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Training as a corrective action

by Donnetta Horseman

Compliance investigations often result in the need for a corrective and preventative action plan (CAPA). Training, or re-training in many cases, is a core component of an effective CAPA. Training content, method of delivery, how it is documented, and expected results will vary depending on the nature and outcome of the investigation.

Training content

Did the investigation identify an internal policy violation or a regulatory/legal violation? What was the violation's impact? Are there notification obligations? What are the consequences of the violation to the organization or the individuals involved? Another key question is whether the involved individual(s) should have had the knowledge/information that would have prevented the violation. Was the violation a failure of the individual or a failure of the organization to properly train on that topic? The answers to these questions will dictate whether you should approach this as a comprehensive initial training versus a refresher training.

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