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A COMPREHENSIVE REVIEW ON DISCOVERY OF NEW DRUGS

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ABSTRACT

Drug discovery is a complex, multidisciplinary, and time-intensive process aimed at transforming an initial scientific concept into a safe, effective, and marketable therapeutic agent. The process encompasses several interconnected stages, including target identification and validation, hit and lead compound screening, optimization of molecular structures, and extensive preclinical and clinical evaluation to ensure efficacy and safety. In recent years, technological innovations have significantly revolutionized the landscape of drug discovery. The integration of Artificial Intelligence (AI), machine learning, and computational modeling has enabled rapid data processing, virtual screening, and predictive analysis of pharmacological and toxicological properties, thereby accelerating the identification of promising drug candidates. Furthermore, diverse molecular sources—such as synthetic libraries, combinatorial chemistry, and natural products—continue to provide invaluable chemical diversity for the development of novel therapeutics. Collectively, these advancements are reshaping modern pharmaceutical research, enhancing efficiency, reducing costs, and expanding opportunities for the discovery of innovative medicines that address unmet clinical needs.

KEYWORDS: Drug discovery, Target identification and validation, Compound screening, Lead optimization, Preclinical and clinical development, Artificial intelligence (AI), Computational drug design.

INTRODUCTION

Drug discovery is a long and challenging scientific process that focuses on finding a chemical substance that can safely and effectively treat a disease. The journey usually begins when researchers understand how a disease develops inside the body. This understanding helps them identify new biological targets and search for molecules that can correct or block the disease process. After a promising compound is identified, it must be prepared in the laboratory, tested for its chemical properties, and examined for biological activity.

Every potential drug molecule goes through several stages such as identification, synthesis, characterization, and screening to check whether it produces the expected therapeutic effect. Only a few compounds move forward because most fail at one stage or another due to safety issues, lack of effectiveness, or undesirable side effects. If a compound shows good results in laboratory and animal studies, it enters clinical development where it is tested in human volunteers through carefully controlled clinical trials.

Developing a new drug requires a large investment of time, money, and scientific expertise. On average, it may take 13–15 years for a single drug to move from the discovery stage to approval for patient use. The cost of this process is extremely high because thousands of compounds are studied, but only one may succeed. Despite the challenges, drug discovery remains essential because it ultimately leads to new treatments that bring hope and improved quality of life to millions of patients worldwide.[1]

Fig. No. 1: Drug Discovery Process.

HISTORY OF DRUG DISCOVERY AND SAFETY REGULATION

The history of discovering new medicines has evolved over thousands of years, moving from traditional observations to modern scientific innovation. In ancient times, people learned about healing substances mainly through experience—plants, minerals, and animal products were used because they showed relief in illness. Civilizations such as India, Egypt, and China documented these remedies, forming the earliest foundations of medicinal knowledge.

A major shift came during the 19th century, when scientists began isolating active chemical compounds from natural sources. This period marked the birth of modern pharmacology. Examples include the isolation of morphine from opium and quinine from cinchona bark. These discoveries proved that diseases could be treated using purified, measurable substances rather than crude mixtures.

In the early 20th century, the concept of synthetic medicine emerged. Researchers realized they could design and modify chemical structures to improve their therapeutic effects. The discovery of penicillin in 1928 further transformed drug discovery, showing that microorganisms could also produce life-saving medicines. This period laid the foundation for antibiotics, vaccines, and hormones.

By the late 20th century, technological progress such as molecular biology, biotechnology, and computational chemistry changed the entire approach. Instead of searching blindly, scientists began targeting specific molecules inside the body. Tools like high-throughput screening, genetic engineering, and recombinant DNA technology enabled faster and more precise discovery of potential drugs.

Today, drug discovery integrates artificial intelligence, genomics, proteomics, and structure-based design. Researchers can predict disease mechanisms, model drug interactions on computers, and develop new therapies for conditions once considered untreatable. The journey from ancient herbal remedies to AI-driven drug design shows how scientific understanding has steadily improved our ability to create safer and more effective medicines.[2]

STAGES OF DRUG DISCOVERY

Drug discovery is a complex, systematic, and multi-step process aimed at developing safe and effective therapeutic agents for human diseases. Each stage ensures that potential drugs are scientifically validated, optimized, and safe for human use.[3,8]

1. Target Identification

Objective: Identify a biological molecule (protein, enzyme, receptor, or gene) that plays a critical role in disease progression.

