



South-East Asia

Current Good Manufacturing Practices (cGMP) - Online Workshops for Pharmaceutical Units

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A first of its kind, Virtual Workshops on Good Manufacturing Practices (cGMP) have been organized and implemented by all three levels of WHO (Country Office, Regional Office, Head Quarters) in collaboration with JSS Academy of Higher Education & Research (JSS AHER), Mysuru, Indian Pharmaceutical Alliance (IPA) under the guidance of Indian Ministry of Health. The activity aimed to strengthen the capacities of pharmaceutical manufacturing in the small and medium enterprises (SMEs) in the country and share global practices to promote availability and access to quality medical products.



Dr Poonam Khetrpal Singh, WHO Regional Director for South-East Asia

“At the heart of these workshops is the underlying philosophy behind cGMP, which is ensuring that products are consistently produced and controlled according to quality standards. WHO is fully committed to supporting such endeavors. Given the encouraging response to the earlier workshops, we hope to expand the outreach and have participation from other countries in the South East Asia Region,” said Dr Poonam Khetrpal Singh, WHO Regional Director for South-East Asia.

In 2020-21, **six online workshops on cGMP** for micro, small and medium scale enterprises in the Indian pharmaceutical industry were jointly organised by WHO South-East-Asia Regional Office (SEARO) and WHO India in collaboration with Ministry of Health and Family Welfare (MoHFW), Department of Pharmaceuticals in *Ministry* of Chemicals and Fertilizers, and Department of Biotechnology (DBT) in the Ministry of Science and Technology. The details of virtual workshops organized are given in the following table. Including the initial pilot, six workshops have been held covering formulations, active pharmaceutical ingredients, medical devices and diagnostics with training imparted to 1115 participants in 323 pharmaceutical units.

The senior leadership teams from Ministry of Science and Technology, Ministry of Chemicals and Fertilizers along with senior MoHFW officials graced the inaugural sessions of these workshops. Wide engagement in the workshops is evident with participation of different ministries.



Ms S Aparna, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India-

In her inaugural address, Ms S Aparna, Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, said, “These workshops have further reinforced and enhanced the capacity and abilities of the Indian pharmaceutical sector, which has shown tremendous dedication for the cause of supplying quality medicines globally since the pandemic started. Their hard work and commitment have resulted in India being recognized as the being the vaccine hub and ‘pharmacy of the world’. The workshops have recognized and identified some of the existing challenges and vulnerabilities and has in fact addressed them, which reinforces the utility and the necessity of these series of workshops. This will have a far-reaching positive impact on enhancing the quality systems for production of high quality active pharmaceutical ingredients (APIs).”

“I congratulate WHO and partners on their approach towards quality assurance through GMP in a very systematic manner and for conducting this timely and much needed initiative,” said Ms Aparna.



"This initiative of providing the requirements of Global standards meets the critical need of enabling further upgradation of in vitro diagnostics and medical devices sector for achieving global standards of quality. This will have a far-reaching positive impact. It reiterates our commitment to quality medical products," said Dr Renu Swarup, Secretary, Dept. of Biotechnology, Ministry of Science and Technology, Government of India.

Mentorship program: The workshops are being followed by a mentorship programme designed to assist in the submission of dossiers and adoption of WHO prequalification standards in the units for global access to quality medical products.



"The initiative of establishing a robust learning and training platform meets the critical need of enabling further upgradation of pharmaceutical sector for global standards of quality. This will have a far-reaching positive impact. It reiterates our commitment to quality medical products and reinforces our position of being the vaccine hub and pharmacy of the world. "I congratulate WHO and partners for this timely and much needed initiative," said Dr Mandeep Bhandari, Joint Secretary, Ministry of Health & Family Welfare, Government of India in his inaugural address.

The participating industries were shortlisted by employing statistical methods on the Indian Annual Survey of Industries 2018-19 database over a wide geographical distribution across the country based on an earlier WCO-SEARO survey. The earlier joint SEARO-WHO India Survey was an inter-ministerial effort spearheaded by the MoHFW on access to quality medicines in pharmaceutical enterprises in India. The workshops are a follow on to the recommendations of the survey that called for strengthening GMP among SME manufacturers for access to quality medical products.



