The Galen

A Pharmacy Magazine

SECOND EDITION: FEBRUARY 2023

Theme: Employment Opportunities of Pharmacy in India

Published By:

Sagar Institute of Pharmacy & Technology (SIPTec),

Opposite International Airport, Gandhi Nagar, Bhopal- 462036 (M.P.)

https://thegalen.siptec.ac.in/

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Role of Pharmacovigilance in health system

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Pharmacovigilance, defined by the World Health Organization as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem' plays a key role in ensuring that patients receive safe drugs. The need for Pharmacovigilance activities continue long after the initial pre-marketing clinical trials, with post-marketing studies forming an important part of the confirmation of the safety and efficacy profile of each new medicinal product. The initial 500,000 to 1,000,000 patients who are the first to take the new drug after it has been released onto the market represent the first large scale safety test. A robust Pharmacovigilance system is clearly of pivotal importance during this particular stage of the products life cycle. Pharmacists, Doctors, Nurses and other health workers report suspected adverse drug reactions each working day around the globe; this is known as spontaneous reporting. They may report to regulatory agencies, national or regional Pharmacovigilance centres or to pharmaceutical companies. As Pharmaceutical companies receive a report of a serious suspected adverse reaction for one of their products on the market, they must report it (generally within 15 days) to the regulatory authorities according to national and international laws.

Medicines safety monitoring is a continuous and dynamic process throughout all the phases of the life cycle of a drug. During the drug development, safety is investigated in different phases. In pre-clinical studies, the primary goal of safety evaluation is the identification of a safe dose in humans and of safety parameters for clinical monitoring. In clinical phase, Phase I studies are designed to estimate the tolerability of the dose range expected to be needed for later clinical studies in healthy volunteers; Phase II studies are focused on determining appropriate range of drug doses in patients with a disease or condition of interest, while Phase III clinical trials are the most important studies to refine understanding of benefit-risk profile of the drug and to identify less common adverse drug reactions. Although drug safety evaluation is very rigorous and thorough, pre-marketing clinical trials have however intrinsic limitations that do not allow to exhaustively evaluate drug safety profile. These studies are conducted on limited numbers of patients that are selected based on strict eligibility criteria and not fully representing real-world populations and have limited duration, thus preventing detection of rare and long-term adverse reactions.

Therefore, the post-marketing assessment of medicines plays a key role for better defining drugs' safety profile in real-world setting and filling the evidence gap of pre-marketing studies.

In the field of drug safety and regulation, a number of challenges have to be faced in the near future.

First of all, COVID-19 pandemic highlighted how relevant Pharmacovigilance and proper risk communication during public health emergency are. Second, the development of advanced methodologies including machine learning techniques and the availability of large amount of electronic healthcare data offer opportunity for optimizing drug benefit-risk profile evaluation in real world setting. Finally, innovative therapeutics, such as advanced therapy medicinal products, digital therapeutics, vaccines developed based on advanced technologies, requiring special Pharmacovigilance monitoring have been increasingly marketed in recent years, often upon accelerated pathway approval. Some of the challenges and future opportunities in this field are briefly discussed below.

During the first wave of the pandemic, the absence of vaccines and drugs for treatment/prevention of COVID-19 led to a rush to repurpose drugs already approved for other indications. As a consequence, a large number of drugs (e.g., hydroxychloroquine, ivermectin and azithromycin) have been off-label used for the treatment of COVID-19 patients, even if underlying scientific evidence on benefits was of low quality and mostly based on in vitro studies. The availability of healthcare data has been tremendously increasing over the last years and will further increase in the near future thanks to massive marketing of digital tools collecting patient-derived data.

Huge amounts of electronic data present an opportunity to apply artificial intelligence (AI) techniques to improve drug safety assessment. Information extraction, using natural language processing (NLP) techniques and text mining to gather relevant insights from available, largely unstructured sources, has been gaining importance within the field of clinical research. As regards pharmacovigilance, text mining and NLP methods can be very useful to gather information on adverse drug reactions (ADRs) and drug-drug interactions from various textual sources, supporting researchers and clinicians in monitoring drug safety. Indeed, both public and private entities are currently trying to develop AI tools that can allow to automatically process ADRs.