Techniques and Tools

- Genomics and transcriptomics for identifying disease-related genes.
- Proteomics for identifying key proteins.
- Bioinformatics and pathway analysis for understanding disease mechanisms.

Outcome: Selection of a therapeutic target that, when modulated, can alleviate or cure the disease.[3,4]

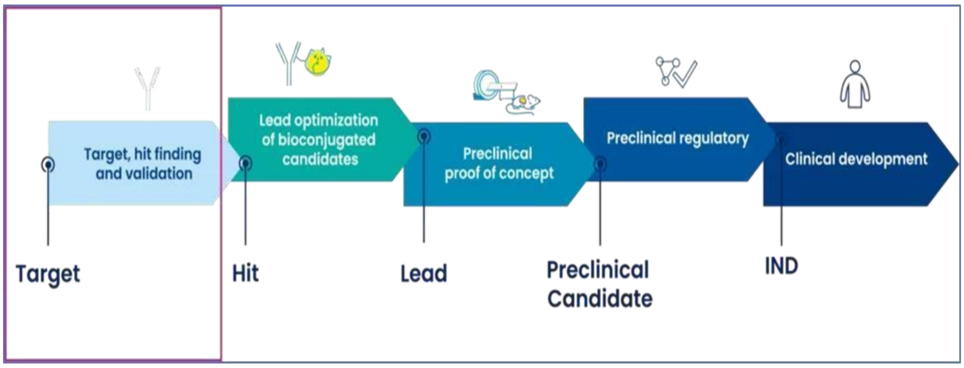

Fig. No. 2: Target Identification.

2. Target Validation

Objective: Confirm that the identified target is suitable for therapeutic intervention.

Methods

- Genetic approaches such as gene knockout or RNA interference (RNAi).
- CRISPR-Cas9 gene editing to study gene function.
- Use of chemical inhibitors or monoclonal antibodies to test target modulation in cellular or animal models.

Outcome: Only validated targets proceed further, reducing the risk of failure in later stages.[4,5]

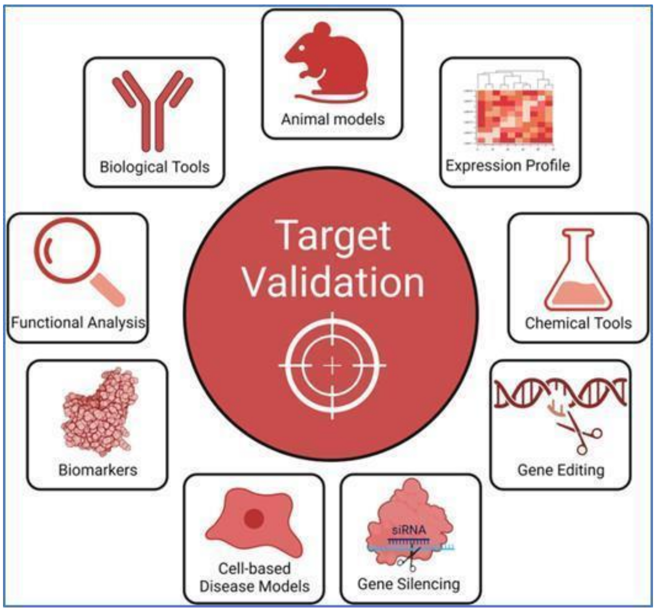

Fig. No. 3: Target Validation.

3. Hit Identification

Objective: Identify compounds ("hits") that interact effectively with the target.

Methods

- High-Throughput Screening (HTS): Automated screening of thousands of chemical compounds.
- Virtual Screening: In silico methods using computational chemistry and AI to predict active compounds.
- Natural Product Screening: Using plant, microbial, or marine extracts as potential sources of bioactive molecules.

Outcome: Identification of initial hits that show activity against the target.[5,6]

4. Lead Identification and Optimization

Objective: Develop hits into "lead compounds" with optimal properties.

Lead Optimization Includes

- Enhancing potency and selectivity toward the target.
- Improving pharmacokinetic properties (absorption, distribution, metabolism, excretion – ADME).

Minimizing toxicity.

Techniques

- Structure-Activity Relationship (SAR) studies to modify chemical structure for better activity.
- Computational modeling and QSAR studies for predicting activity and safety.

