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Dr Renu Swarup inaugurates workshop on GMP to support medical devices industry

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The fourth of a series of six virtual workshops on current Good Manufacturing Practices to support the Indian pharmaceutical/medical devices industry's vision of providing world class quality medical products was inaugurated by Dr Renu Swarup, secretary, Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India.

The Covid-19 pandemic has brought into sharp focus and reinforced the need to enhance quality production for sustainable supply chains to meet national and global needs. These workshops address the vital importance of strengthening the capacities of IVDs-medical devices manufacturing facilities meet current global best practices and sharing global practices to promote availability and access to quality medical products.

This unique initiative is the result of an active collaboration between the Union ministry of health & family welfare (MoHFW), Department of Biotechnology (DBT), ministry of science and technology, the World Health Organization (WHO), JSS Academy of Higher Education & Research at Mysuru (JSS AHER), AMTZ and the Indian Pharmaceutical Alliance (IP Alliance).

In her inaugural address, Dr Renu Swarup, Secretary, DBT said, "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."

Welcoming the capacity-strengthening workshops, Dr V G Somani, Drug Controller General of India, said, "We are committed to the highest regulatory standards to ensure quality, safety and efficacy of medical products. This workshop conducted by team from WHO PQ IVD Assessment team would definitely support Indian Medical devices units to upgrade their quality culture to global standards."

"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 medical devices industry in these workshops. It augurs well for this vitally important sector," he said.

Speaking on the occasion, the WHO representatives from HQ, WHO Regional Office for South-East Asia, and WHO Country Office for India said, "It is for the first time anywhere in the world that we have attempted a programme like this. At the heart of these workshops is the underlying philosophy behind the current Good Manufacturing Practice (cGMP) - ensuring that products are consistently produced and controlled according to quality standards." "WHO is fully committed to supporting such endeavours. Given the encouraging response to the earlier workshops, we hope to expand the outreach and have participation from other countries in the Region through the WHO South East Asia Regulatory Network," they added.

"The virtual workshop for medical devices units is a key step in that direction, and we are delighted to partner in this path-breaking programme," said Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance. "It is an essential and urgent need of the sector, especially at this crucial juncture," he added.

National and international experts, including from WHO (HQ, Regional Office for South-East Asia, Country Office for India) and leading industry voices came together to design a need-based workshop program. This was followed by a successful pilot workshop on cGMP for pharmaceutical units in December 2020 on a unique and dedicated WHO-JSS AHER web portal.

"We are thankful to the health ministry, DBT, WHO and partners for the trust and confidence reposed in us for the conduct of the workshop" said Dr Surinder Singh, Vice Chancellor, JSS AHER. "An important element of these workshops is Mentorship," he shared. To ensure long-term impact, a mentor will be guiding the participants for an informed understanding and implementation of WHO prequalification guidelines and other world-class quality standards.

Importantly, the workshops are also contributing to the larger agenda of access to quality medical products for all. As Dr B Suresh, Pro Chancellor, JSS AHER said, "This workshop is an important step for enabling the enhancement of quality standards of Medical devices manufacturing units. He was hopeful that the industry, which has shown tremendous progression in the reduction of time for RT-PCR testing would further be able to deliver the same at the point of care. We are delighted to be part of this initiative."

Dr Jitendra Sharma, managing director & CEO, Andhra Pradesh Med Tech Zone (AMTZ) expressed that this workshop would propel the Indian Medical Devices industries to higher global standards.

Shirish Belapure, senior technical advisor at Indian Pharmaceutical Alliance, said, "IP Alliance quality forum has one prime objective of upgrading the quality of Indian pharmaceuticals & Medical devices Industries and this workshop is supporting the realization of the same."

Dr Anup Anvikar, director, National Institute of Biologicals (NIB), Veena Kohli, president, Association of Diagnostics Manufacturers of India (ADMI) and Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AIMED) also graced the occasion.

Under this initiative, a total of six workshops are being conducted - two for formulation manufacturing pharma units, three for active pharmaceutical ingredients (APIs) manufacturing units, and one for medical devices and IVD manufacturers. Cumulatively, over 800 plus participants from over 220 units will take part in this capacity-strengthening programme. The fourth workshop is well attended; it has 182 participants from 51 medical devices units.