

Acknowledgements

I would like to say thanks...

...To my parents for having made it possible for me to pursue my first degree and hence everything else that followed.

...To Christina for her support, friendship and encouragement.

...To Herb Tuttle for all the advice he's given me so far and for all the future advice I'll seek.

...To my employer for having paid for this degree.

Confidentiality Notice

Due to the competitive environment in which consumer goods companies operate and the nature of the topic being discussed it was decided to protect the name of the company where this project was developed.

From this point on the company will be referred to solely as “the company”.

Any screen shots of the application which reveal confidential data or the names of products will be partially or fully covered. Any data that may remain displayed is solely for illustrative purposes only and is not to be assumed to be accurate.

Abstract

Consumer complaints are an important indicator of the perception of a product by consumers. It is also in some instances a regulatory requirement that such systems are in place. For those two reasons it is very important to have an effective system to track and analyze this type of information.

The company uses an application called CRS to enter data at the call centers. However, this software is limited in its internal data analysis capabilities. For that reason the raw data from this software is used to externally create reports.

Due to the nature of the complaint data and the output from CRS the process is highly involved and manual in nature. It can take 2-4 days of work by one of the Quality Engineers to generate a report for a particular manufacturing site (there are 4 major sites in North America).

It is the intent of this project to improve the process of creating the consumer complaint reports by using a relational database to import the data and then manipulate it to create the reports.

Executive Summary:

As stated in the Project Goal Statement, the goal of this project was to “significantly reduce the time being spent by the quality engineers generating consumer complaint reports by:

- 1) Automating the import of raw data into the application.
- 2) Providing a “single click” standard monthly report.
- 3) Providing the ability to choose different combinations of data and how it should be displayed.”

The three objectives of the project were successfully met.

In the first goal to the import of raw data, the application is able to open and read the 13 month consumer complaint files and directly import all the required data instead of manually transcribing. The production data is just as easily imported from a two column file containing the product designation and production numbers.

The implementation of the “single click” report was overall successful and exceeded expectations with regard to the flexibility of creating reports. The initial proposal had suggested a standard report to be used by all sites but in the process of developing the report it was found that it would be more advantageous to build in flexibility. This allows for the reports to be created by the users by selecting certain criteria and saving each set of criteria as individual components of the report. A welcome consequence of this approach is that it would also “future-proof” the application should the reporting needs were to change, eliminating the possible need and added expense of programming new reports.

The ability of choosing any and whichever combination of data to be displayed, totalized, broken down, etc. was fully implemented. Again, this goal was exceeded by the addition of “Product Categories/Families” which an extra to the original proposal. This function allows the user to subgroup products within a focus factory.

Validation/Verification

The application has been validated following the guidelines of the corporate software validation template to perform as designed per the Main Functions & Implementation Summary. Supporting evidence is included in the validation appendix.

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1) Introduction

This section will give the reader some background on the Consumer Complaint reporting process, introduce the problem and give justification to the proposed solution.

1.1) Background

The company is a global consumer goods manufacturer with major manufacturing sites in the US and many others overseas. As part of regulatory compliance as well as good manufacturing practice, the company has systems in place to collect consumer complaint information.

In the packaging of each product made the company has placed a phone number that consumers can call to provide feedback about the products. The type of feedback may range from positive to negative and can be categorized into areas such as packaging, product performance, personal preference, personal injury, adverse reaction, etc.

At the call centre the operators log the call in an application named CRS. This application is in turn used to follow up on the case and store data. The application itself is deficient in regards to using the data it collects to generate reports. Its capabilities are generally limited to outputting the data. For that reason the data output from CRS is then manipulated to create useful reports showing rates, trends, particular complaints or products.

Consumer complaint reporting is usually done on a monthly, quarterly and yearly basis. This is done across all multiple manufacturing sites and corporate offices. Two different types of information are needed to calculate the complaint rate: 1) the consumer complaint data from CRS and 2) the production data that can come from a variety of sources.

Currently both sets of data are manually entered into a MS Excel workbook and by the use of multiple tabs gets filtered. After extensive manual manipulation this process yields the data that is to be used for some of the reports. If the data being requested changed or a different analysis is required the spreadsheet template becomes of little help and a new set of tabs would have to be created to extract the necessary data. From this data a report is created and issued. The whole process can take up to 3-4 days worth of work to complete due to its highly manual nature.

The typical data for the monthly reports includes:

- Top 10 complaints for the last year by product
- Top 10 complaint for the last year by type
- Year to date and monthly complaint totals & rates
- Year to date and monthly complaints by product and/or type
- 12 month trend charts (absolute and rate)
- Individual charts for “new products” (that is products for which the first complaint received is less than 6 months old of the product has been in

production less that 9 months) so that they can be separately tracked in the critical first few months in the market

The current process takes up to 3-4 days to complete. Since a great part of the time is now spent transcribing data between CRS output and excel files, automating the import will be a vital part of improving the process. Then, the next step of analyzing the data is cumbersome at best with the current tool (MS Excel) and quite time consuming if a new or different way to look at the data is needed.

1.2) Project Goal Statement

The goal of this project is to significantly reduce the time being spent by the quality engineers generating consumer complaint reports by:

- 1) Automating the import of raw data into the application.
- 2) Providing a “single click” standard monthly report.
- 3) Providing the ability to choose different combinations of data and how it should be displayed.

