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Frontiers of Pharmaceutical Science and Technology and Their Overcoming Strategies



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ABSTRACT

Pharma profession is one of the novel and life sparing profession. The profession develops persistently and has worldwide scope. But there are a few impediments and limits, in view of them the profession have less esteem then it merit. This article investigates the frontiers of pharmaceutical fields and their overcoming strategies. Pharmaceutical profession contains various segments in it and each field contributes for its development and decrements. The number of segments connected with pharma is manufacturing of products, quality assurance, quality control, sales and marketing collectively called industry, Pharma academics, clinical pharmacy and hospital pharmacy etc. Industries have a wide scope but limited growth just because of some barriers like regulatory issues, data integrity, massive projects etc. community pharmacy and hospital pharmacies have their own limitations like patient health literacy, lack of training and practice, work under physician etc. Similarly, other segments have their own issues which retard the growth of pharma profession directly and indirectly. To overcome these there are some approaches discussed in article that can be implement to uplift the profession for batter future aspects.

INTRODUCTION

Frontiers restrict the extend of any profession which constrains the field to develop. Pharmacy is an interdisciplinary field of science comprising almost every aspect of drug discovery manufacturing, sales, marketing, market research, clinical trials academics, dispensing and others. In other words, pharmacy is a health profession that links the health and beneficial science and is charged with ensuring the safe use of medication.

Pharmacy has regarded itself as a major healthcare profession for at least the past 50 years and probably much longer. However, established professions like law and medicine command a much superior status and batter rewards than does pharmacy. There are hierarchies within professions, for example, consultant medical practitioners have higher reward than general practitioners. Thus even though the inputs may be similar between professions but are not equally rewarded. ^[1]

During the twentieth century, the pharmacy profession has evolved through four stages-Traditional era, scientific era, clinical era, and pharmaceutical care era. Traditional era started from early twentieth century which contains formulation and dispensing of drugs from natural sources. Scientific era began after World War II, which generate emergence of pharmaceutical industry and pharmacy education pharmacy education emphasized sciences. Clinical era come with Millis Report in 1975 which defines pharmacist importance for the future and in 1990 Helper and Strand defines the pharmacist role to include appropriate medication use to achieve positive outcome with prescribed drugs therapy i.e. Pharmaceutical- Care era. [2]

The pharmacy profession grows continuously with appreciating rate. The awareness and value of profession uplift respectively. But the presence of some boundaries affects the development of pharmaceutical fields at national and international level. These boundaries and limitation are frontiers of pharmaceutical science and technologies. The consequences of these frontiers are lack of capital, lack of knowledge, shortage of facilities and many more. This is important to diagnose to conquer these limits to up gradate the level of pharmacy profession.

Frontiers of Pharmaceutical Field:

Frontiers of pharmaceutical field can be divided into more specific segments that are highlighted below-

- A. Frontiers relevant to pharmaceutical industries
- B. Frontiers relevant to community pharmacy and hospital pharmacy
- C. Frontiers relevant to pharmacy education
- D. Frontiers relevant to pharmaceutical entrepreneurs
- E. Frontiers relevant to regulatory and governing bodies
- F. Other identified Frontiers

A. Frontiers Relevant to Pharmaceutical Industries:

Pharmaceutical industry contain number of segments and departments, and each have their own operations that are subjected to a variety of laws and regulations that governs the patenting, testing, safety, efficacy, and marketing of drugs.^[3]

The pharmaceutical industry is important because it is a major source of medical innovation. The U.S. research based industry invented about 17 percent of sales in R and D. [4]

The frontiers relevant to pharmaceutical industries are categorized more precisely according to their respective segments in Figure 1-



Figure 1. Different segments of pharmaceutical industry

1. Frontiers Relevant to Pharmaceutical Industries Administrative Segment:

- Absence of lucidity in data and information exchange
- Inappropriate office management strategy
- Inappropriate assets management strategy
- Unable to develop efficient administrative procedures
- Unable act as a connecting link between the senior management and the employees
- Unable makes the rules & regulations and fail to applies these rules in an organization. [5]
- Unorganized membership at the state and national level
- Financial crises
- Unable to provide motivation support
- Employees nonfavorable policies

