Location Matters – Manufacturing Insights from FDA’s Annual Report on Drug Quality

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The Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation and Research (CDER) within the US Food and drug Administration (FDA) published its annual “Report on the State of Pharmaceutical Quality” last week. The yearly report reviews the quality of drug products during the prior year, as measured by recall and product defect information, site inspections of manufacturers, and other post market data. The report provides a few insights that companies may want to consider when working with, or acquiring, contract manufacturers.

1. **The US and EU Outperform Asian Countries.** Sites that manufacture product for the US market must hold a FDA facility registration. The US, India, China, South Korea and Germany have the most manufacturing sites registered with FDA. The US, with 39%, has the lion’s share of those. Of the inspections of the registered facilities, the inspection score for sites in the US and the EU, on average, are higher than the average scores for sites in China and India. The inspection score, on a scale of 1 to 10, reflects a site’s compliance with current good manufacturing practice (cGMP). While FDA said that the average scores in Asia reflect an acceptable level of compliance, it noted that the trend highlights an opportunity for increased surveillance in certain geographies.

2. **The Majority of Inspections Occur Outside of the US.** FDA notes that in FY 2018, 1346 inspections were performed, and the majority of those occurred outside of the US. FDA conducts inspections using a risk-based approach, so this trend makes sense, given the lower inspection scores—on average—of facilities in Asia and the Rest of the World.

3. **There is a Significant Increase in Outsourcing.** Not surprisingly, outsourcing continues to affect the global supply chain. FDA saw an increase of 32% in registrations of Packaging & Labeling sites. Facilities that do not manufacture product, but that package/label products, must register as packaging/labeling facilities. This increase could reflect an increase in the outsourcing of packaging activities, which can increase the complexity of the supply chain.

4. **A Small Number of Manufacturing Sites Account for a Large Number of Drug Products.** Three sites in the US account for almost 10% of all products listed with the US FDA. A similar trend is seen in Asia, where a few facilities in China and India account for more than 10% of all products listed in that region. Although the numbers reflect the number of products manufactured, not volume, the number of products is one of the risk factors FDA considers in prioritizing surveillance inspections.

5. **Sites Making “Non-Application” Products Consistently Underperform.** When looking at data across geographies, FDA notes that sites manufacturing “non-application” products, including OTC products, homeopathic, and unapproved drug, “consistently underperform” sites that make application products (e.g., new drug applications (NDAs) and abbreviated new drug applications (ANDAs)). This trend likely has informed FDA’s continued enforcement against manufacturers of homeopathic products, including a recent batch of Warning Letters to multiple companies for violations of cGMP requirements.
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