The objectives above can be easily met by using a relational database such as MS Access to develop a software application. This off the shelf database software has enough functionality to provide all the required functionality as well as being already installed in most user PC's in the company.

With this application the time spent each month on consumer complaints would be reduced from days to hours for a similar end result (there are 4 people currently in charge of this type of reporting, with a conservative estimate of 16 hours savings times 4 people gives 64 hours or about one and a half week worth of one person's time each month). With the time saved and greater data analysis capability, the quality engineers would be able to do a more in-depth analysis of Consumer Complaints or use the extra free time to tend to other priorities.

This project would benefit all of the facilities that work with consumer complaint data based on the CRS system reports. The scope of this project was limited to the North American division and mainly the USA only given the relatively low number of complaints received in Canada. In all, the project is based on the needs of the 4 main North American plants. However, it is likely that other sites overseas will also benefit since the use of CRS for complaint data collection is the corporate standard.

In summary, the project will consist of managing the development of an MS Access application that can meet the needs stated above as well as a plan for deployment and maintenance (or Quality terms, change/revision control).

The majority of the actual software programming will be bided out to a consultant.

1.3) Project Conceptual Description

The inputs for creating monthly consumer complaint reports consist of consumer complaint data captured in CRS by the Consumer Affairs Department and production data from the plants.

The different plants may house different product categories (bar soap, underarm products, toothpaste, detergents, shaving products, etc.). Within the category there are different product formulas and each formula can have different packaging or units of sale. For example: Product A is sold as a 3oz, 6oz and 8oz package. When dealing with consumer complaints ALL Product A will be put in the same group so that the numbers presented are for the aggregate of all complaints and production for that formula. In other words, complaint data will be formula specific and size/package independent.

Currently there is no standard report used for production reporting and each plant has its own way of extracting the data. For the purpose of this project it can be assumed that there will be a simple, standardized report in csv format that will be used for the importing production data into the application. The first column will contain the production and the second column the number of unit sales.

The consumer complaint data is provided to the Quality Engineers at the plants on a monthly basis by the New York office. The engineers receive a file for each product category produced at the plant. The file has columns for 13 months of data. The numbers provided in this file correspond to the number of calls or complaints of a specific type filed against a product formula. Each type of complaint received in the rolling 13 months against a particular formula is listed. Each type of complaint has a specific complaint code.

The complaint code is a text field composed of a complaint category code, a space, and then a short detail to the specific of the complaint. I.e. “CPK Leaking” stands for packaging problems and the detail is “leaking”; under packaging problems you could also have “Broken Cap”.

The product formula names used in the consumer complaint data are not the same as those used for production reporting so the application must be able to match both names (with user input).

Once the application has imported all the required data, both historical and current, it must be able to provide the users with a way of readily retrieve the data in whichever way the user so desires. For example, broken out by product by date, or total rate over a period of time.

Of course, the application must have error trapping features that will prevent to the best extent possible from making mistakes that would damage the integrity of the data.

1.4) Project Viability

The company culture is very conservative and not technologically oriented hence it was very important to be able to demonstrate to management what a relational database could do for the whole process.

So, the starting point in this project was to prove that the idea could work and was worth pursuing. In order to achieve this two simple MS Access files were created, one that showed how data can be filtered using simple selection of options in a Graphical User Interface and the other that demonstrated how the CRS output files could be successfully imported into a second application.

This achieved two things:

- 1) It proved that this idea could be done
- 2) Quickly convinced management that funding this application could be a worthwhile investment

1.5) Project Bidding

After demonstrating the viability of the project, management requested to obtain quotes for the development of the complete application.

In order to bid out the project, it first had to be defined. A project description was drafted and submitted for review to the Quality engineers who would use the software.

Since the project was being developed and managed from Kansas City it was determined that it could prove advantageous to work with a local company. After inquiry with the local IT department it was found that the local site had not used outside developing services in many years and hence could not provide any recommendations for a developer.

The next logical place to look was the yellow pages using the biggest add approach (find the largest adds, read to see if they offer the desired services and call). A larger add costs more money and so it usually correlates well with bigger, well established companies.

The first three companies contacted were interested and appointments were made for site visit to discuss the project needs. Below is a summary of the three developing companies:

Developer A

Pros:

Well established IT company with solid credentials.
Knowledgeable sales person.
Seem focused on project management.

Cons:

Expensive
Unwilling to bid for a finished project. Their contracts are per hour worked and if budget is running short functionality may be cut to meet budget.

Developer B

Pros:

Competitive price, willing to commit to a finished application

Cons:

They contract their work to a developer for hire. That means that once the project is done the individual who did the work may no longer be available to do updates or corrections should bugs be found later.

Developer C

Pros

The owners came to the meeting (small company). Both are programmers themselves so quickly understood the technical needs.

Competitive price.

Committed to a finished project

Even though they may contract part of the work, the permanent staff is ultimately accountable for the finished product.

Cons

Somewhat lacking project management experience.

Hard to judge overall performance for the project.

Ultimately Developer C was chosen to do the work. Their bid was the same as Developer B and about 30% less than Developer A. An additional factor in the selection of Developer C was that they seemed to be the most flexible of the three. Developer A's contracts are such that give them more leverage. Developer B would contract out and disband so it would be hard to push for any changes. Developer C is a small business interested in making a good impression and obtaining the job hence being more likely to go the extra mile. The risk being that a lack of project management could hurt the project.

