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

Volume 2, Issue I, 10 April 2025

THINK cGMP – cGMP is LIFE

Commitment | Adherence | Creating Quality Culture

In Accociation with

FOPE® Federation of Pharma Entrepreneurs
FOPE for HOPE
Connecting Pharma Enterpreneurs

pharmexcil
PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA
(Set up by Ministry of Commerce & Industry, Govt. of India)

IDMA

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Message from Dr Sharath K Rao, Honorable Pro Vice Chancellor

I am delighted that the Centre for cGMP, under the umbrella of Manipal Academy of Higher Education (Institution of Eminence), Manipal, has launched the first issue of the cGMP Newsletter, "cGMP CONNECT", coinciding with the 2nd NATIONAL cGMP DAY on 10th October 2024. This newsletter serves as a testament to the outstanding cGMP initiatives undertaken by the Centre. It is a pleasure for me to contribute my thoughts to this second issue of "cGMP CONNECT".

It is commendable that the Centre for cGMP has taken on the responsibility of promoting a culture of quality, starting from the academic environment. I take pride in the fact that MAHE, Manipal, is the only university in India with a dedicated Centre for cGMP. The Centre's initiatives and awareness programs are truly praiseworthy. Additionally, its collaboration with the Indian Drug Manufacturers' Association (IDMA), Pharmaceuticals Export Promotion Council of India (Pharmexcil) under the Ministry of Commerce & Industry, Government of India, and the Federation of Pharma Entrepreneurs (FOPE) further strengthens its impact.

I am personally honored to have been the first visitor to the world's first-ever digital museum on quality, "MANIPAL cGMP MUSEUM", dedicated to our visionary founder, Padmashree awardee Dr. TMA Pai. It is also a proud moment that the Centre for cGMP has received the INDIA PHARMA AWARD 2024 in the 'Excellence in Quality' category for the second time, reflecting its consistent commitment to innovation and excellence.

I am confident that the Centre will continue to bridge the gap between industry and academia, ultimately benefiting students and preparing them for industry roles.

I look forward to future editions of the newsletter, featuring updates on novel initiatives, achievements, and cGMP-related insights.

Congratulations once again to Dr. Girish Pai K, Coordinator, and the entire team at the Centre for cGMP.

Dr. Sharath K Rao
Pro Vice Chancellor
Manipal Academy of Higher Education (MAHE), Manipal

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

We, at the Centre for cGMP, are delighted to share a brief overview of our successful initiatives. This journey has given us valuable experiences and numerous opportunities, along with challenges that have been instrumental in our learning and growth.

We are pleased to highlight the significant recognition, awards, and new initiatives undertaken during this period, details of which are given below:

- The Centre for cGMP was honored with the prestigious INDIA PHARMA AWARDS in 2023 and 2024 under the "Excellence in Quality" category. These accolades were in recognition of our efforts in introducing 'NATIONAL cGMP DAY' and conceptualizing the world's first digital museum dedicated to pharmaceutical quality, the "MANIPAL cGMP MUSEUM."

- Our Centre bagged the BEST STALL award in the theme 'PHARMACEUTICALS' during the MAHE RESEARCH DAY held on 13th and 14th November 2024.

