# R&D functioning & its role in Pharmaceutical & Chemical industries: An Overview

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**Abstract:** Life and discovery or research is a journey of self-finding where solitarily and constantly poses some challenges besides and opportunities to learn and grow further more. All are not ever facile paths and confronts often unexpected twists and turns with subsist sense of gone and uncertainty. Nevertheless under any critical states of diversity and crucial instants of adversity that made individual able to hunt inward forte and resilience, so to acquire alongside embrace the unknown or mist with the open perspectives .Research and development (R&D) are visionary plus methodical effort initiated to proliferate the cognizance and knowledge domains. R&D contains viable assortments which are instituted and analysed for authentications so to boost perceptions of firm issues as described by precise consideration to the regulatory bases of preconceptions and mistakes. Such undertakings are considered by means of liability and monitoring of biasness. Research deals the elaboration of kind of preceding exertion in that meadow Vis-a Vis all pros and cons. The research involved testimonial validly of devices, processes, tests, studies which can redo basics of earlier developments or the plans in toto..

**Keywords-**Research, Development, Indian, Pharmaceuticals, chemical, industry, review

**Introduction-**:

This prevalent era faces ever mutable regime of life patterns and scientific progresses

throughout the globe, as each part of life and science else pursue vicissitudes at every gains and attainments every so often as seek by progressive expectations and functioning amenities by each one. Today ever degrading environmental and life patterns emerge with new disasters and diseases which need prominent solutions and medicines to tackle hostilities pose in front of planet-earth and man. Eventually ground-breaking efforts ought to put in the sphere of deteriorating life styles and in the scientific R&D especially with respect to chemical and pharmaceutical industries so as to match prescribed WHO and allied guidelines by regulatory agencies in the respective countries.

The drastic competing era encounters assorted confronting aspects including many open choices in almost all domains of S&T. Yet a good and a cheaper option is not that much accessible and feasible. The main challenge of pharmaceutical and chemical industries is to prepare good quality products/feedstock in a cost effective manner. As like previous age, it is impossible to survive in trade market for long span without its product evaluations' and continuous improvement in product's quality with respect to its cost.

Prior to globalisation in 1992,there was no big completion for chemical as well as pharmaceutical industries and both sectors were having monopolies for their manufactured products besides this their clients were also had no other options. Nevertheless today China has provided multiple cheap solutions for competitive products and appear manifold supplier globally whereas Indian chemical and pharmaceutical industries faces the problem of cost effective products generation at their own end in order survive in market. Due to such global completion boots R&D efforts for each sector of Indian industry to become proficient substitute to China. Indeed industries that don't adopt changes with prevailing time can lost their identity in future. Hence corresponding R&D activities are must to be concern with utmost priority for all industries particularly Pharmaceutical and chemical industries. This overview cites the vitality and functioning of R&D functioning and its role in Indian Pharmaceutical and chemical industries.

**R&D Model**: The research is a non directed rudimentary skill along with directed or

pragmatic science which assisted growth in research and consequences in innovative products, processes from app viable sources. In contrasts to product development, research is an idea exploration than tangible output to be marketed further. As an ambiguity any new idea may or may not be fruitful. While invention is an idea being converted to the practicable aftermath.

Research and development is investigative activity through which any professional decisions are being done calculatingly to be conducted .R&D aims discovery that can either leads to new products, procedures or improvement in existing products or procedures which appears much strategic for prospective growth as per the verdict of managing authorities .R&D owns prime objective of developing a different knowledge purview by affixing inter and or multidisciplinary areas in order to derive profitable solicitude functions. Essentially subsists two kinds of research namely basic and applied being further categorised as academic and industrial. The basic research is a scientific pursuit aimed at generating original knowledge about physical, biological and social phenomena whereas applied research converts idea into direct utilisation via existed understanding and geared to solve the specific confrontations under considerations.

Indian scholars carry out academic and basic kind of research in their innate hosted educational institutes and native universities including IITs, IISc, ICER,IICT and many CSIR laboratories also laid stepping stone for an industrial /applied research. Although industrial /applied research is also being performed in different industry Scientists /chemists in their in-house R&D. All such industrial research are monitored by R&D head and lead by allied team leaders as well as qualified and expertise in concerned fields. Such industrial research comprises of process labs, analytical development lab, intellectual property department and quality assurance cell. Sometimes both basic and applied researches are accompanied as per the organisational need and curiosity e.g. Those pharmaceutical companies which are interested in novel drug discovery and its subsequent commercial production after its approval by regulatory agencies.

**Process Research**: The foremost task of scholars /Scientists in process research is to design, format and implement the acquired projects on commercial scale through

strategic preview. As per learnt and expertise fields, these researchers grow synthetic and systems and execute own developed /invented theories in practice both in chemical and pharmaceutical industries.

Pharmaceutical researches focus on synthesis of active pharmaceutical ingredients (API) and its end use in pharmaceutical application. Synthetic research is conducted so as to discover novel drug moieties along with advanced synthetic routes to be used in formulating pharmaceuticals. Scientists carried an experimental investigations on drugs to be delivered in the form of injections, tablets, oral liquids and ointments .Prior to pharmaceutical formulation, profiles of some novel lead molecules are thoroughly scrutinized by means of progressive analytical methods /techniques including high performance liquid chromatography, Gas chromatography(GC)besides classical analysis through spectroscopic techniques like UV-Visible, NMR, NMR, mass spectroscopy, X-rd, Raman spectroscopy etc. Many time drug modelling and docking is too performed for new chemical entities (NCE)or novel drug discovery.

