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Hearty Congratulations to College Toppers

RGUHS Exams-April/May 2025

B.Pharm First Semester



SGPA - 8.67

Aishwarya G Kalagi



SGPA - 8.30

Heena Kouser



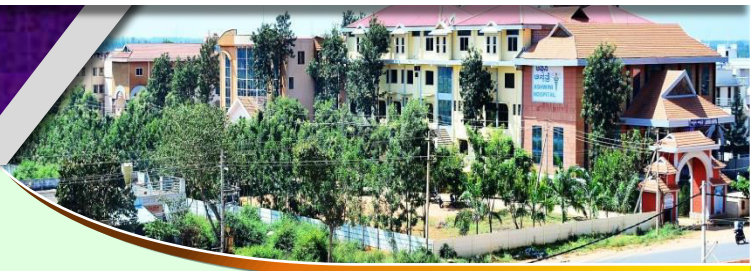
SGPA - 8.07

Maimuna Seher



Management, Principal & Staff
Aruna College of Pharmacy Tumkur





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From

PRINCIPAL'S DESK . . . 



Namaskar,

Warm wishes and Seasons' Greetings to one and all . . .

To be in stride with the global academic pattern and also to suit the professional as well as societal current demands the Indian education system, is undergoing metamorphic changes particularly under the banner of **National Education Policy 2020 (NEP-2020)**. Accordingly most of the apex bodies of different professions have initiated redesigning of their existing curricular structure to sync with the NEP-2020. In this process the **Pharmacy Council of India** has already revised the **Diploma in Pharmacy curriculum** and implemented across the country. Now the Bachelor of Pharmacy curriculum redesigning is underway by the council along with revamping of its existing structure.

Refurbish process proposes to segregate the B.Pharm course from the level of 3rd year/5th semester into clinical and industry oriented, focusing much on the specialty based courses. This step is a welcome move but the introduction of such specialty based segregation at the level of UG may set competition with the existing courses of the same profession.

Further as these specialties have specific & narrow focus and also likely to impart specific skill sets may restrict scope for cross-employment; which the current curricular structure is facilitating. Further mere segregation of course into specialties without real-time/requisite field exposure would also be a challenging for the candidates in this **Artificial Intelligence** and **Machine Learning** dominated era.

Let all of us insist our apex body to welcome/consider the rational suggestions given by the think tanks of the profession who are either serving or expert in those specific domains for the up-liftment of this noble profession.

On behalf of ACOP Tumkur wishing everyone all the best.

Warm Regards

Dr. Bheemachari
Principal
ACOP, Tumkur

Also visit us @

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NETWORK PHARMACOLOGY



Raziya Begum
Associate Prof.
ACOP, Tumkur

Network pharmacology is an interdisciplinary approach that combines systems biology, bioinformatics and pharmacology to study how drugs interact with multiple targets rather than focusing on a single target (as in traditional pharmacology).

It's particularly valuable for understanding complex diseases like cancer, diabetes, and neurodegenerative disorders, where multiple pathways and gene interactions are involved.

The concept of "network pharmacology" was first introduced by British scholar Hopkins in October 2007. He suggested that treating diseases through drugs could be achieved by targeting multiple interactions within biological networks. In 2009, Chinese scientists published a paper titled "Network Pharmacology" in the Chinese Journal of New Drugs and Clinical Remedies, furthering the development of this field.

One notable breakthrough was the early hypothesis linking Traditional Chinese Medicine (TCM) with biological networks. This idea was proposed by Shao Li, five years before the official term "network pharmacology" was introduced.

Recent high-level studies show promising trends, including deeper integration of mathematics and biology, as well as extensive experimentation with multi-component data. There's potential for groundbreaking progress in understanding complex disease mechanisms and the roles of drugs, particularly by studying various interdisciplinary relationships.

Key Concepts in Network Pharmacology

- 1. Multi-Target Drugs-** Drugs can influence more than one biological target, which may improve therapeutic efficacy and reduce side effects.
- 2. Disease-Gene-Drug Networks-** Relationships are mapped among diseases, genes/proteins and drugs to identify potential mechanisms and novel targets.
- 3. Systems-Level Analysis-** By using networks of interactions (e.g., protein-protein interactions, gene regulatory networks), researchers can understand drug effects in a broader biological context.

4. Network Construction- Tools and databases (e.g., STRING, STITCH, Cytoscape) are used to construct interaction networks between:

- Active compounds
- Protein targets
- Disease-related genes

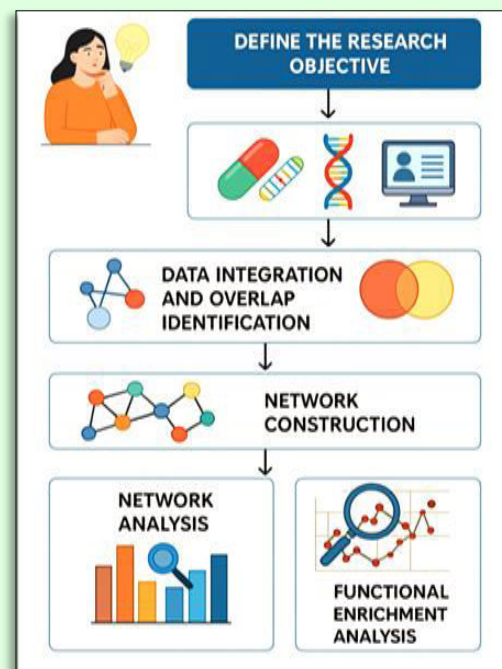
5. Pathway Enrichment Analysis- Identifies biological pathways significantly associated with a drug's targets, using resources like KEGG or Reactome.

Applications of Network Pharmacology

- **Traditional Chinese Medicine (TCM):** To analyze the synergistic effects of multiple herbs and compounds.
- **Drug Repurposing:** Discovering new uses for existing drugs.
- **Polypharmacology:** Designing drugs that act on multiple targets.
- **Precision Medicine:** Personalizing treatments based on an individual's network of gene-drug interactions.

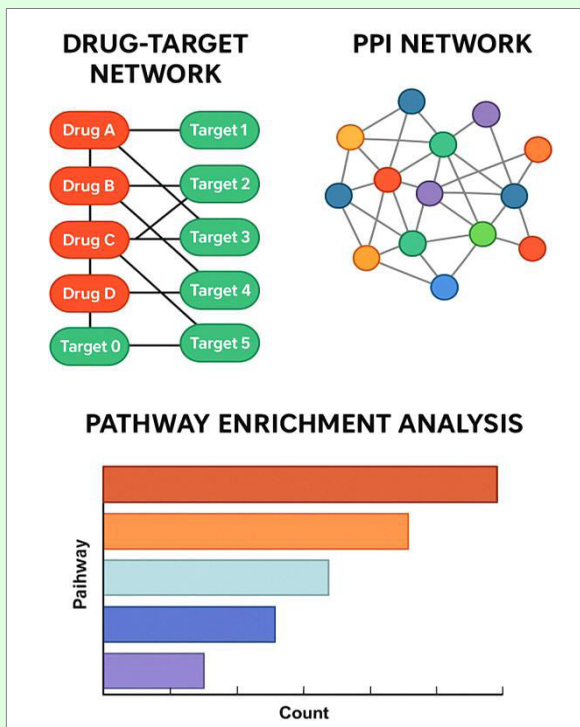
Common Tools & Databases

Cytoscape	Network visualization
STRING	Protein-protein interactions
STITCH	Drug-chemical-protein links
TCMSP	TCM pharmacology database
PharmMapper	Target identification
DrugBank	Drug-target and drug-disease info
Online Tools	Swiss Target Prediction, DAVID, Metascape

