Cleanroom facility in pharmaceutical industry

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HE Indian pharmaceutical industry is changing dynamically. It has grown immensely in the past few years and is expected to grow US\$ 55 billion by 2020 according to a report shared by McKinsey. India is also one of the largest exporters of drugs in the world and the exports are expected to reach US\$ 20 billion by 2020. India exports drugs to more than 200 countries and the US is one of the key markets for India, followed by the UK. America consumes about 25 percent of India's exports. Other key markets include South Africa, Russia, Nigeria, Brazil and Germany.

The increasing growth of the industry has also called for increasing regulatory concerns

and norms. Hygiene and safety regulations are actively under surveillance in India and the number of audits executed by authorities such as FDA (Food and Drug Administration) and US FDA (US Food and Drug Administration) are even increasing.

The rapid growth of the Indian pharmaceutical market is attracting global players to enter the country as a result the local players are looking to up the game by meeting global industry standards. Indian companies are now adopting best practices from global manufacturers and to innovative open approaches. One of the major concerns is to maintain hygiene and safety while manufacturing drugs. It is of utmost importance to make sure that the environment is not contaminated.

Which is why companies are adopting hygiene and safety practices. Protective clothing plays a pivotal role in controlling the contamination of the drugs or lab samples and helps to protect the staff from harmful particles and chemical hazards.

This is where clean room workwear services step in. Cleanroom workwear service is a concept where garments are treated in a closed environment and the number of airborne particles, room temperature, humidity, pressure, and airflow are constantly controlled and monitored specified by classifications and global standards. The presence of particles is kept to a minimum level in cleanroom units to ensure a contamination-free garment for the manufacturing of drugs and vaccines. The classification of cleanliness required



in a cleanroom is dependent on the end-use application and is usually defined by the size and number of particles contained within a unit space.

Over the years companies have been setting up their own cleanroom facility units which requires a significant investment in terms of space, manpower and expertise for maintenance, storage and garment acquisition. Looking at the complexity of maintaining hygiene and safety in the pharmaceutical industry, we have launched India's first cleanroom facility unit in Pune in August this year in order to cater to the needs of cleanroom workwear for the pharmaceutical industry after a decade of providing workwear services in India.

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Garments to be cleaned through special process

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Our cleanrooms operate according to ISO 14644 and adhere to GMP procedures. The unit is spread across a total of 52000 Sq. ft, area that caters to the need of laundering 400000 cleanroom garments monthly. The cleanroom workwear operations are different from the standard workwear operations and hence the staff of cleanroom services receive special training from experts and operate under classified cleanroom environment to guarantee supply of particle free and contamination free garments to its customers. We have cleanroom operations in Finland, Russia and China within the 24 countries we operate in, India now becoming the fourth country to have our cleanroom services.

The cleanroom garments need to be manufactured in a very clean environment with the right fabric through laser-cutting and heat-sealing of the seams which helps to reduce the generation of filaments and lint. It is also important to make sure that the garments do not contain any raw edges to reduce the generation of lint. The garments also contain an added lap seam which reduces contamination. The garments then need to be cleaned through a special process including an RFID reader, soil sorting, washing, particle testing, inspection & folding, packing and the final step - delivery. The units

have a classified controlled area and a non-classified area for washing & sorting, folding and packing, which minimizes the risk of contamination. The cleanroom garments are delivered to the employees at agreed intervals and the volume of garments is directly scaled according to the needs of the employees which helps in avoiding shortage of garments at any point.

The disposal of the cleanroom garments is as essential as the cleaning process. The garments have to be disposed of in a sustainable manner. Experts of cleanroom facility units take care of the entire process starting from sorting the garments to their disposal. The RFID technology provides life cycle tracking of each garment bringing in transparency.

Apart from the pharmaceutical industry, cleanroom services are widely used in various industries where hygiene is important, such as biotechnology, medical devices, health care, stem cell technology, optics, micro electronics, food, automotive, nanotechnology etc.

Lindström India is a subsidiary of Lindström Group, a 170 old Finnish workwear service company, Established in 2007, Lindström India is the only organized rental workwear service company in India. The company clothes more than 300,000 people on a daily basis across India and over

> ly. Headquartered in Mumbai, Lindström India has service centers in 11 cities including Chennai, Mumbai, Delhi, Hyderabad, Kolkata, Bengaluru, Panchkula, Vadodara, Vizag, Tinsukia and Pune. Lindström India's cleanroom facility unit is currently serving workwear requirements to India's leading vaccine manufacturers and is looking forward to establishing more cleanrooms in major pharmaceutical hubs in the future as well.

one million people global-

(The author is Senior VP-Sales & Markets, Lindström Global and Managing Director, Lindström India)