Outcome: Identification of drug candidates ready for preclinical testing.[5,7]

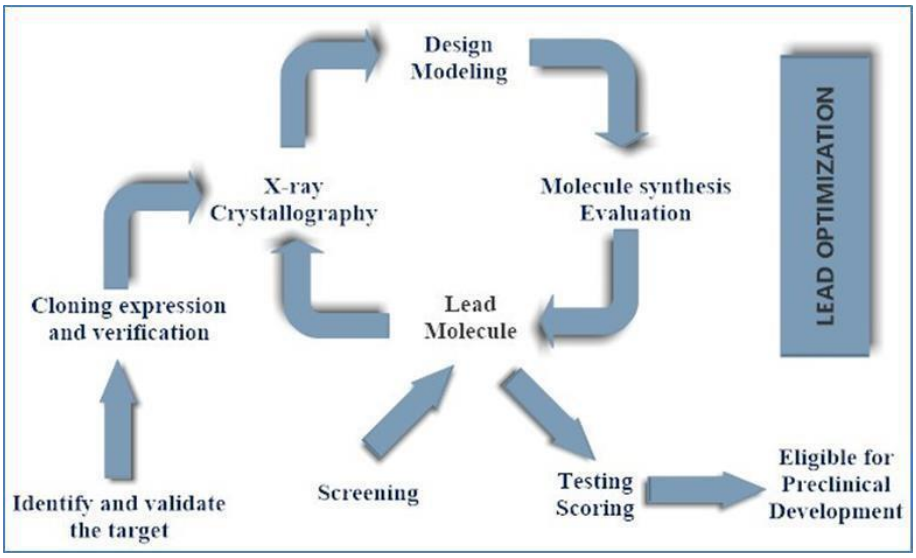

Fig. No. 4: Lead Identification and Optimization.

1. Modern Approaches in Drug Discovery

In recent years, drug discovery has evolved far beyond classical natural-product screening and empirical medicinal chemistry, and now encompasses a suite of advanced, integrated, computational and experimental strategies. Key "modern" approaches include:

Computational / in silico drug design and screening

Methods such as structure-based drug design (e.g. molecular docking, pharmacophore modeling), ligand-based design, quantitative structure–activity relationships (QSAR), and virtual screening of large chemical libraries have become foundational.

High-throughput screening (HTS) and high-content/phenotypic screening

HTS enables rapid testing of thousands to millions of compounds against biological targets. In addition, modern phenotypic screening — often combined with advanced readouts (e.g. imaging, multiomics, single-cell profiling) — allows researchers to detect functional effects of compounds on cells without a priori knowledge of the exact molecular target.

Target expansion and novel modalities

Advances in understanding biology and in biochemical technologies have enabled targeting of “difficult” or previously “undruggable” proteins — e.g. via allosteric modulation, covalent inhibitors, or targeted protein degradation (e.g. PROTACs or molecular glues).

Artificial Intelligence (AI) / Machine Learning (ML) / Deep Learning (DL)

The latest shift combines big data (genomics, proteomics, structural data), large virtual chemical and ligand-binding databases, and computational power to accelerate target identification, lead discovery, optimization, ADMET (absorption, distribution, metabolism, excretion, toxicity) prediction, and more. This reduces time, cost and increases success probability compared to traditional trial-and-error approaches.

Integration of multi-disciplinary data (omics, systems biology)

Use of genomics, transcriptomics, proteomics, metabolomics — often in combination with phenotypic screening and computational modeling — helps understand disease pathways, predict drug response, and identify novel targets in a holistic, systems-level manner.

Accelerated “design-make-test-analyze” (DMTA) cycles and miniaturized chemistry

Modern drug discovery leverages advances in synthetic chemistry (e.g. “click chemistry”), combinatorial chemistry, automation, and rapid synthesis methods — enabling fast generation and testing of compound libraries, shortening hit-to-lead and lead-optimization timelines.

These approaches are not mutually exclusive; in fact, the most powerful contemporary drug-discovery campaigns often combine multiple strategies (e.g. in silico screening → HTS → phenotypic or structural validation → AI-driven optimization → novel modality design) — thereby leveraging computational speed, biological relevance, chemical diversity, and mechanistic insight.

Consequently, modern drug discovery is far more efficient, rational and hypothesis-driven than traditional trial-and-error methods; it's also more capable of tackling complex diseases, previously “undruggable” targets, and delivering safer, more effective therapies.