2.0) Literature Review

TO BE FINISHED

“Special Edition Using Microsoft Access 2000”; Roger Jennings; 2000.

This is a good intro book to MS Access concepts. It has many step by step examples and is a good starting point.

“Mastering Microsoft Access 2002 Desktop Development”; Allison Balter; 2001.

This book starts from the basics but picks up pace rather quickly and teaches the reader higher level concepts that are not usually covered in introductory books. It does a great job of showing how to use the built in Visual Basic development environment to fully utilize the capabilities of the software.

“Development of a Relational Database Application Prototype for a Mail-Order Auction”; Ross Schaller; 2003.

This EMGT field project is about the development and design of a database application. The similarity in the goal of the project made it a good reference on how to structure the field project report.

From the web:

“General Principles of Software Validation; Final Guidance for Industry and FDA Staff”; US Food and Drug Administration, 2002.

This document is a guide for validating software to be used in medical devices or their manufacture. The company does not have any such products but does have some that do fall under FDA regulations. However, even though none of those products come close to requiring the level detail of medical devices, they do have to conform to fairly strict regulations. The FDA does not have a guidance for “less strict” products so it is really up to each company to come up with a compliance strategy.

Internal Company Documents:

“Validation Master Plan Template”; 2004.

This document outlines the general validation strategy for IT projects for the North American Division. It is a fairly new document and this field project is only the 5th to make use of this template. The risk assessment worksheet is an attachment to this document and can be found on the appendix.

“XXXX Calibration Module Implementation”; 2004.

This document is the final validation report for the implementation of the calibration component part of an enterprise system. The “screenshot” approach is widely used in this report. Other principles of the company’s validation strategy are also used here (although for the purposes of this field project the validation is not as stringent). (The XXXX protects the name of the software package in use)

3.0) Main Functions and Implementation Summary

Complaint data import function

Requirements:

- 1) The application must be able to import from the consumer complaint data file for any given timeframe.
 - a. The user will specify the start and end date
 - b. The application will check that no previous data exists for that timeframe and alarm the user.
 - c. The application will check that the number of months specified by the user match the number of months in the data file.

Implementation:

The user will select the file and open it in the application in a manner that is ready for import. The user can then select which months will be imported.

While importing the application will check that the data being imported does not already exist in the database. In other words, old data that may not be overwritten but new may be appended.

There is no need to check for a given number of months due to the way the application imports the data.

- 2) The application will be able to determine new products and complaints from the imported data and add it to its database.
 - a. The application will set a 12 month flag for this data (see Reporting Requirements)
 - b. The application will prompt the user to enter the corresponding production name for that product. Not entering a name will stop/reset the import.
 - c. For complaint codes the application will ask whether the complaint is to be a) shown in menus b) displayed in the standard report.

Implementation:

The “New Product” designation was changed to be 6 months from first complaint or 9 months from the first production month.

While doing the import of the consumer complaint data, the application will prompt the user to match any new or unmatched consumer complaints with the available SPC names. However, if there are complaint codes that are not matched the application will allow the user to continue. The reason for this is that there are some complaint codes that may not be used in the calculations. An example of this would be when a site gets information about a product that is contracted out but the site is not responsible for tracking that product.

Part c. was implemented through the use of user-defined parameters for reports so this is done on the reporting end rather than during import.

- 3) The imported data must have a way of being reviewed prior to a final import.

Implementation:

The user will see the data about to be imported and can select which months he/she wants to import.

- 4) An “Undo Import”/”Step Back” type of function must be implemented for a worst case scenario where the wrong data was put in (including any new products or information that may have been added).

Implementation:

Through the administrative functions the user is able to select the data for a particular month or months (complaint or production data) and delete it; ALL data for the month(s) will be erased. After that the user can re-import any data. Any data product matching will remain in place and will not be affected. The “new product” designation will be re-calculated and corrected if needed.

Production data import function

Production data will consist of a simple CSV file with 1 month worth of data.

Requirements:

- 1) The user will specify the time period.
- 2) The application will check to see whether data already exists.
- 3) The application must be able to determine new products and provide a means to matching them with the corresponding complaint data name.
- 4) The imported data must have a way of being reviewed prior to a final import.
- 5) An “Undo Import”/”Step Back” type of function must be implemented for a worst case scenario where the wrong data was put in (including any new products or information that may have been added).

Implementation:

The application was designed to import only one month of production data at a time so there is no need to specify timeframe or check time span. The application will check to see whether the

production data exist and if there is new data it will append it. Else, it will not overwrite the data (Same approach as for the consumer complaints).

Likewise, while doing the import the user will be able to see the data about to be imported. Then in the same manner as for consumer complaint data, the user can select a month(s) for deletion and start again.

Data filtering, reviewing, editing & exporting

Requirements:

All data must be searchable by time, product, complaint type, etc. The user should also be able to edit the data should there be a need to do so.

A function that exports the result of a data query to a csv file is also required. The csv file has to have a format that will facilitate its analysis in Excel.