Research scientists require high level data analysis/collection of data bases, thus requisite potential skills and experiences of critical problem solving criteria in analysis and characterizing developed novel drug –likely molecules by means of spectroscopic techniques /analytical tools.

Varied R&D scientists can collaborate nationally to get fruitful research outcomes by cascading the mutual expertise and based on assessing methodologies carry out the experiments by referencing earlier documented data bases. These researchers maintain recorded data of all the procedures performed with a synopsis and update the data bases to ensure apt and facile developing processes. Supplementary vital scientific skills are also involved viz. planning, evaluation and execution of the performed tests through studied consequences.

Further pharmaceutical research is broadly alienated as basic research and generic domain. The basic research involves the findings for the development of novel pharmaceutical drugs delivery to the targeted sites by adopting innovative synthesis followed by their clinical trial studies. After efficacious research findings, authority apply

for an intellectual property rights as a patent for the said process /product/design being valid for next 20 years ( no competitor infringe during this process).Europe, USA have patent extension validity of 5 years whereas can has the patent extension validity of just two years only. During this patented span company earn utmost profitability and can get patent extension based on date of filling with expert legal supports. In patent validity period Innovator Company earns all-out revenue due to monopoly being protected under patent right.

**Generic Research**: Generic research is an eloquent tactic meant in comprehending the way entities mark sense of a phenomenon or a situation based on what drive work best in discovering options for queries to be analysed. Such generic research covers developing new drugs at its cost effective manufacturing process. The patent office allows to enter other pharmaceutical companies apart from parent company after the stipulated expiry span of awarded fundamental patent rights. In this phase of research, numerous companies can enter subjected to innate research abilities. Herein Research Company acquires patent protection as process patent with 20 years patent validity span. These companies can't get supreme profitability as like parent company for its basic research due to the access of numerous companies in place of single owner in case of basic research and developments.

Generic Research includes developing novel processes e.g. for parent drugs after its patent expiry rights in cost effective manner by adopting novel route of synthesis. Such R&D involves the alternation of feedstock, solvent, catalyst, reagents and suggesting green preparations in order to reduce environment hazards keeping the final chemical skeleton alike parent drug being non-infringing with the parent company process or processes developed by other competitor companies. Its effect on drug delivery system to human /animal (in vivo/in-vitro) is accessed by means of bio-equivalence study instead of clinical as followed in basic research of novel drugs. Also the cost generic research is not high as like that of basic research.

**Analytical research**-: It is the research for development of analytical methods for novel drugs/generic drugs analysis. This involves chromatographic analysis method, classical analysis method and spectroscopic analysis techniques development. The analytical

scientists also needs to maintain all data bases of procedures worked on which finally needs to get validated its performance before its commercial application.

**Development Quality Assurance (DQA):** The quality assurance is the proactive and reactive activities or processes and practices as intended in certifying the high product quality /value. Being a part of a quality assurance it can ensures the delivered work item to encounter selected quality standards. Quality assurance measures/offers warranty for the quality of synthetic products as derived under manufacturing facility in chemical or pharmaceutical industry. The quality assurances owe a key function of certification /documentation besides it control the industrial system to manufacture the quality products. Quality assurance monitors all the research and development activities performed by progressive scientific and analytical laboratories. Fundamentally quality assurance processes are performed in five prime phases namely discovering, planning, designing, executing and improving. The aim under quality assurance is to define practical and non-functional program requisites and testing concerned correlation within the perspectives and the objectives of commerce /trade.

The quality assurance cell prepare standard operating procedures (SOPS) are used to prepare documents required for all research activities and to ensure the data for calibration of weighing balances, analytical instruments as upheld by working scientists of the labs. Laboratory researchers also screen the fact the facts and findings as generated by scientists in processing and analytical department in proper way as per approved SOPs for enabling easy tracing of data. The approval of the final processes or methods being established by researchers is needed to be scrutinised with calibration /optimisation to avoid native deviations if any. Such activities audit all feasible research activities and suggest some changes if needed. SOP analysis too advises viable alternations and controlling requirement at varied phases of processes/procedures/methods of commercialisation through change control practices.

**Intellectual Property Department (IPD)-:** This is very important department for research activities. It makes available all past data in the form of Literature search to the research scientists for their new product development. It ensures the infringement analysis of processes. Only after the approval by this department; process scientist can

proceed further for their research activities. It controls all legal and scientific activities related with process research /analytical research. Once the process is finalised, the patent is filed by this department and all queries relating with the process are being sorted out by this department.

**Regulatory Affairs-:** In generic pharmaceutical company, The API research files drug master filing (DMF) and Formulation research files Abbreviated New drug application (ANDA) for international market in US and the rest of the world(e.g.US DMF for United states of America & e-DMF for European countries). This is getting analysed by international regulatory agencies of concerned countries/domain. These filings are done by this department after complete internal review of process/procedures/methods. The quality assurance and regulatory department are being interconnected. Only after receiving permission by international regulatory agencies for DMF and ANDA, the said company is getting permitted to do the business in that specified countries.

In short, any research is team activity.

In chemical industry similar type of research activities are performed which are being product application based and it is not having so much critical regulatory requirements as like pharmaceutical product. It is team of scientists /professionals in process research, Analytical research, Quality ass111urance & Intellectual property rights department.

**New product development Process model is being as below**

**Idea generation—Business analysis—Technical Development—Prototype—Pilot trials—Market introduction**

The expenditure on R&D by any industry is set by considering its return on investment by entrepreneur. The product development phase requires spending more expenditure which is hampering the product cost during its initial commercialisation phase.