2. Frontiers Relevant to Pharmaceutical Industries Regulatory Segment:

- Challenges around pricing in the domestic market
- Increased regulations
- Data integrity ^[6]
- Different guidelines of different countries
- A number of regulatory bodies all over the world like WHO, ICH, FDA etc
- Different and vast regulatory requirement for different pharmaceutical products like the API, biological products, Drugs and cosmetic industries have different regulatory requirement that are regulated by different governing bodies
- different standard parameters and approaches for domestic and export market products
- GMP and regulatory deviations and quality issues [7]

- Massive project like In 2011, the Health Ministry brought out a National List of Essential Medicines (NLEM) needed for healthcare in the country and promised to make the 348 drugs in the list available virtually free of cost to the poor and needy. This is indeed a challenging job and considering that health sector is in the state list of responsibilities, ways and means of funding
- Traceability: maintain compliance with strict government and regulatory requirements^[8]

3. Frontiers Relevant to Production Segment:

Dependency on Suppliers

- Companies are looking to transition to lower-cost suppliers located off-shore. Over the past few years, several major manufacturers have been caught producing inferior and potentially dangerous medicines.
- Creativity in Deal Structuring
- Value of Integrated Systems like a company may have manual processes set up in the warehouse (some still operate without any barcodes or scanning procedures) which are not linked to the accounting records. While there is requirement for detailed production records and tracking for FDA compliance purposes, not all companies have built systems to integrate that information into the accounting records automatically.^[9]
- Need number of regulations to be followed like GMP, cGMP
- Higher rate of production but low quality of products

4. Frontiers Relevant to Quality assurance Segment:

- Laborious and old documentation techniques
- Rigid and lack of flexibility
- Too much theories but unimplemented
- Different standards of SOPs, STS & STPs, Validation process *etc* in different industries and in different countries^[10]

- Lazy quality and safety system
- 5. Frontiers Relevant to Quality Control Segment:
- Heavy workload
- Absence of documentary evidences
- Standard of instruments and equipments
- Inability to understand the need of customers
- Improper instrument handling skills
- 6. Frontiers Relevant to Research and development Segment:
- Problems occurs in measurement of output in private goods sector [11]
- The cost of developing new drug has sky socket, and time required to doubled [12]
- No mechanism for sharing losses [13]
- Defective licensing policies
- Obsolete machinery, equipments, products and techniques [14]
- Higher cost of processes and innovation
- Lengthy processes and delayed outcomes [15]
- 7. Frontiers Relevant to Pharmaceutical products Marketing Segment:
- Physician dependant sale
- Confined market
- Market competition
- Inefficient market strategies

8. Miscellaneous:

- Financial crises
- Lack of knowledge and skilled staff
- Lack of concentration
- Lack of responsibility
- Employee nonfriendly policies
- Heavy workload
- Increase generic competition
- Lack of attention on regulation
- Lack of motivation
- Heavy competition
- Lack of Teamwork
- Sickness of industries
- Unsatisfied employees relationship
- Corruption

B. Frontiers Relevant to Community and Hospital Pharmacies:

A community pharmacy, often referred to as retail pharmacy or retail drug outlets, is places where medicines are stored and dispensed, supplied or sold. The general population usually calls community pharmacies "medical stores." Pharmacists working in the community practice setting are either diploma pharmacists or graduate pharmacists with B. Pharma degrees. Throughout this paper, the word "Pharmacist" has been used to describe both types.



Hospital pharmacies usually stock a larger range of medications, including more specialized and investigational medications (medicines that are being studied but have not yet been approved), than would be feasible in the community setting. Hospital pharmacies typically provide medications for the hospitalized patients only, and are not retail establishments and therefore typically do not provide prescription service to the public.