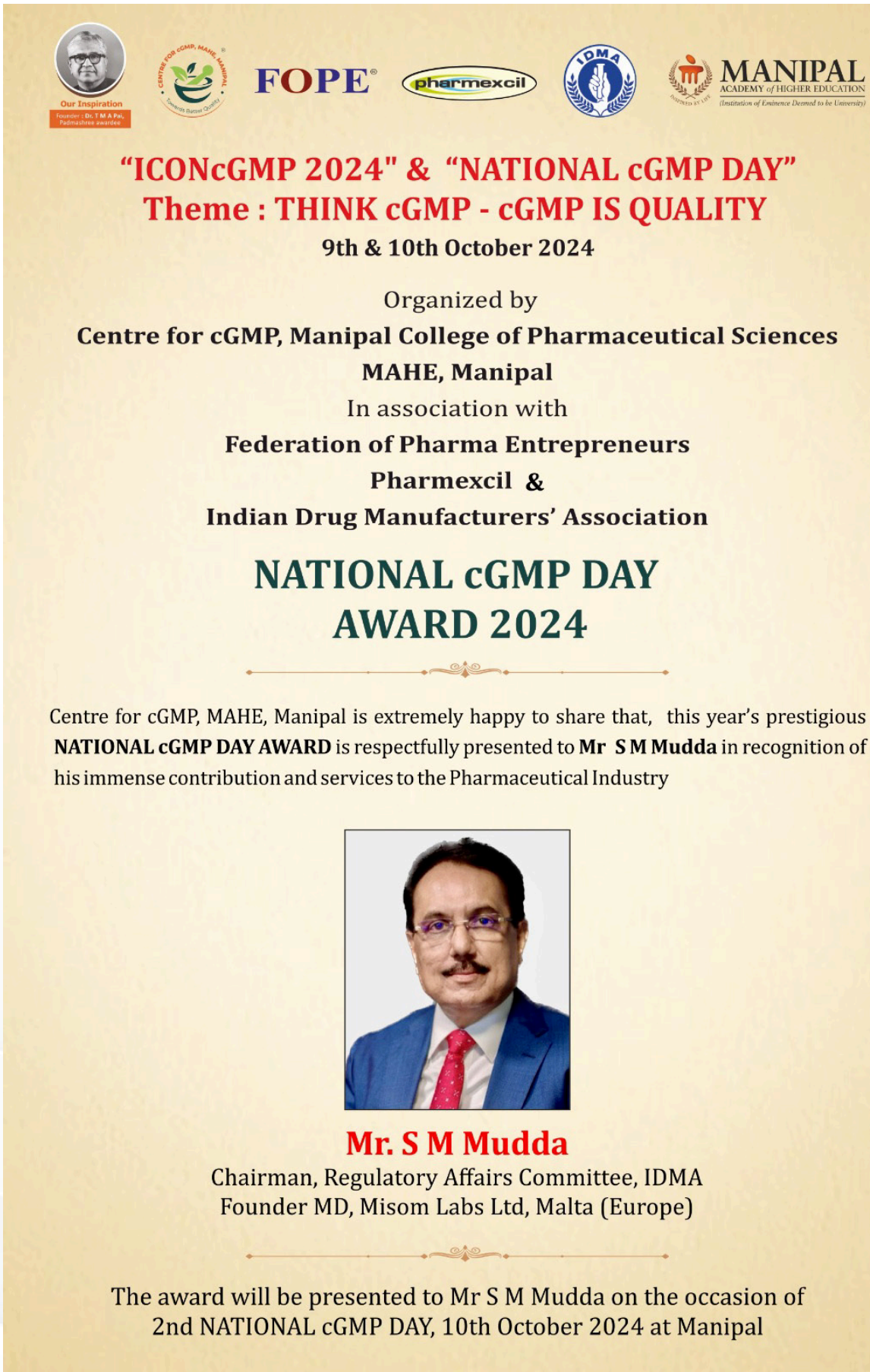
- We launched the cGMP Lecture Series in March 2024, inviting industry experts to educate pharmacy students on critical aspects of good manufacturing practices.

- In collaboration with the Indian Drug Manufacturers' Association (IDMA) and Pharmexcil, we initiated the "cGMP AWARENESS SERIES." The first flyer, "Understanding a Standard Operating Procedure (SOP)," was officially released by the Vice Chancellor of MAHE, Lt Gen (Dr) M.D. Venkatesh, and Registrar, Dr. P. Giridhar Kini. This flyer was also presented virtually by Dr. Viranchi Shah, National President of IDMA, at the Executive Committee Meeting on April 19, 2024.