Artificial intelligence and machine learning may also be useful in pharmacovigilance for

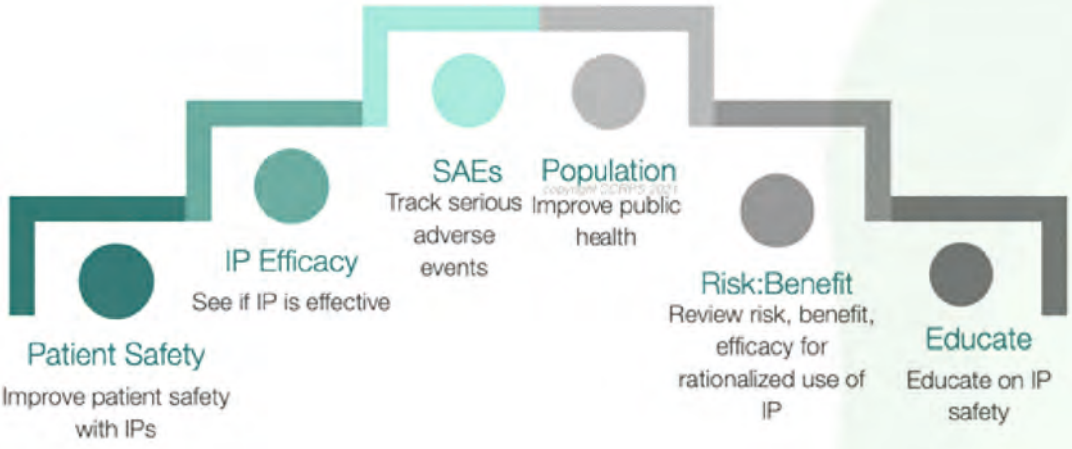
1) The automatic execution of tasks associated with case report entry and processing,

2) The identification of clusters of adverse events representing symptoms of syndromes,

3) The conduction of pharmacoepidemiological studies,

4) Data linkage, through the conduction of probabilistic matching within datasets and

5) The prediction and prevention of adverse events through specific models using real-world data.



If you're looking to boost your career prospects in the pharmaceutical industry, drug safety training is a great string to add to your bow. Whether you want to move into clinical research or enhance your profile in your existing company, certification is crucial.

If you run a company and want to provide your staff with drug safety training to increase their knowledge and provide a safer working environment, our course is for you too.

What do Pharmacovigilance Officers do?

The exact nature of each role varies, but in essence, Pharmacovigilance Officers (PVs) collect adverse event data on drugs (Phase 4) to analyse and create usage warnings for the drug.

Some roles insist on physicians, nurses, or those with a Master of Science degree. A Master's in Pharmacovigilance is your best route into the industry – but that takes up to 2 years and is very expensive.

Article 2:

Role of pharmacist in Clinical Pharmacy in India

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Key Words: Pharmacist, clinical pharmacy, adverse drug reaction

Clinical pharmacy is the branch of pharmacy in which clinical pharmacists provide direct patient care that optimizes the use of medication and promotes health, wellness, and disease prevention. Clinical Pharmacy services were developed in the United States in the 1960's and expanded rapidly in subsequent decades. Studies have found that clinical pharmacy services can improve medication use in hospitals and ambulatory care settings and improve patient outcomes.

Clinical pharmacy describes the new role of the 21st Century's pharmacists. It doesn't restrict the role of a pharmacist merely to good manufacture practices, easy procurement, proper preparation, distribution and control of drug products. In addition, it also comprises functions necessary to discharge a particular set of social responsibilities related to proper therapeutic use of drugs in the aspects like prescribing, dispensing and administrating drugs, documenting professional services, direct patient involvement, Reviewing drug use, Education, Consultation and Counseling.

This novel profession in India extends its diversions to good manufacturing practices, procurement/preparation/distribution of medication, reporting **ADRs** (Adverse Drug Reactions)/ **ADEs** (Adverse Drug Events) and on the whole to a very promising aspect of patient health care service. The state of clinical pharmacy in India is in the informational state showing serious positive promising changes in the past couple of years. Even hospitals have started distinguishing the importance of clinical pharmacy and have taken initiatives for making it possible although at a **budding stage** (being in an early stage of development). There is a growing demand for clinical pharmacists, with the number of jobs in the field increasing 170% every year.