At minimum these options must be made available to the user:

- Ability to select a product or combination of products
- Ability to select a complaint type or combination of complaints
- Ability to group complaints by complaint category
- Ability to chose the time frame
- Chose between an average or monthly data
- Group individual complaints or show them broken out
- Show top 10 highest by rates of complaints based on the options above.
- Show top 10 highest by absolute number of complaints based on the options above.
- For any grouping or averaging, for any “new products” (that is products for which the first complaint received is less than one year old) there must be an option to include or exclude them from the report or calculation.

Implementation:

This functionality was implemented through a very simple user interface that allows the data to be grouped together or separated depending on the functions chosen. The approach taken maximizes the flexibility of the application. An option to export to excel was provided.

Reporting

Requirements:

All reports and output from the application must be compatible with MS Excel, Word, etc. (i.e. implement a “View in MS Word” or “Analyze in MS Excel” function).

The application will have 3-4 standardized reports. The contents are not yet defined but will include data such as:

- Top 10 complaints for the last year by product
- Top 10 complaint for the last year by type
- Year to date and monthly complaint totals
- Year to date and monthly complaints by product and/or type
- 12 month trend charts for user selectable complaints (absolute and rate).
- For any “new products” (that is products for which the first complaint received is less than one year old) there must be an option to include or exclude them from the reports.

Implementation:

This aspect of the project was changed such that the user will be able to build the reports based on the filtering function. The user will be able save different filtering options and set them as part of a standard report. Whenever the standard report is called for, each filter marked part of this report will be run and the data saved in excel.

The approach taken will allow for changes in the future without the need to program a new report. It will also allow each site to put together the reports that make most sense for their needs.

Calculations

For any given product:

R_n = Rate for the n^{th} month per 100 000 units

P_n = Production for the n^{th} month

C_n = Number of complaints for the n^{th} month

Monthly complaint rate: This is the current month’s number of complaints for any given complaint type divided by the average of the previous 3 months.

$$R_n = (3 * 100\,000 * C_n) / (P_{n-1} + P_{n-2} + P_{n-3})$$

Complaint rate averages:

For a period of months from month i to month k for a given product and same selection of rate data;

Average rate: $100\,000 * (C_i + \dots + C_{k-2} + C_{k-1} + C_k) / (P_i + \dots + P_{k-2} + P_{k-1} + P_k)$.

NOTE: ANY calculation that uses “All Products” will exclude products marked as new (i.e. new product launches will not be included for one year since the time the first complaint was received.)

Implementation:

ALL the calculations throughout the application use the 3 month average data. At import time the 3 month averages are calculated and stored separately from the raw data. That 3 month data is then used for the calculations. In that way the reporting calculation is both simplified and handled at a noticeable faster speed.

Rates are never averaged or used for subsequent calculations, production and complaint data are always used. The application will add the production and complaint data for each group (the data would be grouped according to how the user selects the options. I.e. by Focus Factory, by product, YTD by category, etc.).

Technology

The application was developed entirely in MS Access and is compatible with Access 2000 onwards.

Change Control

Definitions:

Source code: This is the actual text of the programming language and the means by which changes to the program can be made. A copy of the application that has not been compiled has the source code available for changes.

Compiled code/copy: When the source code is translated to machine language all access to the source code is lost. It is impossible to make modifications to an application that has been compiled.

The source code is owned by the Company, as such the company will be able to make changes and improve the application in the future.

The application will be distributed as a compiled application. In this manner the source code is not accessible, visible, or modifiable. This will prevent any changes from happening outside the proper change control.

Initially, the responsibility to archive the original non-compiled copy of the software will rest between the Divisional Documentation Specialist and the Kansas City Documentation Specialist. Over time, a new person may be identified as the best suited to be the owner of the application.

In order for a change to be made to the application these are the steps that should be followed:

- 1) The site requesting the change will consult with the division as well as the other sites. If the change is agreed upon, the proper change control procedures will be followed detailing the change, the purpose, scope, resources.
- 2) Once the change control documentation is approved and the resources are allocated for making the change, the person responsible for the source code will provide a copy of it to the person responsible for making the changes.
- 3) After the changes are made, they will have to undergo a validation process to ensure that they a) work as designed and b) do not interfere with the existing validated functions. That documentation will be appended to this document.
- 4) When the changes to the application have been validated, a compiled copy of the program as well as the source code copy will be given to the person in-charge of keeping the files. At this point, the compiled version of the software will be distributed along with a list of the changes made and their impact.

Security

The security strategy will consist of two access levels: Developer and User.

In the Developer level the source code will be available for changes and modifications to the program. This will be controlled by physically limiting the access to the source code copy (i.e. distributing only compiled copies) of the application. Access to this copy will be granted only through the change control process outlined above.

The User level access will in essence be implemented by the distribution of a compiled version of the application. In this way the users will have the ability to use the full array of tools the application provides but will not be able to make any changes to the program itself. This will ensure that the application will only be used as intended without the risk of a user purposely or not making a change to the inner workings of the program.

Given that each copy of the application will only be used by only one or two individuals it was recommended by the developer that site-level security be implemented by either physically limiting access to the application or by using file-level security in the network drive. If the application resides in an individual's computer hard drive the file is inherently secured by the access to the machine itself. If stored on a network drive, a separate folder would be set up by IT and read-write permission be given ONLY to the person in-charge of consumer complaint reporting.

The benefits of this approach is that it avoids having to tailor a copy of the program for each individual site (some sites have different methods for working with MS Access databases). If this application were to be used by a large number of users then the strategy followed above would not be practical but in this case it is the most cost effective way to ensure an acceptable level of security and integrity to the application.

