MANIPAL
ACADEMY of HIGHER EDUCATION
(Institution of Eminence Deemed to be University)

# cGMP CONNECT

**Our Inspiration**

Founder : **Dr. T M A Pai,**
Padmashree awardee

## Centre for cGMP
Manipal College of Pharmaceutical Sciences

**INAUGURAL ISSUE**
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# THINK cGMP – cGMP is LIFE

Commitment | Adherence | Creating Quality Culture

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## Message from Lt. Gen. (Dr.) M.D. Venkatesh, Honorable Vice Chancellor

I congratulate the Centre for cGMP, a Centre of Excellence and one of the vibrant Centers under the aegis of Manipal Academy of Higher Education (Institution of Eminence), Manipal for bringing out the first issue of cGMP Newsletter "cGMP CONNECT" on the momentous occasion of 2nd NATIONAL cGMP DAY. The newsletter is a testimony to all the spectacular cGMP initiatives taken up by the Centre for cGMP.

As a fledgling Centre of MAHE, this is a commendable effort that will bring quality to the contents and showcase the unique initiatives and disseminate the GMP trends and news from time to time.

I am extremely proud to share the following contributions and achievements of the Centre for cGMP.

- Conceived the idea and initiated the practice of celebrating 'National cGMP Day' starting 10 October 2023 onwards.
- Conceptualized world's first-ever digital museum on pharmaceutical quality "Manipal cGMP Museum" dedicated to Dr TMA Pai, founder of MAHE, Manipal.
- Releasing 'cGMP AWARENESS SERIES' flyer on 10th of every month starting May 2024 onwards.
- Published an exclusive book "Pharmaceutical Consumer Complaints – A guide to academia and pharmaceutical industry".
- Centre for cGMP is also a recipient of prestigious 'INDIA PHARMA AWARDS 2023' for Excellence in Quality Assurance.

I look forward to reading about various initiatives, activities, achievements and writeups on cGMP news in the upcoming issues of the newsletter.

Once again congratulations to Dr Girish Pai K, Coordinator and the team at Centre for cGMP.

**Lt. Gen. (Dr.) M.D. Venkatesh, VSM (Retd).**
Vice Chancellor
Manipal Academy of Higher Education (MAHE), Manipal

## Significance of cGMP Principles in Formulation R & D

Current Good Manufacturing Practices, or cGMP, play a very significant role in pharmaceutical formulation research and development (R&D). cGMP compliance in formulation R&D is of extreme importance for several reasons, primarily for the safety and efficacy of the pharmaceutical product to gain regulatory approval. The government, through agencies like the FDA, EMA, and WHO, assures cGMP requirements, and thus, the pharmaceutical products are accurately produced and controlled with suitable quality standards.

The basic requirement of cGMP in formulation R&D lies in ensuring that the drug product developed is of good quality and free from contaminants. Any drug development cycle would encompass several steps, including selecting an API, selecting/ developing excipients, and developing the dosage forms. Strict following of cGMP in such a scenario would ensure that every step of the process is observed with utmost care and attention, hence reducing all possibilities of contamination, the percentage ratio of ingredients, or poor-quality components. The implementation of cGMP rules also helps in avoiding cross contamination and ensures that production environment is controlled to ensure the purity of the experimental formulations.

Good R&D practices governed by cGMP principles further ensure strong documentation. Record documentation of experiments, materials used and procedures adopted facilitates the researcher to repeat successful formulations or troubleshoot any problems at hand with minimal time. It also plays a key role in submitting reports. In that regard, cGMP acts as a basement for gaining regulatory clearance and fast-tracking the pathway of the drug from R&D to commercialization.