The public perception of community pharmacy and the pharmacist is very weak. The general population considers community pharmacists as drug traders and obviously not better than the general store owners. Consumers and patients consider a visit to the medical store to purchase drugs in much same way they consider a visit to a grocery to buy food items. The pharmacists are portrayed as poor compounders, who are assistants to doctors in mainstream films and dramas. This is not surprising because the national health policy 20029 while declaring current levels of healthcare professionals maintain a stoic silence about the pharmacists. The Indian Public Health Standards formulated recently under the National Rural Health Mission (NRHM) does not place much emphasis on the role of pharmacists as compared to other categories of personnel such as nurses and laboratory technicians. In the recently accepted union government's sixth pay commission report, pharmacists have been placed in the lowest band and structure along with other non technical persons. [16]

There are some highlighted points which affect community pharmacy profession:

- Lack of emphasis on the role of pharmacists as compared to other categories of personnel
- Low pay scale
- Patient health literacy
- Lack of training and practice
- Lack of professional knowledge on health topics
- Some of less trained pharmacist having misinformation about the body as well as nature and cause of disease
- Lack of interest in patient
- Communication errors

- Inappropriate methods of stocking and inventory management which affect demand fulfillment
- Lack of facilities to counsel patient in hospitals
- More workload and less staff in hospital pharmacies
- Lack of employee facility in hospitals
- Work under the physician

C. Frontiers Relevant To Pharmacy Education:

India, formal pharmacy education leading to a degree began with the introduction of a 3-year Bachelor of Pharmacy (B. Pharm) at Banaras Hindu University in 1937. At that time, the curriculum was presented as a combination of pharmaceutical chemistry, analytical chemistry, and pharmacy, which prepared graduates to work as specialists in quality control and standardization of drugs for pharmaceutical companies,^[17] but not for pharmacy practice. Before India gained independence in 1947, there were 3 institutions offering pharmacy degree programs.^[18] In 1944, the Punjab University started a pharmacy department; in 1947 L.M. College was established in Ahmadabad.

The concept of pharmacy practice was not realized until after independence was gained. In 1948, the Pharmacy Act ^[19] was enacted as the nation's first minimum standard of educational qualification for pharmacy practice to regulate the practice, education, and profession of pharmacy. Prior to mid 1980s, the growth of publicly funded institutions of higher education (including pharmacy institutions) was very slow. ^[20] Until early 1980s, there were 11 universities and 26 colleges offering pharmacy education at the bachelor's and master's levels. In addition, there was at least 1 government school in every Indian state offering the D. Pharm program. Since the late 1980s, due to rapid industrialization in the pharmaceutical sector, privatization, and economic growth, pharmacy education has been developing faster in India than anywhere in the world. In 2007, there were 854 institutions that admitted more than 52,000 students to the B. Pharm degree program and 583 institutions that trained more than 34,000 students in the D. Pharm degree program. ⁹ Most of the institutions, however, are privately funded colleges or privately funded universities. The private sector, which accounted for about 10% of the students admitted in the 1980s, now accounts for 91% of all

pharmacy students admitted.^[21] Pharmacy education in India is regulated by 2 organizations: the Pharmacy Council of India (PCI), under the Pharmacy Act of 1948, and the All India Council for Technical Education (AICTE),^[22] which was established under the AICTE Act of 1987.

Although the craze and status of pharmacy education increase day by day in India and whole of the world, but there are some of the frontiers which limit it.

Pharmacy education system is composed of three major elements which having their own frontiers (Figure 2):

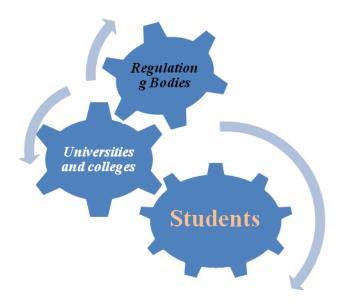


Figure 2. Major elements of Pharmaceutical education system

i. Frontiers relevant to Regulatory Bodies:

- A large expansion, as a result, the quality of education is heterogeneous and among professionals, there are dissimilarities in their quality professional training.^[23]
- Regulation by more than one regulatory bodies like in India pharmacy education is regulated by PCI, AICTE, and BTE.
- Independent syllabus and examination procedures & format for self finance universities.

ii. Frontiers relevant to universities and colleges:

- Academic integrity
- Complain of not getting 'right man for right job
- Failing entry level remunerations and sliding glamour of Pharmaceutical education in students
- Large populous of universities affiliated management institutes, AICTE recognized institutes and UGC approved institutes are churning hoard of Management
- Teachers with no business experience
- No provision for practical experience
- Paucity of funds with self-funded management institutions
- Lack of industry interaction
- Theoretical nature of assessment of students^[24]
- Lack of facilities for practical like chemicals, instruments, apparatus
- More focus on quantity not on quality
- Private college are devoted for money not for education
- Standards and direction are on documentation not follow in genuine
- Lack of discipline
- Lack of problem solving ability of faculties
- Faculty Communication Skills
- Increasing costs and shrinking university budgets

iii. Frontiers relevant to students:

Students do not seem to possess expected knowledge and skills

- Lack of attention in study
- Sexual harassment
- Student privacy
- Wrongful termination
- Discrimination,
- Disabilities
- Student rights^[25]

D. Frontiers Relevant to Pharmaceutical Entrepreneurs:

In the country's total Rs 1, 50,000-crore worth of pharmaceutical production, Gujarat contributes about Rs 50,000 crore or nearly 33 per cent. The state has about 800 pharma manufacturing companies, of which nearly 80 per cent are SMEs.

According to industry experts, government support is required to make contract manufacturing lucrative for entrepreneurs and boost exports from India. Last year, India exported pharma products including formulations and active pharma ingredients (API) wroth Rs 90,000 crore. India exports pharma products to about 210 countries with 28 percent going to the US, 19 percent to Europe and 19 percent to Africa. [26]

- Highly regulated stream
- Need large capital to start pharmacy business
- Increasing competition
- Costly machinery, stringent regulatory norms and price controls
- Zero defects requirement ^[26]
- Changing business scenario^[27]

E. Frontiers Relevant to Regulatory And Governing Bodies:

The global pharmaceutical industry is currently in a dynamic state due to the rise in the number of partnerships, mergers, and acquisitions that have taken place in the past few years. Therefore the recent political changes across the globe are set to make things more uncertain.

The US may be seeing major changes under the leadership of the new Government. We can expect to see a number of changes, such as the repeal of Obamacare, reduced taxes and regulations, and lowered drug prices based. [28]

- Government regulation lengthens the process for bringing new pharmaceuticals to market and restricts the drugs sector to protect public safety.
- Various Regulatory Laws and amendments for example: In India, drug manufacturing, quality and marketing is regulated in accordance with the Drugs and Cosmetics Act of 1940 and Rules 1945. This act has witnessed several amendments over the last few decades. The Drugs Controller General of India (DCGI), who heads the Central Drugs Standards Control Organization (CDSCO), assumes responsibility for the amendments to the Acts and Rules. Other major related Acts and Rules include the Pharmacy Act of 1948, The Drugs and Magic Remedies Act of 1954 and Drug Prices Control Order (DPCO) 1995 and various other policies instituted by the Department of Chemicals and Petrochemicals. Some of the important schedules of the Drugs and Cosmetic Acts include: Schedule D: dealing with exemption in drug imports, Schedule M: which, deals with Good Manufacturing Practices involving premises and plants and Schedule Y: which, specifies guidelines for clinical trials, import and manufacture of new drugs.
- In accordance with the Act of 1940, there exists a system of dual regulatory control or control at both Central and State government levels. The central regulatory authority undertakes approval of new drugs, clinical trials, standards setting, control over imported drugs and coordination of state bodies' activities. State authorities assume responsibility for issuing licenses and monitoring manufacture, distribution and sale of drugs and other related products.
- Patents and Data Protection related issue
- Various Policies relating to clinical trials in different countries

- Different policies related to Drugs, Drug products, APIs, Medical devices, surgical products *etc*
- Numbers of principal provisions are available like Ten categories of sterile devices: cardiac and drug eluting stents, catheters, bone cement, heart valves, scalp vein sets, orthopedic implants, internal prosthetic replacements, IV cannulae and intraocular lenses; would be considered as drugs and consequently regulated.
- Proliferation of spurious and substandard drugs in the Indian market
- Dual licensing mechanism acts as a deterrent to uniform implementation of regulatory procedures.^[29]
- Much variation in adoption rates of different regulations.
- A majority of regulations greatly reduce pharmaceutical revenues [30].
- Lack of transparency in licensing procedures
- Inadequate regulatory expertise and testing facilities to implement uniform standards
- Need for greater thrust on institutional support to small scale firms to enable speedy implementation of Schedule M upgradation and standardization of drug quality
- Need for greater clarity on patentability of pharmaceutical substances and conditions under which firms can apply for compulsory licenses to prevent legal battles between local firms, MNCs and civil rights groups.
- Need for greater coordination, accountability and transparency in functioning among different ministries concerned with drug regulation.
- High level of corruption

