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## PHARMACEUTICAL REGULATORY AFFAIRS AND IPR

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Good supply practices: Why are we still vulnerable?

Troy Fugate

Compliance Insight, Inc., USA

Toxic Cough Syrup in Panama: In 2007, when 4-year old Allan Gutierrez died, the symptoms that he displayed baffled Doctors. Severe nausea, violent heart palpitations and paralysis were among the issues noted that eventually lead to at least 365 confirmed deaths. At first, the investigation was difficult, but eventually it was discovered that the imported diethylene glycol used in the medicine was originally named TD glycerin, which apparently indicates that it is a glycerin substitute. The fatal ingredient originated in China. It was shipped to a Spanish company and then on to a private company, Medicom, in Panama. Medicom resold it to the country's Social Security system, which mixed the medicine in its laboratory. Thought Panamanians they were getting glycerin, a component of many medicines. The poisonings seem to be a confluence of confusion over labeling and sloppy controls along the supply chain. Why then did this event happen when we have FDA or other regulations in place along with Quality by Design concepts, Operational Excellence, Supplier Relationship Management, etc.? Thus, in 2012, a group of academia, industry and regulatory colleagues met to identify the actual problem and resolve the issues. Initially focusing on the suppliers only, it became evident that various factors were at risk across the entire supply chain including the finished manufacturers. After five years, the Xavier Health initiative has evolved to the feasibility stage and is nearing completion with adoption considerations by several regulatory bodies.

TFugate@Compliance-Insight.com