Accidental contamination

The situation
The quality manager of a dry ingredient company received a notice from the company's contracted independent laboratory stating that presumptive salmonella had been found in a sample during a routine microbial testing on a production lot. The quality manager notified the plant manager of the matter and they directed the laboratory to complete the confirmation test for salmonella. Products produced from the lot in question had already been shipped to customers who had used the dry ingredients to make their finished products. The plant manager therefore immediately notified the customers to hold off utilising and distributing the suspected lot of dry ingredient and any finished products manufactured using the lot.

The laboratory report came back two days later confirming the lot was contaminated with salmonella. The company determined that they needed to contain two additional product lots as a result of this information. The company notified the US Food and Drug Administration (FDA) and reported the details for the recall on the Reportable Food Registry. Two FDA inspectors arrived at the plant the next day to begin their investigation.

Assistance
A red24assist consultant instructed the client to confirm with the independent laboratory if it was using positive and negative controls for its salmonella tests. The laboratory confirmed that it used both.

red24assist requested that the remainder of the production lot sample be sent to a different laboratory for salmonella testing as it was possible that the contamination occurred at the laboratory. The consultant also advised the client to have the samples analysed for DNA to determine the serotype of salmonella. Finally, the consultant advised the client to maintain the samples with chain of custody documentation.

The contracted laboratory used salmonella typhimurium as its positive control which is a very common strain. The finished product handled by the laboratory was found to contain the same strain of salmonella.

The company was able to prove to the FDA that its product was not contaminated with salmonella prior to going to the laboratory and that the laboratory was the cause of cross-contamination with its samples. The finished products using these lots of alleged contaminated dry ingredients had to be disposed of. The company was able to put the contracted laboratory on notice for the value of the product lost in the claim. red24assist's consultant provided the company with documentation to use in support of the alleged laboratory cross-contamination of its samples resulting in the recall.