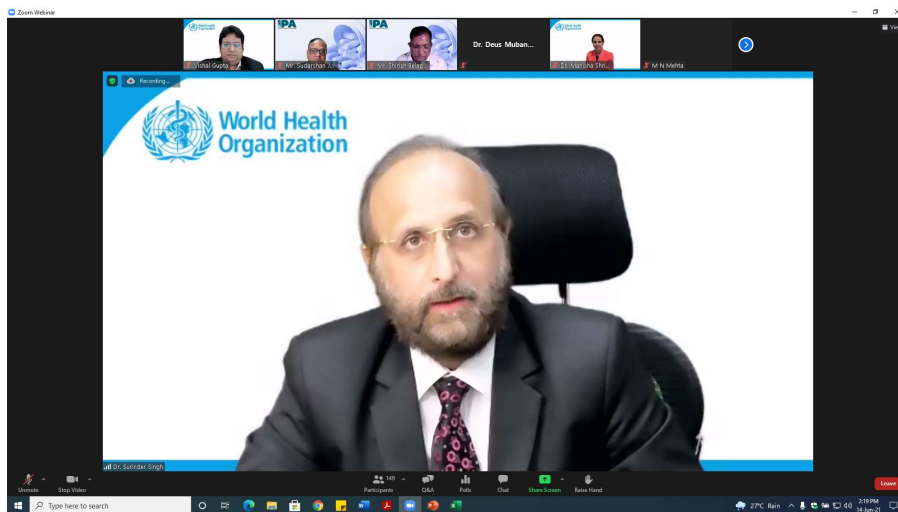
“We are committed to the highest regulatory standards to ensure quality, safety and efficacy of medical products. It is our constant endeavor that our standards are at par with the best in the world. The objectives of the workshop are aligned with the broader goals of the national regulatory authority and in this context, I am particularly pleased to see the enthusiastic participation of the pharma industry in these workshops. It augurs well for this vitally important sector,” said Dr V.G. Somani, Drug Controller General of India, Ministry of Health & Family Welfare, Government of India.

The goal of this initiative is to prepare Indian pharmaceutical/medical devices units to upgrade and adopt global standards of quality. The workshops aimed to create awareness and generate interest in WHO Pre-Qualification for higher quality standards among medium-sized units engaged in manufacturing formulations, bulk drugs and medical devices.

The COVID-19 pandemic and the consequent restrictions on gatherings was turned into an opportunity whereby pharmaceutical unit personnel attended online workshop sessions from the workplace. The personnel could participate in training and attend to day-to-day activities in their units thus improving efficiencies and outcomes.

The workshops have led to facility/systems upgradation, improved the understanding of cGMP in the context of a risk-based and quality system-based approach, improved knowledge to meet WHO Prequalification requirements and other world class quality standards beginning with a pilot phase in

India and followed by a rollout to other South-East Asia member states.



“An important component of these workshops is mentorship. To ensure long-term impact, a mentor will be guiding the participants for an informed understanding and implementation of WHO cGMP, prequalification guidelines and other world-class quality standards,” said Dr Surinder Singh, Vice Chancellor, JSSAHER, Mysuru, India



“The virtual workshops on cGMP are a key step in that direction, and we are delighted to partner in this path-breaking program,” said Mr Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance. “It is an essential and urgent need of the sector, especially at this crucial juncture,” he added.

The workshops also helped to improve the understanding of capacity building and upgradation of quality culture and quality management in medical products, including medicines, vaccines, medical-devices manufacturing enterprises, and the use of Artificial Intelligence in drug design and development and clinical trial data analytics.

Workshop	Category	Dates 2020-2021	Number of Participating Units	Number of Participants	Duration (in days)
Pilot	Formulation	1 -14 December	33	101	12
1.	Formulation	5 May -18 May	40	143	12
2.	APIs	24 May –5 th June	35	139	12
3.	APIs	14 June-26 th June	49	166	12
4.	Medical Devices	5 July -9 July	51	165	05
5.	APIs	19 July -30 July	115	310	12
Total			323	1115	