In Pharmaceutical Industry the worldwide expenditure on R&D was £141million in 2006 which has been increased by 40 % in 2015 & was expected to rise by 60% in 2020.

Due to higher cost on R&D, innovative drugs are being more costly than generic drugs. Indian government is supporting new research activities in industry as well as in various academic universities. This is monitored by department of Science & Technology (DST). However this funding provided by them is too much lesser as compared with that provided in developed nations. There is steady rise of 13% on R&D expenses from 1970.

The development of new drugs requires a longer period of research activities, because science & technological advancement have progressed a state where there are no more easy targets to identify and increased competition to exploit new opportunities in the market leads to decline in Pharma productivity.

**Types of R&D activities-:**

A) New product Development

B) Process Development

C) Product Improvement

D) Technical services

**A) New Product Development**

It is actually related with new molecular entities invention for various applications. The new product development is undertaken based on assigned objectives by entrepreneur in association with company's higher management. It is being thoroughly analysed in business point of view. The entrepreneur expects maximum returns on investment. This activity takes longer time for research & if it is pharmaceutical product it will take more time as compared with chemical product as it involves development & drug delivery through clinical trials through different phases and approval by regulatory agencies like FDA While development of new molecular entity, special attention is required to pay for its cost effectiveness, legal and environmental implications.

**B) Process Development**

This type of research activity relates with existing products running in industry. It

involves process time cycle reduction, use of novel catalyst for increasing % conversion of reaction, replacement of costly reagents by cheaper one all of which are related ultimately the cost reduction of product. This is required due to increased competition in market. Sometimes strictness by government pollution controlling agencies bans some product manufacturing even it will be profitable & good revenue generating product for industry. In such cases, higher management of industry insists adoption of green chemistry for that particular process.

### C) Product improvement

This is also related with existing product & process carried in industry. Sometimes product requires better quality as demanded by end customers .This involves reduction in impurity profiling & other quality attributes for improving its performance.

### D) Technical Service

This is related with existing products & newly launched products by industry. Marketing professionals are requiring technical support for queries regarding company's product & sometimes trouble shootings at plant level with proper solution are needed. All these are supported by R&D & known as Technical service

### Importance of R&D -:

- It is crucial for industries for surviving in competitive market either by launching new chemical entities or improvement in existing process as per company's objective
- For fulfilling changing demands of customers.
- For continuous Technology evolution /improvement of products as per customer needs.
- It is fundamental for marketing professionals for their technical support requirement.
- For developing efficient production process in terms of cost reduction, social impacts & environmental implications.

- For new vendor qualifications by performing exhibit batches & study its impact on product quality

**How does the new product selection in R&D-:**

Based on business analysis, market analysis, management sets their objectives for their growth which in turn reflects in terms of maximum revenue & profitability. While selecting new products, industry management studies the feasibility of said process in their existing production facility. The newly introduced product should not hamper the existing production process as revenue from new products trials is uncertain till its successful market introduction. If required, company can erect new production facility based on product market demand. Management also analyse the strength of existing man power, process & product safety in order to make minimum loses if any

While selecting the products, company management needs to consider two aspects of product portfolio which are as below,

- The products which are low volume with high profit margin
- The products which are high volume with low profit margin

The products like gemcitabin, anastrazole, Cis-platin etc comes under first category & used for anticancer treatment whereas the products like Etodolac (anti-inflammatory drug), Lumefantrine (Antimalarial drug used in combination therapy) comes under second category. This is the case of generic drug pharmaceutical industries. Same cases are applicable to Chemical industries.

The case of new chemical entities (NCE) product selection solely depends on the strength of R&D professionals, facility available, and funding capacity of said industry and government policies for encouraging new research. Most of the innovator industries are from US, Japan, Germany, China etc (Johnson & Johnson, Novartis, GlaxoSmithKline, Easai Pharmaceuticals etc.) .Even India has much pool of talents, but it is regretful that no one Indian Pharmaceutical Company becomes Innovator Company. Some Indian host pharma-companies viz; Dr. Reddy’s Lab, Glen mark, and Ranbaxy etc., are trying to develop innovative drugs but unfortunately cannot reach to final phase of

drug approval by regulatory bodies & cannot commercialize the new molecular entities.

Germany is being parental country for most of the colorants development (Pigment & dyes).Same case is there for NCE in chemical industries except the Company like Gharada chemicals which was research driven & had been pocketed number of national &international awards for their innovative products & process. Actually Indian chemical industry has huge potential of Chemical manufacturing & outperformer .The Indian chemical industry has potential to place India's name on international map. This sector is projected to grow by 11 to 12% in 2021-27 & 7 to 10% in 2027 to 2040.New governmental policies are more encouraging for new entrepreneurs in this sector. R&D needs to develop green technologies & commercially viable process. There are still some chemicals used pharmaceutical /chemical industry for which India has to depend on China and other countries for its cost effective supply.e.g-7-Ethyl Tryptophol a key starting material of Etodolac. No single commercial manufacturer found for this chemical in, India till date even number of patents & papers have been published.

## How should be Industrial R&D facility?

- Industry should have delegate R&D professionals for developing cost effective environmental friendly moieties/processes with good profitability. They should be able to do cost reductions of existing process/products in order to compete in market.
- Company should provide adequate R&D facility for carrying out hazardous reaction like cyanation, oxidation, nitration Chlorination in safe manner.
- Good awareness of safety is required in all professionals.
- Should have good documentation practices as required by regulatory bodies & audit ting team with proper traceability. Availability of desired sops (standard operating procedures) for all types of operations performed in R&D.
- Adequate Library and or online literature search facility
- Regular trainings.

