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Can Asian biologics manufacturers live up to global regulatory standards?

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When it comes to contract biologics manufacturing, despite the increasing opportunities, there is a concern regarding the Asian countries' ability to abide by the regulatory system that complies with global standards. Though opportunities exist in abundance, there are only a few companies that can offer large-scale biologics manufacturing.

Biologics manufacturing is a complex and highly regulated process. In comparison to chemical drug manufacturing, biologics manufacturing demands better planning, investment, and knowledge of the specific tasks since the risk of not getting the end result is higher. Regulations in India and China need to improve to meet the demand of the international market.

Commenting on regulatory compliance in Asia, Mr Tim Oldham, president, Hospira Asia Pacific, says, "As our partnership with Celltrion in South Korea shows, Asia is home to some very high quality biologics manufacturing capabilities. Given that the average Asian manufacturing and compliance standards for small molecule pharmaceuticals are not yet the same as that of the western markets, it is not surprising that the same is true, on average, for biopharmaceuticals."

These products are more complex than small molecule sterile injectable or oral products, he explains, pointing out that the regulatory environment in many Asian markets has also evolved differently.

"While biopharmaceuticals are expensive, western markets did not suffer major access issues, so regulatory pathways evolved with a rigorous focus on safety and comparability. In many Asian countries, the high cost of biopharmaceuticals drive significant restrictions on access to care and resulted in the approval of a large number of cheaper "copy" biologics that were not comparable. These simpler approval pathways are becoming less accessible as regulators move to adopting comparability requirements similar to the EU," he says.