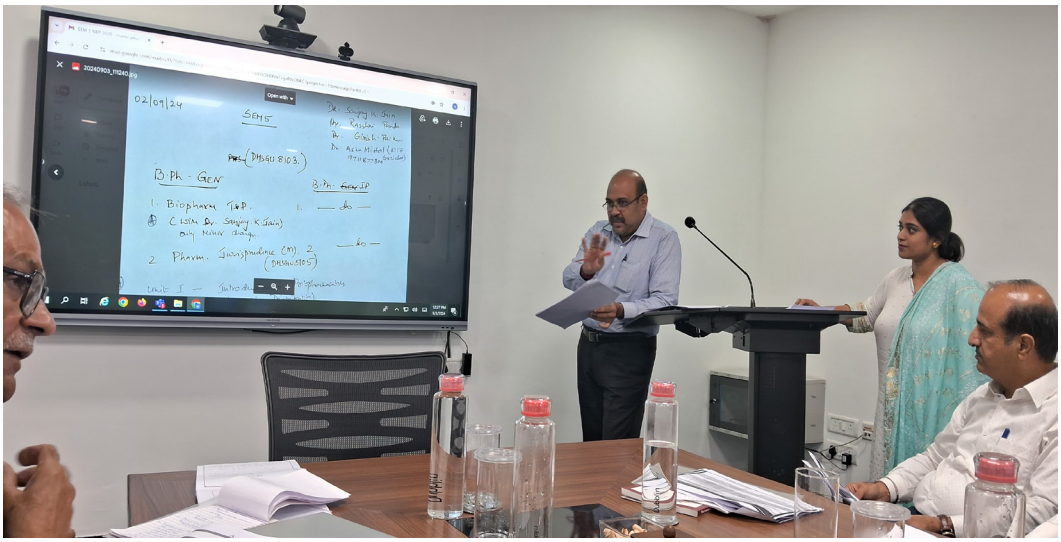
- The Centre for cGMP, MCOPS, MAHE, Manipal, became the first academic institute to launch an international conference on cGMP, "ICONcGMP." Dr Montukumar M Patel, President, Pharmacy Council of India was the Chief Guest for the first ICONcGMP 2024 event.

- Second NATIONAL cGMP DAY was celebrated on 10th October 2024. Sri Mehul Shah, Secretary General of IDMA and Managing Director of Encube Ethicals Pvt Ltd, Mumbai featured as the Chief Guest for this program. On this occasion, we also unveiled our first-ever newsletter, "cGMP CONNECT," released by Sri Mehul Shah.

The esteemed NATIONAL cGMP DAY AWARD 2024 was conferred upon Mr. S. M. Mudda, Chairman of the Regulatory Affairs Committee, IDMA, in honor of his significant contributions and dedicated service to the pharmaceutical industry.



- Dr Girish Pai K, Faculty at Department of Pharmaceutics, MCOPS & Coordinator- Centre for cGMP, MAHE, Manipal was invited as an expert by Education Regulation Committee (ERC), Pharmacy Council of India (PCI) for a two-day workshop on NEP 2020 organized by Pharmacy Council of India, New Delhi. The meeting and workshop were chaired by Dr Montukumar M Patel, President PCI, Prof (Dr) Atul Nasa, PVC- SGT University & EC member and Dr Deependra Singh, Chairman ERC.



- With a strong commitment to lead the way in "Training the PHARMACISTS ," the Centre for cGMP, Manipal Academy of Higher Education (MAHE), Manipal, shouldered the responsibility of educating and training healthcare professionals who are the last point of contact for patients – the pharmacists. This training program aims to prevent defective medicines from reaching patients, ensuring better patient safety and care. Centre for cGMP expressed its gratitude to Mr Prasanna Kumar, Chief Pharmacist at KMC Attavara (MAHE), Mangaluru, and Mr Vishwas, Senior Sales Manager at Intas Pharmaceuticals Ltd (Oncology division), for their support in this unique endeavor. The first training was held on 17th January 2025 at Mangalore.

We dedicate 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 team at the Centre for cGMP and I 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

Quality Maturity: A New Paradigm

Abstract:

Pharmaceutical Industry comply with current good manufacturing practices by implementing Quality Management System (ICH Q10) framework which helps organisations to improve their quality, reduce risks (ICHQ9) and achieve patient satisfaction. FDA recommends to continually improve quality management practices and achieve mature quality management systems that go beyond current good manufacturing practices (cGMP).

