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Review Article

Pharmaceutical industry visit: a mesmerizing reflection of academic knowledge towards the industrial playground of applications

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ABSTRACT

Industrial visit is a part of a college curriculum, seen more often in a pharmacy course, during which students visit companies and get insight regarding the internal working environment of a company and how a company functions, as well as useful information related to the practical aspects of the educational course which cannot be visualized in lectures. The industrial visit is considered one of the most tactical methods of teaching. It provides students with an opportunity to learn practically through interaction, working methods and employment practices. Visiting a company gives students a practical perspective on the world of work; it gives them exposure to current work practices as opposed to possibly theoretical knowledge being taught at college. Industry visits are relevant to media students too. A visit to a green research domain in a drug discovery company makes understanding concepts easier.

Keywords: Competitive intelligence, Intellectual property rights, Research and Development, Good Manufacturing Practice, World Health Organization, Food and Drug Administration, Quality Assurance, Quality Control, Abbreviated New Drug Application, New Chemical Entity, Quality by Design

INTRODUCTION

The pharmaceutical industry develops produces and markets drugs or pharmaceuticals for use as medications. Pharmaceutical companies may deal in generic or brand medications and medical devices. They are subjected to a variety of laws and regulations that govern the patenting, testing, safety, efficacy and marketing of drugs. The Pharmaceutical industry in India is the world's 3rd largest in terms of volume and stands 14th in terms of value. According to Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, the total turnover of India's pharmaceuticals industry between 2008 and 2009 is US$21.04 billion. Mumbai, Hyderabad and Ahmedabad are the major pharmaceutical hubs of India, while the domestic market is worth US$12.26 billion as of 2012 and is expected to reach US$49 billion by 2020. The government started to encourage the growth of drug manufacturing by Indian companies in the early 1960s and with the Patents Act in 1970. However, economic liberalization in 90s by the former Prime Minister P.V. Narasimha Rao and the then Finance Minister, Dr. Manmohan Singh enabled the industry to become what it is today. This patent act removed composition patents from food and drugs and though it kept process patents, these were shortened to a period of five to seven years.[1]

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Figure-1: Industry visit

The lack of patent protection made the Indian market undesirable to the multinational companies that had dominated the market and while they streamed out. Indian companies carved a niche in both the Indian and world markets with their expertise in reverse-engineering new processes for manufacturing drugs at low costs. Although some of the larger companies have taken baby steps towards drug innovation, the industry as a whole has been following this business model until the present. India's biopharmaceutical industry clocked a 17% growth with revenues of Rs.137 billion ($3 billion) in the 2009-10 financial year over the previous fiscal. Bio-pharma was the biggest contributor generating 60% of the industry's growth at Rs.8,829 crore, followed by bio-services at Rs.2,639 crore and bio-agri at Rs.1,936 crore.

Figure-2: Industry personnel

A pharmaceutical formulation and its research play important role in the young generation of the pharmacy students because without seeing the process we don't know about the formulation and development of any medicine because of that an industrial visit should be compulsory to the pharmacy students. Pharmaceutical industry is a most diverse, R&D oriented, hypercompetitive and knowledge sensitive industry. Competitive intelligence (CI) is a process of ethically and systemic data gathering from operating system to draw important business conclusions. Use of CI for drawing important conclusions regarding present scenario and future forecasting is very important and growth determining practice of pharmaceutical industries. Intellectual property rights (IPR) is an integral part of the industry and IPR related information is freely available in public patent databases. By analyzing patents company can derive important conclusion regarding competitor's R&D activities, quality of research, collaboration and alliance and can convert this information to knowledge which can play important role in taking future decisions.[2-4]

Figure-3: Good Manufacturing Practice

Pharmaceutical industry in one of the prominent industry though out the globe and further it is in growing phase, so innovative activities and strategies play important role in the growth of industry. However the flip side is that, there is stiff competition between companies for same drug molecule, same disease area or for the same treatment. Ethically looking over strategies and tactics of competitors, company can drive important conclusions regarding present scenario and can also forecast about future. Intellectual property rights (IPR) is an integral part of the pharmaceutical industry. Information of patents is freely available in various patent databases. By analyzing intellectual property (IP) information important conclusion regarding rivalry activities can be drawn out, so pharmaceutical industry uses IP as a tool for competitive intelligence (CI). Further advents of IP in CI are elaborated in coming section.