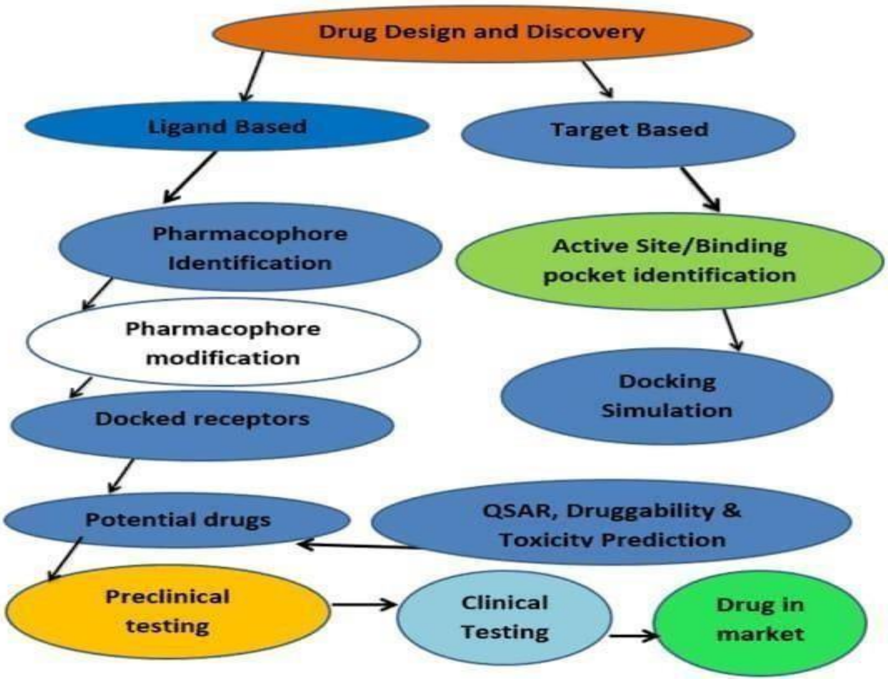

Fig. No. 5: Modern Approches In Drug Discovery.

Drug Discovery from Natural Sources

Natural sources have been one of the richest reservoirs of biologically active molecules used for developing new medicines. These sources include plants, microorganisms, marine organisms, fungi and animals. Many successful drugs in modern medicine—such as penicillin, paclitaxel, artemisinin and statins—were originally discovered from nature.

1. Importance of Natural Sources

Natural products are extremely valuable in drug discovery because:

They have unique chemical structures that are often difficult to create synthetically.

They show strong biological activity, as many evolved naturally to interact with biological systems.

They serve as templates for semisynthetic modification, allowing scientists to create improved analogues. A large percentage of current medicines are directly obtained from, or inspired by, natural compounds.

2. Steps in Drug Discovery from Natural Sources

a. Selection of Natural Material

Natural sources such as medicinal plants, soil bacteria, marine sponges or fungi are selected based on traditional knowledge, biodiversity studies or ecological clues.

b. Extraction and Isolation

The biological material is processed using solvents to obtain crude extracts.

These extracts are separated into fractions, and individual compounds are later purified using chromatography.

c. Bioactivity Screening

Extracts or isolated compounds are tested using cell-based, biochemical, antimicrobial or enzyme inhibition assays to identify biological activity such as anticancer, antibacterial, anti-inflammatory or antiviral effects.

d. Structure Elucidation

Active compounds are characterized using: NMR spectroscopy

Mass spectrometry

X-ray crystallography

Biopharmaceutical and Biotechnological-Based Drug Discovery

Biopharmaceutical and biotechnological approaches have transformed modern drug discovery by allowing the development of highly specific, targeted, and personalized therapies. These approaches rely on biological systems, living cells, genetic engineering, and advanced molecular technologies to create medicines that cannot be produced through traditional chemical synthesis.

1. Overview

Biopharmaceutical drug discovery focuses mainly on biological molecules such as: Monoclonal antibodies

Recombinant proteins Vaccines

Gene therapies RNA-based drugs Cell-based therapies

Biotechnology enables the manipulation of genes, proteins, and cellular pathways to design, produce and optimize these advanced therapeutics.

