



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.

View Entity - Microsoft Internet Explorer
Address: http://thelaptop/GrandAvenue/Core/Info/ViewEntity.aspx?EntityID=38&EntityType=ProductComplaint

Failure/Malfunction Code: No Failure/Malfunction
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 | jwey | 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