- Collaboration with academic institutes like universities, NCL, IICT, IIT etc. for manpower hiring & scientific support from distinguished professors for better technological evolution.
- Availability of proper analytical team & instruments for proper analysis of product developed & in process analysis. Otherwise a good public analytical lab should be available in local or nearby area for carrying critical analysis. Without proper analysis, R&D Scientists cannot progress his work.
- All R&D professionals need to follow strictly Good laboratory practices (GLP)

## Pathway of R&D functions

The pathway of R&D function is the way from product development stage to its commercialisation step. The different practices are being adopted by chemical, generic drug manufacturer & innovative drug manufacturing company

### A] R& D-Chemical Industries-:

- Allocation of projects for New molecular entities by management
- Literature search
- Finalisation of innovative routes for its chemical synthesis.
- Infringement analysis by intellectual property rights department (Stage I)
- Ordering of required chemicals.
- Checking & screening of finalised chemical routes.
- Optimisation of screened chemical synthesis route
- Parallelly analytical method development work is started for its in process, intermediate and final product.
- Structure elucidation and confirmation of intermediates & final product by spectroscopic techniques like NMR, IR, UV spectrometer, XRD etc.

- After route feasibility and structure confirmation, the feasible process is optimised with respect to its yield improvement, process time cycle, reprocessing of product solvent recovery, environmental aspects, preliminary HAZOP study etc., green technology adoption wherever possible.
- Infringement analysis by intellectual property rights department (Stage II)
- Analytical standard .preparation with its characterisation analysis
- Raw material vendor development & approval
- After optimisation, Lab scale up study is performed from gram scale to kilogram scale.
- Study on particular on chemical application.
- Pilot plant study is carried out in order to study its plant feasibility for equipment selection, scale up on plant scale; waste generation etc. Here generally three batches are performed with fresh solvents &raw materials and one with recovered one.
- Complete analysis of products obtained after pilot plant trials.
- Plant trials of said process with its process validation
- Final HAZOP study.
- Complete analysis of product after plant trials with respect to its plant trials
- Final Infringement analysis by intellectual property rights department (Stage III)
- Consumption norm &Cost analysis review.
- Introduction of product in market
- Product/Process filing by IPR for its novelty.
- Commercialisation of Product.

## B) R&D in generic Pharmaceutical Industries

It is type of applied research & follows similar steps as like chemical research. But the facility required for its scale up and its commercialisation is required to meet GMP guidelines & research is required to follow ICH Q11 guidelines. It involves the process research for drug substances and drug product development.

Drug product-drug product is a finished dosage form e.g. tablet, capsule, or solution ,that contains a drug substances, generally but not necessarily ,in association with one or more ingredients which are used for the treatment of different diseases in human being or animals.

Drug Substances-Any substances or mixture of substances intended to be used in the manufacturing of drug product and that when used in the production of drug becomes an active ingredient of a the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure mitigation, treatment or prevention of diseases or to affect the structure and function of body.

The research carried out for the development of drug substances is known as API (Active pharmaceutical Research) Research whereas the research carried out for the development of drug product is known as formulation research or formulation development (F&D)

The steps involved in API are being similar to Chemical research carried out in chemical industry. But some additional study like polymorphism and microbiological study of drug substances carried out. While developing the manufacturing process of drug substances quality, process development tools, design space are needed to properly study. The quality of drug substances obtained by developed manufacturing process is required to meet its critical quality attributes (CQA) and the quality target profile(QTPP) as the intended quality of drug substances can influence the development of concerned drug product.

Impurities are an important class of potential drug substances CQAs because of their

potential impact on drug product safety. For chemical entities, the impurities are of different classes viz-

a) Organic impurities (including potential Genotoxic impurities)

b) Inorganic Impurities

c) Residual solvents

d) Process-related impurities

In addition to this, forced degradation study is carried out in order to establish the probable degraded product impurity profile in drug products.

The Quality risk management (QRM as described in ICH Q9) can be used in variety of activities including assessing options for the design of manufacturing process, assessing quality attributes & manufacturing process parameters.

A control strategy is used to ensure the process performance and drug substances quality.

The consideration for design space has been addressed in ICH Q8 an enhanced approach to the development of drug product and drug substances. The design spaces enables to assess accurately the significance of the variability of material attributes and process parameters on drug substances CQAs. For chemical entity, design space development ,a major focus is knowledge of formation, fate purge of impurities through every step of manufacturing process. All steps (or unit operations) should be evaluated to establish appropriate acceptance criteria for impurities as they progress through multiple process operations.

In formulation research, drug product is developed from drug substances along with other ingredients & pharmo-kinetics study like bio-availability and bioequivalence studies are performed. Bioequivalence study is special type of study where two drugs or two sets of formulation of the same drugs are compared to show that they have nearly equal bioavailability & PK/PD parameters.

**Qualitative Generic Research**-:

Generic medications differ from branded drugs in several aspects such as the manufacturing process utilised in drug development, Excipients and Packaging .Still they are bioequivalent to branded drugs in terms of strength, dose, quality, safety, performance and efficacy. Generic drugs become available when the patents for already marketed medications expire. Generic Medications are not associated with particular manufacturer, are often controlled by governments worldwide

The generic drug market is segmented on the basis of type, brand,, indication route of administration, end users and distribution channel. The growth amongst these segments will help us to analyse major growth segments in industries and provide the users with valuable market overview and market insights to help them make strategic decisions for core market applications.

