



CAPA Solution Highlights

- Web-based submission of CAPA requests.
- Integrated solution for corrective, preventive and continuous improvement requests.
- Early review of request to determine validity as a CAPA.
- Immediate prioritization and backlog management.
- Detailed root cause management and action planning.
- Formal review of proposed action plans.
- Tracking of individual actions and verification of effectiveness.
- Optional long term verification and follow-on actions.
- Workflow-driven due dates and reminders based upon the overall schedule.
- Flexible search of CAPA's.
- Integrated storage of requests, documents, evidence, results, verification data and markups.
- Up-to-date charts/reports of status and trends.

Background Information

Requestor	rschmitz	Source Type	Nonconforming Material
Request Date	8/15/2003	Source Info	Nitrofurran Raw Material
Affected Department	Quality	Follow-on To CAPA	N/A

CAPA Description

Description of Problem, Concern, Idea, or Opportunity

QA receipt of Nitrofurran raw material resulted in an FTIR spectrum which did not meet Quality Assurance control spectrum peak values. QA control peak values for the raw material are as follows: 1200, 1800, 1650 and 650. Spectrum values for received lot #1234 were recorded as follows: 1200, 1880, 1650 and 650. The value at 1880 is out of specification for the control tolerance of +/- 50 units.

Articles Affected by Problem, Concern, Idea or Opportunity

Article Type	Article ID	Article Revision	Serial Number	Lot Number	Supplier ID
No affected articles identified.					

Solution Plan

Root Cause	FTIR lens was dirty during testing. A dirty lens can cause false spectrum peaks. Operators are instructed to clean the FTIR lens prior to sample placement, this was not done.				
Corrective Action	Change procedure to use a new lens prior to each tested sample instead of having the operator clean after each use.	rschmitz	8/30/2003		
Corrective Action	Retrain all operators on new procedure.	rschmitz	9/15/2003		
Corrective Action	Nitrofurran batch on hold must be tested to an AQL of 0.25 (see ANSI/ISO Z1.4 for sample plan) before release. 10 samples of batch #1234 must be tested with no spectrum failures for identification.	rschmitz	9/30/2003		

Screen Capture: CAPA Solution