2. Key Steps in Biopharmaceutical & Biotechnological Drug Discovery

a. Target Identification

Biological targets (proteins, receptors, enzymes, RNA sequences) are identified using: Genomics

Proteomics Bioinformatics

Disease pathway analysis

These tools link genetic or molecular abnormalities to disease processes.

b. Lead Generation

Biotechnology enables several strategies for discovering potential drug candidates: Hybridoma technology for creating monoclonal antibodies

Phage display libraries for selecting high-affinity peptides or antibody fragments Recombinant DNA technology for producing therapeutic proteins

CRISPR and gene-editing tools for correcting genetic defects

mRNA technology for designing vaccines and gene-based therapeutics

c. Optimization and Engineering

Candidate molecules are refined to improve:

Stability Half-life Specificity

Reduced immunogenicity

Target affinity

Examples include humanization of antibodies and modification of protein domains.

d. Production Using Biotechnology Large-scale manufacturing uses: Mammalian cell cultures (CHO cells) Microbial fermentation (E. coli, yeast) Viral vectors for gene therapy

Bioreactors to ensure purity and biological activity

Preclinical Research in Drug Discovery

Preclinical research is the stage of drug development that occurs after lead optimization and before human clinical trials. Its main purpose is to determine whether a drug candidate is safe, effective and suitable for human testing. This stage uses both in vitro (test-tube or cell-based) and in vivo (animal) models to evaluate the biological profile of a new compound.

1. Objectives of Preclinical Research

To evaluate safety (toxicology, organ effects, dose limits). To study efficacy in biological models of the disease.

To examine pharmacokinetics (PK) — absorption, distribution, metabolism and excretion. To assess pharmacodynamics (PD) — how the drug acts on the body and target.

To identify starting dose and risk assessment for first-in-human trials.

2. Components of Preclinical Research

a. In Vitro Studies

These laboratory tests help understand:

Mechanism of action Receptor binding Cytotoxicity Metabolic stability

Drug–drug interaction potential

Cell models, stem-cell assays, and high-throughput platforms are commonly used.

b. In Vivo Animal Studies

Animal models help predict how the drug behaves in whole organisms. Key assessments include:

Acute toxicity (single-dose harmful effects) Sub-acute and chronic toxicity Reproductive and developmental toxicity Genotoxicity and carcinogenicity

Safety pharmacology (heart, lungs, CNS)

Animal studies also generate data on PK/PD relationships to support dose selection.

c. Pharmacokinetic Studies

These studies measure:

How fast the drug is absorbed How widely it distributes in tissues

How it is metabolized (including enzyme pathways) How it is eliminated

PK helps predict drug exposure in humans.

d. Pharmacodynamic Studies

PD studies relate drug concentration to its biological effect, helping determine: Effective dose range

Potency

Duration of action Biomarkers of activity

e. Formulation and Stability Testing

During preclinical development, formulation scientists ensure: Suitable stability

Appropriate delivery method (oral, IV, inhalation, etc.) Adequate bioavailability

Clinical Trials in Drug Discovery

Clinical trials represent the most crucial stage of the drug development process, where a potential new medicine is tested in humans to confirm its safety, efficacy, optimum dose, and overall therapeutic value. These trials are conducted after successful preclinical studies and follow strict scientific and regulatory guidelines to protect participants and produce reliable data.

1. Purpose of Clinical Trials

The main goal of clinical trials is to determine whether a new drug:

Is safe for human use

Produces the expected therapeutic effect Has an acceptable risk–benefit ratio

Shows appropriate pharmacokinetics and pharmacodynamics

Demonstrates superiority or non-inferiority compared with existing treatments

Phases of Clinical Trials

Phase I (Safety and Dose-Finding)

Conducted in 20–100 healthy volunteers or sometimes patients. Focuses on safety, tolerability, and pharmacokinetics.

Determines the maximum tolerated dose (MTD). Usually lasts a few months.

Phase II (Efficacy and Dose Optimization)

Conducted in 100–300 patients with the target disease.

Evaluates preliminary efficacy and identifies the most effective dose range. Assesses short-term side effects.

Often divided into Phase IIa (proof-of-concept) and Phase IIb (dose-finding).

Phase III (Large-Scale Efficacy Trials)

Involves 1,000–3,000 patients across multiple clinical centers.

Confirms therapeutic efficacy, monitors side effects, and compares the drug with standard therapy. Generates data required for regulatory submission.

This phase is the longest and most expensive part of clinical development.

Phase IV (Post-Marketing Surveillance)

Conducted after regulatory approval.

Monitors long-term safety, rare adverse effects, and real-world effectiveness. Helps refine clinical guidelines and detect previously unobserved risks.