The article describes the concept of quality maturity in detail to achieve and optimise matured quality system. The article covers quality management maturity grid, model, program, attributes, plan, benefits, and challenges. The drivers of quality best practices are described along with quality culture implementation. It also suggests the way forward to develop matured quality system specifically focused on agile mindset, increase efficiency, fostering continual improvement, aid in making informed decisions and disrupt manufacturing, improve supply chain reliability, and robust quality management systems to ensure customer trust on safe and effective medicines.

The article was published in a souvenir which was released during Pharmaceutical Analysts' Convention 2024 organised by Indian Drug Manufacturers' Association from October 24 - 25, 2024 at Mumbai, India.

The complete article can be viewed by clicking on the link
https://drive.google.com/file/d/1LRTdJE_9JQ6v42P7YJA3T1zx2UCwWeSl/view?usp=sharing

Kaushik Desai*, ExCo, Industrial Pharmacy Section, FIP
Dr. Satish Desai, Quality Consultant
*National Advisory Board Member, Centre for cGMP, MAHE, Manipal.

Understanding The Uniqueness Of The Pharmaceutical Business: Compliance, Product Quality, And Patient Safety

The pharmaceutical industry is unlike any other business. While speed of delivery is important, the true differentiators are compliance, quality, and, above all, patient safety. At its core lies a fundamental paradox: "The medicines tested in the laboratory are not sold, and those sold are not individually tested, but tested batch-wise as part of the destructive testing." This trust in the unseen is made possible by the principles of current Good Manufacturing Practices (cGMP), which ensure consistency and reliability in every unit of medicine produced.

The Role of cGMP in Pharmaceutical Manufacturing

cGMP provides a robust framework to ensure that every unit of medicine matches the quality of the batches tested in laboratories. This framework extends far beyond state-of-the-art facilities, advanced technologies, or vibrant infrastructure. At its heart is a culture of trust, integrity, and quality upheld by every individual involved in GxP operations.

Take, for example, a legacy semi-automated plant that has operated for over 25 years without a single aseptic process simulation (APS) failure or product recall. This achievement speaks volumes about the resilience of its quality systems and processes. Yet, the "current" in cGMP underscores the need for continuous improvement to proactively adapt to evolving challenges. Compliance and quality must never remain stagnant.

Modern Shifts in the Pharmaceutical Environment

Pharmaceutical quality systems are increasingly guided by product and process knowledge and Quality by Design (QbD) principles. These principles emphasize Critical Quality Attributes (CQA), Critical Process Parameters (CPP), Critical Aspects (CA), and Critical Design Elements (CDE). Risk-based decision-making has replaced traditional, rule-based approaches. For instance, the establishment of dedicated manufacturing facilities is now guided by Quality Risk Management (QRM), with key considerations like Health-Based Exposure Limits (HBEL), Acceptable Daily Exposures (ADE), and Permitted Daily Exposures (PDE). These modern metrics have largely replaced the traditional, category-based rules applied to certain hormones, antibiotics, and cytotoxic agents. Additionally, the traditional "V-model" approach to DQ, IQ, OQ, and PQ has transitioned to a science and risk-based approach for "Commissioning and Qualification (C&Q)".

Contamination control strategies (CCS) have also become central to minimizing risks posed by bioburden, pyroburden, and particulate matter. In parallel, Data Integrity Risk Assessment (DIRA) is increasingly critical for evaluating the reliability of data, assessing current controls, and identifying gaps. These shifts emphasize that compliance is a continuous journey requiring regular assessment and incremental improvements.

Addressing Cross-Contamination Risks

Cross-contamination remains one of the most pressing concerns in pharmaceutical manufacturing. According to Pharmaceutical Engineering (ISPE, March/April 2023), contamination-related product recalls often arise from microbial contaminants introduced through raw materials, water, personnel, environmental conditions, or process equipment.

Table 1: Contamination-associated recalls from 2017 to 2021.

