



## Complaint Handling Solution Highlights

- Web-based submission of issues.
- Review of issues to determine proper disposition: CAPA, complaint, log as an issue.
- Automated links between issues, CAPA's and complaints.
- Flexible investigation workflow with activity log of research, evidence and data.
- Tracking of reporting tasks and timelines.
- Electronic creation of reports using Word templates.
- Site defined coding/customer parameters for complaints.
- Charts, reports and trends generated based upon coding values.
- Workflow-driven due dates and reminders based upon the overall schedule.
- Flexible search of complaints and issues.
- Integrated storage of issues, complaints, documents, evidence, results, findings and reports.

Failure/Malfunction Code

Type of Reportable Event

Type of Follow-up Report

### Research Tasks

Instructions	Status	Assignee	Task Due Date
Check to see if other products are experiencing the same problem	In Progress	jvey	11/28/2003

### Activity Log

Description	File Name	Date Created	Created By	Date Last Updated	Updated By
called a couple of patients. They expressed similar concerns. Seems to be a widespread and unanimous problem.		11/26/2003 6:24:01 PM	rschmitz	11/26/2003 6:24:01 PM	rschmitz
Reviewed the current patient info that we provide as a manufacturer. It is not written for patients.		11/26/2003 6:24:53 PM	rschmitz	11/26/2003 6:24:53 PM	rschmitz
Checked with a couple of health care facilities. They generally do not provide any info about the overall patient problem and solution for use when the patient goes home. Hence, I can confirm that there is a information void once the patient leaves the hospital.		11/26/2003 6:26:15 PM	rschmitz	11/26/2003 6:26:15 PM	rschmitz
Talked to clinic at Health East. They have a nice brochure for Big Dude Competitor that they give to all patients of this procedure.		12/2/2003 5:10:48 PM	rschmitz	12/2/2003 5:10:48 PM	rschmitz

### Regulatory Reporting by Zone

Reporting Zone	Reportable Event?	Initial Reporting Due Date	Initial Reporting Status	Initial Forms Submitted Date	Followup Forms Submitted Date
Info United States	No	N/A	Complete	N/A	N/A
Info European Union	No	N/A	Complete	N/A	N/A

Screen Capture: Complaint Handling Solution