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Topco Pharmaservices, Inc.: Quality Improvement in the Clinical Supply Outsourcing Process

On a Monday afternoon in 2017, Jennie Wren and Sydney Carton looked at each other and breathed a sigh of relief. Their presentation on Statistical Process Control (SPC) to Sarah Gamp, supply chain quality assurance manager in the Clinical Supply division of Topco Pharmaservices, had gone well.

Gamp had requested a comprehensive analysis of Topco's error-prone documentation process for outsourcing the manufacture of clinical drugs. To address her request, Wren and Carton, students at the University of Michigan's Ross School of Business, had spent their summer internship at Topco's offices in Cambridge, MA, poring over thousands of documentation records and conducting dozens of employee interviews to determine the root causes behind the errors plaguing Topco's documentation process.

Their presentation convinced Gamp that Topco's documentation process for outsourcing clinical drug manufacture was indeed experiencing high rates of errors and corrective rework and was, therefore, in need of a fix. SPC was certainly an option, but Gamp decided to lead a team—including Wren and Carton—to determine a recommended action plan. She really didn't have much choice; Stephen Blackpool, vice president of the Clinical Supply division, wanted a list of recommended solutions by the beginning of next week. So Gamp needed to find out quickly whether SPC was the solution, and if so, how it should be implemented within Topco.

Topco Background

Topco Pharmaservices was one of the largest pharmaceutical contract services companies in the US with 2017 revenues in excess of $4 billion (US) and over 1,000 people employed worldwide. In 2015, Topco was formed as a carve-out of Ultiver Pharmaceuticals. Facing pressure to develop new drugs as efficiently as possible to offset revenue losses from the patent expirations of existing drugs, Ultiver had drastically streamlined its clinical trial processes to try to bring its pipeline of drugs to market as quickly and efficiently as possible. However, after several late-phase drugs were terminated due to unanticipated side effects, Ultiver was in trouble by late 2014. Yet Ultiver had managed to achieve some efficiency in running clinical

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