

The role of safety monitoring to detect manufacturing quality issues

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In the early days of vaccine development, it was often manufacturing quality defects such as the well-known Cutter incident with the first polio vaccine or the hepatitis contamination of yellow fever vaccines that led to safety issues with vaccines. Over the last decades, scientific efforts to monitor the safety of vaccines have focused on hypotheses that were largely driven by public concerns regarding diseases with unclear etiology such as autism or multiple sclerosis. However, the recent contamination of heparin products has raised attention again to the importance of keeping manufacturing quality in mind when monitoring potential adverse reactions.

For any vaccine, product quality is primarily ensured through a rigorous set of quality controls of all batches before they are released for distribution. Following the distribution, the quality of a vaccine is further monitored by collecting and analysing so-called product complaints. The safety of a vaccine, on the other hand, is measured first in a set of clinical trials before the product is authorised for marketing. Once a vaccine is licensed, its safety is further monitored through a combination of activities, one of which is the collection and analysis of spontaneous reports of adverse events.

At GSK Biologicals, a systematic comparison is made between the information collected through the product quality channel (product complaints) and the information collected through the pharmacovigilance channel (adverse event reports). The teams in charge of the respective data meet frequently to exchange information on observed signals and to monitor whether any quality signals or safety signals are potentially linked to each other. In addition, the pharmacovigilance team runs periodic disproportionality analyses to identify batches with an unexpectedly high proportion of adverse events.

Thus far this system of checking and double-checking has not identified any manufacturing defects or safety concerns.

During the panel discussions, participants will further debate and answer questions on the added value of such a labour-intensive system in detecting manufacturing or safety concerns, beyond the mechanisms that are already in place to monitor the quality and safety of vaccines.