

A Systematic Approach to Investigations Yields Rapid Results

Pharmaceutical

CLIENT

This global biopharmaceutical company manufactures prescription pharmaceuticals in several therapeutic areas. The plant implementing this initiative produces solid and injectable pharmaceutical products.

CHALLENGE

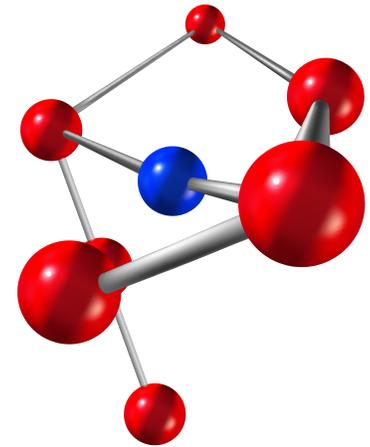
Although operating in an FDA-regulated environment, this pharmaceutical products plant did not have a standard, systematic approach to finding the root cause of manufacturing deviations. In fact, engineers and scientists often relied on trial and error approaches that led to unnecessary investigations, lengthened investigations, or created recurrences of deviations because true cause was not found and corrected.

RESPONSE

Site managers believed that a formal methodology for investigations would reduce the number of investigations, accelerate investigations, and improve results. After a rigorous evaluation, a decision was made to implement the Kepner-Tregoe (KT) investigation methodology because it accelerated troubleshooting, provided superior documentation, and ensured accuracy. Site managers developed implementation plans around four major actions:

1. *Create investigation teams based on the type of operation:* To help structure the investigation process, teams were formalized and roles and responsibilities were defined.
2. *Redefine investigations according to specific criteria.* To better focus efforts on critical deviations, site managers defined higher impact events that required use of KT methods.
3. *Implement the KT program as the methodology for investigations.* A training program introduced all employees to KT problem solving and developed KT problem solving and decision making skills in investigations teams. Two employees were trained as instructors and facilitators. SOPs that incorporate the KT methods were created for documentation of all investigations.
4. *Define business goals for performance.* Two goals guided the initiative:
1.) Perform manufacturing investigations in 30 days or less; 2.) Reduce the number of investigations by 20%.

(continued)



Scorecard

- Within a year, a plan was developed and implemented that:
- Reduced required investigations by 33%
- Integrated a systematic, well-documented approach to investigations
- Built confidence in the abilities of investigations teams— as expressed by the team members themselves and by plant management

RESULTS

The work plan to improve the investigation process and incorporate KT as the investigation methodology was completely developed and implemented in less than six months. Within one year, management and investigations teams reported new confidence in their ability to conduct investigations quickly and accurately. Comparing year-to-year, the number of investigations fell by 33% and open investigations dropped 13%. As a result of these successes, Investigation teams are more focused and disciplined, and systematic KT approaches have been integrated into other business functions to facilitate concerns and critical decision-making.