It further assures that the drug formulation produced is consistent in scale-up from lab experiments to industrial-scale production. A formulation that functions well in a lab must also consistently perform when it is manufactured on a large scale. The utilization of validated equipment, in conjunction with standardized process conditions and meticulous testing protocols, guarantees the stability and efficacy of the final product, irrespective of batch size.
Adherence to current Good Manufacturing Practices is an important precursor for research and development in formulation. This is vital in as much as it will ensure the quality of drugs, the safety of patients, regulatory compliance, and smooth transition from the development phase to full-scale production. In this regard, if cGMP standards are complied with during formulation R&D, it will minimize associated risk profiles in new drug development and maximize the likelihood of successful drug development.

**Dr Srinivas Mutalik**
Principal and Professor
Manipal College of Pharmaceutical Sciences (MCOPS), MAHE, Manipal

**From the desk of Dr Girish Pai K, Coordinator, Centre for cGMP**

We all know that India is the world's pharmacy, with sound research capabilities integrated with state-of-the-art manufacturing facilities, producing life-saving medicines for patients across the globe. However, I believed it was necessary to emphasize the importance of cGMP aspects right from academia to impart adequate knowledge to the pharmacy graduates, thus making them industry-ready, quality conscious and stay committed towards one noble cause, i.e. "Quality medicines for all suffering patients".

Keeping this thought in mind, a comprehensive long-term plan was drawn up to educate the pharmacy students with a strong commitment towards imparting cGMP knowledge to pharmacy students. This began with establishing the Centre for cGMP under the aegis of the Manipal Academy of Higher Education (Institution of Eminence Deemed to be University) in the year 2021. The team started small but dreamt big and with the support of MAHE management, the Centre for cGMP, which started just with 5 co-coordinators and 4 industry experts and expanded phenomenally, adding 3 International advisory board members and 23 National advisory board members, thus onboarding experts from Industry and Academia of considerable repute. Thanks to the management of MAHE for unconditional support, guidance and advice to the team at the Centre for cGMP from time to time.

Centre for cGMP wishes to thank the Indian Drug Manufacturers' Association (IDMA), Dr Viranchi Shah, IDMA national President, Sri S M Mudda, Chairman of the Regulatory Affairs committee at IDMA, Dr George Patani, our Illustrious alumni and Vice President, IDMA, Dr S V Veeramani, Chairman, Pharmexcil and Sri Harish K Jain, President Federation of Pharma Entrepreneurs (FOPE) and all our well-wishers immensely for their advice and support in making our cGMP journey meaningful and to create positive impacts.

I dedicate all the success of Centre for cGMP's initiatives to the late Dr TMA Pai, Padmashree awardee, architect of Manipal and our source of inspiration.

My guiding spirit is my beloved father, late Dr Kulyadi Suresh Pai, a student of Dr TMA Pai and an alumnus of KMC, Manipal, who instilled strong values and ethics in me. These values made me work selflessly and inspired me to contribute to the field of cGMP.

My team at the Centre for cGMP and I also wish to thank all the pharmacy students, faculty, and industry colleagues for joining hands with us in all our initiatives and making this journey more meaningful and fruitful.

**Dr Girish Pai K**
Associate Professor - Department of Pharmaceutics
Co-ordinator, Centre for cGMP
MCOPS, MAHE, Manipal

**Interview with Dr S V Veeramani, Chairman - Pharmaceuticals Export Promotion Council of India**

- 1.Centre for cGMP: Sir, could you please give us a brief introduction about yourself?

Born into a middle-class family, my early life was fairly ordinary. My father was an Engineer in the Telephones department, and my mother was a homemaker. I started my career as a Medical Representative with Dey's Medical in Calcutta. During my early years, I read books by Napoleon Hill, and even now I vividly remember the opening quotation from his book on - Grow Rich with Peace of Mind. It says that "The creator has given man a mind with unlimited potentials. It is up to him to realize the same and work for the goals of his dearest dreams". So, when I started working with this spirit and confidence, I succeeded in a big way to becoming the company's top-performing salesperson. My initial success spurred me to become a Pharma Entrepreneur.

- 2.Centre for cGMP: What is the story behind the FOURRTS? How was this name coined?