	Recalls Attributed to Contamination	Contaminant/Impurity					
		Microbial	Process Related	Metal	Packaging Related	Other Drugs	Unknown
US FDA	177	78	41	3	5	13	37
UK MHRA	67	27	27	2	2	2	7
Australia TGA	84	28	22	-	6	-	28

Cross-contamination poses a significant threat through mechanisms such as

- mix-ups during production,
- retention of residues on equipment,
- mechanical transfer between processing areas (e.g., cleaning equipment, trolleys), personnel movement between different processing areas in common clean corridor facilities), and
- airborne transfer of contaminants

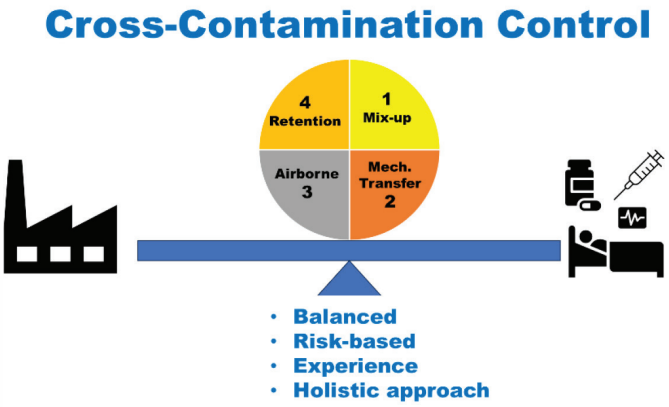
Each mode presents unique challenges that demand tailored preventive measures and controls.
Effective CCS must address all stages of the product lifecycle, from raw material sourcing to manufacturing and distribution. Even small lapses can jeopardize patient safety—such as using a shared tablet-counting tray in pharmacies, use of a needle for air displacement in the sterile IV fluid administration in the hospitals, or unvalidated polythene bags lining clean containers. Additionally, cleaning materials such as cloths used on equipment must meet stringent standards.

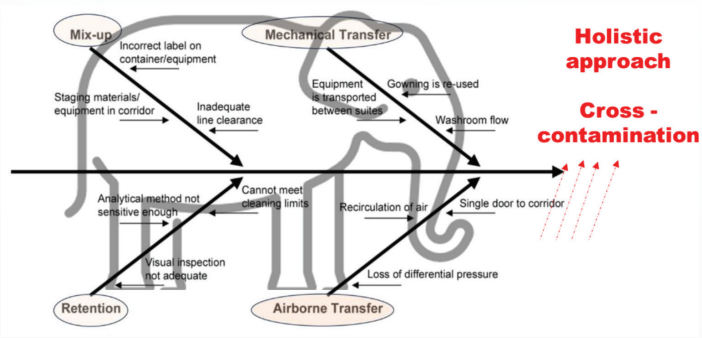
Compliance: A Pragmatic and Cultural Appro

Compliance is not a one-time milestone but a continuous journey. It demands a realistic understanding of the current scenario, a balanced stepwise approach, and sustained efforts to improve. It's vital to recognize that "Not one size fits all". Each step should enhance compliance, product quality, and patient safety rather than merely generating volumes of documentation.

However, a critical yet often overlooked factor—the "elephant in the room"—is the systemic and cultural gaps that amplify contamination risks. These include insufficient training, lack of accountability, resistance to adopting advanced measures, and failure to address root causes of contamination issues. Addressing these cultural deficiencies is as crucial as implementing technical controls.

An integrated approach to contamination control that considers technical, operational, and organizational risks is essential. By fostering a culture of accountability and adaptability, manufacturers can ensure meaningful and sustainable improvements. This holistic strategy strengthens contamination control and reinforces the pharmaceutical industry's ultimate goal: safeguarding patient health and ensuring the quality of medicinal products.





Rajesh Pai,
VRPai's (PTY) Ltd. Pharmaceutical Consultant, South Africa

"Voice of a future PHARMACIST"

The pharmaceutical industry plays a crucial role in global healthcare, ensuring that medicines are safe, effective, and of the highest quality. However, the gap between academic learning and industry expectations has long been a challenge for students entering this field. Recognizing this need, our very own teacher, Dr. Girish Pai K, Associate Professor, Department of Pharmaceutics and Coordinator, Centre for cGMP took the visionary step of pioneering the Centre for cGMP (Current Good Manufacturing Practices) at Manipal Academy of Higher Education (MAHE, an Institution of Eminence). His brainchild, the first of its kind in any Indian university, is dedicated to integrating industry-relevant knowledge into academia, equipping students with both technical expertise and practical skills essential for success in the pharmaceutical sector. Being part of an institution that prioritizes such progressive initiatives is a privilege, offering us unparalleled opportunities to bridge the gap between learning and real-world application.

