Potential GMP Trouble Spots at India's API Firms Include Equipment Handling, CAPA, Documentation, and Training, India Auditing Expert Finds

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Potential GMP concerns among India's expanding number of API suppliers include equipment handling, CAPA, documentation and training, Semler Research Center COO/Director Gurudatta Gayatri reported at the DIA Annual Meeting in June.

Gayatri highlighted the rapid growth of the Indian API industry as a supplier to the US and Europe, the areas of relative weaknesses he has seen among the Indian API manufacturers he has audited on the part of interested US and EU companies, and the initiatives underway in India to centralize and strengthen its regulatory oversight.

During the numerous audits Gayatri has conducted of Indian API facilities, the most common GMP weaknesses he has seen are in the areas of:

● cleaning validation ● qualification of equipment ● documentation ● analytical method transfer ● CAPA, and ● training of temporary staff.

There is a lack of general understanding regarding cleaning validation in "many companies," he said. Firms may focus only on validating cleaning for the product being manufactured and miss the requirement to validate the removal of a different API manufactured beforehand on the same equipment.

Gayatri explained that the concept and practice of requalification of equipment may also be poorly understood. "People have been using equipment for five years or ten years [and] there is no checking on the wear and tear of the equipment," although periodic requalification is expected. The ISO standard 14644.3 has only been recently recognized as important guidance in the qualification of air handling units, he said.

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