Clinical Pharmacy courses can pursue **Doctorate of Pharmacy** after their Class 12th to get into this field. Another way is to do **Bachelors in Pharmacy**, then **Masters in Pharmacy** along with practice at the hospitals to get to know the job requirements better.

Clinical pharmacy also has an obligation to contribute to the generation of new knowledge that advances health and quality of life. Some skills for Clinical Pharmacist are as followings:

1. Proven experience as clinical pharmacist
2. Residency training and current license are required
3. Excellent understanding of pharmaceutical therapy and direct patient care
4. Solid knowledge of drug administration and health & safety guidelines
5. Working knowledge of computers
6. Team player with outstanding communication skills (verbal and written)
7. Aptitude in problem-solving and decision-making
8. Strong professional ethics
9. Degree in Pharmacy/Pharmacology.

People in India expect community pharmacists to provide them with medications that are efficient, secure, and reasonably priced. Other requirements for Indian pharmacists include dispensing medications in accordance with regulations and providing accurate instructions on how and when to take medications, what to do in the event of adverse drug reactions, and advise on common illnesses.

Unavoidably, the neighborhood pharmacy has fallen short in offering all these patient-focused services. Perhaps the 1991 revision to our D. Pharm. course which sought to shift the emphasis away from preparatory and compounding pharmacy and toward patient care, was unsuccessful. However, the recent establishment of the Doctor of Pharmacy (Pharm. D.) programme in India may not benefit the community pharmacy industry, and concerns have been expressed about the use of this programme to gain international recognition and address the US lack of pharmacists.

In a brief, India confronts enormous difficulties in meeting the health care needs of its sizable and expanding population. Community pharmacy services are essential to the safe and successful administration of medications in developing health, despite numerous obstacles. It is envisioned that community pharmacy practise will adapt in line with the quick changes in healthcare delivery and rising patient expectations.

Article 3:

PHARMACY PRACTICE NOW A DAYS IN INDIA

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Keywords: Regulatory affairs, Quality assurance, Pharmaceutical care,

The health care system in India is going through dramatic changes due to growth in the demand for health care and patient needs. The educational and professional responsibilities of pharmacists are being constantly redefined. Many pharmacy institutions in India have started offering like programs in pharmacy practice and clinical pharmacy. The Pharmacy Council of India (PCI) has initiated steps to rise by implementing exit exam policy [Diploma in Pharmacy Exit Examination (DPEE)] for the diploma pass outs, the minimum qualifications of registered pharmacists. Pharmacy scholars are considered to be industry-oriented professionals who prefer to join various departments in the pharmaceutical industries, such as production, **quality assurance, regulatory affairs,** and marketing.

Bachelor of Pharmacy (Practice) abbreviated as B. Pharm (Practice) is a programme conducted as per the Pharmacy Council of India regulation 2014. The purpose of this programme is to provide an additional qualification to the Diploma registered pharmacists.

The Pharmacy Council of India introduced a **Pharm D (Doctor of Pharmacy)/ Pharm D PB (Post Baccularate)** program in 2008 that emphasizes the clinical and patient-oriented aspects of the pharmacy profession. India still requires sweeping changes in the healthcare and education systems to meet international standards for pharmacy practice. The role of today's pharmacist needs to be expanded to include pharmaceutical care concepts, making the pharmacist a health care professional other than a drug seller in a commercial enterprise.

Today in India over 200 colleges are offering courses in Pharmacy Practice and Clinical Pharmacy including B. Pharm, D. Pharm, Pharm D as well as M Pharm programmes, thus creating a vast opportunity for the individuals interested in updating their knowledge and who are willing to work for the development of society. In the current scenario there are many opportunities available for the B.Pharm/ Pharm D/ M.Pharm students to frame their career in private as well as the government organizations. Various fields where the B.Pharm/ Pharm. D/ M.Pharm students can pursue their career are – Pharmacovigilance (Private/ Government sector), clinical research, medical writing, health economics and outcome research, clinical pharmacist, academics and research. Currently these booming fields provide a better platform where one can frame their career.

Article 4:

Industrial Opportunity in the Quality Control Department

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Keywords: Before consuming any type of medicine, they need to be tested and approved for consumption in prepared pharmaceutical laboratories, so that they can be sold and consumed by the population. In this article, we will see in some topics how these processes work and their main function.