4.0) Appendix:

4.1) Validation Justification & Approach

4.2) Risk assessment worksheet

4.3) Verification of calculations:

Part 1 – 3 Month Average Calculation

Part 2 – Simple rate calculation

Part 3 – Aggregate data rate calculation

Part 4 – Method Comparison

4.1) **Justification & Approach**

This application was determined to have a low regulatory risk and low business risk hence the validations strategy was limited to a verification of functionality. See the next section for details.

The main drivers and most important components of this application are the ability to import data and then calculate consumer complaint rates based on that data.

The approach taken to validate those functions was two-fold. The first part involved verifying the calculations against internal data (data that had already been uploaded and available for use by the application). In order to do this, the data contained in the database was retrieved and used in MS Excel to calculate rates and totals. Those results were then compared to the reporting output from the application. With this first step the different steps that lead up to a final result can be methodically tested and any the root cause of any inconsistencies can be quickly identified.

The calculations can be broken up in the following way:

Step 1) Calculation of the 3 month average production. After importing the production data the application creates a secondary table with the 3 month averages. This table is then used for all subsequent calculations so it is vital that the data is correct. See Part 3 of the Appendix, Calculation Verification part 1.

Step 2) Simple rate calculation. This is the next logical step where the application must retrieve data from the different tables, link the products correctly as per the settings specified by the user and then calculate a rate based on simple, one to one data (not an aggregate number like for various months or products combined). See Part 3 of the Appendix, Calculation Verification part 2.

Step 3) Aggregate data calculation. This step verifies that the application is capable of correctly grouping products and calculating a rate based on a multiple months or products combined.

The second part of the validation involved a method comparison. The application was required to replicate the results for PADD consumer complaint data that had been reported since the beginning of 2005 (January – May).

Step 4) Method comparison. This final step will implicitly serve as a second verification of the steps above as well as demonstrate that the application is capable to accurately importing data. Any failure of the application to replicate the data already calculated with the old method can only be attributed to one of four things: An error in the original calculation, an error in the application's calculation, a data entry error in the old method or an import error in the application.

Results:

The application passed all internal calculation checks. Only a few rounding errors of +/- 0.33 units were seen in the 3 month production averages. This error did not have an effect in the rates when calculated to 2 decimal places.

The application passed the method comparison. There were two instances where the rates reported by the application did not match the old reported numbers. Quickly those errors were traced back to using different consumer complaint data in the calculations. The application's dataset was compared to the original 13 month consumer complaint data files and were in agreement. The old calculation used slightly different numbers from those in the original data. When both scenarios were calculated using the correct numbers the rates matched perfectly.

Conclusion:

The Consumer Complaint Application can accurately upload data and calculate rates based on single product and month selections as well as multiple groupings.

Appendix 2) Risk Assessment

Identification/Owner	
Process: Assigned Business - CP: Assigned IT Resource: QA: Assessment Date:	Calculation of Consumer Complaint Rates Not Applicable Amadeo Martinez (Owner) 6/28/2005

Question - GXP Relevance	Yes/No
Does the process impact the control of raw materials, labeling or packaging materials, including goods receipt, identification, traceability, quarantine, storage, handling, sampling, or testing throughout the production processes?	No
Does the process impact the control of master production and control records such as material masters, bills of materials, or formulas?	No
Does the process impact the picking, goods issue, or delivery of products?	No
Does the process impact the transfer of finished goods to customer or remote distribution sites with regard quarantine or stock rotation?	No
Does the process impact the quality status of raw materials, packaging materials or finished goods lots including the quarantine, release, hold, rejection, and recall?	No
Does the process create, modify, maintain, archive, retrieve or transmit GxP-related information in electronic format that is required by regulatory agencies in an audit scenario?	No
Does the process create, modify, maintain, archive, retrieve or transmit records used in regulatory submissions for new products? (i.e.. Experimental Manufacturing Orders, etc.)	No
Does the process impact to management and assignment of security authorization profiles that assure processes in master production and control records or other records are instituted by authorized personnel?	No

Risk Assessment	Yes/No
If a system failure or upset were to occur, where there is a lack of a documented back up process or procedure, would there be a significant impact on the company's ability to operate?	No
Could a system failure or upset result in significant monetary loss either as a direct result of the failure or as a result of decisions based on inaccurate data as a result of the system failure or upset?	No
Has the process been implicated or deficient by any regulatory authorities?	No
Could a system failure result in an inappropriate decision or action relative to product quality or consumer safety such as release or shipment decisions?	No

Summary

GxP Relevance:	No
Risk:	Low

Appendix 3) Verification of Calculations – Part 1

Internal Data:

Verifying that the 3 month rolling average is correct.

Step 1. Gather the raw data from the database

Step 2. Calculator the 3 month ave in excel

Step 3. Com pate the calculated value against the numbers from the CC App.

From "TblProduction", raw-imported data.

