals. _ Competence and Dedication—Group members are competent and confident in each other's ability and dedication.
- Urgent but Well-reasoned, Goal-Focused Activity— Activity is goal-focused, with the general work pace being a healthy blend of urgency and contemplative, well reasoned, deliberate progress.
- Involvement—Productivity, personal growth, and morale will be high if everyone feels involved in the planning, decision-making, and movement of the department toward its goals.
- Individuality—Everyone wants to be treated as an important, unique individual.
- Acceptance—Related to individuality, each person is valued just as they are; idiosyncrasies are tolerated, even appreciated, because variety is the ''spice of life,'' and no one is perfect.
- Civility—''Good management starts with good manners, society's means of ensuring consideration of others as people'' . . . Anonymous.
- Agreeableness, Amiability, Friendliness—These are potent antidotes for nervous tension and anxiety and create as much tranquility in a work environment as civility.
- Honesty, Candor, Openness—If trust is basic to all good things in human relationships, honesty, candor, and openness are basic to sustaining/strengthening those relationships.
- Stability, Security, Predictability—The manager needs to be ethical, fair, and consistent without being inflexible. This minimizes uncertainty and anxiety and makes employees feel safe and secure. More energy can then be focused on productive work.
- Cooperation—When co-workers respect and care for one another and when all people feel safe and secure about their ''place in the sun,'' the stage is set for cooperation rather than for competition, for mutual esteem and pride rather than for envy.
- Recognition—Everyone is recognized for his or her accomplishments and value to the organization. Consequently, they feel good about themselves, their colleagues, their boss, and the corporation.
- Thoughtfulness (Consideration for Others)—It has been said that nothing is more contagious than nervous tension, but surely thoughtfulness must run a close second. This can take many forms, but it generally involves getting outside oneself, being significantly oriented toward others rather than solely toward oneself. It means giving rather than taking.
- Genuineness, Realness—A quality work environment helps workers feel safe, secure, and accepted, thus encouraging them to be themselves, ''warts and all.'' This reduces facades, protectiveness, and defensiveness, and allows people to focus their energy on productive work.
- Independence and Interdependence—When employees are valued for their basic worth and respected for their individuality, they develop a strong sense of independence. Consequently, they will have little need to ''throw their weight around'' or assert their individuality at the expense of others.When people feel good about themselves and receive emotional support from colleagues, they develop a strong sense of both independence and interdependence.
- Cohesive Group Spirit—Under good management, a group develops a close, family-type working relationship in which individual members care for, trust, and respect, and have confidence in one another.
- Deference—If the aforementioned characteristics are operative and the manager seeks advice from and defers to hands-on workers, group members will defer to one another's expertise and judgment when appropriate.
- Pride (but not Arrogance)—Realistic pride in oneself and in the work group strengthens group cohesiveness and individual self-confidence and fosters a ''can-do'' attitude toward innovation and technical challenges.

- Loyalty and Enthusiasm—When colleagues work at being civil and respectful, loyalty and enthusiasm will arise spontaneously. As Napoleon said, ''An army's effectiveness depends on its size, training, experience, and morale . . . and morale is worth more than all the other factors combined.''

Honorable and Successful Management Practices

The following are specific suggestions for managing drug development. Two quotes say it all: Honor is the quality of personal integrity. It is won slowly by a lifetime of small decisions where one places the virtues of compassion and justice ahead of his own advancement. — Anonymous the only way to be a successful manager is to learn to behave like one. — Jay Hall

Behaving Ethically

This is listed first because everything must be based on consistent ethical principles and behavior. R&D managers work in an especially complex environment: they hold great power and interact in complicated ways with hands-on workers, peers, upper management, customers, local and national government agencies, and citizen groups. R&D managers also face a unique situation because often results must be taken on faith. Most projects involve extensive experimentation and complex interpretation; some involve equivocal results.