The main objective of quality control (QC) in the Pharmaceutical Industry is to test the drugs in their various stages of production, verifying that they are able to proceed to the next stage and release the manufacturing process in accordance with the regulations and specifications required for consumption. For complete control of the quality of the medication that is being produced, they need to be tested in several work areas. The main areas of research and analysis are:

1. Physical-Chemical Laboratory
2. Microbiological Laboratory
3. Packaging Material Laboratory
4. Process Control Laboratory

There are some necessary regulations so that there is a correct production and quality control of medicines. Each country has its rules and laws that govern these processes and each industry must follow and have the proper authorizations for production. To ensure that the rules and laws are being applied correctly, there are internal and external audits, aiming at the inspection of good medicine manufacturing practices.

Quality control laboratories may perform some or all quality control activities, e.g. sampling, testing of APIs, excipients, packaging materials and/ or pharmaceutical products, stability testing, testing against specifications and investigative testing.

Quality control is an overall function designed to ensure that manufactured products meet meaningful specifications. It involves the recognition and removal of identifiable causes or defects and variations from the set standards of quality. Quality control is entrusted with the task of minimizing this variability. Quality control enters into all phases of the manufacturing process. It begins with designing of product so that it has high customer appeal in terms of appearance, function, life, etc.

Quality Control had two different divisions

A)Wet Analysis B) Instrumental Analysis

The Quality will be checked in three different stages.

1) Raw material analysis

2) In Process Sample analysis

3) Finished Product analysis

Once the raw material enters the factory premises and before going to the Stores department the Quality of the material will be checked by QC department. If the quality is as per the guidelines then the QC department approves the raw material. This is called Raw material analysis. The concerned QC chemist will perform the basic duties and the Group leader or Manager approves.

The In Process Analysis will be done while the Product (Chemical or Formulation) is being Prepared/Manufactured

Finished Product analysis will be done after the Product/material is manufactured.

Scope of quality control :

There are three broad areas where quality control should be applied in manufacturing industry.

1. Supply quality assurance. Supplier quality assurance (SQA) is a contract with the supplier of raw materials and components. Under this agreement, the manufacturer ensures that incoming materials and parts will be of uniform and acceptable quality. It is also called incoming material control wherein the quality of bough-tout components and materials is continuously manicured and maintained.

Unless the materials and parts conform to the establish quality standards, quality of finished products cannot be maintained despite best efforts in manufacturing. Moreover, poor quality materials lead to rejections, idle time, wastage of processing time and labour cost and delay in supplies to customers. Therefore, effective control should be exercised on all incoming materials, components and sub-assemblies.

2. In-process control. During the stage of processing materials, random samples of the product are taken and their quality is measured against predetermined standards of quality. Such tests may reveal certain defects in the production process. Corrective steps are taken to ensure that right quality products are manufactured. In process control helps in building the desired quality into the finished product and prevents production of sub-standard products.

A process is considered satisfactory or under control so long as it continues to produce products of desired quality and specification. In process control techniques involve evaluation of process standards in terms of rework, scrap, dimensions, rejection, etc. In process control consists of all the procedures employed to evaluate, maintain and improve quality standards at different stages of manufacture.

3. Post-mortem inspection. It is taken after the products are manufactured or completed. It is a technique of evaluating the quality of a product and of classifying the units into acceptable and reject-able categories. Inspection controls are often called quality assurance. Design controls after the products leave the plant are known as reliability.

Carrier in Quality Control (QC) department

Qualification required to work in QC department:

B.Pharm/M.Pharm/ Ph.D

Apart from Pharma the candidates can work in the following Industries

1) Phyto Chemical/ Herbal

2) Food / Beverages/Breweries

3) Oil and Gas

4) Chemical/ Petro Chemical

5) Fertilizers/Pesticides

6) Cosmetics /Perfumes

7) Biotechnology

Career Path/ Growth in Quality Control (QC) department

Entry Level

Designation	Qualification	Experience
Trainee	B.Sc / M.Sc / B.Pharm	0-1 Yr
Chemist	B.Sc/ M.Sc/ B.Pharm	1Yr -2 Yrs
Sr.Chemist	B.Sc / M.Sc / B.Pharm	2-4 yrs
Officer	M.Sc / B.Pharm / M.pharm	2-5 Yrs