GMP- It is the sum total of the organized arrangements with the objective of ensuring that products will be of the quality required for their intended use. WHO defines Good Manufacturing Practices (GMP) as "that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by

the marketing authorization?" GMP covers all aspects of the manufacturing process: defined manufacturing process; validated critical manufacturing steps; suitable premises, storage, transport; qualified and trained production and quality control personnel; adequate laboratory facilities; approved written procedures and instructions; records to show all steps of defined procedures have been taken; full traceability of a product through batch records and distribution records; and systems for recall and investigation of complaints. Good manufacturing practice guidelines provide guidance for manufacturing, testing and quality assurance in order to ensure that a food or drug product is safe for human consumption. Many countries have legislated that food; pharmaceutical and medical device manufacturers follow GMP procedures and create their own GMP guidelines that correspond with their legislation.[5]

Figure-4: Quality Assurance

All guidelines follow a few basic principles:

- Hygiene: Pharmaceutical manufacturing facility must maintain a clean and hygienic manufacturing area.
- Controlled environmental conditions in order to prevent cross contamination of food or drug product from adulterants that may render the product unsafe for human consumption.
- Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
- Manufacturing processes are controlled and any changes to the process are evaluated. Changes that have an impact on the quality of the drug are validated as necessary.
- Instructions and procedures are written in clear and unambiguous language.
- Operators are trained to carry out and document procedures.
- Records are made, manually or by instruments, during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the food or drug was as expected. Deviations are investigated and documented.
- Records of manufacture (including distribution) that enable the complete history of a batch to be traced are retained in a comprehensible and accessible form.
- The distribution of the food or drugs minimizes any risk to their quality.
- A system is available for recalling any batch from sale or supply.
- Complaints about marketed products are examined, the causes of quality defects are investigated and appropriate measures are taken with respect to the defective products and to prevent recurrence.

Practices are recommended with the goal of safeguarding the health of consumers and patients as well as producing good quality food, medicine, medical devices, or active pharmaceutical products. In the United States, a food or drug may be deemed "adulterated" if it has passed all of the specifications tests, but is found to be manufactured in a facility or condition which violates or does not comply with current good manufacturing guideline. Therefore, complying with GMP is mandatory in all pharmaceutical manufacturing and most food processing.

GMP guidelines are not prescriptive instructions on how to manufacture products. They are a series of general principles that must be observed during manufacturing. When a company is setting up its quality program and manufacturing process, there may be many ways it can fulfill GMP requirements. It is the company's responsibility to determine the most effective and efficient quality process. The quality is built into the product and GMP is the most essential part of ensuring this product quality.[6]

Quality assurance- It is the sum total of the organized arrangements with the objective of ensuring that products will be of the quality required for their intended use.

Quality control- Is that part of Quality Assurance aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use.

Pharmacy is a subject which runs on its two legs: chemistry and biology. Chemistry part involves in pharmaceutical chemistry including medicinal chemistry and quality assurance division which focus on synthesis and quality improvement by quality assurance followed by drug design.

Chemistry is totally involved in pharmaceutics and biopharmaceutics through formulation strategy by dosage form design followed by physical chemistry aspects. Chemistry and biology both are also incorporated in pharmacology and bioanalytical division where the drug-receptor concept is followed by quantitative structure activity relationship (QSAR) studies to produce the lead molecule to process for further toxicological assays followed by acute, sub-acute, chronic, teratogenic, carcinogenic studies to get lower therapeutic index by ED_{50}/LD_{50}.[7-9]

Figure-5: Quality Control

Clinical pharmacy gives the reports on clinical trials by phase-I, phase-II, phase-III and phase-IV studies on the drug. Pharmacognosy shows the origin of drug from natural source (plant, animal and mineral) sources to get the parent moiety for various substitutions to produce a potent drug. Drug or active pharmaceutical ingredient (API) which is a xenobiotic because it is administered into the body from outer source which is a chemical entity having specific structural network having property to bind with macromolecular bioreceptor platform to control the biochemical malfunction inside the body with minimum toxicity. A drug can't be administered directly into the body, so it is formulated into a specific formulation (tablet, capsule, injection, inhalation, cream/ointment etc.) so that it can be easily taken by patient with no compliances.