**Type**

- Simple Generics
- Super Generics

**Brand**

- Pure Generic
- Branded Generic

**Indication**

- Central Nervous System
- Cardiovascular
- Dermatology
- Oncology
- Respiratory

- Others

**Route of Administration**

- Oral
- Topical
- Parenteral
- Others

**End-Users**

- Hospitals
- Homecare
- Speciality Clinics
- Others

**Distribution Channel**

- Hospital Pharmacy
- Online Pharmacy
- Retail Pharmacy

Some of the major players operating in the generic market are as follows,

- Teva Pharmaceuticals industries Ltd (Israel)
- Mylan NV (US)
- Novartis AG ( Switzerland)
- Pfizer Inc (US)

- Lupin Pharmaceuticals Ltd (India)
- Sun Pharmaceuticals Industries Ltd (India)
- Fresenius SE & Co.KGaA ( Germany)
- Endo International Plc.( Ireland)
- Aurobindo Pharma (India)
- Hikma Pharmaceuticals PLC. (UK)
- Eli Lilly and Company (US)
- STADA Arzneimittel AG ( Germany)
- Aspen Holdings (South Africa)
- GlaxoSmithKline PLC. (USA)
- Abbot Laboratories
- Sandoz International GmbH

## The Key Factors of generic Market Dynamics

- Rise in demand for artificial intelligence (AI) technology will booster the market growth
- India’s thriving Pharmaceutical Industry Propelling India generic drug market

## Opportunities

- Rise in cancer cases will act as an opportunity for generic drug market.

## Restraints/Challenges

- Stringent regulations will hinder the growth of generic drug market

Stringent controls, as the FDA assesses the accuracy side effects and other substances

used in generic pharmaceuticals are one of the main factors limiting generic drugs. Pharmaceutical drugs are typically recalled if the producers don't follow the regulatory requirements. The key elements that influence the quality of generic drugs are purity, Potency, Stability and drug release .These should be managed within appropriate limit, range or distribution to obtain the desired drug quality. As result of the strict government al rules, approval is needed for generic pharmaceuticals which is projected to hinder the generic market expansion

**Quantitative Generic Research-**

The World Health Organisation estimates that each year, there are between 2 to 3 million instances of non-melanoma skin cancer and 1,32,000 cases of melanoma Skin cancer. In addition, the prevalence of psoriasis in the world varies from 0.09% to 11.43% making it serious condition that affects at least 100 million people worldwide. The fact is that topical drug administration is the primary therapy method for most skin conditions and the market for advanced topical products is projected to grow in the upcoming years.

Data bridge Market Research analyses that generic drug market which is USD 622.02 million in 2022 is expected to reach USD 1323.68 million by 2030.In addition to the insights on the market scenarios such as the market value, growth rate, segmentation, geographical coverage and major players, the market reports curated by the Data Bridge Market Research also include in depth expert analysis, patient epidemiology, Pipeline analysis, Pricing analysis and regulatory framework.

The Global generic drugs market size was valued at USD 439. 37 billion in 2022 and projected to hit around USD 670.82 Billion by 2030growing at CAGR of 5.4%over the forecast period of2022to2030.By 2024, Pharma industry analysts predict that generics will have the luxury of generating $ 60 billion in net growth. According to World Health Organisation, China accounts for 20%of global API output. The FDA records have been claimed that 72% of API manufacturing facilities for the US market were located outside of the country, with 13% in China.

The pure generics segment accounted largest revenue share 52.6in 2020.Emerging

markets are home to more than 70% of the world's population cover 46% of the planet's surface and generate 31% global GDP.

In terms of revenue, the pure generics segment was contributed USD 220.26 billion in 2021 and registering a CAGR of 4.8% from 2022 to 2030. Whereas the branded generics segment was valued at US$194.30 billion in 2021 with CAGR of 7.75%over the forecast period of 2022 to 2030. The Oral segment was reached at USD 272.48 billion in 2021 with CAGR of 5.1% over the forecast period of 2022 to 2030. The injection segment was valued at USD 87.37 billion in 2021 with CAGR of 5.7% from 2022 to 2030.

The cutaneous segment contributed at USD 32.27 billion in 2021 with CAGR of 5.5% between 2022 to 2030.Generic Drugs market share by route of Administration in 2020 was as follows,

| Segment | 2020(%) |
|---|---|
| Oral | 65.7% |
| Injection | 21.2% |
| Cutaneous | 7.8% |
| Others | 5.2% |

On the basis of drug type, simple generic drugs segment is dominant owing to its low cost over super generic. These drugs also yield the same therapeutic effect and prescribed in the same dosing with the same quality and the same way of consumption and usage. Super generics of drug type of segment is expected to

hold share more than 25% in global generic market.

- In terms of Revenue, the simple generic was valued at USD 255.36 billion in 2021 and is expected to reach

  USD 387.90 billion by 2030 registering a CAGR of 4.7% from 2022 to 2030
- The oncology segment was valued at US$46.48 billion in 2021 with a CAGR of 6.8%over forecast period 2022 to 2030.
- The respiratory segment was reached at US$28.47billion in 2021 with a CAGR of 5.5%from 2022 to2030.
- The cardiovascular segment was valued at US$98.87 billion in 2021 with a CAGR of 5.6% between 2022 to 2030.