cGMP guidelines serve as the backbone of pharmaceutical manufacturing, ensuring that medications are consistently produced and controlled according to quality standards. These regulations safeguard public health by minimizing risks related to contamination, incorrect dosages, and inconsistent formulations. The industry thrives on adherence to these standards, and it is imperative that students and academicians alike understand their significance. The Centre for cGMP at MAHE has been instrumental in incorporating these industry-driven regulations into academic curricula. By doing so, it fosters a deeper understanding of the manufacturing process, quality control measures, and regulatory compliance among students, making them well-equipped for industry roles upon graduation.

One of the biggest challenges in pharmaceutical education is the disconnect between theoretical knowledge and practical industry requirements. The Centre for cGMP is actively working towards addressing this issue by creating an ecosystem that integrates academic learning with industrial applications. By exposing students to real-world challenges and innovative solutions, the initiative ensures that graduates are industry-ready and equipped with essential skills. To further this mission, National cGMP Day was conceptualized and celebrated for the first time on October 10, 2023. This day is now set to be an annual observance, highlighting the importance of quality practices in pharmaceuticals. Such initiatives not only enhance awareness but also instils a culture of compliance and excellence among future pharmaceutical professionals.

The Centre for cGMP also pioneered the first-ever digital museum on pharmaceutical quality – the Manipal cGMP Museum. Dedicated to Dr. TMA Pai, the founder of MAHE, this museum serves as an educational hub where students, researchers, and industry professionals can explore the evolution of pharmaceutical quality practices. This innovative approach ensures that knowledge is preserved and disseminated in an interactive and engaging manner, making learning more effective and accessible. One of the most impactful initiatives by the Centre for cGMP was the International Conference on cGMP – ICONcGMP held on the 9th and 10th October 2024. This two-day conference provided an unparalleled opportunity for students to engage with top leaders in the pharmaceutical industry, gain insights into emerging trends, and participate in thought-provoking discussions.

As a proud participant, I had the honour of presenting my poster on the topic "Root Cause Analysis of Manufacturing Defects in Oral and Injectable Medications" at ICONcGMP 2024. This experience was invaluable, as it allowed me to showcase my research, receive constructive feedback, and engage in discussions that enhanced my understanding of manufacturing challenges and solutions. Beyond technical knowledge, the conference also focused on soft skill development, a crucial aspect often overlooked in academic training. Panel discussions highlighted the importance of communication, leadership, problem-solving, and adaptability—skills that significantly enhance employability in the pharmaceutical sector.

ICONcGMP 2024 and 2nd National cGMP Day was honoured to host several distinguished leaders from the pharmaceutical industry and regulatory bodies, whose insights added immense value to the conference. The event was inaugurated by Dr. Montu Kumar Patel, President of the Pharmacy Council of India (PCI), New Delhi, in the esteemed presence of Dr. Vibhu Sahani, Chairman of the Finance Committee and Central Council Member, PCI, New Delhi. Joining them were key industry figures, including Sri Harish Jain, National President of the Federation of Pharma Entrepreneurs (FOPE) and Managing Director of Embiotics Labs (P) Ltd.; Sri Mehul Shah, General Secretary of the Indian Drug Manufacturers' Association (IDMA) and Managing Director of Encube Pharmaceuticals Pvt Ltd.; and Sri Daara B Patel, Secretary General of IDMA. Their collective expertise provided students with a deeper understanding of industry expectations, the role of regulatory frameworks, and the essential skills needed to excel in the pharmaceutical sector. Through their thought-provoking discussions, they laid out a clear roadmap for aspiring professionals, highlighting the significance of continuous learning, innovation, and adherence to global quality standards.