Each pharma industry has four main branches: pharmaceutical chemistry, pharmaceutics, pharmacology and pharmacognosy. All these subjects are being taught in all pharmacy academic institutions in details in both undergraduate (B. Pharm) and postgraduate (M. Pharm) levels in theory and practical. Implementation of all academic knowledge in industrial level is known as industrial visit where the students get chance to learn about the manufacturing of these lifesaving entities. ANDA (abbreviated new drug application), NCE (new chemical entity), QbD (quality drug design) are latest strategies in modern pharmaceutical sciences.

An **Abbreviated New Drug Application** (**ANDA**) is an application for a U.S. generic drug approval for an existing licensed medication or approved drug. The ANDA is submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, which provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the public. Electronic submissions of ANDAs have grown by 70% since November 2008. The Section IV challenge has been credited with suppressing new drug innovation. A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. All approved products, both innovator and generic, are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). The publication ***Approved Drug Products with Therapeutic Equivalence Evaluations*** (the List, commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act.

Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal and *in-vitro*) and clinical (human) trial data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug). One way scientists demonstrate bioequivalence is to measure the time it takes the generic drug to reach the bloodstream in 24 to 36 healthy volunteers. This gives them the rate of absorption, or bioavailability, of the generic drug, which they can then compare to that of the innovator drug. The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as

the innovator drug. In cases of topically active drugs, the bioequivalence of a drug can be demonstrated by comparing drugs dissolution or transdermal drug absorption is compared with the innovator drug. In cases of systemically active drugs, active drug blood concentration of that drug is compared with the innovator drug.

Using bioequivalence as the basis for approving generic copies of drug products was established by the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This Act expedites the availability of less costly generic drugs by permitting FDA to approve applications to market generic versions of brand-name drugs without conducting costly and duplicative clinical trials. At the same time, the brand-name companies can apply for up to five additional years longer patent protection for the new medicines they developed to make up for time lost while their products were going through FDA's approval process. Brand-name drugs are subject to the same bioequivalence tests as generics upon reformulation.[10]

A **new chemical entity** (**NCE**) is, according to the U.S. Food and Drug Administration, a drug that contains no active moiety that has been approved by the FDA in any other application submitted under section 505(b) of the Federal Food, Drug and Cosmetic Act. A **new molecular entity** (**NME**) is a drug that contains an active moiety that has never been approved by the FDA or marketed in the US. An active moiety is a molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other non-covalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

An NCE is a molecule developed by the innovator company in the early drug discovery stage, which after undergoing clinical trials could translate into a drug that could be a cure for some disease. Synthesis of an NCE is the first step in the process of drug development. Once the synthesis of the NCE has been completed, companies have two options before them. They can either go for clinical trials on their own or license the NCE to another company. In the latter option, companies can avoid the expensive and lengthy process of clinical trials, as the licensee company would be conducting further clinical trials and subsequently launching the drug. Companies adopting this model of business would be able to generate high margins as they get a huge one-time payment for the NCE apart from entering into a revenue sharing agreement with the licensee company.

Under the Food and Drug Administration Amendments Act of 2007, all new chemical entities must first be reviewed by an advisory committee before FDA can approve this products.[11]

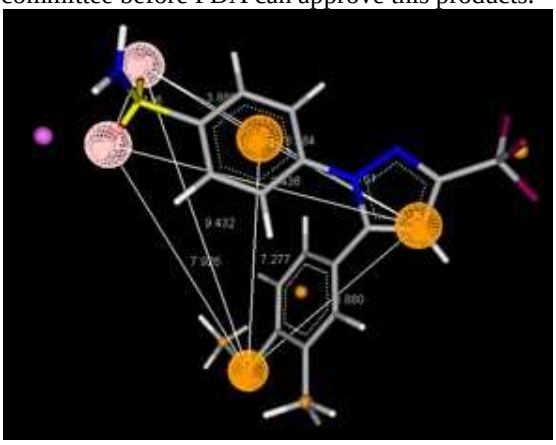

Figure-6: New Chemical Entity

Quality by Design (QbD) is a concept for The New Steps for Planning Quality into Goods and Services. Designing for quality and innovation is one of the three universal processes required to achieve breakthroughs in new products, services and processes. It is believed that quality could be planned and that most quality crises and problems relate to the way in which quality was planned. While Quality by Design principles have been used to advance product and process quality in every industry and particularly the automotive industry, they have most recently been adopted by the U.S. Food and Drug Administration (FDA) as a vehicle for the transformation of how drugs are discovered, developed and commercially manufactured. Modern design and planning seeks to create features in response to understanding customer needs. These are customer-driven features. The sum of all features is the new product, service, or process. It is not a statistical design method as Design for Six Sigma is considered. It is often used to design new services and processes. The steps are as follows:

1. Establish the project design targets and goals.
2. Define the market and customers that will be targeted.
3. Discover the market, customers and society needs.
4. Develop the features of the new design that will meet the needs.
5. Develop or redevelop the processes to produce the features.
6. Develop process controls to be able to transfer the new designs to operations.

7. The Quality by Design model and its associated methods, tools and techniques have been developed because in the history of modern society, organizations rather universally have demonstrated a consistent failure to produce the goods and services that unerringly delight their customers.

Integrated planning

Integrated planning requires a team with a leader whose sole accountability is for the total success of the new product from defining the opportunity through customer purchase, use, service and recommendation to others. This team leader reports directly to a senior executive, or the team leader can be a senior executive. Each team member's job is to ensure the success of the new product.

- In addition to organizational integration, a successful team must begin with clearly articulated common goals for the product that are measurable and authorized by the enterprise. These goals must, at a minimum, cover such elements as:
- The customers or customer segments to be served by the new product
- The relative and absolute quality goals
- The volume of sales or revenue to be generated in an initial time period and for the long run
- Market share, penetration, or sales relative to key competitors
- The release date

Figure-7: Quality by Design

The team will follow a structured process. The structure is the common framework for all participants in launching the new product and helps ensure success. Quality by Design starts and ends with the customer. Every new product introduction always has some amount of trade-off involved. If there are multiple customers, they may have conflicting needs. Even the same customer may have needs that compete with each other. Capacity and speed compete with cost of operation. Capacity can compete with speed. Flexibility and feature-rich offerings may have reduced ease of use, and so on. Quality by design offers a range of tools and methods to make these tradeoffs explicit and optimal for the customer. Some tools are highly mathematical, and others relate more to customer behavior.

Creativity and innovation must be highly valued, and Quality by Design sets strong expectations for creative approaches to functional design, product features and goals, and production design. Because quality by design provides strong and systematic assurances that the final design will create delighted, loyal customers, creativity will have significant payoff. The risks of innovations that will not sell, or creative designs that will not work, are much lower when companies observe the principles of quality by design. The chances of a truly magnificent innovation succeeding are greatly increased within this structured environment that ensures the defect-free delivery of that great design.

Figure-8: Industrial Research

Quality by design incorporates modern tools to dominate variation rather than merely suffer and recover from its consequences. These tools and methods always begin by measuring and understanding the variation that exists. Using historical data, testing, and modeling helps to forecast, analyze and eliminate the deleterious effects of variation using standard statistical

techniques. Process control consists of three basic activities:

1. Evaluate the actual performance of the process
2. Compare actual performance with goals
3. Take action on the difference

The final activity of the quality by design process is to implement the plan and validate that the transfer has occurred. A great deal of time and effort has gone into creating the product plan, and validating that it all works is well worth the effort. The FDA imperative is outlined in its report "Pharmaceutical Quality for the 21st Century: A Risk-Based Approach." In the past few years, the agency has implemented the concepts of QbD into its pre-market processes. The focus of this concept is that quality should be built into a product with an understanding of the product and process by which it is developed and manufactured along with a knowledge of the risks involved in manufacturing the product and how best to mitigate those risks. This is a successor to the "quality by QC" (or "quality after design") approach that the companies have taken up until the 1990s. The QbD initiative, which originated from the Office of Biotechnology Products (OBP), attempts to provide guidance on pharmaceutical development to facilitate design of products and processes that maximizes the product's efficacy and safety profile while enhancing product manufacturability.