Fourrts was founded by me along with a few partners. We started with a small capital, but great determination. Initial days were tough, but ultimately, we overcame all the challenges to become one of the notable pharma companies.

The name Fourrts was derived from "Forte" indicating strength. But the spelling was modified. Our goal was to build a robust and resilient company.

- 3.Centre for cGMP: How old is your organization and what is the success mantra?

With over 45 years of impressive standing in the industry, Fourrts has made available a range of innovative, value-added, evidence-based products for ailing patients. The achievement of Fourrts has been its ability to produce high-quality products consistently over the years. The people of the company are our greatest asset. We are an ethical and reliable organization. We market evidence-based pharmaceutical products in various fields of Nephrology, Gastro Enterology, Diabetology and Respiratory diseases. Based on this foundation and values, we have been continuously striving for excellence. We market our products not only in India, but also in over fifty countries.

I strongly believe that a leader should carry everyone together and encourage them to find joy in their work. Commitment to excellence and the ethical approach to work serves as an inspiration to all those who work with me.

- 4.Centre for cGMP: You have spent about 40 plus years across various leadership roles at FOURRTS, what keeps you going and growing in an industry like pharmaceuticals that is full of challenges and uncertainties?

My strong desire to succeed and constant striving for excellence has kept me going. In my life, I would like to support people in the pharmaceutical industry. I wish to prove that honesty, integrity and striving for excellence, will always succeed.

With respect to challenges and uncertainties in pharmaceuticals, I accept the same as a reality and do my best to overcome them.

- 5.Centre for cGMP: As a successful pharma entrepreneur, what is your advice to the future and young aspiring pharmacists?

  My advice is to choose an area of interest in pharmaceuticals, amongst various disciplines like manufacturing, quality control, quality assurance, research & development, regulatory, academia, clinical pharmacy, pharmacovigilance, Artificial Intelligence, Biotech, etc. I would urge them to choose one area of interest amongst this and work on the same intensely. They should aspire to become an expert in their field of interest and be the best in such a manner, that they should ultimately become a great contributor in that field.

  I strongly believe that if you have the three qualities of Willingness to learn, Eagerness to succeed and Capacity for hard work, then sky is only the limit

- 6.Centre for cGMP: Finally, what advice would you offer to the Centre for cGMP? We will consider your guidance a valuable blessing.

  Good Manufacturing Practices are vital for the pharmaceutical industry, considering that we are dealing in patients' welfare. GMP should be a prayer for all those who work in the pharmaceutical industry. It is most welcome that Manipal Institutions, known for their standards, have commenced their Centre for cGMP. It is indeed a great initiative of MAHE, Manipal, well-steered by Dr Girish Pai with guidance from Industry Experts and Stalwarts.
  My advice to the Centre for cGMP is that we should never ease up and keep our quest for Quality throughout going Academia and Industry.

- 7.Centre for cGMP: What is your advice to academic institutions to narrow the gap between industry and academic institutions?
  Industry and Academic institutions have to interact more frequently. Academic institutions should engage with industry to explore how they can offer support and contribute to their needs. The pharmaceutical industry, in turn, should seek assistance from academic institutions, particularly for Research & Development projects.

  Developed countries such as the USA and Japan are introducing new products, particularly through research institutions. We should strive to achieve the same in India, with MAHE potentially leading the way as a trendsetter in this endeavour.

**Dr S V Veeramani**
Chairman - Pharmaceuticals Export Promotion Council of India
(Pharmexcil - 'Set up by Ministry of Commerce and Industry, Govt. of India') &
Managing Director – Fourrts Labs Ltd, Chennai.

## National cGMP Day 2024: Building a Culture of Quality

Taking into account the various international, national and thematic awareness days across different sectors (health, education, environment, social causes), there are possibly 500 to 700 days dedicated to raising awareness, honoring achievements, and promoting specific causes worldwide. These 'Days' vary in their level of global recognition and impact, with some being celebrated more regionally while others gain international significance.
The National cGMP day was first celebrated in India on October 10, 2023. The objective of the National cGMP Day was to create an awareness of the importance of current Good Manufacturing Practices (cGMP) and to build a culture of quality in the pharmaceutical industry in India. The National cGMP day was celebrated across India by industry, academic institutions and ably supported by various Government bodies.