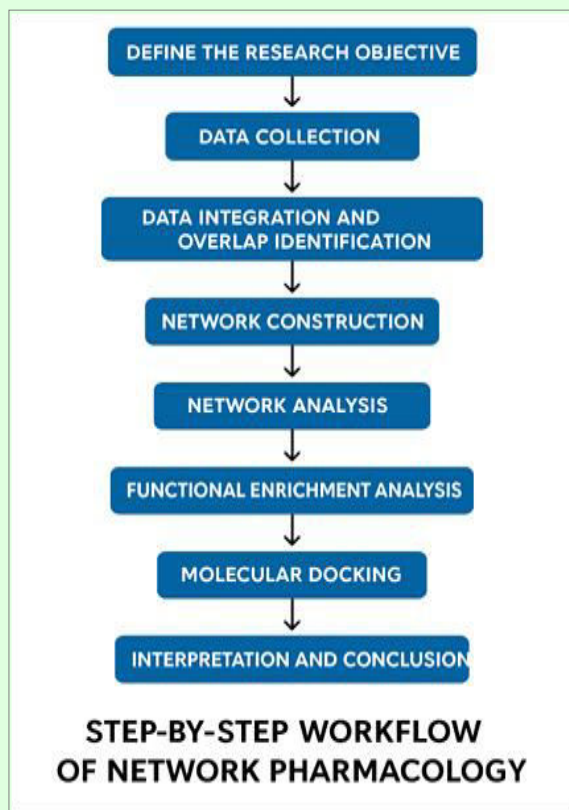


STEP BY STEP WORK FLOW OF NETWORK PHARMACOLOGY

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EXAMPLES OF NETWORK PHARMACOLOGY RESULTS

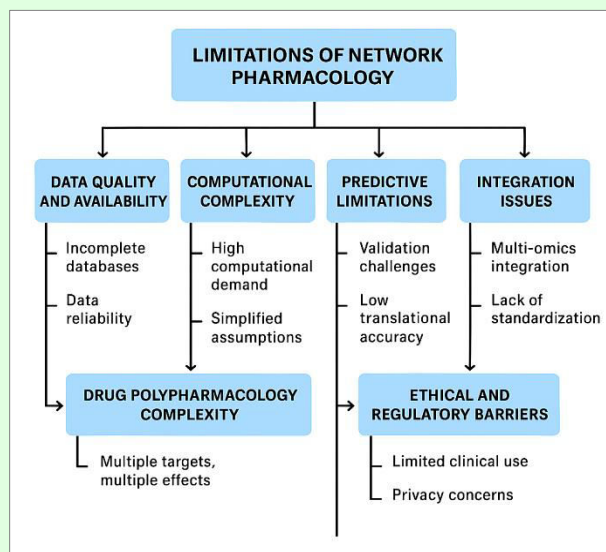


RESULTS

- 1. Compound–Target Network**
Identifies multitarget potential of compounds; highlights key compounds and hub targets.
- 2. Protein–Protein Interaction (PPI) Network:**
Identifies hub proteins critical for disease progression; useful for target prioritization.
Tools: STRING, Cytoscape
- 3. Target–Pathway Network:**
Reveals how compounds might modulate specific cellular processes or signaling pathways.
- 4. Gene Ontology (GO) Enrichment:**
Explains the biological significance of targets.
 - **Biological Process (BP)**
 - **Molecular Function (MF)**
 - **Cellular Component (CC)**
- 5. ADMET Prediction:**
Screens drug-likeness and safety profiles.
- 6. Disease–Target–Compound Network:**
Helps in understanding multi-component, multi-target mechanisms of herbal formulations.
- 7. Molecular Docking Results:**
Validates compound-target interactions suggested by in silico prediction.
- 8. Pharmacological Mechanism Hypotheses:**
Provides insights for experimental validation or drug repurposing.

Conclusion

Network pharmacology has emerged as a powerful tool in modern drug development, offering a systematic framework for revitalizing and validating herbal medicines. Despite its growing utility, several limitations must be addressed to fully harness its potential.



FRESHERS DAY CELEBRATION 2024-25 BATCH



VINCA ALKALOIDS: AS AN POTENT ANTI-CANCER AGENT

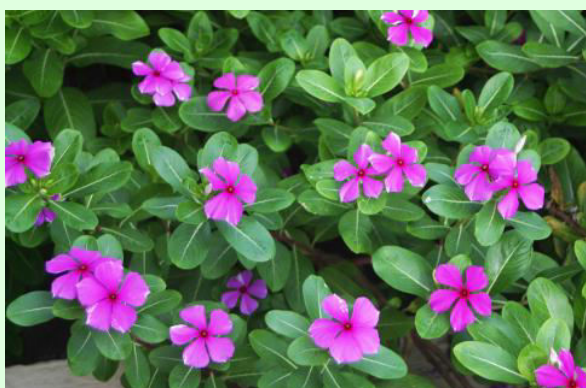
INTRODUCTION



Likhitha V
Assistant Prof.
ACOP, Tumkur

Vinca alkaloids are a class of naturally occurring or semi-synthetic compounds derived primarily from the ***Catharanthus roseus*** plant, commonly known as the Madagascar periwinkle. These alkaloids are well-known for their potent

anticancer properties and have been widely used in chemotherapy.



- **Carcinomas** (from epithelial cells – e.g., breast, lung, colon)
 - **Sarcomas** (from connective tissue – e.g., bone, muscle)
 - **Leukemias** (from blood-forming tissues)
 - **Lymphomas** (from the immune system)
- Cancer is one of the leading causes of death globally, and its treatment typically involves one or a combination of **surgery, radiation therapy, chemotherapy, immunotherapy, or targeted therapy.**

Types of Vinca Alkaloids

Vinca alkaloids are classified into **natural** and **semi-synthetic** types based on how they are obtained and modified. All vinca alkaloids share a common origin from the *Catharanthus roseus* plant and are known for their ability to inhibit cell division by targeting microtubules.

Mechanism of Action:

Vinca alkaloids exert their antineoplastic effects by binding to **tubulin**, a protein essential for the formation of microtubules. By inhibiting microtubule polymerization, these drugs disrupt **mitotic spindle formation**, thereby **arresting cell division in metaphase.**

Vinca Alkaloid	Chemical Characteristics
Vincristine	Complex dimer of catharanthine and indoline with a formyl group
Vinblastine	Similar to vincristine but has a methyl group instead of a formyl group
Vindesine	Semi-synthetic derivative of vinblastine with a modified acetyl group
Vinorelbine	Semi-synthetic ; contains a naphthyl side chain instead of indole
Vinflunine	Fluorinated derivative of vinorelbine (contains fluorine atoms)

Cancer is a group of diseases characterized by the **uncontrolled growth and spread of abnormal cells** in the body. Normally, cell growth and division are tightly regulated processes. However, in cancer, mutations in DNA disrupt these controls, allowing cells to divide uncontrollably, evade apoptosis (programmed cell death), invade nearby tissues, and sometimes spread to distant parts of the body through the blood or lymphatic system (a process called **metastasis**).