Regulatory control of Pharmaceutical sector

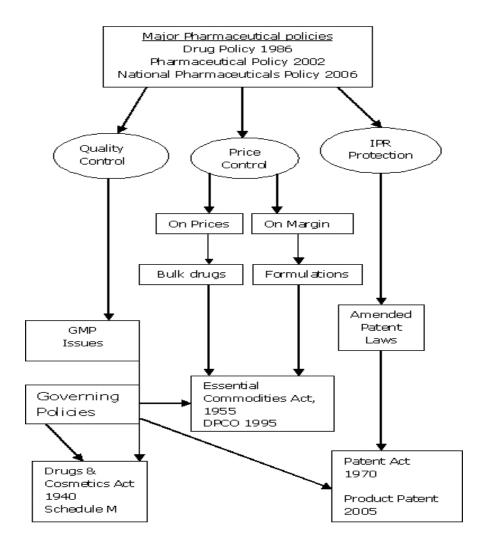


Figure 3. Regulatory control of pharmaceutical sector

F. Other Identified issues:

- Hide Pharmaceutical Scopes for example, Pharmacovigilance, Clinical Research, Drug Regulatory Affairs, Medical Coding *etc*.
- Lack of interest
- Lack of financial issues
- Lack of motivation
- Lack of dedication
- Less pay scale

- Lack of professionalism
- More regulated but less discipline field
- Less student awareness and sincerity regarding profession

Strategies to Overcome Pharmaceutical Frontiers:

It's no secret that the pharmaceutical industry has been grappling with diminishing productivity. ^[31] Global pharmaceutical markets are in the midst of major discontinuities. While growth in developed markets will slow down, emerging markets will become increasingly important in the coming decade. ^[32] This is important to approach for betterment of pharmaceutical industries. Some of the most focus areas in each segment of pharma field to be improved are discuss hereunder:

1. Approaches to long viability of industries:

- Determine therapeutic area of focus
- Increase focus on innovation
- Focus on diversification
- Synergies for R&D capabilities
- Improve manufacturing, marketing and sale techniques
- Specialization
- Develop global strategies specific to target region
- Develop better market model
- Communicate more clearly and openly with customers
- Avoid the mistakes many companies have made
- Focus on lifecycle management and develop standard process and tools to make this a part of the organization function under normal operation conditions

- Maintain patient safety and develop & maintain brand loyalty
- Address unmeet medical needs, enlarge the global business footprint and diversify source of revenue
- Broaden potential sources of treatment for patient care
- Invest more in biological therapies
- Ensure patient safety
- Seeking additional indications that can benefit patient
- Make target investment in areas that help advance the treatment of disease not currently being address
- Re-establish a working relationship with these stakeholders built on trust and openers.
- Partner with FDA and regulatory agencies to use technology to make the approval process more efficient leading to quicker approval as well as earlier discovery of risk and safety issue.
- Develop a process or standard to clearly and transparently communicate product safety risk and efficacy to regulatory agencies.
- Take the time to access the medicinal needs of the people in the regions and countries they want to do business in. Do not just try to find a source of additional income.
- Develop an organization staffed and trained to support the execution of the business area necessary to deal with the dynamics of growing and changing organization.
- Try to meet the standard requirement as per regulatory authorities in the targeted country to establish guideline for safety and efficacy target.
- Invest skilled workers and provide sufficient training and knowledge program at each level to them.
- Accommodate good services to employees, channels of distributions and consumers to address the unmeet needs.