We are aware that there is great dependence on the Indian Pharmaceutical industry for the supply of quality pharmaceutical products. To ensure the production of quality products, India will require skilled and qualified manpower. To provide skilled and qualified manpower, it is important that our colleges, universities and academic institutions produce graduate students that are employable in our pharmaceutical industry. It is not only important that we review the current syllabus of our undergraduate/graduate programs but also review the methodology used by our teaching faculty. A quick review of the current syllabus shows great emphasis on teaching the past and the history/evolution of the various subjects rather than focusing on the application of knowledge/concepts in the discipline. Rather, emphasis must be placed on exposing the students to the current industrial setting and the future of the individual disciplines considering developments such as artificial intelligence and automation. Considering the great importance being assigned to quality assurance, students must be introduced early in their professional careers to concepts such as deviation management, change control and the use of CAPAs to manage a pharmaceutical manufacturing environment. These practices are fundamental to ensuring the safety and quality of medicines. The National cGMP Day serves to underscore India's dedication to producing high-quality, defect-free pharmaceutical products.

**Dr George Patani**
Vice President, Indian Drug Manufacturers' Association (IDMA)
Director, Inga Laboratories P. Ltd., Mumbai.

**"Emphasis of GMP in Academia: Building the Students' Foundation as Future Pharmaceutical Professionals"**

The pharmaceutical industry is one of the most highly regulated sectors in the world, as its products directly impact human health and well-being. In recent years, the Pharma Sector in India has demonstrated robust exponential growth. Within this highly regulated environment, ensuring the quality, safety, and efficacy of products is paramount.
This is where Quality Assurance (QA) and Quality Control (QC) come into play, serving as integral parts of Good Manufacturing Practice (GMP). GMP sets the standards for pharmaceutical manufacturing, ensuring that companies protect patients and uphold the industry's integrity. These practices allow for innovation and growth while maintaining compliance with stringent regulatory standards.

Given the critical nature of the pharmaceutical industry, where human lives are at stake, the importance of GMP cannot be overstated. GMP forms the foundation of the entire manufacturing process for products such as drugs, food, and medical devices.

One of the critical resources for the Pharmaceutical Industry is the human resource, that is, the students studying in Pharmaceutical Sciences and Health Sciences courses besides other Courses. Incorporating Good Manufacturing Practices (GMP) into the Pharmacy academic curriculum is crucial for preparing students for successful careers in the pharmaceutical industry. GMP provides the foundational framework for ensuring product quality, safety, and compliance with regulatory standards.

By integrating GMP into their studies, students gain theoretical knowledge and a practical understanding of industry expectations. This focus helps bridge the gap between academia and industry, making graduates more industry-ready. To prepare students for careers in this sector, it is also mandatory that industry-experienced faculty deliver comprehensive and updated lectures on GMP principles to give students a real-world scenario.

A key enabler in the teaching-learning process is establishing regular industry-academia interactions. These interactions facilitate training and internships for students in pharmaceutical sciences, biotechnology, and life sciences, which are critical for transforming learners into professionals. Such experiences allow students to apply their academic knowledge in real-world settings, understand the importance of GMP, and develop the skills needed to contribute effectively to these sectors.

In the present times, beyond the traditional classroom, students have access to various self-taught learning and development (L&D) resources that can enhance their skills and knowledge. Examples include Massive Open Online Courses (MOOCs), webinars, online workshops, certificate courses, industry conferences, e-books, and virtual internships. These value-added resources, combined with classroom education, help students develop a well-rounded skill set, preparing them for future challenges.