Managers must:

1. Trust the competence and honesty of laboratory workers and.
2. Make honest use of the group's experimental results. The leader is primarily responsible for the ethical attitude, behavior, and performance of the department.

Here are three ways to ensure success:

1. Set a good example—the manager sets the tone for any group, acting as a role model. When employees observe that the boss is consistently ethical, they will set similar high standards for themselves.
2. Minimize unethical conformity and groupthink— Peer pressure dominates most teenagers (''All my friends do it . . . ''), but adults must resist the slightest unethical behavioral norms.
3. Create a safe, stable, predictable work environment—unless they are pathological, people suffer ethical lapses out of confusion, fear, and insecurity, not out of evil. When workers are afraid of punishment or dismissal if schedules aren't met, work tends to become sloppy. When R&D vice-presidents fear their jobs are in jeopardy, they might manipulate the information going to corporate management so that their organization will look good.

In summary, leaders need to have the personal qualities of candor, genuineness, and integrity. If not, they are in danger of becoming manipulators of people and situations.

Empathizing (The Golden Rule of Management)

As one of the six cornerstones of successful management, the importance of empathy cannot be overemphasized. Before managers make decisions affecting workers (read ''almost all decisions''), they need to remember the Golden Rule of Management: How would I like to be treated? This safeguard on managerial behavior is nearly infallible; here are two examples:

Promotions

Case A:

An experienced laboratory scientist believes that he deserves a promotion to the next grade. He raises the issue with his supervisor; she tells him that he has potential, but she is not yet convinced that he has sufficiently proven himself. Nineteen months later he is promoted.

Case B:

An experienced research scientist's manager comes into his laboratory and informs him that he has been promoted to the next grade. The scientist is delighted but surprised; he didn't expect promotion for another year. The manager says that it may be a little early, but based on his performance and obvious potential, she believes that he deserves to be promoted now.

Reading this example, managers need to play the role of the laboratory scientist and ask themselves how would they would like to be treated by their boss; and would A or B elevate their spirit and incentive to work hard?

Treating employees as well-intentioned, responsible adults
Case A:
Laboratory workers discover that, inadvertently, they are not in compliance with several Good Laboratory Practices regulations. When they inform the manager, he calls a department meeting, scolds all of them, orders them to shape up or else, and demands a full report within 3 days.

Case B:
When the manager is informed of the GLP violations, he calls a department meeting, thanks them for alerting him to the problem, and asks them if he can be of any help; who would like to take charge of correcting the situation; and what deadline should be set so that he can reassure his boss. Again, managers should play the role of laboratory workers and ask themselves how they would like to be treated, A or B.

Communicating
Here are two quite different definitions of communication:
1. The goal of communication is to persuade the listener to agree with the speaker. In this case, one gives little thought to the other's position. Most time and energy are spent thinking about what to say next rather than listening.
2. The purpose of communication is to create understanding. Here the emphasis is on listening, accepting differences of opinion, and freely expressing feelings. Many sounds (street noise, small talk at a party) are assimilated through a process of hearing. This is primarily a physical phenomenon, with only a small mental element and virtually no emotional component. But when someone tries to communicate something they consider important, hearing becomes inadequate; instead, the other person needs to listen to and understand what they have to say. Now the process requires three components—physical, mental, and emotional— and becomes much more complex.

Generalizations aside, managers need to look at how communication skills apply to their job. First, the leader needs to communicate to employees the kind of person he or she is. Good working relationships, the cornerstone of good performance, depend on people getting to know one another. It is the manager's responsibility to initiate and encourage the communication process that brings about understanding. For example, he should meet at least once a year with each employee to find out:
- How things are going, personally and on-the-job;
- What is good and what is bad about the work environment;
- Always refer to the department as ''ours,'' never ''mine;''
- Always say, when introducing a group member to someone else, ''she works with me,'' never, ''she works for me;''
- Encourage being called by his first name, because hierarchy tends to disappear when people are on a first-name basis;
- Try to be the first one at department meetings; too many managers, for various reasons, wait until everyone else is assembled and then walk into the room. Making people wait is an inherent sign of disrespect, intended or not;
- Keep employees informed by posting all nonconfidential memos and notices on a large bulletin board under the categories of ''urgent,'' ''new,'' and ''old.'' These actions are not gimmicks as long as they represent a sincere effort by the manager to communicate clearly and emphatically that everyone in the group is important.