Middle Level

Designation	Qualification	Experience
Executive / Sr.Executive	B.Pharm / M.Pharm / M.Sc	4-8 Yrs
Asst / Dy.Manager	B.Pharm / M.Pharm / M.Sc	5-10 Yrs
Manager	B.Pharm / M.Pharm / M.Sc	8-12 Yrs
Sr.Manager	B.Pharm / M.Pharm / M.Sc	10-14 Yrs

Sr. Level

Designation	Qualification	Experience
AGM / DGM	B.Pharm / M.Pharm / M.Sc/ Ph.D	14-17 Yrs
G.M	B.Pharm / M.Pharm / M.Sc / Ph.D	15-22 Yrs
Sr. GM	B.Pharm / M.Pharm / M.Sc / Ph.D	17-25 Yrs

Qualities/Competencies required for getting entry level Jobs

1) Able to work in teams
2) Concentration
3) Able to update the knowledge regularly
4) Subject Knowledge with recent trends in Pharma Industry
5) Professional /Industrial training
6) Working Knowledge about different Instruments used in Pharma Industry

Article 5:

Quality Assurance in the Pharmaceutical industry

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Quality in the Pharmaceutical industry is defined as products that are safe for intended use, are effective and meet patient expectations. Quality Assurance professionals are responsible for the step-by-step process of ensuring goods and services meet specific quality, efficacy and safety requirements, as per their intended use. Some key examples of their role are:

- Assuring healthcare professionals, the product prescribed has the correct efficacy.
- Protecting the public from harm that could be caused by: design defects, manufacturing errors, problems from packaging or storage and incorrect instructions.
- Making sure all products comply with industry regulations, laws and guidelines.

Functions of Quality Assurance:

- ·Checking raw materials, equipment, vendors & testing methods during the development stage
- All incoming containers of RM, packing materials, components in the warehouse or store
- All productions record and review them periodically
- All manufacturing process and in-process checks during production
- Preparing and monitoring documentation
- Ensuring employees are trained on protocols & processes and training documentation is up to date
- Investigating any issues that stem from customer complaints
- Conducting internal audits and inspections on documentation, processes, training and equipment
- To write Standard Operating Procedures (SOP)
- Release of every batch manufactured with due record process
- Maintaining warehousing storage of finished goods

- Reviewing product by stability and self-life evaluation of finished products Complaints handling
- Handling of change of control system
- Internal quality inspections and system reviews
- **Summary :** The Pharmaceutical Quality Assurance focuses on basic principles of Total Quality Management and GMP (Good Manufacturing Practice) within the pharmaceutical industry. QA plays the role of FDA envoy in manufacturing site who ensure a product which compiles all quality parameters.

Students Chapter

Article 1:

Scope of Pharmacy in India

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A pharmacy is a crucial component of the global healthcare system, and a pharmacist is a vital member of the medical staff. Pharmacists are essential players in every aspect of healthcare, whether it is vaccine development, antibody research, community-based care, or the dispensing of medications. Pharmacists are essential players in every aspect of healthcare, whether it is vaccine development, antibody research, community-based care, or the dispensing of medications. In the field of pharmacy, career options are constantly expanding. Following are some possible careers for pharmacy graduates:

- R & D of new drug
- Clinical trials in medicine
- Pharmacovigilance
- Retail market etc.

The profession of pharmacy has developed substantially over the past ten years in India, where pharmacists make up the third-largest group of healthcare professionals worldwide.

By optimising the advantages of pharmaceuticals and their safety, pharmacists today have expanded their function from distribution to pharmaceutical care. The expansion of work-related activities has had an impact on pharmacists' job satisfaction and the calibre of work they deliver, either directly or indirectly.

Careers for pharmacy graduates include the following:-

Pharmacy graduates can work in the regulatory division, which is crucial for the approval of novel medicines without compromising the analysis of the data supporting the treatment under consideration.

They can also join the FDA and CDSCO to assist the national regulatory body in regulating pharmaceuticals, cosmetics, their distribution, and production facilities.