- The central nervous system (CNS) segment generated revenue at US$78.03 billion in 2021 with a CAGR of 5.9% over forecast period of 2022 to 2030.
- North America contributed revenue around USD 147.91 billion in 2021 and registering a CAGR of 4.0% from 2022 to 2030.
- The Asia Pacific was valued at USD 88.89 billion in 2021 and growing at a CAGR of 8.2% over the forecast period of 2022 to 2030.
- Europe has generated revenue USD 106.77 billion in 2021 and registering a CAGR of 4.7% between 2022-2030.

The pharmaceutical industry in India is expected to reach $65 billion by 2024 and to $130 billion by 2030.The Pharmaceutical industry in India is currently valued at $50 billion .India is a major exporter of Pharmaceuticals with over 200+ countries served by Indian Pharma exports. India supplies over 50% of Africa's requirement for generics, ~40% generic demand in US and ~ 25% of all medicine requirements in UK. All above Quantitative data of generic pharmaceuticals is helpful to Indian pharmaceutical industry for Investing on R&D to develop new generic products and subsequently its manufacturing to avail export Opportunities in order to get lucrative revenues.

### C) Innovative drug Research-

It is the discovery of new pharmaceutical substances and products which does not having prior availability in authorised form. It is very complex process of research and requires distinguished knowledge in drug chemistry. And also it requires a heavy financial investment and huge facility starting from drug research to its final medicinal application.

New drug discovery is tested for particular medicinal treatment (disease or disorder) in three phases of clinical trials. Its approval is sought from regulatory body like FDA after its successful clinical trials.

The new drug discovery process begins with biologists identifying a promising new drug target such as an enzyme involved in a disease critical pathway. The search then begins for potential drug professionals that can specifically interact with the desired target to cause a beneficial change. But to become a successful drug, a molecule will also need a

host of other properties including nontoxicity, solubility & stability. A medicinal chemist requires performing number of experiments to optimise the synthetic process of drug substances & its subsequent formulation research to achieve desired pharmacological activity.

The new drug discovery is lengthy and slow process due to limitations of human brain. In recent days, artificial intelligence is entered into this field to speed up research activity and aimed to bring the said new drug in market for treating specified diseases or disorders on fast track. Synthetic chemistry has largely relied on the knowledge and expertise of medicinal chemists and their ability to come up with original ideas for synthesizing new molecules. But recent advances in AI may help boost their chances of success, speeding up the progress of drug discovery projects. The well-known companies like Merck, Novartis, Johnson & Johnson, Eli lily etc., are being the major players in new drug discovery.

**D) Analytical Research-:** The development of pharmaceuticals and chemicals brought a revolution in Human life. Pharmaceutical products and substances will serve their intended use only if they are free from impurities and administered in an appropriate amount. To make drugs serve their purpose various chemical and instrumental methods are developed at regular intervals which are used for the estimation of drugs. The pharmaceutical products may develop impurities at various stages of their development, transportation and storage which makes pharmaceutical risky for administration. Thus they must be analyzed and quantified &thus analytical methods are useful for assessing the quality of drugs. The various analytical methods like titrometric, chromatographic, spectroscopic, electrophoric, electrochemical and corresponding methods have been applied in analysis of pharmaceuticals. For investigational new drug molecules, analysis create preliminary safety and efficacy data are prerequisites to identification of drug candidates for further detailed investigation i.e. analysis of drug product in preclinical phase which is required to pass, then only the regulatory authorities grants for its clinical trials

The team of analytical Research scientists carries the research for analytical method development for new chemical entities viz., ew chemicals, intermediates, drug

substances and drug products as well as raw materials. This is developed for chemical analysis and instrumental analysis like HPLC, GC, ICP, IR etc. For all those analysis method development, goal setting is required. In case of HPLC and GC analysis method development, methods are required to resolve known/unknown potential impurities and degradation products. In case of residual solvent as impurities analysis Head space GC analyser is used and the methods are developed as per required limits. For generic drug substances and drug products, analytical scientists can refer pharmacopeia references like USP, BP, EP, WHO etc.

Thus analytical method development research is helpful for

- Identifying safety and efficacy of pharmaceutical products
- Identifying storage conditions of pharmaceutical products
- Finding suitable condition of transportation.
- Deciding the dosage quantification
- Preclinical analysis of IND molecules decides the grant for its clinical trial by regulatory authority.
- Deciding the right quality of raw materials and other ingredients for synthesis and formulation of drug substances and drug products respectively.

These analytical methods are also helpful for finding the safety of chemical products for their end applications. E.g. the use of Pthalocyanine pigments in plastic toys is analysed and restricted on the basis of its PCB content (polychlorobiphenyls) as PCB is carcinogenic in nature.

**Challenges for R&D-:**

Every company either it may be chemical or pharmaceutical one needs new product technology on commercial level in order to survive in increased market competition. But they needs to face number of challenges which requires to ruin out by proper solution and management decision. Some of the challenges are briefly mentioned as below,

- Non availability of proper R&D infrastructure for carrying out advanced research and research on fast track as each company needs new product in stipulated time frame.
- Non availability of skilled /experienced manpower which are expert in domain field.
- Non availability of raw materials and equipment/machineries at local level on immediate basis as its delay can cause extension of project work undertaken.
- Non availability of some top universities, national level institutes like IIT, ICT, IICT, and IISC for hiring of skilled manpower & knowledge support.
- Unwillingness of employees as self-starter.
- Safety unawareness in employees.
- Non availability of advanced & sophisticated analytical instruments like NMR,IR,AAS,LCMS,GCMS ICP etc., which are required to interpret the structure elucidation. The delay in analysis cause in project extension or cannot be completed in stipulated pressure.
- Research is team work. Sometimes proper team built is not observed due to improper management.
- The ability of R&D to deliver the competitive advantages to the company which is expected by top management of company from R&D. The failure of which can lead hampering the output of R&D and consequently affect the growth of company.