Another valuable communication tool is seldom used—anonymous employee opinion surveys conducted by the manager, in addition to those of the Human Resources department. Annually, workers are asked to submit to the secretary their answers for three questions. The secretary then combines all responses:
1. What I like about my job;
2. What I don't like about my job; and
3. What my boss can do to make things better.

Then (and most important), the manager should call a department meeting and ask the group to decide the priorities for improving the work environment.

Organizing Hands-on laboratory workers
Experts agree that the number-one problem in any corporation is the underutilization of employees. This stems from management's failure to appreciate their intelligence and potential. Douglas McGregor (2) says that most people enjoy working and, given the chance, prefer to exercise self-direction and self-control. They are highly motivated, seek responsibility, and can be a major positive force in company operations if management allows them.

For example, too often Ph.D.s (scientists) are informal project leaders when B.S.- level laboratory workers (associate scientists) can do that job very well, allowing the Ph.D. to act as theoretical science advisors for several project teams. Then Laboratory Assistants (Technicians or Assistant Scientists) with high school diplomas or 2-year degrees can do most of the daily laboratory work with relatively little supervision rather than being treated as a ''pair of hands.'' When employees feel respected and are encouraged to grow and take as much responsibility as possible, they will consult with higher-level scientists when necessary to minimize mistakes and to ensure group success.

First-line supervisors
Group Leaders/Section Heads should be responsible for approximately 15 laboratory workers and should think of themselves as supervisors, not superscientists. The non-supervisory Ph.D.s should make most of the broad scientific decisions; the Group Leader/Section Head should concentrate on becoming a successful manager of people.

Management
Most organizations have too much management; the number of supervisors at all levels should be minimized.

Supervising
      Douglas McGregor says that the supervisor should act as a helper, teacher, consultant, and colleague. Rarely should she assume the role of authoritative boss. Tom Peters agrees, saying ''Leaders are servants.'' Hands-on workers produce results; the manager's primary job is to support them and remove obstacles that prevent them from doing their best. The best supervisor will ask workers what she can do to help; rather than making sure the jobs get done, she assists the workers in doing so. Many leaders feel this approach reduces their organizational power (using ''power'' in the good sense), but the exact opposite is true.
1. The manager ''sees over'' more clearly because discussions with employees will sharpen the view of the situation for everyone.
2. Control and communication are enhanced because employees will interact frequently with a manager who is viewed as a source of help rather than as a giver of orders.
3. Treating employees as competent, responsible adults will greatly increase her influence with them.

Controlling
      Originally, controlling meant running a tight ship; the boss watched over everyone and everything, told employees what to do and when to do it, and made all the important decisions himself. But this made the leader and hands-on workers antagonists, resulting in the manager knowing relatively little about what really went on in the trenches. In contrast, appropriate (nonauthoritarian) control means emphasizing employees' self-control simply because most people are trustworthy. This is especially true in R&D organizations in which the emphasis is on high technology, creativity, and innovation. Peter Drucker, Tom Peters, and Douglas McGregor agree:
1. Drucker says that to be productive, workers need to have control over their work; control is a tool of employees and must never be their master.
2. Peters calls this the control paradox: less is more. Less central control and more genuinely delegated self-control for those closest to the action translates into tighter overall control.
3. McGregor believes that successful supervision is largely dependent on the manager's ability to predict and control human behavior, and the essence of control is selective adaptation. People control the physical world around them, not by expecting nature to do their bidding, but by adjusting their actions to natural laws. For example, humankind does not control surface water by commanding it to flow uphill; rather, people dig channels, adjusting to the fact that water obeys the law of gravity. Similarly, effective management control consists of channeling workers' energies, interests, and capabilities into activities that meet organizational objectives. Management controls the work force by adjusting its decisions and actions to the realities of human nature, and not by telling people what to do and expecting blind obedience.