They can work in the pharmaceutical marketing industry, where they are critical to guaranteeing honest and moral practices in the sale and distribution of drugs and vaccines. Another developing field is the creation, development, and commercialization of medical devices.

Opportunities at various test labs:-

A great opportunity exists for recent pharmacy graduates in the government's numerous testing facilities, which carry out accurate testing of drugs, including recently proposed vaccines or treatments. They can even enter the hospital pharmacy, where they play a crucial part in ensuring the continuous availability of necessary medications and other supplies for patient care. They can assist with diagnosing problems with the critical care drug supply chain and modifying the process to protect personal protective equipment. Pharmacy graduates can work in pharmacovigilance, which entails monitoring drug interactions, documenting them, and reporting any negative outcomes.

Article 2:

Pharmacy growth in India

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Pharmacy is a versatile, dynamic, growing, and increasingly diverse profession, one which creates an excitement because there are so many opportunities for service. It is an age-old profession which has transformed into a hub for "Global Healthcare" and evolved as a multidisciplinary and multifaceted field in recent times. With the phenomenal rate of advances in the pharmaceutical industry, the health sector has thrown open a sea of opportunities for pharmacy professionals.

The pharmaceutical industry is considered to be a crucial component of the Indian healthcare sector, which is predicted to be valued 10,000 crore and expanding at a CAGR of 22.9 percent. The Indian pharmaceutical market is the third largest in the world in terms of volume and ranked 13th in terms of value.

The responsibility of establishing a link between the realms of health sciences and basic pharmaceutical sciences lies in the hands of the pharmacist.

Pharmacy encompasses various professional skills, such as knowledge for drug synthesis. The professionals may also perform administrative duties in pharmaceutical practice.

Also, there are many types of pharmacy such as:

- Community Pharmacy
- Hospital Pharmacy
- Clinical Pharmacy
- Industrial Pharmacy
- Compounding Pharmacy
- Consulting Pharmacy
- Ambulatory Care
- Pharmacy Regulatory Pharmacy
- Homecare Pharmacy, and so on.

Since pharmaceutical firms currently produce the majority of the pharmaceuticals, professional practise is shifting toward a clinical focus. As a result, the pharmacy can simply position itself for a bright future.

Conclusion: It is up to medical and paramedical personnel to treat a patient. One of them, pharmacists, has to make an effort to perform to the best of their skills. Only if the pharmacists acquire the necessary knowledge about the safety and effectiveness of medications and patient counselling during their studies will this be possible.

Article 3:

Employment prospect for Pharmacy profession in the world

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Pharmacy is a health profession based on the chemical, biological and medical sciences. It is concerned with the design, evaluation, production, and uses of medicine and the provision of medicine related information to the public. Pharmacy is a blend of theory and practice so the job opportunities are wide spread offering diversity. The global pharmaceutical manufacturing market size was estimated at USD 486.62 billion in 2021 and is expected to reach USD 957.59 billion in 2028. The field of Pharmacy has always been an ever thriving, dynamic, diverse and growing age old profession.

Being employed in the field of Pharmacy is not just about dispensing medicine in a corner Pharmacy or working as a scientist in a research laboratory. There are so many opportunities that can provide Pharmacy graduates with a exciting and rewarding employment. It offers a wide area of employment across the world. A Pharmacist can go for the Hospital Pharmacy, Community Pharmacy, Retail Pharmacy, Industrial Pharmacy, Veterinary Pharmacy, Social or Administrative Pharmacy, Pharmacy Journalism, the Academia, Pharmacovigilance. Pharmacist can earn good salaries and the hours are often very flexible. Thus, Pharmacy is a promising career and after completing a professional degree in this field numerous options opened up. This advancement in the role of Pharmacist calls to be the part of broader healthcare team, working for better healthcare system providing lots of employments opportunities across the India.