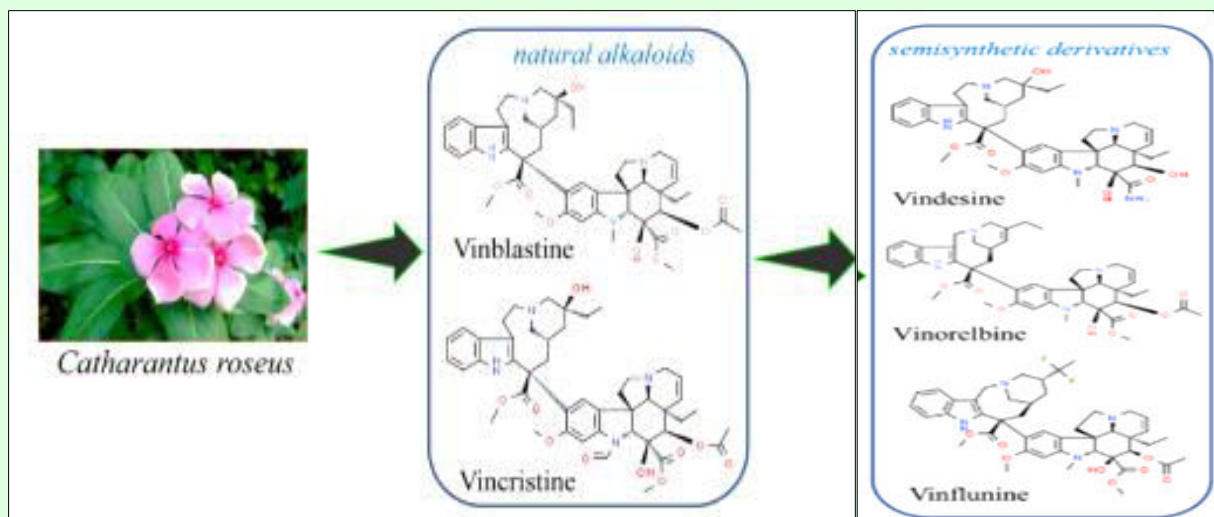
There are over 100 types of cancer, commonly classified by the organ or tissue where they originate, such as

This makes them particularly effective against rapidly dividing cancer cells.

Current use in cancer therapy and clinical applications:

Vinca alkaloids are used to treat a wide range of cancers:

- **Vincristine:** Used for leukemias, lymphomas (e.g., Hodgkin's disease), neuroblastoma.
- **Vinblastine:** Effective in Hodgkin's lymphoma, testicular cancer.
- **Vinorelbine:** Primarily used in non-small cell lung cancer and breast cancer.
- **Vindesine:** Used in acute leukemias and certain solid tumors.



Research and Emerging Applications:

Drug delivery systems: Liposomal and nanoparticle-based formulations to reduce side effects and enhance targeting.

Combination therapy: Used with monoclonal antibodies, immunotherapy, and targeted agents for synergistic effects.

Neuroprotective strategies: Ongoing research into ways to reduce vincristine-induced neuropathy.

Future Role of Vinca Alkaloids in Cancer Therapy
While vinca alkaloids like **vincristine** and **vinblastine** have been mainstays in chemotherapy for decades, their **future role** in cancer therapy is evolving. Current research is focused on improving efficacy, minimizing toxicity, and expanding their use in **targeted and combination therapies**.

Future Potential of Vinca Alkaloids

Targeted delivery	Increased efficacy, lower toxicity
Structural modification	Better safety, reduced resistance
Combination with immunotherapies	Enhanced tumor-killing power
Personalized therapy	Precision dosing and patient selection
New indications	Treatment of difficult and rare cancers

CONCLUSION

Vinca alkaloids are a crucial class of chemotherapeutic agents that have significantly advanced cancer treatment since their discovery. However, ongoing advancements in drug delivery systems, semi-synthetic derivatives, and combination therapies are addressing these limitations and expanding their clinical utility. Looking forward, vinca alkaloids continue to hold a promising future in cancer therapy especially through innovations like nanotechnology, antibody-drug conjugates, and personalized medicine. As part of integrated treatment strategies, they remain vital tools in the fight against cancer.

* * * * *

NATIONAL PHARMACY EDUCATION DAY 2024

Aruna Educational Trust
ARUNA COLLEGE OF PHARMACY
Behind Ashwini Hospital, Ring road, Maralur
TUMKUR - 572 105

Celebrates the Birth Anniversary of
Prof. M L Schroff

PHARMA ANVESHAN **NATIONAL PHARMACY EDUCATION DAY 2025**

Guest of Honor Chief Guest Presided by

Dr. Radhesh Rao
Trustee
Aruna Educational Trust (R)
Tumkur

Dr. Veeresh P Veerapur
Professor
Sree Siddaganga College of Pharmacy
Tumkur

Dr. Bheemachari
Principal
Aruna College of Pharmacy
Tumkur

Coordinators:
Mrs. Bindu C, Mrs. Razya Begum & Ms. Pooja R, Asst. Profs. ACOP

6th March 2025 B.Pharm LH



watch videos @ aruna college of pharmacy tumkur

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ROLE OF REGULATORY AFFAIRS IN GLOBAL PHARMA PRODUCTION

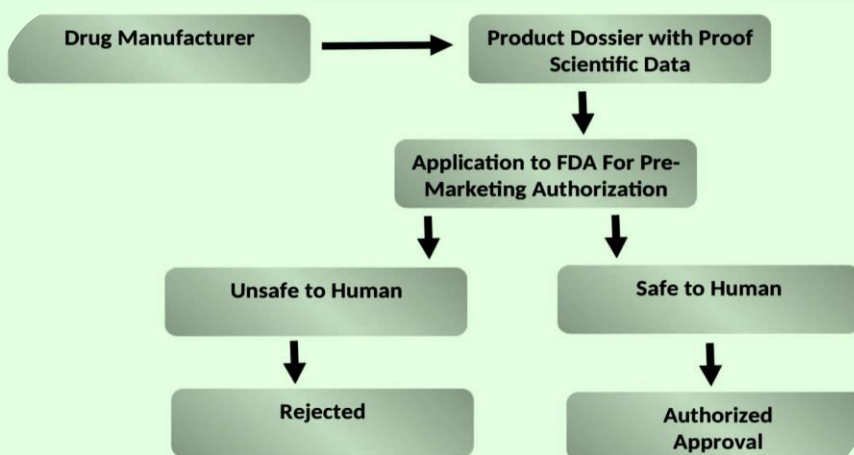


Bindu C
Assistant Prof.
ACOP, Tumkur

Regulatory affairs have been a very important department in the pharmaceutical company during the last few years. Currently, this department helps safeguard the products' life cycle and guide the company on regional and global laws/regulations set forth by different regulatory authorities.

All companies, whether they are multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of regulatory Affairs. The success of a regulatory strategy is less dependent on the regulations than on how they are interpreted and connected within companies and to outside constituents.

Regulatory affairs have been the very prime department in pharmaceutical Companies during the last few years in Asia and other countries. Currently, this department helps to guard the product life cycle and lead the company on regional and global laws/regulations set forth by different regulatory authorities. Principally, this consists of data proving that the drug has quality, efficacy and safety properties suitable for the intended use, additional administrative documents, samples of the finished product, and reagents necessary to perform analyses of the product. Therefore, they are the vehicle in a country through which drug sponsors formally propose that the regulatory agencies approve a new pharmaceutical for sale and marketing.