- Products and services made available to patients at affordable costs.
- Not only try to document the standards but should implement the same.^[33]

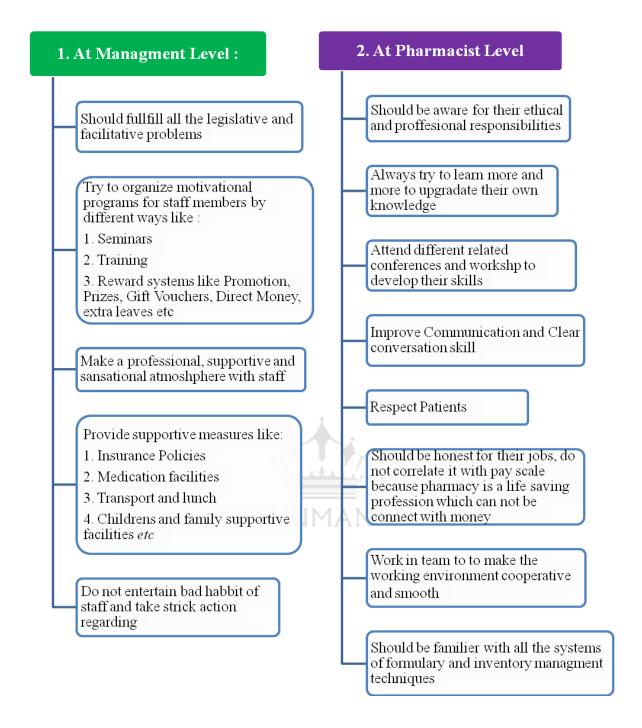
2. Approaches To Overcome Community And Hospital Pharmacy Frontiers:

A Pharmacy either it is community or hospital pharmacy composed of two major parts each have their own frontier. So these can be overcome at their own levels discuss hereunder (Figure 4):



Figure 4. Major Parts of Community and Hospital Pharmacy

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3. Approaches to Overcome Pharmacy Education Frontiers:

The upgradation in an education system can be achieved by targeting one of three sites which affect each other in following manner (Figure 5):

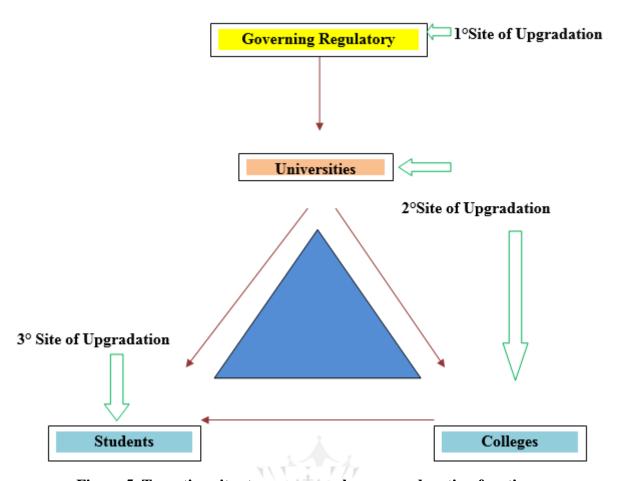


Figure 5. Targeting sites to overcome pharmacy education frontiers

The figure represents all the major segments of education system with are connected to each other in a triangular model. The governing bodies are primary sites of upgradation because all the segments of triangle work as per the rules and guidelines of governing bodies like AICTE, PCI *etc*. The governing bodies are directly linked with Universities. They gives direction for Universities which are to be followed by all three segments in direct and indirect manner. Upgradation in governing bodies' policies will help in the upgradation of all the segments of education system.

Universities and colleges are secondary site of upgradation because they both follow the rules and guidelines of governing bodies and work for regulation of students. Universities regulate both the colleges and students so upgradation in universities processing directly help in upgradation of both colleges and students.

Colleges follow the regulation of universities and regulate students. The students are tertiary sites of upgradation.

There are the following approaches to overcome the frontiers of education system:

a) Approaches at the Level of Governing Bodies:

- Update guidelines and rules regarding education standard and following techniques.
- Application of TQM and innovation ecosystem in pharma education.
- Update Quality Curriculum and educational syllabus.
- Mandate the education sector for better Practical Knowledge than only theoretical.
- Mandate the counseling system for education.
- Funding of Research project.
- Develop new updating system and reward schemes.
- Take steps regarding awareness of research, Funding and reward system to each academic source and student level, to make them keener to work.
- Organize national and international level talent workshops to get more and more talent.
- This should be mandatory to industries to provide training yearly to particular number of students as well as teachers.
- Support technical and smart education strategies, not only mastery education system.
- Generate updated and national internship programs.
- Approved only dedicated colleges which have all the scopes of educating student not just to teach students.
- Contribute to develop the word wide community of research in education evaluation.
- Work in a direction to make India a better platform for research and innovation in true way.
- There should be a quality assurance system in pharma education. [34]

b) Approaches at the Level of Universities and Colleges:

- Prevent the entry of Non-meritorious students in the course.
- Follow focus and specialized way of Teaching.
- Increase interrelationship of industries and clinical exposure by inviting guest lecture from industries and clinical fields for more relevant study design and more realistic study methods of understanding.
- Focus on practical handling and practical skills.
- Generate smart learning techniques.
- Fulfill all the requirements and facilities like sufficient teaching staff, appropriate laboratories, Instruments, equipments, apparatus *etc*.
- Follow government recommendation regarding education, carefully and honestly.
- Promote a system that should be sufficient to provide learning environment and adept innovation ideas.
- A counseling cell should be available in each college to support student professionally and personally.
- Adopt advance methods of learning like workshops, conferences, seminars etc.
- Provide various reward systems like scholarship on Talent, fee consation Future study advantages *etc*.
- A system should be devised so that each and every student gets equal opportunity to think free and develop his/her skill to the maximum.
- Teachers should be such a capable to give an initial pulse to the student and nurture their talent.
- Universities and colleges should have adequate training and development programs for both the teachers and students.

- An updating cell should be there to aware the students that what are the latest changes going in the field of pharmacy and other fields also.
- Contribute to develop a worldwide community of researchers in education evaluation.

c) Approaches at the Level of Students:

- Students should not work hard only; they always try to adopt smart working skills.
- Try to focus on practical methods of learning.
- Be familiar with new technologies and try to involve it in innovation.
- Student should focus on their own talents and try to grow up their talent.
- Students should focus on their own weakness and try to overcome from these.
- Does not study to get qualify only, try to learn something new always.

4. Approaches to Overcome Pharma Entrepreneur Frontiers:

Establishment of Pharmacy business is very critical because it is one of the highly regulative businesses worldwide. There are a lots of legislative and market requirements to run a pharmacy business. With some of the approaches we can make easy this tough path:

- Identify suitable government policies and beware of all for economic friendly business startup.
- Beware of government schemes and take benefits of these schemes for smooth startup of pharmaceutical business.
- Try to make contact with governing and ruling authorities at local and nation level that support the business.
- Do not be only money minded. Encourage the quality of product and consumers expectations.
- Make promoting and motivational environment for employees.
- Continue learning about new technologies and updating.

- Be honest with product both at domestic and international level.
- Maintain the quality of product.
- Adopt advance changes in product to bear the competition in market.
- Try to make the product available at reasonable prices because pharma products are essential for survival at serious condition so each people can afford it to save and betterment of life.
- Maintain honesty, ethics, dedication, and discipline in pharma profession.
- There are following segments of a pharma business and each have their own importance in the development of business, so it is important to focus on the requirement of each segment at each level of development stage (Figure 6):

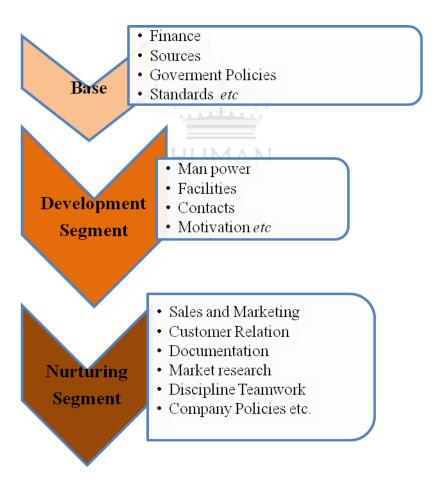


Figure 6. Major segments of Pharma Business

5. Other Relevant Approaches to Uplift Pharma Profession:

- Awareness programs for ethical role of Pharmacy profession and Responsibilities.
- Awareness regarding scope of pharmacy profession which is less common.
- Take measures to uniform regulatory requirement of pharmaceutical products and services all over the world.
- Work for excellence in major pharma segments like R& D, clinical and dispensing practices *etc*.
- Do not pollute the pharma profession by incorporating corruption.

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