ProductionGUID	MonthYear	ProductID	Totals	ImportSessionDate
772	October 2004	2	931630	5/4/2005 15:03
773	October 2004	1	60708	5/4/2005 15:03
774	October 2004	3	155940	5/4/2005 15:03
775	October 2004	5	307452	5/4/2005 15:03
776	October 2004	4	25944	5/4/2005 15:03
777	October 2004	7	169404	5/4/2005 15:03
778	October 2004	6	125604	5/4/2005 15:03
779	October 2004	8	324656	5/4/2005 15:03
780	October 2004	9	250500	5/4/2005 15:03
781	October 2004	10	393848	5/4/2005 15:03
782	October 2004	11	148572	5/4/2005 15:03
783	October 2004	12	106428	5/4/2005 15:03
784	October 2004	13	89520	5/4/2005 15:03
785	October 2004	15	36576	5/4/2005 15:03
786	October 2004	17	0	5/4/2005 15:03
787	October 2004	18	332480	5/4/2005 15:03
788	October 2004	19	1795336	5/4/2005 15:03
789	October 2004	20	4185204	5/4/2005 15:03
790	October 2004	21	1890831	5/4/2005 15:03
791	October 2004	22	607185	5/4/2005 15:03
792	October 2004	23	78879	5/4/2005 15:03
793	October 2004	24	382080	5/4/2005 15:03
794	October 2004	25	452320	5/4/2005 15:03
795	October 2004	26	114912	5/4/2005 15:03
796	October 2004	27	72384	5/4/2005 15:03
797	October 2004	28	44472	5/4/2005 15:03
798	October 2004	29	85872	5/4/2005 15:03
799	October 2004	30	45840	5/4/2005 15:03
800	October 2004	31	41832	5/4/2005 15:03
801	October 2004	32	40752	5/4/2005 15:03
802	October 2004	34	50088	5/4/2005 15:03
803	October 2004	39	0	5/4/2005 15:03
804	October 2004	36	76968	5/4/2005 15:03
805	October 2004	37	45360	5/4/2005 15:03
806	October 2004	38	0	5/4/2005 15:03
807	November 2004	2	870448	5/4/2005 15:04
808	November 2004	1	0	5/4/2005 15:04
809	November 2004	3	219468	5/4/2005 15:04
810	November 2004	5	480645	5/4/2005 15:04
811	November 2004	4	0	5/4/2005 15:04

812	November 2004	7	210618	5/4/2005 15:04
813	November 2004	6	0	5/4/2005 15:04
814	November 2004	8	306112	5/4/2005 15:04
815	November 2004	9	210360	5/4/2005 15:04
816	November 2004	10	359492	5/4/2005 15:04
817	November 2004	11	137796	5/4/2005 15:04
818	November 2004	12	63792	5/4/2005 15:04
819	November 2004	13	59244	5/4/2005 15:04
820	November 2004	15	78912	5/4/2005 15:04
821	November 2004	17	0	5/4/2005 15:04
822	November 2004	18	128336	5/4/2005 15:04
823	November 2004	19	1538322	5/4/2005 15:04
824	November 2004	20	3063364	5/4/2005 15:04
825	November 2004	21	1618692	5/4/2005 15:04
826	November 2004	22	541407	5/4/2005 15:04
827	November 2004	23	195021	5/4/2005 15:04
828	November 2004	24	473655	5/4/2005 15:04
829	November 2004	25	674432	5/4/2005 15:04
830	November 2004	26	172899	5/4/2005 15:04
831	November 2004	27	100320	5/4/2005 15:04
832	November 2004	28	173040	5/4/2005 15:04
833	November 2004	29	104928	5/4/2005 15:04
834	November 2004	30	156576	5/4/2005 15:04
835	November 2004	31	97752	5/4/2005 15:04
836	November 2004	32	74520	5/4/2005 15:04
837	November 2004	34	10080	5/4/2005 15:04
838	November 2004	39	0	5/4/2005 15:04
839	November 2004	36	0	5/4/2005 15:04
840	November 2004	37	0	5/4/2005 15:04
841	November 2004	38	60792	5/4/2005 15:04
842	December 2004	2	1211653	5/4/2005 15:04
843	December 2004	1	47202	5/4/2005 15:04
844	December 2004	3	238764	5/4/2005 15:04
845	December 2004	5	388806	5/4/2005 15:04
846	December 2004	4	29760	5/4/2005 15:04
847	December 2004	7	126372	5/4/2005 15:04
848	December 2004	6	6456	5/4/2005 15:04
849	December 2004	8	65136	5/4/2005 15:04
850	December 2004	9	0	5/4/2005 15:04
851	December 2004	10	42084	5/4/2005 15:04
852	December 2004	11	65856	5/4/2005 15:04
853	December 2004	12	46752	5/4/2005 15:04
854	December 2004	13	19992	5/4/2005 15:04
855	December 2004	15	0	5/4/2005 15:04
856	December 2004	17	38016	5/4/2005 15:04
857	December 2004	18	184512	5/4/2005 15:04
858	December 2004	19	951661	5/4/2005 15:04
859	December 2004	20	1977831	5/4/2005 15:04
860	December 2004	21	1309380	5/4/2005 15:04
861	December 2004	22	239094	5/4/2005 15:04