2. Ethical and Regulatory Requirements

Clinical trials must follow

Good Clinical Practice (GCP) Informed consent procedures

Independent ethical review board approval
Strict monitoring and reporting of adverse events

These safeguards ensure that human participants are protected and that data integrity is maintained.

3. Importance of Clinical Trials

Clinical trials are essential to:
Transform laboratory findings into real therapeutic solutions Ensure drugs meet global safety and efficacy standards Support regulatory submissions (e.g., FDA, EMA, CDSCO)
Build scientific evidence for healthcare professionals and patients

Regulatory Approval in New Drug Discovery

Regulatory approval is the final and most critical stage of the drug development process, ensuring that a new medicine is proven safe, effective, and manufactured with consistent quality before it reaches patients.

Regulatory agencies—such as the US FDA, European Medicines Agency (EMA), and India's CDSCO—evaluate all scientific evidence generated throughout drug discovery and development.

1. Purpose of Regulatory Approval

The main objective of regulatory approval is to
Protect public health
Ensure the drug meets strict safety, efficacy, and quality standards Verify that the benefits outweigh the risks
Confirm that manufacturing follows Good Manufacturing Practices (GMP)

2. Key Components of the Regulatory Submission

Before approval, companies must compile a large scientific and technical dossier known as:

a) Investigational New Drug (IND) Application Submitted before human trials begin. It includes

Preclinical pharmacology and toxicology data Manufacturing and formulation details Proposed clinical trial protocols
Safety monitoring plans

Once approved, the drug can enter clinical trials (Phase I–III).

b) New Drug Application (NDA) / Marketing Authorization Application (MAA) Submitted after Phase III trials. It contains:

All clinical data (safety, efficacy, dosing)

Preclinical results

Manufacturing process and quality control details Labeling information, warnings, and instructions Risk management plan

Regulators review this dossier through scientific committees and external experts.

4. Regulatory Review Process

The review includes several steps

1. Administrative screening – checks completeness of documentation.
2. Scientific evaluation – assesses clinical trials, toxicology, pharmacology, and statistics.
3. Manufacturing inspection – ensures GMP compliance.
4. Benefit–risk assessment – compares therapeutic advantages with potential risks.
5. Final approval decision – if the drug meets all criteria, it is authorized for marketing.

Some countries also offer fast-track, priority review, or accelerated approval for drugs addressing serious diseases.

5. Post-Approval Requirements

Even after approval, regulatory responsibility continues: Pharmacovigilance reporting (detecting rare or long-term adverse effects) Phase IV studies

Periodic safety update reports (PSURs)

Monitoring of product quality and manufacturing consistency

This ensures the drug remains safe and effective throughout its life cycle.

Post-Market Monitoring in New Drug Discovery

Post-market monitoring—also known as Phase IV surveillance—is the continuous evaluation of a drug's safety, effectiveness, and quality after it has been approved and released to the market. Even though extensive preclinical and clinical studies are performed before approval, some rare or long-term effects may only appear when the drug is used in a larger and more diverse population.

Therefore, post-market monitoring is essential for maintaining patient safety and improving therapeutic outcomes.

1. Purpose of Post-Market Monitoring

The main goals include:

Detecting rare, delayed, or long-term adverse effects Assessing the real-world effectiveness of the drug

Monitoring drug–drug interactions not observed in clinical trials Ensuring manufacturing consistency and product quality

Identifying risks in special populations such as elderly, pregnant women, or patients with comorbidities

This stage ensures the drug continues to have a positive benefit–risk profile throughout its life cycle.

2. Key Components of Post-Market Surveillance

a) Pharmacovigilance Reporting

Healthcare professionals, patients, and manufacturers report any unexpected adverse effects to regulatory agencies. These reports help in identifying new safety signals.

b) Periodic Safety Update Reports (PSURs)

Manufacturers must regularly submit PSURs, which include:

Adverse event data Benefit–risk evaluations Updated safety information

These reports allow regulators to make informed decisions regarding the drug's continued use.

c) Phase IV Clinical Studies Conducted after marketing approval to:

Evaluate long-term safety

Explore new therapeutic uses

Compare real-world performance with existing treatments

d) Risk Management Plans (RMPs)

Companies must provide a plan outlining how they will: Detect risks

Minimize adverse reactions

Educate healthcare providers on safe usage

e) Product Quality Monitoring Regulators also inspect:

Manufacturing facilities Batch quality

Storage and distribution practices

Quality problems may lead to warnings, recalls, or manufacturing updates.