ROLE: Regulatory affairs (RA) professionals play critical roles. People who work in regulatory affairs negotiate the interaction between the regulators, the regulated and the market to get high standard products to the market and to keep them there preventing substandard products from being marketed. They give strategic and technical advice at the highest level in their companies, from the beginning of the development of a product, making a major contribution both commercially and scientifically to the success of a company as a whole.

In today's competitive environment the reduction of the time taken to reach the market is critical to the company's success.

SCOPE OF REGULATORY AFFAIRS

PROFESSIONAL IN INDUSTRIES:

- Regulatory affairs professionals are employed in industry, government regulatory authorities, and academics.
- Wide range of regulatory professionals includes in these areas: Pharmaceuticals, Medical Devices, In vitro diagnostics, Biologics, biotechnology, Nutritional Products, and Cosmetics.

DMF (Drug Master File)

Drug Master File is a submission to the Food and Drug Administration (FDA) that may be used to provide confidential detailed information about facilities, processes, manufacturing, processing,

packaging, and storing of one or more human drugs. The information in the DMF used to support the following,

- Investigational New Drug Application (IND),
- New Drug Application (NDA),
- Abbreviated New Drug Application (ANDA),

TYPES OF DMFs:

Type I	Type II	Type III	Type IV	Type V
Manufacturing Site, Facilities, Operating Procedures, and Personnel	Drug Substance, Drug Substance Intermediate, and Material Used in drug preparations, or Drug Product	Packaging Material.	Excipient, Colorant, Flavor, or Essence	FDA Accepted Reference Information

DOSSIER: A document containing detailed records on a particular person or subject. Any preparation of pharmaceutical product for human use experiences the process of reviewing and assessing the dossier of a pharmaceutical product which contains detailed information about administrative, quality, non-clinical and clinical data and the permission permit by the regulatory agencies of a country intending to support its marketing is called as "the Marketing approval" or "registration Marketing authorization" or "Product Licensing".

dossier for the registration of Medicines and designed to be used across Europe, Japan, and the United States. CTD was developed by the European Medicines Agency (EMA, Europe), the Food and Drug Administration (FDA, U.S.), and the Ministry of Health, Labor and Welfare (Japan). The CTD is maintained by the International Conference on Harmonization for Registration of Pharmaceuticals for Human Use. The agreement to assemble all the quality, safety, and efficacy information in a common format have revolutionized the regulatory review processes.

COMMON TECHNICAL DOCUMENT (CTD):

CTD is a set of identification for application

Module 1	Module 2	Module 3	Module 4	Module 5
Administrative information	CTD summary documents	Information on quality	Nonclinical study reports.	Clinical study.

CONCLUSION: Regulatory Affairs is very important for all pharmaceutical companies around the world. The main focus of the regulatory affairs department is to give safe and effective medicine to people around the world. In this study, we show the responsibility of regulatory affairs professionals. Drug regulatory agencies of various countries give the rules which must be followed by pharmaceutical companies. A regulatory affair is also important for research and development, product management, Clinical trial, and marketing authorization. All pharmaceutical companies

have their regulatory affairs department. Regulatory Affairs is also a good profession for Post Graduate in Pharmacy with pharmaceutical Administration and Management or Regulatory Affairs specialization will be the preferred qualification to qualify for as a RA professional. To become a good regulatory affairs officer executive, some special skills are needed like sound knowledge about regulatory affairs and drug laws, and good communication skills. Regulatory Affairs is an intellectually stimulating and highly regarded profession within pharmaceutical companies.

HEALTH AWARENESS SESSION BY Dr. SAWTHI SOMAYAJI



Aruna Educational Trust
ARUNA COLLEGE OF PHARMACY
(Approved by PCI New Delhi, Govt. of Karnataka & Affiliated to RGUHS)
Behind Ashwini Hospital Ring Road, Maralur
TUMAKURU-572102

Guest Lecture On
Health - Hygiene - Happiness

Resource Person



Dr. Swathi M Somayaji
BAMS, MD, YIC (MAPC)
Asst. Professor
Ashwini Ayurvedic Medical
College & Research Centre
Ring road, Maralur
TUMAKURU-572 105

Presided By



Dr. Bheemachari
M.Pharm., PhD
Prof. & Principal
Aruna Pharmacy College
Behind Ashwini Hospital
Ring road, Maralur
TUMAKURU-572 105

📅 24th February 2025 Monday
📍 B.Pharm 1st Semester LH



DESIGN OF EXPERIMENTS (DOE)

Introduction



Meghana Aradhya
Asst. Prof.
ACOP, Tumkur

Design of Experiments (DOE) is a structured, organized method for determining the relationship between factors affecting a process and the output of that process. It is a powerful statistical tool used in engineering, manufacturing, agriculture, and scientific research to optimize processes, improve quality, and reduce variability. DOE involves planning, conducting, analyzing, and interpreting controlled tests to evaluate the factors that control the value of a parameter or group of parameters. The main goal is to identify cause-and-effect relationships and interactions between multiple input variables (factors) and the desired outputs (responses).

agriculture, and scientific research to optimize processes, improve quality, and reduce variability. DOE involves planning, conducting, analyzing, and interpreting controlled tests to evaluate the factors that control the value of a parameter or group of parameters. The main goal is to identify cause-and-effect relationships and interactions between multiple input variables (factors) and the desired outputs (responses).

Future Trends in DOE

1. Smart Manufacturing and Industry

In smart factories, DOE will be used for real-time process optimization, adaptive quality control, and predictive maintenance through embedded sensors and IoT devices.

2. Artificial Intelligence and Machine Learning

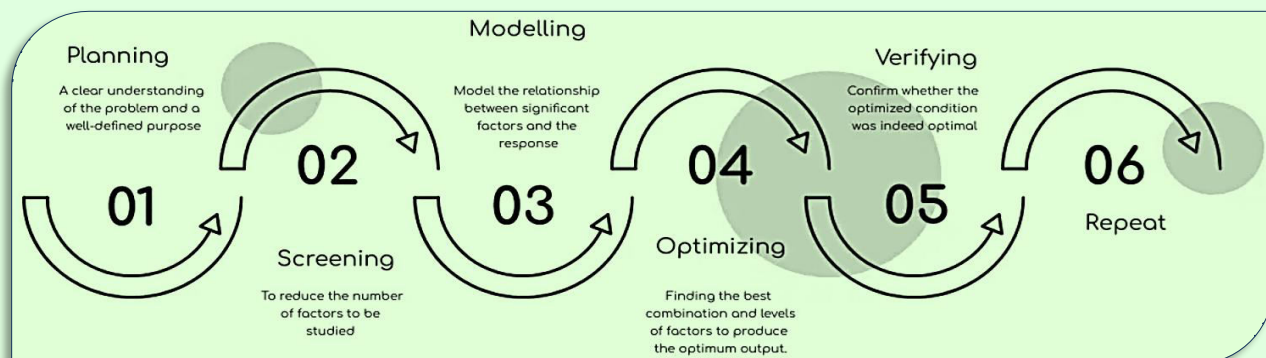
DOE will support and complement AI algorithms by structuring high-quality training data and validating model predictions through controlled tests.

3. Personalized Healthcare and Biotech

DOE will play a central role in optimizing personalized treatment protocols, gene editing experiments, and drug formulation—especially where variables interact in complex ways.