Figure-9: Molecular Docking and Clinical Trials

QbD activities within FDA

The following activities are guiding the implementation of QbD:

- In FDA's Office of New Drug Quality Assessment (ONDQA), a new risk-based pharmaceutical quality assessment system (PQAS) was established based on the application of product and process understanding.
- Implementation of a pilot program to allow manufacturers in the pharmaceutical industry to submit information for a new drug application demonstrating use of QbD principles, product knowledge, and process understanding. In 2006, Merck & Co.'s Januvia became the first product approved based upon such an application.
- Implementation of a Question-based Review (QbR) Process has occurred in CDER's Office of Generic Drugs.
- CDER's Office of Compliance has played a role in complementing the QbD initiative by optimizing pre-approval inspection processes to evaluate commercial process feasibility and determining if a state of process control is maintained throughout the lifecycle, in accord with the ICH Q10 lifecycle Quality System.

While QbD will provide better design predictions, there is also a recognition that industrial scale-up and commercial manufacturing experience provides knowledge about the process and the raw materials used therein. FDA's release of the Process Validation guidance in January 2011 notes the need for companies to continue benefiting from knowledge gained, and continually improve throughout the process lifecycle by making adaptations to assure root causes of manufacturing problems are corrected. On the other hand - the premise that the current iteration of QbD places too much emphasis on mathematical algorithmic Design of Experiment (DoE) models unsuitable for application to complex, multifactorial, non-stochastic pharmaceutical processes has been advanced.[12]

The Clinical Pharmacology Unit (CPU) prepares reports in accordance with Food and Drug Administration (FDA) guidance in the development of both IND and NDA submissions and investigational brochures. The CPU customizes its approach to meet our clients' needs, including: Protocol design and review, Dosing plans, Subject recruitment and Interpretation of PK (pharmacokinetic)/PD (pharmacodynamic) from phase I-IV trial sample data.

The CPU conducts state-of-the-art laboratory analysis (LC/MS/MS) of pharmacotherapeutic compounds and biomarkers in a variety of biological matrices. This includes ADME (absorption, distribution, metabolism and

excretion), Pharmacokinetics and Pharmacodynamics studies. Working with clinical investigators in academic research units, the pharmaceutical industry, and contract research organizations, the CPU offers customized solutions for our clients' clinical research needs. Functions of CPU: Clinical trial modeling and simulations, Phase I and II clinical trial design and protocol review, Design and conduct kidney function testing (GFR/ERPF), Cotinine analyses for smoking exposure, Perform in vitro studies such as drug uptake, transport, and liver metabolism, Analyze study data using PK and PD modeling, Perform pharmacogenomics studies, Conduct preclinical pharmacokinetic distribution and toxicology studies and Prepare clinical pharmacology sections of FDA applications.[13]

