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Third-party ingredient verification key for drug supply chain

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The last few decades have been defined by a series of disruptions to the global drug supply chain, and the industry continues to be complex and vulnerable. Many intermediaries play a role in drugs' production, distribution, and delivery with companies from several different regions collaborating to develop one product.

For example, almost a third of the world's active pharmaceutical ingredients (APIs) are manufactured in India or China. Country of origin and supply chain complexities are two major external risk factors for manufacturers working to produce quality drug products and ingredients.

Other external risk factors include material value and economic motivation for adulteration, the reputation of manufacturers and distributors, and transportation practices. Internal factors can also increase risk, including source of material, amount and type of processing, lack of or failure to comply with compendial standards, complexity of material, and product variability due to season or temperature conditions. However, while disruption to the supply chain can be a threat to drug development, it does not have to mean compromising the quality of your APIs.

One major disruptor today is the COVID-19 pandemic. Manufacturers have had to streamline and simplify operations, which, in some cases, may come at a cost to ingredient quality. Companies are trying to build their capacity to keep up with increasing demand, while also navigating operational changes due to safety concerns, such as decreased staff on the manufacturing floor and forgoing on-site audits.

Additionally, high demand for certain ingredients and products are causing shortages and consequential surges in production of said ingredients or products. These ongoing shortages have increased the need for generics, resulting in accelerated approvals by the U.S Food and Drug Administration (FDA) and the lifting of existing import alerts. While shortages are worrisome, so are surges, materials coming from new suppliers to combat shortages may lack quality.

For instance, with the US government and certain EU countries raising concern over the quality of medical supplies, China

has responded by imposing new certification and inspection requirements on surgical face masks, testing kits, and thermometers.

But supply chain risk factors impacted drug-product manufacturers before the pandemic. In 2019, many of the FDA's warning letter citations were related to product testing, followed by a lack of data integrity and major equipment failures surrounding cleaning and maintenance.

Additionally, from 2001 through September 2007, the FDA reported more than 1,984 recalls, which are most often caused by contamination, mislabeling, adverse reaction, defective product, and incorrect potency. For example, in the past few years, N-nitrosodimethylamine (NDMA) has been found above the FDA's acceptable daily limit in multiple drug products.

According to the FDA, from May 25, 2020 to August 18, 2020, 102 metformin products, a drug used by 120 million people in the world who are living with diabetes to control high blood sugar, were recalled due to NDMA contamination. Some of these recalls were manufactured in different regions around the world including China and India. Product recalls, whether voluntary or involuntary, have severe financial and reputational consequences for drug-product manufacturers.

At the end of the day, it is the drug product manufacturer's responsibility to mitigate risks and prevent them from compromising the quality of the final product. Third-party quality verification programmes can help drug product manufacturers reduce the risk of inconsistent, substandard quality ingredients by helping them to qualify their ingredient suppliers and verify results on the ingredient suppliers' or contract manufacturing organizations' certificates of analysis (COAs).

By working with an independent scientific organization, manufacturers can help build trust that good manufacturing practices (GMP) and product quality standards are being met. As the drug supply chain continues to become more complex, prioritizing quality of ingredients through third-party verification is more important than ever before.

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