4. Sustainability and Green Engineering

DOE can be applied to develop sustainable solutions by optimizing the use of energy, materials, and waste reduction processes in industries.



Key Elements of DOE

- 1. Factors** – The input variables that are changed during the experiment
- 2. Levels** – The values or settings of each factor.
- 3. Response** – The output or result measured during the experiment.
- 4. Experimental Runs** – The set of combinations of factor levels tested.

Types of Experimental Designs

- A. Full Factorial Design:** Examines all possible combinations of factor levels.
- B. Fractional Factorial Design:** Studies only a subset of all possible combinations, useful for screening important factors.
- C. Randomized Design:** Experimental runs are randomized to avoid bias.
- D. Block Design:** Accounts for variations between different groups or batches.

5. Cloud-Based Experimentation and Collaboration

Cloud platforms will enable collaborative DOE projects across global teams, with shared access to experiment design, data analysis, and modeling.

6. Automation and Robotics

Robotic platforms will conduct DOE-guided experiments with high precision, speed, and reproducibility, accelerating research and innovation in labs.

Present Applications of DOE

Design of Experiments (DOE) is widely used today across various industries for improving processes, optimizing product design, and making data-driven decisions. Its ability to analyze multiple factors and interactions simultaneously makes it a powerful tool in modern engineering, science, and business environments.

1. Manufacturing Optimization

- DOE is used to improve product quality, reduce waste, and enhance process efficiency.
- Common applications include determining the ideal mix of materials, machine settings, and process conditions.

2. Pharmaceutical and Biomedical Research

- DOE helps in drug formulation, clinical trials, and optimizing bioprocess parameters.
- It ensures safety, efficacy, and consistency in drug development.

3. Agriculture and Food Science

- Applied to test crop yields, fertilizer effectiveness, irrigation techniques, and food preservation methods.
- Helps in developing sustainable farming practices.

4. Product Design and Development

- DOE is used during prototyping to test design parameters and material combinations.
- Enables faster development cycles and better-performing products.

5. Automotive and Aerospace Industries

- Helps in testing engine parameters, fuel efficiency, noise reduction, and aerodynamic features.
- Ensures reliability and performance under various operating conditions.

6. Chemical and Process Industries

- Used to optimize reactions, mixing rates, and temperatures.
- Ensures consistent product quality and safe operations.

7. Service Industries and Business Analytics

- DOE is used to optimize customer satisfaction strategies, staffing levels and service delivery processes.
- Applied in marketing to test campaigns and pricing strategies.

8. Software Testing and IT Systems

- DOE principles are applied to test software configurations and system performance under different conditions.

Benefits of DOE

1. Reduces development time and cost.
2. Provides deeper insight into processes.
3. Enables data-driven decision-making.
4. Improves quality and performance.

Conclusion

Design of Experiments is not just a statistical tool—it’s a powerful strategy for innovation, optimization, and quality improvement. Its advantages make it essential in industries ranging from manufacturing and pharmaceuticals to agriculture and product development. Design of Experiments is more than just a statistical technique it’s a mindset for systematic problem-solving and continuous improvement. By applying DOE, organizations can make smarter decisions, optimize performance, and stay competitive in today’s data-driven world.

* * * * *

GLIMPSES OF PARENTS MEETING





WEBINAR ON : RGUHS EXAMS-WHAT & ALL YOU NEED TO KNOW



(Approved by PCI, GOK & Affiliated to RGUHS)



Webinar On

RGUHS Exams- What & all you need to know !! ??



Opening Remarks
Dr. Ashok Kumar Maipani
Dean, Faculty of Pharmacy-RGUHS
Principal
RME'S College of Pharmacy, Kalaburgi



Mandatory Procedures
Dr. Bheemachari
Principal
Aruna College of Pharmacy, Tumkur



Presentation Skills, Do's & Don'ts
Mrs. Raziya Begum
Associate Professor
Aruna College of Pharmacy, Tumkur



Event Host
Mrs. Bindu C
Assistant Professor
Aruna College of Pharmacy, Tumkur



Monday 7th April 2025 at 2.30 PM

<https://us06web.zoom.us/j/83037812691?pwd=p80IUksMJ2QwWAvja3kSrBeE1uX2L1.1>

Admissions to B.Pharm // D.Pharm Contact: +91-9036172956

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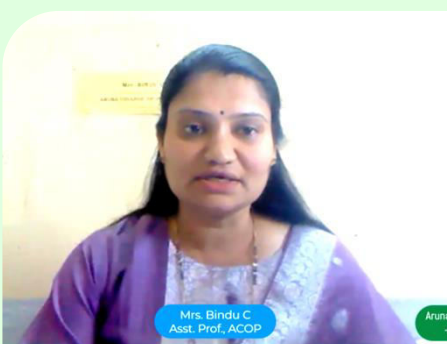
To be considered

- All exam activities will be under CCTV surveillance
- Carry Hall Ticket and College ID card
- Do not carry Electronic Gadgets/Smart watches
- Report to the Exam Centre sharp at 8.15 am /1.15 pm
- Occupy your designated place sharp at 8.30 am/1.30 pm
- Check the answer booklet for
 - Intactness
 - Page nos. are correct
 - No damages/Folds/irregular margins etc.
 - Question nos. are serially present
- If found issue
 - Do not use / Do not write your details
 - Report to the Invigilator immediately



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Aruna College of Pharmacy
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Behind Ashwini Hospital, Ring Road, Maralur, TUMAKURU - 572 105

COUNT DOWN TO EXAMS

- MOTIVATE
- KEEP YOUR SPACE QUITE
- GIVE YOURSELF ENOUGH TIME TO STUDY
- ORGANISE
- GET HOLD OF RECENT EXAM PAPERS
- CREATE

TIME REMAINING

19:28:56

Mrs. Raziya Begum
Assoc. Prof., ACOP

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3D PRINTING IN PHARMACEUTICAL TECHNOLOGY

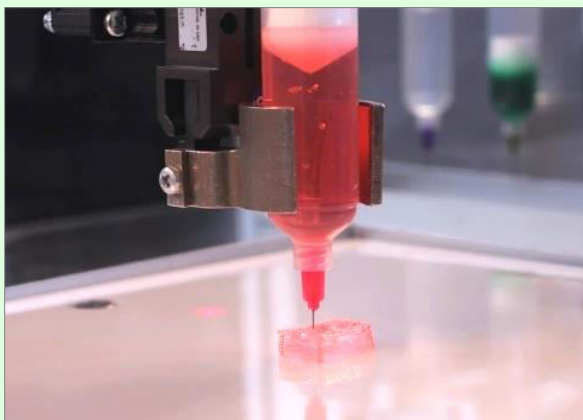
INTRODUCTION



Harshitha Devi S
Assistant Prof.
ACOP, Tumkur

Three-dimensional printing is matchless method which uses computer aided drafting technology and programming to make three dimensional objects by layering material onto a substrate. It is a process of making three dimensional

solid objects from a digital file. Now a days, 3D printing could be extended throughout the drug development process, ranging from preclinical development and clinical trials to frontline medical care.



Different types of drug delivery systems for instance oral controlled release systems, micro pills, microchip, drug implants, fast dissolving tablets and multiphase release dosage forms have been developed using three-dimensional (3D) printing technology. When compared to the manufacturing methods of conventional pharmaceutical product, it has a lot of advantages like high production rates owing to its fast operating systems, capability to achieve high drug loading with much desired precision and accuracy exclusively for potent drugs that are applied in small doses; reduction of material wastage can save the cost of manufacture and pliability to more classes of pharmaceutical active ingredients comprising poorly solubility in aqueous, proteins and narrow therapeutic index drugs.

