CALIFORNIA STATE UNIVERSITY SAN MARCOS

PROJECT SIGNATURE PAGE

PROJECT SUBMITTED IN PARTIAL FULLFILLMENT OF THE REQUIREMENTS FOR THE DEGREE

MASTER OF SCIENCE

IN

BIOTECHNOLOGY

PROJECT TITLE: INCREASING EFFICIENCY IN COMPLAINT HANDLING BY STANDARDIZED REPORTING OF INVESTIGATIONS

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THE PROJECT HAS BEEN ACCEPTED BY THE PROJECT COMMITTEE IN PARTIAL FULLFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE IN BIOTECHNOLOGY.

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Executive Summary
Increasing Efficiency in Complaint Handling by Standardized Reporting of Investigations
CCR Company
Denisse Reyes
May 14, 2014
Professional Science Master in Biotechnology, PSMBt

A complaint is an expression of dissatisfaction made to a company in relation to their products or services where a response is expected. Efficiency in responding to customer complaints is essential in the biotechnology industry. The Semester-in-Residency Project was conducted at CCR Company. CCR Company is a company located in San Diego County that manufactures in-vitro diagnostic products such as quality controls, calibrators, calibration verifiers and reagents used for laboratory instruments. The majority of these products are purchased by medical laboratories to ensure that their instruments are functioning properly. Taking action to correct any issues with these products is crucial before they affect the interpretation of patients’ test results. Ensuring that an instrument is functioning properly reduces the risk of obtaining false results. The delivery of satisfactory products, free from all mistakes, is a difficult goal to achieve. The purpose of this project was to implement a standardized reporting system for investigations and to decrease resolution time for complaints received at CCR Company. In order to accomplish this, a Complaint Investigation Report template that organized and clarified the steps taken to investigate and resolve complaints was developed. This report was implemented for all complaints received from November 1st, 2013 to February 28th, 2014. The implementation of the report showed a reduction in resolution time. The average resolution time decreased from 49.6 days in the time-frame from November 2012 to February 2013 to 42 days in the time-frame November 2013 to February 2014 when the report was implemented. Customer satisfaction records were also examined with the assumption that they are impacted by the resolution time of a complaint. If a complaint investigation is handled in an efficient timely manner, it is likely that the customer will be more satisfied with the outcome than when a complaint resolution time is long. The Complaint Investigation Report was also used to provide customers with a summary of the investigation for their complaint. A plan for the report is to make it an official fill-in document that CCR’s personnel can use to document complaint investigations.
Increasing Efficiency in Complaint Handling by Standardized Reporting of Investigations

Denisse Reyes
CCR Company
California State University San Marcos
Professional Science Master in Biotechnology, PSMBt
Located in San Diego county

Manufactures in–vitro diagnostic products
  ◦ Controls
  ◦ Calibrators
  ◦ Calibration verifiers
  ◦ Reagents

Ensure that laboratory instruments are functioning properly.

It is crucial that any issues are reported to manufacturer before they directly affect patient test results.
Overview of Presentation

- Background
- Purpose of Project
- Description of Project
- Methods
- Report Template
- Example of Report
- Results
- Discussion and Conclusion
- Future Direction
Customer satisfaction is a measure of how products and services supplied by a company meet or surpass customer expectation.
When the first complaint a customer makes is handled appropriately and resolved in a timely manner, it is likely that the customer will continue to make future purchases.
Companies need to have a standardized system for documenting, managing, and responding to customer inquiries and complaints.

**Steps in Complaints Handling**

1. Assess community preferences to design methods of complaints handling
2. Design guidelines and process for complaints handling based on community input and program resources
3. Sensitize community on complaints handling process
4. Train staff on complaints handling process
5. Finalize development of complaints handling process (roles, procurement, reporting, etc)
6. Receive feedback on complaints

7. Enter complaints into a complaints register with a plan for investigation
8. Investigate complaints
9. Respond to complaints based on the findings of the investigation
10. Track trends in complaints received and report these regularly to management
11. Review trends in complaints and response with management and make necessary program adjustments
12. Review effectiveness of complaints methods and make adjustments
The purpose of this project was to implement standardized reporting for investigations.

- Reduce complaint resolution time.
- Increase customer satisfaction.

Assumptions:
- Complaint Resolution time has an impact on customer satisfaction.
- Equal number of complaints would be received during the same months.
Methods

- Develop a Complaint Investigation Report Template.

- Implement Complaint Investigation Report to all complaints received during the November 2013–February 2014 time period.