862	December 2004	23	0	5/4/2005 15:04
863	December 2004	24	80880	5/4/2005 15:04
864	December 2004	25	127296	5/4/2005 15:04
865	December 2004	26	62472	5/4/2005 15:04
866	December 2004	27	40392	5/4/2005 15:04
867	December 2004	28	0	5/4/2005 15:04
868	December 2004	29	0	5/4/2005 15:04
869	December 2004	30	0	5/4/2005 15:04
870	December 2004	31	0	5/4/2005 15:04
871	December 2004	32	0	5/4/2005 15:04
872	December 2004	34	30240	5/4/2005 15:04
873	December 2004	39	84216	5/4/2005 15:04
874	December 2004	36	130680	5/4/2005 15:04
875	December 2004	37	59472	5/4/2005 15:04
876	December 2004	38	0	5/4/2005 15:04

Verification

Product #	sum	Ave	From "TbIProductionAverage" for month of January			difference between methods
			ProductionDate	ProductID	AverageProduction	
1	107910	35970	01-Jan-05	1	35970	0
2	3013731	1004577	01-Jan-05	2	1004577	0
3	614172	204724	01-Jan-05	3	204724	0
4	55704	18568	01-Jan-05	4	18568	0
5	1176903	392301	01-Jan-05	5	392301	0
6	132060	44020	01-Jan-05	6	44020	0
7	506394	168798	01-Jan-05	7	168798	0
8	695904	231968	01-Jan-05	8	231968	0
9	460860	153620	01-Jan-05	9	153620	0
10	795424	265141.3333	01-Jan-05	10	265141	-0.333333 *
11	352224	117408	01-Jan-05	11	117408	0
12	216972	72324	01-Jan-05	12	72324	0
13	168756	56252	01-Jan-05	13	56252	0
14	0	0				0
15	115488	38496	01-Jan-05	15	38496	0
16	0	0				0
17	38016	12672	01-Jan-05	17	12672	0
18	645328	215109.3333	01-Jan-05	18	215109	-0.333333 *
19	4285319	1428439.667	01-Jan-05	19	1428440	0.333333 *
20	9226399	3075466.333	01-Jan-05	20	3075466	-0.333333 *
21	4818903	1606301	01-Jan-05	21	1606301	0
22	1387686	462562	01-Jan-05	22	462562	0
23	273900	91300	01-Jan-05	23	91300	0
24	936615	312205	01-Jan-05	24	312205	0
25	1254048	418016	01-Jan-05	25	418016	0
26	350283	116761	01-Jan-05	26	116761	0
27	213096	71032	01-Jan-05	27	71032	0
28	217512	72504	01-Jan-05	28	72504	0
29	190800	63600	01-Jan-05	29	63600	0

30	202416	67472	01-Jan-05	30	67472	0
31	139584	46528	01-Jan-05	31	46528	0
32	115272	38424	01-Jan-05	32	38424	0
33	0	0				0
34	90408	30136	01-Jan-05	34	30136	0
35	0	0				0
36	207648	69216	01-Jan-05	36	69216	0
37	104832	34944	01-Jan-05	37	34944	0
38	60792	20264	01-Jan-05	38	20264	0
39	84216	28072	01-Jan-05	39	28072	0

*** Rounding errors.**

ProductionDate	ProductID	AverageProduct
1/1/2005	1	35970
1/1/2005	2	1004577
1/1/2005	3	204724
1/1/2005	4	18568
1/1/2005	5	392301
1/1/2005	6	44020
1/1/2005	7	168798
1/1/2005	8	231968
1/1/2005	9	153620
1/1/2005	10	265141
1/1/2005	11	117408
1/1/2005	12	72324
1/1/2005	13	56252
1/1/2005	15	38496
1/1/2005	17	12672
1/1/2005	18	215109
1/1/2005	19	1428440
1/1/2005	20	3075466
1/1/2005	21	1606301
1/1/2005	22	462562
1/1/2005	23	91300
1/1/2005	24	312205
1/1/2005	25	418016
1/1/2005	26	116761
1/1/2005	27	71032
1/1/2005	28	72504
1/1/2005	29	63600
1/1/2005	30	67472
1/1/2005	31	46528
1/1/2005	32	38424
1/1/2005	34	30136
1/1/2005	36	69216
1/1/2005	37	34944
1/1/2005	38	20264
1/1/2005	39	28072

Screenshot from “tblProductionAverage” showing the averages as calculated by the application.

Verification of Calculations – Part 2

Verifying that the application is pulling the correct production data and then calculating the rates correctly.