ADVANTAGES OF 3D PRINTED DRUG DELIVERY

- High drug loading capability compared to conventional dosage forms.
- Accurate and Precise dosing of potent drugs which are administered at small doses for activity.
- Reduced production cost due to less wastage of materials.
- Suitable drug delivery for difficult to formulate active ingredients like poor water solubility and narrow therapeutic windows drugs.
- Medication can be tailored to a patient in particular based on age, gender, genetic variations, ethnic differences and environment.
- Treatment can be customized to improve patient adherence in case of multi-drug therapy with multiple dosing regimen.
- As immediate and controlled release layers can be incorporated owed to flexible designs, manufacturing method of dosage form and it helps in pick out the best therapeutic regimen for an individual.
- Evades batch-to-batch variations met in bulk manufacturing of conventional dosage forms.

DISADVANTAGES

- Problems related to nozzle are a major challenge as stopping of the print head which affects the final products structure.
- Powder printing clogging is another hurdle.
- Possibility of modifying the final structure on to mechanical stress, storage condition adoptions and ink formulations effects.
- Printer related parameters and these effects on printing quality and printer cost.

TECHNIQUES IN 3D PRINTING

There are numerous varieties of manufacturing practices intricate in 3D printing, which are grounded on digitally organized depositing of materials (layer-by-layer) to create free form geometries.

Thermal Ink-Jet Printing

In thermal inkjet printing, the aqueous ink fluid is transformed to vapours state through heat, expands to push the ink drop out of a nozzle.



It is used in the preparation of drug-loaded biodegradable microspheres, drug-loaded liposomes, patterning microelectrode arrays coating, load drug eluting stents. It is also an effectual and applied method of generating films of biologics without negotiating protein activity.

INKJET PRINTING

Inkjet printing known as ‘mask-less’ or ‘tool-less’ approach for its desired structure formation mainly depends upon the inkjet nozzle movement or substrate movement for an accurate and reproducible formation. In this methodology, the Ink is deposited onto a substrate either in the form of Continuous Inkjet printing / Drop on demand printing. Hence it provides a capability of high-resolution printing. It has a low cost, rate of processing in printing and generation of low level of wastes. It gives CAD information in a ‘direct write’ manner and process material over large areas with minimal contamination

LASER-BASED WRITING SYSTEM

On grounded to the photo polymerization principle, the free radicals which can contribute to the numerous diseases are released then to the interactions in among the photo originator and Ultra Violet light.

SELECTIVE LASER SINTERING

Selective laser sintering (SLS) act as a way in the powder bed to bind. The laser is designed to draw a specific pattern on the surface of the powdered bed during the printing process, thus creating a 3D structure. For example, Paracetamol is an Orodispersible tablet prepared by this manner. It is currently used for industrial manufacturing of plastic, metallic and ceramic objects.

POWDER BASED 3D PRINTING

This method customs powder jetting/powder bed to feast thin layers of powder and instantaneously applying liquid binder drops with ink jet printers. The ink (binders and APIs or binder solutions) is sprinkled over a powder bed in two-dimensional (2D) approach to make the

decisive product in a layer by layer fashion. The adaption of this approach into pharmaceutical manufacturing is at ease than other approaches as powder and binder solutions are broadly used in the pharmaceutical industry. The own disadvantages of this approach are; to remove solvent residues additional drying is required, during printing excess powder ac cumulates and contributes to wastage and due to the permeable design of the powder the drug delivery system’s mechanical strength may poor.

CHALLENGES IN 3D PRINTING TECHNOLOGY

Although proved promising results are there in drug delivery, still under the developing stage. Several challenges such as versatile use, appropriate excipient selections, post treatment method to advance the enhancement of 3D printed products and to magnify the application scope in novel drug delivery systems.

The built-in flexibility might be a most important resource of liability from safety point of view for re-designing through 3 Dimensional printing.

The primary parameters are to be modified to improve quality of 3DP such as printing rate, passes, print heads line velocity, printing layers interval time, nozzles and powder layer distance etc.

APPLICATIONS OF 3D PRINTING

Potential use in improving process, modifying performance for industrial design, aerospace, medical engineering, tissue engineering, architecture, pharmaceuticals.

It mostly targets on the two potential sites to rise pharmaceutical product development to unexplored areas, manufacturing sophisticated structures for the delivery and personalized medicine.

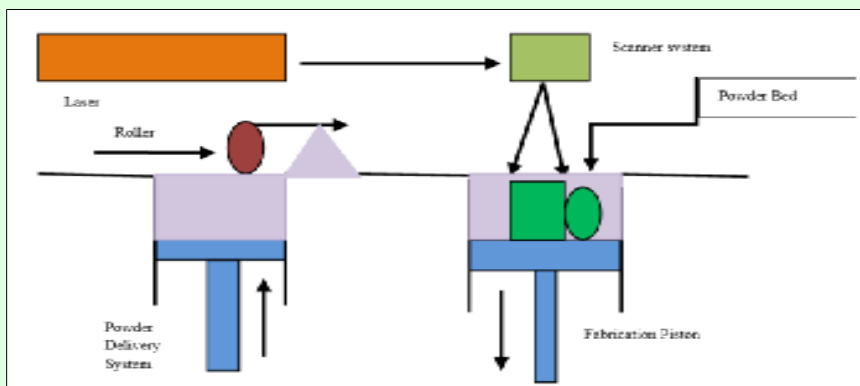
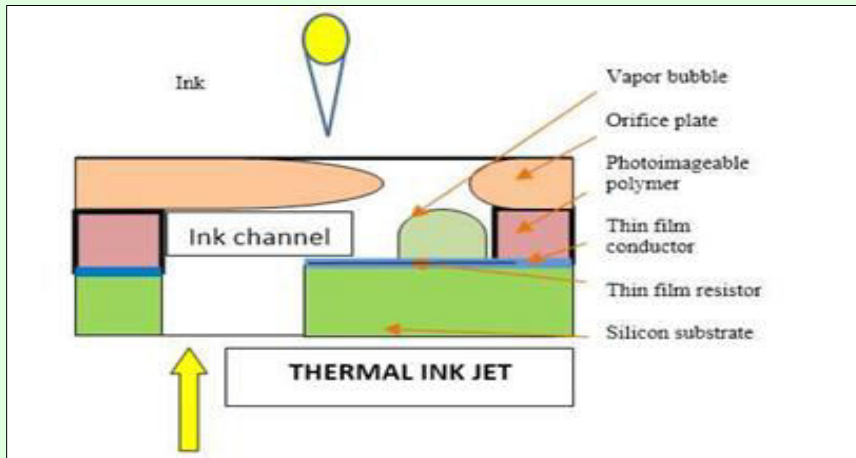
In Healthcare industry to create dental implants. On fabricating an organized release multi-drug implant for bone tuberculosis remedy.

Helps in Organ printing, biomaterials and cell-laden materials.

RISK ASSESSMENT DURING 3D PRINTING PROCESS

Mainly it was performed to prevent failure of quality assurance parameters such as assay, content uniformity, appearance, etc. Risk factors are identified with the process and process variables to conform the quality of product which was manufactured in industries.