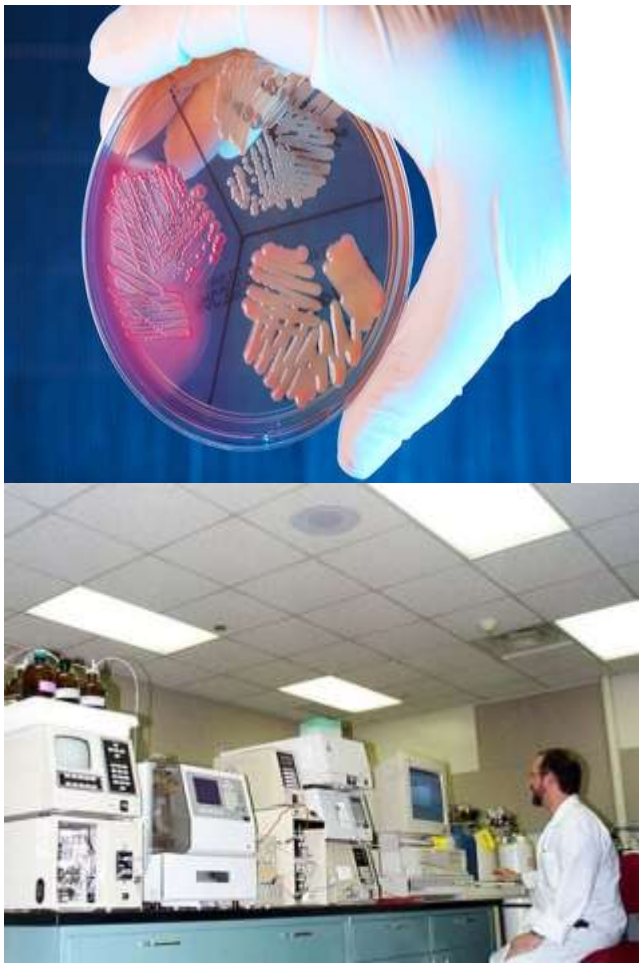

Figure-10: Industrial Serology and Quality by Design

ICH activities

Working with regulators in the European Union (the European Medicines Agency) and Japan, the FDA has furthered Quality by Design objectives through the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH guidelines Q8 (on Pharmaceutical Development), Q9 (on Quality Risk Management), and Q10 (on Pharmaceutical Quality System) provide some assistance for manufacturers to implement Quality by Design into their own operations. The ICH Steering Committee meets twice a year to discuss the progress of its efforts. This practical input should help ensure that quality risk management and knowledge management are used to make lifecycle adaptations that maintain process control and product quality.

Conclusion

Pharmacy is a practical oriented subject which is the master key because each and every step in any process either pharmaceutical chemistry or pharmaceutics or pharmacology or pharmacognosy needs the identification test followed by confirmatory test done by practical. Sharing of knowledge among various aspects of pharmaceutical sciences in academia by faculty-students is further reflected in industrial domain in between industrial personnel-industrial workers. Knowledge of entire BPharm is implemented in MPharm level and knowledge of MPharm is being implemented in academics as well as in industry to produce a fruitful outcome in this cutting edge era of fast moving life. Industry visit is essential for each and every students of DPharm, BPharm and MPharm level to gain more and more industrial exposure for betterment in pharma profession.

India is the world's third largest pharmaceutical industry in terms of volume and world's 14th largest pharmaceutical industry by value. The top 8-10 companies including Sun Pharma, Lupin, Dr. Reddy's Labs and Cipla occupy 70-80% of the Indian pharmaceutical market space. The domestic market is expected to do better this time as the projected growth rate is 10-12% during 2015-16 as compared to 9% in 2014-15. List of Top 10 Pharmaceutical Companies in India:

Sun Pharmaceuticals: Sun Pharma, officially known as Sun Pharmaceutical Industries Limited, was founded in 1983 by Dilip Shanghvi. The company is headquartered in India's financial capital Mumbai, Maharashtra. Active Pharmaceuticals Ingredients (APIs) and formulations are known to be Sun Pharma's specialized areas. It targets a wide spectrum of chronic and acute treatments. Its therapeutic segments of over 3000 high quality molecules include psychiatry, anti-infectives, neurology, cardiology, orthopaedic, diabetology, gastroenterology, ophthalmology, nephrology, urology, dermatology, gynaecology, respiratory, oncology, dental and nutritionals. On 15 June 2015, Sun Pharma was India's largest pharmaceutical

company with the market capitalisation valued at Rs. 2,01,706.41 crore. Its products: Formulations, Active Pharmaceutical Ingredients (APIs), Over-The-Counter (OTC), Antiretrovirals (ARVs).

Lupin: Headquartered in Mumbai, Lupin Limited is a multinational pharmaceutical company. An associate professor at BITS-Pilani in Rajasthan, Dr. Desh Bandhu Gupta established Lupin in 1968, which is today one of India's leading pharmaceutical companies. In Pune, Maharashtra, Lupin has a state-of the-art research and development unit. It is one of the fastest growing companies as far as oncology, cardiology, gastroenterology, central nervous system, anti-infective, anti-asthma and diabetology therapies are concerned. Lupin's market capitalisation amounted to Rs. 77,115.19 crore on 15 June 2015. Its products and services may be categorised as: Branded Formulations, Advanced Drug Delivery Systems, Generics, Novel Drug Discovery, APIs, Biotechnology.

Top ten multinational companies in India

Dr. Reddy's Labs: Based in Hyderabad, Telangana, Dr. Reddy's Laboratories is a multinational pharmaceutical entity. It was founded in 1984 as a manufacturer of APIs. A vast range of pharmaceutical products are offered by Dr. Reddy's Labs. It has 60 APIs and 190 medications to treat various kinds of ailments. It is now India's third largest pharmaceutical company in terms of market capitalization, which was valued at Rs. 56,638.13 crore on 15 June 2015. Its products and services may be categorized as: Generic Formulations, Active Ingredients, Pharmaceutical Services, Biosimilars, Propriety Products.