List of New Approved Drugs

Sr.	Drug Name	Indication	Approvle Date
1	Tafamidis	Bulk Drug (no finished formulation)	16 Jan 2025
2	Letermovir Bulk Drug & Tablets (240 mg, 480 mg)	for CMV prophylaxis in transplant patients	17 Jan 2025
3	Fexuprazan hydrochloride Bulk Drug & Tablets 40 mg	for erosive esophagitis	10 Feb 2025
4	Edoxaban Tosylate Monohydrate	Bulk Drug	11 Feb 2025
5	Edoxaban Tablets 15 mg / 30 mg / 60 mg	anticoagulant for stroke/embolism, DVT/PE	20 Feb 2025
6	Sodium Zirconium Cyclosilicate (LOKELMA)	Powder for oral suspension – for hyperkalaemia	05 Mar 2025
7	Rimegepant Oral disintegrating tablets 75 mg	acute migraine	27 Mar 2025
8	Doravirine Bulk Drug & Tablets 100 mg	for HIV-1 infection	28 Mar 2025
9	Tucatinib Bulk Drug & Tablets (50 mg, 150 mg)	HER2-positive metastatic breast cancer	08 Apr 2025
10	Zanubrutinib Capsules 80 mg	various B-cell malignancies	08 Apr 2025
11	Linaclotide Bulk Drug & Capsules (72 mcg, 145 mcg)	chronic idiopathic constipation	21 Apr 2025
12	Siponimod Bulk Drug & Tablets (0.25 mg/1 mg/2 mg)	secondary progressive multiple sclerosis with active disease	09 May 2025
13	Ivosidenib 250 mg film-coated tablet 250 mg film-coated tablet	AML/IDH-1 mutated cancers & cholangiocarcinoma	May 2025
14	Tegoprazan Tablets (50 mg & 25 mg)	For GERD/erosive disease & maintenance	May–Jul 2025
15	FDC: Relugolix + Estradiol + Norethindrone Acetate Tablets	For heavy menstrual bleeding with fibroids	15. 16 Jul 2025
16	Lutetium Lu-177 Vipivotide Tetraxetan (Injection)	Radioligand therapy for PSMA-positive metastatic prostate cancer	23 Jul 2025
17	Stamicis 1 mg Kit	Radiopharmaceutical preparation for myocardial perfusion imaging	Jul 2025

IPR and Drug Discovery: Role & Importance

Intellectual Property Rights (IPR) protect new ideas, discoveries, and technologies in the pharmaceutical industry. They are essential because drug development is costly, lengthy, and high-risk.

What Are IPR in Pharma?

IPR gives inventors exclusive rights to use their innovations for a limited time. Types include:

Patents – Protect new drugs, processes (20 years). Trademarks – Protect brand names and logos.

Copyrights – Protect written scientific materials.

Trade Secrets – Protect confidential formulas and manufacturing methods.

Why IPR Is Important in Pharma

1. Encourages R&D

Patents allow companies to recover high research costs and continue innovating.

2. Prevents Counterfeits

Protects patients by ensuring medicines are genuine and safe.

3. Boosts Economic Growth

Strengthens market competitiveness and supports industry expansion.

4. Balances Innovation & Access

After patent expiry, generics enter the market and improve affordability.

5. Attracts Investment & Partnerships

Strong IPR systems encourage investors, biotech firms, and academic collaborations.

CONCLUSION

The discovery of new drugs is a continuous and evolving journey that plays a vital role in improving human health. As diseases become more complex and new health challenges keep appearing, the need for safer and more effective medicines is increasing. Modern drug discovery combines scientific creativity with advanced technologies such as computational tools, molecular modeling, high-throughput screening, and biotechnology. These innovations have made it possible to understand diseases more clearly and identify promising drug candidates faster than ever before.

Although the process is long, expensive, and filled with uncertainty, every step—from target identification to clinical trials—adds value to the development of a successful medicine.

Collaboration among researchers, industries, healthcare professionals, and regulatory bodies strengthens the discovery pipeline and ensures that new drugs are developed responsibly and ethically.

Overall, the discovery of new drugs is a challenging but essential process. With continuous research, technological growth, and interdisciplinary teamwork, the future of drug discovery holds great promise for developing novel therapies that can address unmet medical needs and improve the quality of life for patients across the world.

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