**How to overcome these challenges & create successful R&D base -:**

R&D is being long time horizon& risky activity. It is almost uncertain to predict the return on investment done on R&D activities by entrepreneur. However in recent days, the investment in R&D is done on the basis of commitment for maximum return in terms of knowledge generation and business profitability. There are various factors to make R&D a successful activity & different departments in organisation play a vital role in R&D success

## a) Infrastructure

An infrastructure is created in chemical or pharmaceutical industry not only to provide solutions to certain technical problems but also for adding knowledge to the pool of technological advancement.

While erecting R&D infrastructure by a chemical and or pharmaceutical Industry, the following requirements are needed to consider for making it effective,

- Measurement and calibration facilities
- Testing and analytical equipments.
- Proper fume cupboards laboratory set up for carrying & handling of hazardous reactions.
- Advanced fume cupboards for carrying out the reaction related with oncological products & substances development in which there is no direct exposure of person working on that project.
- Cold/refrigeration room for storage of temperature sensitive raw materials, intermediates & finished goods.
- Library and documentation Unit
- A computer room with e-mail, internet, C.D.ROM etc., facilities.
- Animal house for conducting the trials of innovative drugs
- Pilot plant facility for scale up of technology developed.
- Conference rooms for discussion of research scientists with production personnel whenever required, on evolving policy, planning & development policy

The infrastructure requirement for creating R&D department in a company will vary depending upon the type of industry. Good R&D infrastructure always attracts the skilled and experienced person from Other Competitive industries/reputed academic institutes.

And industry is also able to deliver the new Product development projects in market on fast track.

### b) Skilled Manpower-:

The skilled manpower is being one of the important assets for Industry. In today's age, the availability of skilled manpower for industrial R&D is becoming major problem. This is depends on industry location & its R&D infrastructure. On availability of reputed education institutes in nearby area and the remuneration package offered by company are being two major hurdles. The HR department of industry is playing important role in this regards. They have to make strong HR policies for offering good remuneration package for right candidates & other benefits. To retain manpower once recruited for long time they have to focus on carer growth prospects in the organisation & self-esteem of employee's& D is team work and higher management needs to develop team spirit in existing employees in order to retain them for long duration & get the profitable benefits from their brain for organisational growth. The two important aspects are observed in the working of any team Apart from this, tie up with good educational institutes and set up of R&D infrastructure in good location can attract skilled man power. Company management has to understand & take care of employee's family Problems by offering lucrative benefits.

### c) Raw material & machinery availability-

Preplanning by R&D department for raw materials and machineries in co-ordination with department & it's enough stock in premises, finding out local suppliers can resolve the problems of project delay pertaining due to raw material and machineries, its part non availability. Appointment of departmental purchase professional that can coordinate with company's central purchase department. Incorporation of supply chain management or value chain management can sort out this problem.

### d) Employees Mind-set as self-starter

- The team leader, departmental heads and human resource department has to collectively develop the team spirit among the company R&D employees by making

the awareness about the value of his work for organisational growth & this can be done with different HR perceptions like

- Task aspects-What is to be achieved or carrying out and the related aspects
- People or Relationship aspects –How do the members feel while interacting and working with each other? How do they communicate with each other? How do they respond? Who is trying to dominate any leadership issues? Are there any conflicts? and how conflicts are resolved? Answers to these questions by company management can understand people or relationship aspects. Here the team leader, Department HOD and HR manager has to collectively find solution.
- The ability of R&D team to interact with cross functional team is very important for delivering successful R&D projects
- The team sprit can be enhanced by identifying the following factors,
    - Task fulfilment
    - Team maintenance
    - Self –orientation
    - Freedom for creativity

**e) Competitive Advantages-:**

A company /Industry can enjoy competitive advantages in several ways .it can gain the competitive advantages because

- The price of its product is lower
- The quality of its product is higher
- The availability of its product will be just in time.
- Customer service is better

- Attractiveness of its product is greater.
- Awareness of its product is greater.
- Other social, Psychological and ideological factors.

Customers today expect high reliability and low prices and these are mutually reinforcing attributes that supplier is expected to achieve just to be in the competition. The winning competitor must have both the lowest price and highest reliability or achieve one of the other competitive advantages that customer value. An Industry having strong R&D base, can influence all these factors positively and contribute to the competitive advantages of company. Competitive advantage views R&D activities as a way of improving process, thus reducing costs or providing customers with best class of benefits.

Company is needed to link its R&D strategy to get competitive advantages. If company chooses low cost-low price strategy, then low cost technologies are needed to develop by R&D which are consistent with maintaining acceptable levels of quality, availability, attractiveness and so forth.

Whereas if company chooses the differential strategy, then R&D has to perform activities in such way that can maximise the specific competitive advantages in terms of providing products capable of higher performance, innovative products etc., should be used, consistent with price premium customers are willing to pay for the uniqueness.

### Characteristics of Successful R&D team

The research activity is being the continuous process and it is difficult to define its start time and end time. The output of R&D team is measured in terms of their products launched in the market. For to be successful R&D teams, the below tactics and strategies need to be concerned:

- R&D team members are required consistently to work hard and displays high level of interest, dedication and motivation in the projects assigned in order to achieve its targeted goal. The team leader requires being comfortable in environment of high

uncertainty.