Cipla: Dr. K. A. Hamied set up Cipla Limited in 1935, which is one of the biggest biotechnology and pharmaceutical multinational companies of India today. APIs and formulations are produced at 34 state-of the-art Cipla plants spread across the country. Primarily, medicines for treatments of ailments like depression, obesity, cardiovascular diseases, arthritis and diabetes are developed by Cipla. It is India's fourth largest pharmaceutical company accounting for a market capitalization worth Rs. 47,025.38 crore on 15 June 2015. Its products and services may be categorized as: APIs, Formulations, Veterinary.

Aurobindo Pharma: Aurobindo Pharma was founded by K. Nityananda Reddy and P.V. Ramaprasad Reddy with others in 1986. Headquartered in Hyderabad, Telangana, Aurobindo Pharma Limited manufactures APIs and generic pharmaceuticals. Six prime therapeutic areas of medication addressed by the company are anti-allergic, gastroenterology, antiretrovirals, antibiotics, central nervous system and cardiology. With the market capitalization valued at Rs. 37,281.76 crore on 15 June 2015, Aurobindo Pharma Limited is India's fifth largest pharmaceutical company. Its products and services may be categorized as: Formulations, APIs.

Cadila Healthcare: The city of Ahmedabad in the western Indian state of Gujarat is home to the head office of Cadila Healthcare that was founded in 1952. The company has around 20 different manufacturing locations across the country. Cadila Healthcare is India's sixth largest pharmaceutical company in terms of market capitalization that amounted to Rs. 36,159.61 crore on 15 June 2015. Its products and services may be categorized as: APIs, Formulations.

GlaxoSmithKline: One of the oldest and most experienced players in the pharmaceutical industry of India, GlaxoSmithKline Pharmaceuticals

Limited was established in 1924. GlaxoSmithKline Pharmaceuticals is one of the world's top research-based health management and pharmaceutical companies. Major therapeutic areas of medication addressed by the company are anti-infectives, dermatology, oncology, gynaecology, diabetes, cardiology and respiratory products. In addition to that, it provides vaccines for cervical cancer, hepatitis B, hepatitis A, rota-virus, influenza, tetanus, chickenpox, pertussis and diphtheria amongst many. The market capitalization of GlaxoSmithKline Pharmaceuticals Limited stood at Rs. 27,522.55 crore on 15 June 2015.

Glenmark Pharmaceuticals: Glenmark Pharmaceuticals is an Indian pharmaceutical company founded in 1977 and headquartered in Mumbai, Maharashtra. It specialises in developing and marketing APIs and formulations and covers segments such as diabetology, dermatology, ENT, internal medicine, gynaecology and paediatrics. Glenmark Pharmaceuticals is India's eighth largest pharmaceutical entity by market capitalization, which was valued at Rs. 25,045.36 crore on 15 June 2015. Its products and services may be categorized as: Formulations, Active Pharmaceutical Ingredients.

Divi's Laboratories: Divi's Laboratories was set up in 1990 with the sole purpose of research and development in the life-sciences segment. The company mainly focuses on the development of modern innovative methods of manufacturing pharmaceutical intermediaries and other APIs. It is India's ninth largest pharmaceutical company by market capitalization, which amounted to Rs. 23,493.97 crore on 15 June 2015. Its products and services may be categorized as: Generics, Intermediates, Protected Amino Acids, Chiral Synthesis, Carotenoids (Synthetic) and Nutraceuticals.

Torrent Pharmaceuticals: Based in Ahmedabad, Gujarat, Torrent Group's flagship unit is Torrent Pharmaceuticals, founded in 1959. It is a major in therapeutic realms such as central nervous system and cardiovascular, spanning over segments like diabetology, gastroenterology and anti-infectives to name some. Torrent Pharmaceuticals is operational in over 50 countries and has a significant presence in India where it is rated as one of the top 10 pharmaceutical companies operating in the country. On 15 June 2015, the market capitalization of Torrent Pharmaceuticals was Rs. 21,555.59 crore.

Some other leading pharmaceutical companies: Dabur, Ranbaxy, Nicholas Piramal, Aventis Pharma, Dishman Pharmaceuticals, Surya Pharma, Biocon, Orchid Chemical, IPCA Laboratories, Abbott India, Sterling Bio, Alembic Pharma.

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