- Monitoring the powder aqueous content and powder molecule size distribution can prevent the uneven layers.
- Ensuring the particle size distribution and monitoring inkjet flow can reduce or eliminate the print head clogging.
- Binder surface tension or binder viscosity variation leads to inconsistent agglomeration.



Risk factors are checked in these conditions

- Software controls should be employed, if a particular printer cannot print a particular pattern.
- Layer thickness variability has to be controlled by real – time layer thickness monitoring.
- Controlling the temperature and moisture content of the production place caused to improper layering, mainly it was a result of changes in environmental conditions.
- Improper location throughout printing might be avoided by tracking print head height and print head speed can prevent the inaccurate position in the printer.


CONCLUSION

3D printing technology can make complex formations as cost and time efficient. It may improve its applications in Pharmaceutical Research and Biotechnological fields. 3D printing involves wide technical range in pharmaceutical field with novel drug delivery system, generation of new excipients, improvements of drug compatibility and customized dosage forms. In future 3D printing can be regulated and followed by pharmaceutical and all other sectors with needed level of safety and security concerns.

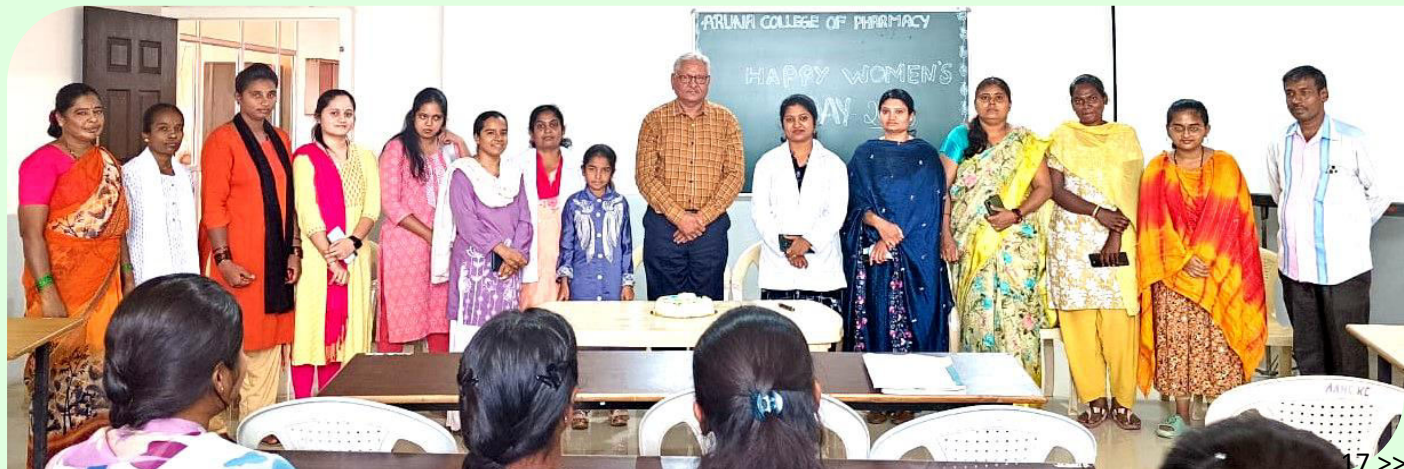
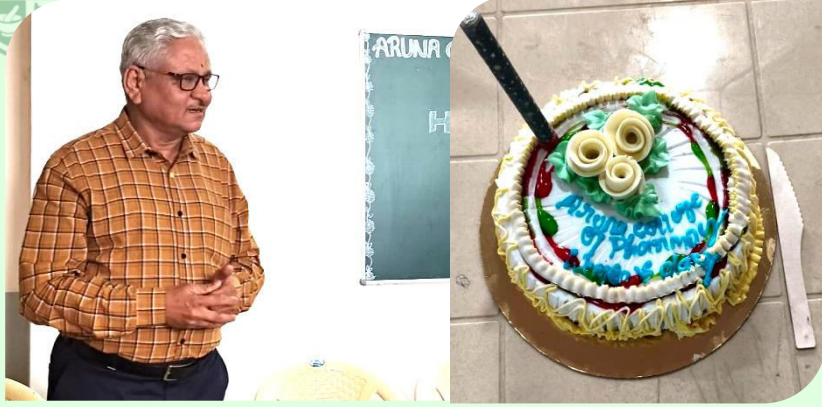
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ARTIFICIAL INTELLIGENCE: THE RISE OF SMART MACHINES

Introduction



Pooja R
Assistant Prof.
ACOP, Tumkur

Regulatory affairs have been a very important department in the pharmaceutical company during the last few years. Currently, this department helps safeguard the products' life cycle and guide the company on regional and global laws/regulations set forth

by different regulatory authorities.

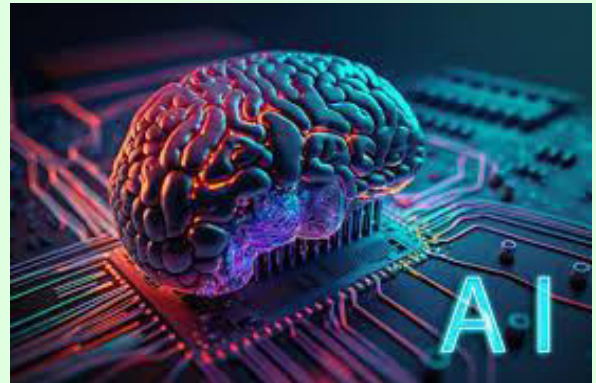
History and Evolution of AI The idea of intelligent machines can be traced back to ancient myths and early philosophical writings. However, modern AI began to take shape in the mid-20th century. In 1956,

the term "Artificial Intelligence" was coined during the Dartmouth Conference, marking the official birth of AI as a field of study.

Early AI research focused on symbolic approaches — using logical rules and decision trees. In the 1980s, expert systems emerged, simulating human decision-making in narrow domains. The late 1990s and 2000s saw significant milestones, such as IBM's Deep Blue defeating chess champion Garry Kasparov in 1997.

AI's recent breakthroughs have been fueled by three key factors:

1. **Massive Data Availability:** The rise of the internet and digital devices generates vast amounts of data.
2. **Improved Algorithms:** Machine learning, especially deep learning, allows machines to improve performance over time.
3. **Computing Power:** Advances in hardware (especially GPUs) enable the processing of complex algorithms.



Types of Artificial Intelligence

AI is often classified into the following types:

Narrow AI (Weak AI): Performs specific tasks efficiently but lacks general understanding. Examples include virtual assistants, facial recognition systems, and recommendation engines.

General AI (Strong AI): A hypothetical system that would understand, learn, and apply knowledge across different domains like a human being. This form is still under development and research.

Super intelligent AI: A theoretical form of AI that surpasses human intelligence across all fields. Experts debate its possibility and potential risks.

Core Technologies Behind AI

- **Machine Learning (ML):** A subset of AI where machines learn from data. It includes:
 - ▶ **Supervised Learning**
 - ▶ **Unsupervised Learning**
 - ▶ **Reinforcement Learning**
- **Deep Learning:** A type of ML using artificial neural networks inspired by the human brain, particularly useful in image and speech recognition.
- **Natural Language Processing (NLP):** Enables machines to understand, interpret, and generate human language.
- **Computer Vision:** Allows computers to interpret and understand visual data.
- **Robotics:** Combines AI with mechanical systems to build intelligent machines that can perform physical tasks.