- Calculated the resolution time of complaints where report was used and compare to the prior year.
  - November 1\textsuperscript{st}, 2013 – February 28\textsuperscript{th}, 2014 vs November 1\textsuperscript{st}, 2012 – February 29\textsuperscript{th}, 2013

- Customer satisfaction records were examined.
CCR Company

123 Main Street
San Marcos, CA 92078
Complaint Investigation Report
Empty Bottle Received in Kit
Complaint #1455

Report developed by:
Denisse Reyes
Empty Bottle Received in Kit

Complaint Investigation Process at CCR Company

- Define
- Measure
- Analyze
- Improve
- Control
Empty Bottle Received in Kit

1. Description of Complaint

Technical service specialist received a call from a customer stating they received a kit that contained an empty bottle of product for part number 1234 lot 147H852. ISS was informed that there were no visible cracks, splits, or leaks on either the bottle or the cap and that both the bottle and cap were intact. Customer is requesting a replacement kit.

Customer Name: John Smith Laboratories
7425 Elm Street Suite 210
Los Angeles, CA 90262

Product Part Number: 1234
Lot Number: 147H852
Empty Bottle Received in Kit

2. Complaint Investigation
   a. Document Review
      Review of the batch record showed that the bottles were filled using XYZ instrument. The target fill volume for each bottle is 5mL. All fill volume checks were within specification. All torque checks of the cap met the specifications. No non-conformities were observed during the fill.

      A total of 1 reported empty bottle out of the 1,000 filled results in 0.001% being affected.

   b. QC testing/Return Product Inspection
      Technical services requested the empty bottle to be returned to CCR. The customer stated that the empty bottle had been disposed of. Once again, customer stated that there were no visible cracks, spills, or leaks that were observed and both the bottle and the cap were intact.

      Bottle used in this product is part number 753.
      Cap used in this product is part number 159.

   c. Confirmed/Not Confirmed
      Issue is not able to be evaluated as the empty bottle was not returned to CCR.
Empty Bottle Received in Kit

3. Complaint History
   Review of the last 500 complaints received by CCR showed that there have not been any related issues where customer received an empty bottle of product using bottle part number 753. This is the first complaint received by CCR regarding an empty bottle in kit using the bottle part number 753 and cap part number 159.

4. Root Cause
   A definite root cause is unknown at this time. Customer stated that there were no visible cracks, spill, or leaks. Vial was asked to be returned to CCR but customer had disposed of it. It is difficult to determine if the bottle was not filled during filling process or if it leaked during shipment. An amount of 1 empty bottle out of the 1,000 bottles filled for lot 1478852 results in 0.001% being affected. A root cause is not able to be determined at this frequency.

5. Proposed Corrections
   Send replacement kit to customer.

6. Verification of Correction
   Replacement kit was received by customer. See shipping/tracking sheet in complaint folder.

7. Customer satisfaction
   Customer is satisfied to have received the replacement kit.

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8. Closure
   Issue will continue to be monitored via CCR’s complaint database.
The number of complaint received per month during the Nov. 2013–Feb. 2014 time frame increased when compared to Nov. 2012–Feb. 2013.
The average complaint resolution time decreased during the time period when the Investigation Report was implemented.
Customer satisfaction showed decreased when the Complaint Investigation Report was implemented.
Assumption that the same number of complaints would be received during the November 1, 2012 – February 29, 2013 and November 1, 2013 – February 28, 2014 was proven incorrect.

- Increase in number of complaints (Nov. 2013–Feb. 2014).
  - 21 complaints vs 16 complaints received prior year.
    - Increase in number of products manufactured.
    - Company’s expansion

Complaint resolution time decreased

- 49.6 $\pm$ 85.46 days (Nov. ‘12–Feb.’13) vs 42.0 $\pm$ 29.22 days (Nov. ‘13–Feb.’14).

Customer satisfaction increased

- 12 complaints were still undergoing investigation.
- 5 complaints in the Nov. ‘12–Feb.’13 timeframe were customer satisfaction was listed as ‘other.’
Conclusion

- Cannot yet be determined if the report had a direct impact on the resolution time of the complaints.
  - Need to collect data for a longer period of time.

- Cannot yet conclude that report had an impact in customer satisfaction.
  - 12 complaints were still undergoing investigation.

- Allowed CCR Company to provide customers with efficient resolutions for their complaints.

- Allowed CCR Company to provide customers with a summary of the investigation performed for their complaint.

- Will allow CCR Company to use report to show auditors how complaints were handled.
Future Direction for Complaint Investigation Report

- Allow for reference of prior complaints

- Effective “fill-in” document
  - Standard Operating Procedure

- Continue to monitor resolution times for complaints.
  - Need a longer period of time to determine the impact of the report.