The initiatives led by the Centre for cGMP at MAHE, Manipal mark a significant step in redefining pharmaceutical education. By fostering industry-academia collaborations, emphasizing hands-on learning, and integrating regulatory frameworks into academic training, this centre is shaping the next generation of industry-ready professionals. For students like me, being a part of such a transformative initiative is both an honour and a learning experience. The exposure to industry leaders, participation in knowledge-driven discussions, and access to innovative resources have provided a holistic understanding of pharmaceutical manufacturing and quality assurance. As we move forward, the goal remains clear—to continue learning, innovating, and upholding the highest standards of pharmaceutical excellence. With the unwavering commitment of MAHE and the Centre for cGMP, we are confident that this initiative will continue to shape the future of pharmaceutical education and industry practices, bridging gaps and building a stronger, more competent workforce.

A heartfelt gratitude to Dr. Girish Pai K, along with the dedicated co-coordinators, esteemed industry experts, the National Honorary Advisory Board members, Manipal College of Pharmaceutical Sciences, and Manipal Academy of Higher Education for conceptualizing and driving such a transformative initiative. Their vision and relentless efforts have not only created a platform for bridging academia and industry but have also empowered us students with invaluable knowledge, skills, and opportunities that will shape the future of pharmaceutical sciences.

Akashka Kalam
General Secretary, MAPS - Manipal College of Pharmaceutical Sciences
BPharm student (3rd year & Batch of 2022).

CENTRE FOR cGMP, MAHE, MANIPAL
Towards Better Quality

Glimpses of National cGMP Day & ICONcGMP - 2024

Congratulations to Sri S M Mudda

FOPE pharmexcil IDMA MANIPAL ACADEMY of HIGHER EDUCATION

NATIONAL cGMP DAY AWARD

Mr. S M Mudda

"THE FUTURE OF PHARMACEUTICAL MANUFACTURING LIES IN OUR ABILITY TO INNOVATE PROCESSES THAT GUARANTEE THE HIGHEST QUALITY AT EVERY STEP." – **Janet Woodcock,** Director of the FDA's Center for Drug Evaluation and Research

On the historic occasion of the second 'NATIONAL cGMP DAY' and the first-ever International Conference on cGMP "ICONcGMP 2024", the Centre for current Good Manufacturing Practices, MAHE, Manipal have decided to honor a leading professional from our fraternity who embodies quality in every path of his life and has been the guiding light for many quality professionals in the field of Pharma manufacturing who have contributed immensely to strengthen the quality of manufacturing.

Today, we are privileged to honor Mr. S. M. Mudda for his highly commendable service for more than four decades in the field of Pharmaceutical Manufacturing and Quality Management.

Mr. Mudda earned a bachelor's degree in pharmacy and further enhanced his qualifications with a Postgraduate Diploma in Management Studies. He served Micro Labs as Executive Director, Technical and Operations and later as Director-Global Strategies.

He is the Founder Managing Director of Misom Labs Limited, Malta (Europe). Mr Mudda has been the President–NSF Health Sciences (India & Asia Pacific), representing NSF International, United Kingdom. He is actively associated with IDMA as Chairman of the Regulatory Affairs Committee and is on the Board of many leading Indian companies as Technical Advisor and Leadership Mentor. Mr. S M Mudda was the person who designed & implemented the best-in-class Pharmaceutical Quality Management System for consistent implementation of Good Manufacturing Practices (GMPs) harmonized with the global requirements. He is a major contributor with Technical and Strategic leadership for the Design and Operation of Pharmaceutical manufacturing plants consistent with global Standards for Operations and Quality Excellence. Globally, the industry and its employees have benefitted immensely from his knowledge, expertise, and services.

For your altruistic service in the field of Pharmaceutical Manufacturing and Quality Management and for educating budding pharmacists with Pharmaceutical Quality Management program, the Centre for current Good Manufacturing Practices, MAHE, Manipal is pleased to honor you with this citation in the presence of dignitaries, luminaries from Industry, Academia and Regulatory bodies.

NATIONAL cGMP DAY
10th October 2024

Centre for current Good Manufacturing Practices
(Center for cGMP), Manipal College of Pharmaceutical Sciences,
Manipal Academy of Higher Education (Institution of Eminence) Manipal

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