In recent years, India has also emerged as a hub for Global Capability Centres (GCCs) across various sectors, most importantly pharmaceuticals and healthcare industries. These centres support various global functions of top Pharma MNCs outsourced from India, such as QMS, contract research, RWE, regulatory filings, NDDS and drug discovery. The GCCs leverage emerging technologies like Gen AI, AR/VR, and IoT . This offers Pharmaceutical Sciences students valuable opportunities and the potential to develop high-end skills to build a strong foundation for their careers, contributing to India's growing importance in the global pharmaceutical industry.

In Conclusion, emphasising on basic and advanced cGMP training and teaching in the pharmacy college curricula is crucial for equipping students with the practical knowledge and skills required in the highly regulated pharmaceutical industry. By emphasizing cGMP principles, quality control, and regulatory compliance, educational institutions can better prepare students to meet the industry's stringent demands. This focused preparation enhances students' employability and ensures that the future workforce is well-equipped to uphold the highest standards of safety, efficacy, and quality. Ultimately, this approach fosters a stronger connection between academia and industry, driving innovation and excellence in the pharmaceutical sector.

**Prof. Prakash V Mallya**
Experience - Pharmaceutical Industry 35 yrs & Academics Teaching and Training 15 yrs
MS (PharmSci) – Graduate Teaching Assistant, School of Pharmacy, University of the Pacific, California, USA
Bachelor of Pharmacy, from MCOPS, Manipal
More than 35 years of Pharma Industry Experience, Domestic and Global, in World Regulatory Affairs, Bio/Clinical Studies, Marketing, Training, Medico-Marketing, Product Management, Strategic Business Initiatives, In/Out-Licensing, Co-Marketing, Joint Ventures & Mergers.
Has 15 years In Academics, presently working as Director & Professor, Krupanidhi College of Pharmacy- Bangalore.

## GXP Nexus for Pharma Research

The origination of a drug product begins in the research and development (R&D) phase of the pharmaceutical process. This is where scientists and researchers conduct experiments to discover / new compounds, identify potential therapeutic targets, develop innovative drug candidates, conduct formulation / analytical / process development and the validations. GMP principles are not just about ensuring the safety and quality of manufactured drugs; they also play a crucial role in the origination of drug products in R&D. By adhering to GMP guidelines, researchers can improve the efficiency, reliability, and reproducibility of their work, ultimately accelerating the discovery and development of new / innovative / generic medicines.

GXP principles, which encompass Good Laboratory Practices (GLP), Good Clinical Practices (GCP), and Good Manufacturing Practices (GMP), are essential throughout the entire pharmaceutical R&D process. GLP ensures the quality and reliability of non-clinical studies, GCP guarantees the ethical conduct of clinical trials, and GMP ensures the safety and efficacy of manufactured products. By adhering to GXP principles, pharmaceutical companies can maintain high standards of quality, safety, and regulatory compliance, ultimately improving the outcomes of drug development efforts and protecting public health.

By incorporating these practices into our daily routine, we can contribute to a culture of quality and safety within the pharmaceutical industry. Remember, GMP is not just a set of rules; it's a mindset that should be embraced by all employees to ensure the production of safe and effective medications.

GLP, GMP, and GXP understanding, and practices can significantly enhance career opportunities for fresh graduates in the pharmaceutical industry. These principles provide a strong foundation in quality assurance, regulatory compliance, and scientific rigor. By demonstrating proficiency in GXP, graduates can differentiate themselves from peers, making them more attractive to potential employers. This knowledge is particularly valuable in roles such as quality control, regulatory affairs, research and development, and manufacturing. Furthermore, GXP expertise can open doors to international career paths, as these standards are universally recognized and applied in the pharmaceutical industry worldwide.

**Dr Dinesh Shenoy B**
President – R & D
Eugia Pharma Specialities Ltd, Hyderabad

## DATA INTEGRITY IN THE PHARMACEUTICAL INDUSTRY: ENSURING ACCURACY AND COMPLIANCE

Data integrity is a cornerstone of the pharmaceutical industry, crucial for maintaining the trust of regulatory agencies, ensuring product quality and efficacy and, most importantly, patient safety. It involves accurate and reliable data generation, collection, storage and management throughout the product lifecycle, from product/process development to commercial manufacturing and post-marketing surveillance.