Delegating
      Managers should delegate because employees like, want, and need to do things their own way. The wise leader assigns research projects only after consulting with laboratory workers, preferably at a department meeting, because bench scientists tend to have a much better feel than the manager concerning who has the time; who is most qualified; and how best to divide up responsibilities. Also, employees feel more respected and involved when they are part of the work-assignment process.

Delegation, not relegation
      Since the biggest waste in any organization is underutilization of employees, delegation makes sense. Unfortunately, too many leaders confuse delegation with relegation. Delegation means assigning responsibility and authority to a representative. Relegation, on the other hand, connotes consignment to an inferior position. When managers give employees narrow, menial tasks and expect them to do all ''delegated'' work exactly as they would, their action is relegation, not delegation.

Goals of delegation
Three primary goals of true delegation are to:
1. Relieve managers of some of their workload so that they have more time to think, meditate, plan, learn, and grow;
2. Move work and responsibility as far down the organizational ladder as possible, increasing efficiency; and
3. Offer all employees maximum challenge and opportunities for growth, even when formal promotions are not immediately available. This increases productivity and develops future leaders. In harmony with these goals, proper delegation has two distinguishing characteristics:
- Most of the delegated tasks are a meaningful part of the manager's job and not just drudgery to avoid;
- Workers are allowed, even encouraged, to perform the delegated work in their own way, with the manager helping only when asked. Case study: In the movie Bullitt, a police lieutenant is working on a case that is of intense interest to a powerful U.S. senator. The senator is not happy with the way the lieutenant is conducting the investigation, so he pressures the lieutenant's boss to force him to proceed differently. As it happens, the captain agrees with the senator but refuses to interfere, saying ''It's his case, Senator.''

Monitoring

Here managers can be either authoritarian (running a tight ship) or smart. They can foolishly spend much of their valuable time monitoring their operation or they can wisely delegate most of that function to employees, thus improving productivity and orderliness, fostering growth, and freeing up more time for broader, long-range tasks. In a good work environment, the impetus for monitoring comes from below, not from above. This places a positive focus on the process. The manager trusts group members and does not feel a need to monitor the operation closely. At the same time, employees are eager to keep managers informed because they sense that they are interested in their work and in departmental progress. They also recognize the need for management to know the general situation, to be informed of major progress or problems.

On the other hand, authoritative monitoring will yield negative results.

- Workers can't help but feel that managers don't trust them—else why would two people do one person's job? Most employees feel, correctly, that it is part of their job to monitor progress and to address problems.
- The situation is inherently and perceived management inanities contribute to employee disrespect and alienation.
- Workers tend to lose interest in doing a careful job of monitoring when they see the boss repeating what they do.
- Management seldom performs lower-level tasks well. Hands-on employees, to whom such tasks are often challenging, are much more motivated and equipped to do them properly.
- Efficiency and productivity suffer, not only because of the redundancy, but because employees are forced to spend time educating the manager about the details.
- If managers get too involved with minutia, they tend to meddle in workers' jobs, and soup is not the only brew spoiled by too many cooks.

Advocating

This management task never appears in a job description, yet it is vital to enhancing the culture, environment, and performance of an R&D operation. The world is not a fair place, and the world of work is even less fair. Why? In a free society, adults make most of their own decisions, but not in the workplace, where management and corporate rules reign supreme. Employees feel vulnerable, and ''results only'' oriented management practices can adversely affect their performance and well-being. In unionized organizations, the agent or steward serves as employees' advocate (although R&D scientists are seldom part of a labor union); in non-union companies, the Human Relations department usually fills that role. Seldom is management viewed as an advocate for workers, and rarely does management perceive itself that way. In fact, employees often consider the boss a powerful adversary—the very reason they need an advocate Surely productivity, not to mention loyalty and enthusiasm, suffers when workers and management consider themselves adversaries.