- The team is required to have good patience and should be able to find success in failures also
- They should have good creative and innovative mind ability.
- The team leader should be problem oriented and problem solver ability (both technical and administrative).
- The R&D team members should have ability of speedy work and able to adjust in all situations.
- They should have endurance and high level of energy.
- R&D teams should be well organised with respect to their roles, responsibilities and authority. The information flows should be well defined & are required to be understood by all members.
- The project should have clearly defined objectives & well established plans, schedules, budgets and monitoring & reporting systems.
- The team leader as well as team members should have positive outlook & ability to display enthusiasm, energy & “can-do “attitude.
- The assigned task is required to understand and accepted by all team members.
- The atmosphere of team should be informal, comfortable and relaxed.
- There should not be struggle for power and leadership dominance.
- High degree of confidence and trust is required among the team members and leaders.
- Team leader should create supportive atmosphere.
- There should be ability of all team members to influence each other as well as the

leader in a constructive and purposeful manner.

- Proper co-operation and conflict free environment in a team.
- There should be prospects for individual development opportunities among team.

For effective working of a team, all the team members are expected to fulfil eight different roles

- Coordinator
- Shaper
- Plant
- Monitor
- Implementer
- Resource investigator
- Team worker
- Finisher

**Futuristic Aspects**: Due to increased competition in global market and client's stringent product quality requirement, every pharmaceutical and chemical industry will require strong R&D back up in order to sustain in market. Only those industries can become competent and dominant which are having strong R&D base. Success for any industries will be possible only through innovative product/process technologies. Affixing with old technologies, no industries can't get pivotal position in market. Some key accomplishments are:

**Digital Therapeutics:** Prescription software and digital interventions will play a significant role in managing certain medical conditions, providing non-pharmacological treatment options.

**Nanotechnology**: Nanoparticles and Nano-carriers will enhance drug delivery methods,

allowing precise targeting of specific tissues and cells, reducing side effects, and improving therapeutic outcomes.

**Biotechnology Advancements:** Techniques like CRISPR-Cas9 gene editing and synthetic biology will enable precise modifications to genetic material, leading to innovative treatments and therapies.

**Organ-on-a-chip Technology:** Microfluidic devices that mimic human organs' functionalities will aid in drug testing and toxicity studies, reducing reliance on animal testing and increasing accuracy.

**Virtual Clinical Trials:** Digital platforms and wearable will facilitate decentralized clinical trials, making participation more accessible and collecting real-time patient data efficiently.

**Block chain in Drug Supply Chain:** Block chain technology will enhance transparency, traceability, and security in the pharmaceutical supply chain, minimizing the risk of counterfeit medicines.

**3D Printing:** Customized drug manufacturing using 3D printing will allow for personalized dosages and formulations based on patient needs.

**Bioinformatics and Big Data:** Analyzing vast datasets from clinical trials, patient records, and research studies will uncover valuable insights and aid in the development of targeted therapies.

**State-of the Art:** The present article is well elaborating about the structure and functioning of Industrial R&D in pharmaceutical and chemical industries along with its importance for organisational growth in competitive environment. It will be very helpful to those aspirants who are willing to make career in industrial R&D by making them well awareness of industrial R&D functioning (Chemical and Pharmaceutical industries) as well as to those entrepreneurs who are going to functionalise their R&D centres/department in their company to meet their growth target’s needs.

Pharmaceutical companies have been focusing on developing targeted therapies that aim to treat specific molecular targets associated with diseases. This approach allows for more personalized and effective treatments. Biologics and gene

therapies have gained significant attention in R&D. These treatments are designed to work with the body's biological processes and show promising results in treating various diseases, including cancer and genetic disorders.

Artificial intelligence and machine learning have been increasingly utilized in drug discovery and development processes. These technologies can analyze vast amounts of data to identify potential drug candidates, predict drug interactions, and optimize clinical trial designs. Immunotherapies, which harness the body's immune system to fight diseases, have revolutionized cancer treatment. Continued research in this area has led to the development of novel immunotherapeutic approaches.

Pharmaceutical companies have been exploring continuous manufacturing processes to improve efficiency, reduce costs, and enhance quality control during drug production. Drug repurposing, also known as drug repositioning, involves finding new uses for existing drugs. This approach has gained traction as it can accelerate the drug development process and lower costs. Regulatory agencies have been working to streamline and expedite drug approval processes, allowing for faster access to innovative treatments.

**Conclusion**-: The above discussion amplifies the functioning and structure of industrial R&D. The technological superiority can be achieved by both pharmaceutical & chemical industries with the help of progressive and proficient R&D efforts through innovative product development and adopting the best techniques /processes. In today’s era the R&D is mandatory for all the kinds of industries in order to sustain in competitive business environment which is helpful to fulfil customers requirement with cost effective manner.

Targeted Therapies focus on developing treatments that target specific molecular mechanisms associated with diseases for personalized and effective care. Biologics and Gene Therapies emphasis on biologics and gene therapies, leveraging the body's biology to treat diseases like cancer and genetic disorders. AI and Machine Learning has increased use of artificial intelligence and machine learning in drug discovery, predicting drug interactions, and optimizing clinical trials. Immunotherapy

advancements are made in utilizing the body's immune system to combat diseases, particularly in cancer treatment. Drug Repurposing is the research into finding new uses for existing drugs, accelerating drug development and lowering costs.

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