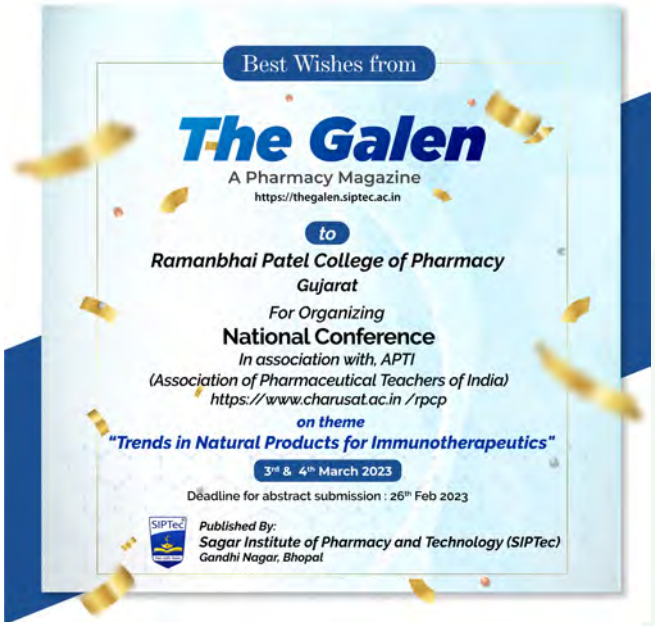
About Sagar Group and SIPTec

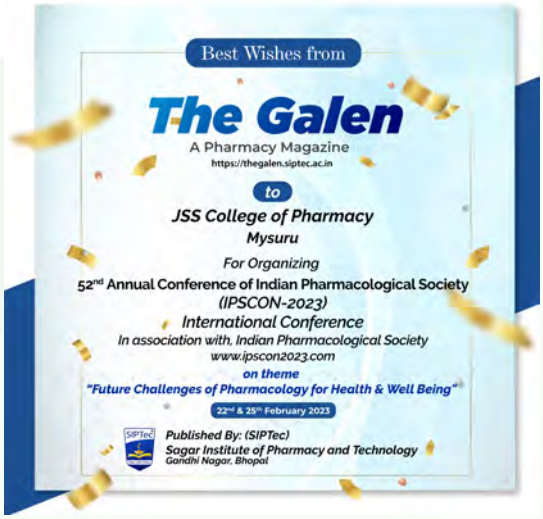
Sagar group came into existence in the year 1983 under the visionary leadership of Chairman Shri Sudhir Kumar Agrawal. Over the years, it has now transformed into one of the largest corporate house and business conglomerate of Central India. In its journey of over three decades, the group has successfully ventured in the field of education, real estate, production and manufacturing to employ 5000+ people and impact lives of more than two lakh people every day. **Sagar Group** has been felicitated with IBC24 Excellence Award 2017 for its contribution to Madhya Pradesh's Industrial Development and Incredible Societal Development. **Agrawal Builders** have established its presence as one of the leading Real Estate giants with over 39 years of rich experience in building state-of-art residential projects. **Sagar Manufacturers Pvt Ltd** has pledged to use the best fibers to produce superior quality yarns with the world-class production technology. In a short span of time the company has achieved an installed capacity of 2,00,000 spindles and exporting its products to over 20+ countries. **Sagar Nutriments Pvt Ltd** is **Sagar Group's** recent venture in food processing premium quality basmati rice.

Sagar Group has earned a lot of praise across the nation empowering youth of Madhya Pradesh with a bright career and life. The group provides world class school and technical education under **Sagar Group of Institutions** to 20000+ students with 2000+ dedicated faculties. The group imparts schooling through the chain of **Sagar Public Schools (SPS)** to nurture the young mind. Today, SPS is considered as the most preferred brand forholistic education and Indian Value System to its core featuring amongst the **Top 100 schools in India** with its campuses at **Saket Nagar, Gandhi Nagar, Rohit Nagar, Ratibad, Katara Extension and Dwarka Dham. Sagar Group of Institutions** are engaged in providing the best technical education in the field of engineering, pharmacy, and management.

Sagar Institute of Pharmacy and Technology (SIPTec) is the premier institution known for its high standards in teaching and research in pharmaceutical sciences. SIPTec was established in 2008. The Institute is also registered under **CCSEA**. Today, within a short span of 14 years, the institute has gained a reputation of being one of the **top Pharmacy Colleges in MP** that provides total pharmaceutical education comprising B.Pharm. and M.Pharm. (Pharmaceutics & Pharmaceutical Chemistry).

Media coverage of recent conferences by this magazine





Next Theme:
The Active Role of Pharmacists in Combating COVID-19

Deadline for article submissions:
15 March 2023, 05:00 PM