### a.Significance of Data Integrity

Data Integrity directly impacts the quality and safety of drugs. Various regulatory agencies, including the U.S. Food and Drug Administration (FDA), the U.K. Medicines and Healthcare Regulatory Agency (MHRA), the European Medicines Agency (EMA) and the World Health Organisation (WHO), have put down stringent requirements for data integrity to ensure that data generated throughout the product lifecycle are accurate and reliable.

### b.Regulatory Framework

Regulations and guidelines such as the FDA's 21 CFR Part 11, the EMA's Annex 11, MHRA's GxP Data Integrity Guidance, WHO's Technical Report Series No. 1044, Annexure 4 outline the requirements for maintaining the integrity of data for manual documentation as well as for electronic records and electronic signatures. These guidelines mandate that data must follow the ALCOA+ principles, which require the data to be Attributable, Legible, Contemporaneously recorded, Original, Accurate (ALCOA) and Complete, Consistent, Enduring, and Available (+). They emphasize the importance of establishing robust systems to prevent data tampering, falsification, and unauthorized access and maintain the integrity of the data for its entire lifecycle.

### c.Challenges in Maintaining Data Integrity

Maintaining data integrity in the pharmaceutical industry involves several challenges:

•Complexity of Data Sources: The volume of data generated is huge, coming from development, clinical trials, manufacturing processes, etc., and it is a challenge to ensure the accuracy and consistency of data coming from different sources.

•Technology: The risk of data breaches and cyber-attacks is increasing by the day; hence, it is very important to ensure that electronic systems are secure, up-to-date and backed up.

•Human Error: The most sophisticated system can fail due to human errors. Mistakes in data entry, analysis, or interpretation can compromise data integrity. Comprehensive training and adherence to standard operating procedures (SOPs) are essential to mitigate this risk.

•Data Management Systems: Proper data management systems are critical for ensuring data integrity. This includes implementing rigorous validation procedures for software and hardware, maintaining audit trails, and ensuring that data is stored and retrieved accurately.

### d.Strategies for Ensuring Data Integrity

Pharmaceutical companies employ several strategies to ensure that data remains integral throughout the product lifecycle.

•Validation of Systems: This process verifies that systems perform as expected and comply with regulatory requirements.

•Data Governance: Implementing robust data governance frameworks helps manage data quality and ensure integrity through data management policies, audits and monitoring systems.

•Training and Education: Continuous training on the importance of data integrity and best practices with refresher courses and updates on regulatory changes.
•Audit Trails: Maintaining and reviewing comprehensive audit trails ensures that all changes to data are recorded and can be traced back to the source.
•Risk Management: Identifying potential risks to data integrity and implementing mitigation strategies is vital. This includes addressing both technical and human factors that could compromise data quality.

## e.The Future

As technology advances, the pharmaceutical industry faces new challenges and opportunities in data integrity. Companies must remain vigilant and adaptable and constantly update their systems and practices to counter emerging risks.

Finally, data integrity is an essential component of the pharmaceutical industry, emphasising on regulatory compliance, product safety, and public trust. By implementing robust systems, adhering to regulatory requirements, and continuously improving practices, pharmaceutical companies can ensure that their data remains accurate, reliable, and trustworthy.

**K Mahesh Rao**
Chief Quality Officer, Integrated Biopharma & Pharma Solutions, Goa

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**Dr George Patani**
Vice President, IDMA & Director, Inga Laboratories P. Ltd

**Dr S V Veeramani**
Chairman - Pharmaceuticals Export Promotion Council of India
(Set up by Ministry of Commerce and Industry, Govt. of India) & MD – Fourrts Labs Ltd

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# Glimpses of National cGMP Day & INDIA PHARMA AWARDS - 2023


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