Applications of AI in Daily Life

1. Healthcare

AI assists in medical diagnosis, analyzing scans, predicting disease outbreaks, and developing personalized treatment plans. Example: AI algorithms can detect cancer in radiology images with high accuracy.

2. Education

Personalized learning platforms adapt content based on student performance. AI catboats provide tutoring support, answer questions, and monitor learning progress.

3. Business and Finance

AI is used in fraud detection, automated customer service, and stock trading. Predictive analytics helps businesses understand market trends and consumer behavior.

4. Transportation

Self-driving cars use AI to interpret sensory data and make real-time driving decisions. AI powers traffic management systems, route optimization, and autonomous delivery services.

5. Entertainment

Streaming services use AI for personalized content recommendations. AI tools are now used in music composition, video editing, and gaming.

Advantages of AI

- **Efficiency and Productivity:** Automates repetitive tasks and increases output.
- **24/7 Availability:** AI systems can operate continuously without fatigue.
- **Accuracy:** Reduces human error, especially in precision-critical fields like surgery or data analysis.
- **Data Analysis:** Processes massive data sets quickly and finds patterns that humans might miss.

Challenges and Ethical Concerns

Despite its advantages, AI brings several challenges and ethical dilemmas:

1. **Job Displacement:** Automation could eliminate millions of jobs, particularly in manufacturing, transportation, and administrative roles.
2. **Bias and Discrimination:** AI systems can reflect the biases in their training data, leading to unfair or discriminatory outcomes.
3. **Privacy Concerns:** AI systems often rely on collecting personal data, raising concerns

about surveillance and data misuse.

4. **Security Risks:** AI can be used maliciously in cyber attacks, deep fakes, and autonomous weapons.
5. **Accountability:** When an AI system makes a mistake, it's unclear who should be held responsible — the developer, the company, or the user.



Regulation and the Future of AI

Governments, tech companies, and international organizations are beginning to discuss frameworks for the ethical use of AI. Key principles being proposed include:

- **Transparency:** Making AI decisions understandable to humans.
- **Fairness:** Ensuring AI does not discriminate.
- **Accountability:** Assigning responsibility for AI actions.
- **Privacy Protection:** Respecting users' data rights.

The future of AI is promising but uncertain. If developed and governed responsibly, AI can help solve global challenges like climate change, healthcare inequality, and education gaps. However, careful oversight and human values must guide its development.

Conclusion

Artificial Intelligence is one of the most powerful and transformative technologies of our time. It has already begun to revolutionize industries, reshape economies, and redefine how humans interact with technology. As we move into an increasingly AI-driven world, it is crucial to balance innovation with ethics, opportunity with responsibility, and automation with empathy. The way we choose to shape AI today will determine its role in the future of humanity.

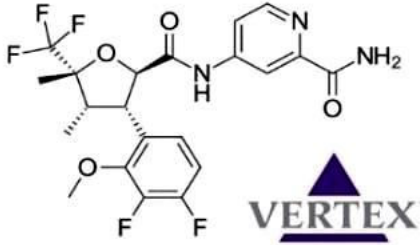
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Novel Drug Approvals (1Q25)



© Chris De Savi

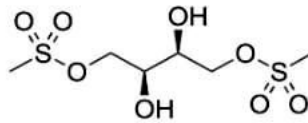


Suzetigrine (Jornavx)

To treat pain

RoA PO

Mechanism - Nav1.8 inhibitor



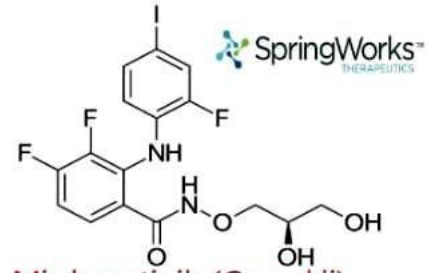
medac

Treosulfan (Trecondi)

Conditioning treatment prior to alloH SCT

RoA PO, IV

Mechanism - DNA alkylating agent

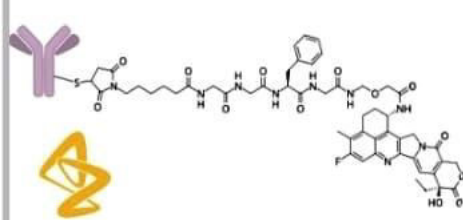


Mirdametinib (Gomekli)

To treat neurofibromatosis Type 1

RoA PO

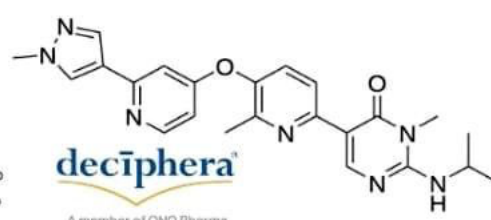
Mechanism - MEK1/2 inhibitor



Datopotamab deruxtecan (Datroway)

To treat HR+, HER2- breast cancer

Mechanism - Trop-2-directed mAb and topoisomerase inhibitor ADC



Vimseltinib (Romvimza)

To treat tenosynovial giant cell tumor (TGCT)

RoA PO

Mechanism - CSF1R inhibitor

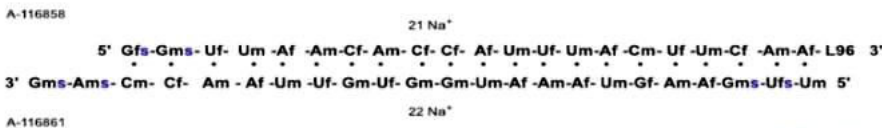


Gepotidacin (Blujepa)

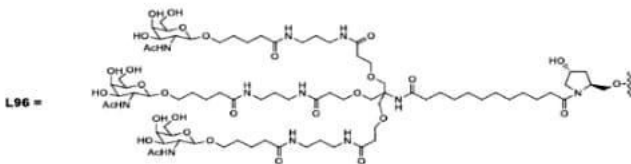
To treat uncomplicated urinary tract infection

RoA PO

Mechanism - DNA gyrase / topoisomerase IV inhibitor



Af, Cf, Gf, Uf = 2'-deoxy-2'-fluoro ribonucleotides
Am, Cm, Gm, Um = 2'-OMe ribonucleotides
s = phosphorothioate



Fitusiran (Qfitlia)

To treat hemophilia

RoA SC

Mechanism - an antithrombin-directed small interfering ribonucleic acid (siRNA)

SANOFI

Alnylam
PHARMACEUTICALS

Collected
By

Nagaraj Guptha
Assistant Prof.
ACOP, Tumkur

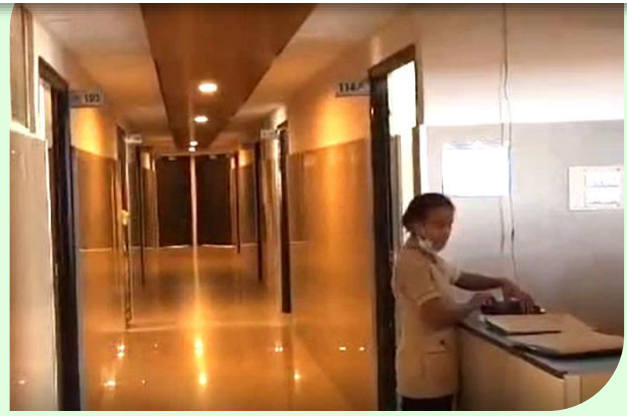


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