The manager as advocate

In a well managed, people-oriented organization, the primary advocate for each employee is the immediate supervisor. Not only is that individual in the best position to know and help workers, but she is the major beneficiary of the increased productivity, loyalty, and enthusiasm that follow. Experience has shown that if workers believe their manager is for them and wants them to succeed, and a helper and facilitator rather than an overseer; there is little they won't do for the manager. In fact, when she is under great stress or trouble, the roles become reversed and employees will rush to her aid. Some managers believe that they should be neither advocates nor adversaries but impartial judges. However, social science professionals have shown that managers are no more rational or impartial than anyone else, that everyone labors under a cloud of personal bias. Furthermore, strict impartiality usually results in impersonal treatment, and no one likes being regarded as a ''non-person.''

DISCUSSION

Overwhelming social science data show that this approach will optimize productivity, efficiency, and creativity, while fostering employee growth, enthusiasm, cooperation, and loyalty. Companies are organized differently; for example, the various engineering responsibilities may be in one or more departments. A brief description of typical functions follows: _ Synthetic chemistry synthesizes NCE candidates for pharmacological testing. _ Pharmacology examines the in vivo activity of the NCE in animals. Other involved departments/disciplines that are equally important as the above groups include Analytical Chemistry, Biochemistry, Biopharmaceutics/ Pharmacokinetics/Drug Metabolism, Chemical Pilot Plant, Experimental Engineering, Packaging Development, and Statistics. Additional significant contributors include Purchasing and Quality Assurance/ Documentation. So the management in R&D Process in CRO's and Pharmaceutical Companies has various steps and techniques which are clearly justified by the above article specifically with the role of management and its importance and authors are 'Recommend future Research'

REFFERENCE

1. Argyris, C. Personality and Organization: The Conflict between the System and the Individual; Harper & Row: New York, 1976.
2. Bennis, W.; Nanus, B. Leaders' Strategies for Taking Charge; Harper Collins: New York, 1997.
3. Drucker, P.F. The Practice of Management, 2nd Ed.; Harper Collins: New York, 1993.
4. Goleman, D. Emotional Intelligence: Why It Can Matter More Than IQ; Bantam Books: New York, 1995.
5. Hall, J. The Competence Process: Managing for Commitment and Creativity; Teleometrics International: Woodlands, TX, 1980.
6. Leavitt, H.J.; Bahrami, H. Managerial Psychology: Managing Behavior in Organizations, 5th Ed.; University of Chicago Press: Chicago, 1988.
7. Likert, R. New Patterns of Management; McGraw-Hill: New York, 1987.
8. Maslow,A.H. Eupsychian Management: A Journal; Irwin-Dorsey: Homewood, IL, 1965.
9. Maslow, A.H. Motivation and Personality, 2nd Ed.; Holtzman, W.G., Murphy, G., Eds.; Harper & Row: New York, 1970.
10. McGregor, D. The Human Side of Enterprise; McGregor, C., Bennis, W.G., Eds.; McGraw-Hill: New York, 1985.
11. Rogers, C.R. Freedom to Learn for the 80s; Charles, E.M., Ed.; Columbus, OH, 1983.
12. Rogers, C.R. Carl Rogers on Personal Power: Inner Strength and Its Revolutionary Impact; Delacorte Press: New York, 1977.
13. Sampson, R.C. Managing theManagers;McGraw-Hill: NewYork, 1965.
14. Tingstad, J.E. Good Technical Management Practices: A Complete Menu; Interpharm Press: Buffalo Grove, IL, 1999.

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