Step 1. Get the 3 month averages for the products from the database

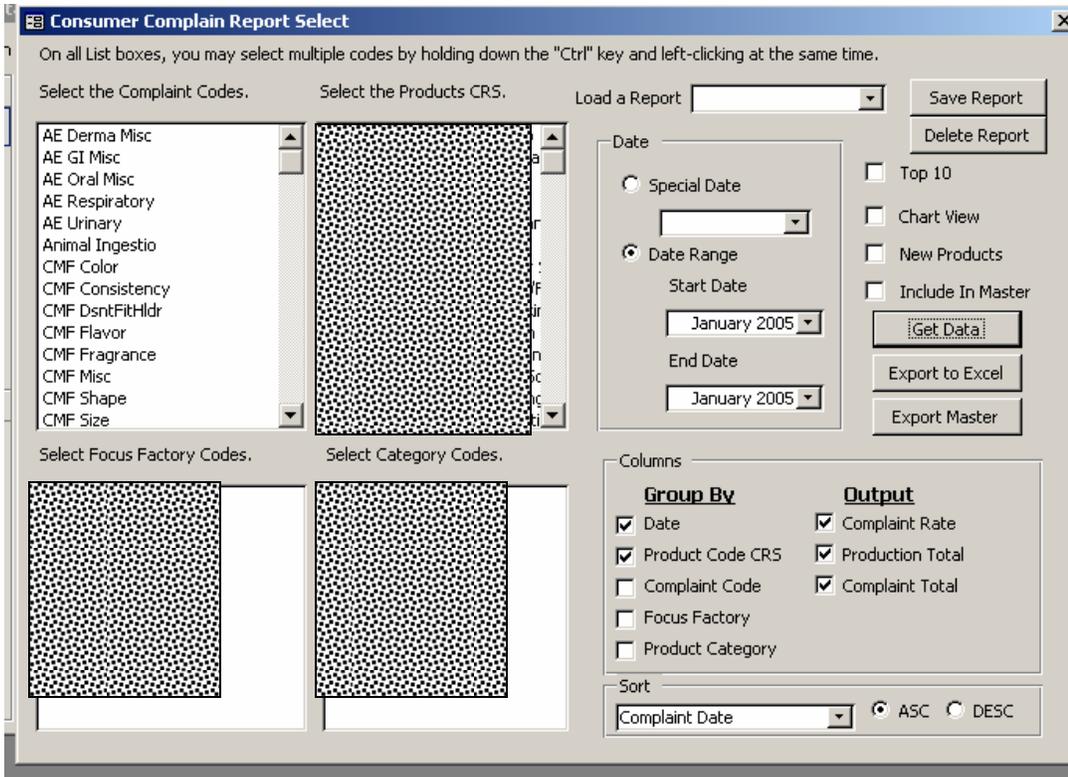
Step 2. Run a report for the same dataset and get the production, # complaints, rate as calculated by the app.

Step 3. Compare the production data

Step 4. Calculate the rate in excel and compare the results.

The data below (in gray) is the data as calculated by the reporting function.

ProdID	Production from "TbIProductionAverage"	difference in production	Complaint Date	Product Code CSR	Complaint Total	Production Total	Complaint Rate	calculated rate	difference
8	231968	0	January 2005	CB	2	231968	0.862187888	0.862188	0
20	3075466	0	January 2005	IS	85	3075466	2.763808802	2.763809	0
19	1428440	0	January 2005	ISA	56	1428440	3.920360673	3.920361	0
21	1606301	0	January 2005	ISIB	102	1606301	6.349992934	6.349993	0
22	462562	0	January 2005	ISS	7	462562	1.513310648	1.513311	0
24	312205	0	January 2005	ISWC	5	312205	1.601511827	1.601512	0
7	168798	0	January 2005	PAGBSP	62	168798	36.73029301	36.73029	0
2	1004577	0	January 2005	PAGL	79	1004577	7.864006443	7.864006	0
3	204724	0	January 2005	PAGMF	27	204724	13.18848792	13.18849	0
5	392301	0	January 2005	PAGSB	31	392301	7.902095585	7.902096	0
18	215109	0	January 2005	POG	0	215109	0	0	0
25	418016	0	January 2005	POS	4	418016	0.956901171	0.956901	0
26	116761	0	January 2005	PPTX	0	116761	0	0	0
38	20264	0	January 2005	VEL	61	20264	301.0264508	301.0265	0



Selection criteria to retrieve data.

Complaint Date	Product Code CSR	Complaint Total	Production Total	Complaint Rate	Message
January 2005		2	231968	0.86218788798	
January 2005		85	3075466	2.76380880166	
January 2005		56	1428440	3.92036067318	
January 2005		102	1606301	6.34999293408	
January 2005		7	462562	1.51331064809	
January 2005		5	312205	1.60151182716	
January 2005		62	168798	36.730293013	
January 2005		79	1004577	7.86400644251	
January 2005		27	204724	13.1884879154	
January 2005		31	392301	7.90209558477	
January 2005		0	215109	0	
January 2005		4	418016	0.95690117125	
January 2005		0	116761	0	
January 2005		61	20264	301.026450849	

Screenshot of application output used for the calculations in this section.

Verification of Calculations – Part 3

- Testing that when selecting multiple months the aggregate calculation is correct.
- Step 1. Run a query for one month for a few products
 - Step 2. Run a query for the next month for the same products
 - Step 3. Run a query for both months together
 - Step 4. Calculate the expected rate for 2 month together based on the data from individual months
 - Step 5. Compare both results.
 - Step 6. Calculate the overall rate for the two months and all products selected
 - Step 7. Run a query for the Focus Factory to see the total rate for the products selected
 - Step 8. Compare the data

Complaint Date	Product Code CSR	Complaint Total	Production Total	Complaint Rate
January 2005		85	3075466	2.763808802
January 2005		56	1428440	3.920360673
January 2005		7	462562	1.513310648

Complaint Date	Product Code CSR	Complaint Total	Production Total	Complaint Rate
February 2005		80	2715768	2.945759726
February 2005		62	1352156	4.585269747
February 2005		15	460192	3.259509074

No date selected so it adds up the raw data and then calculates the rate.

Product Code CSR	Complaint Total	Production Total	Complaint Rate
	165	5791234	2.849133708
	118	2780596	4.243694517
	22	922754	2.384167395

Product Code CSR	Complaint Total	Production Total	Complaint Rate	difference
	165	5791234	2.849133708	0
	118	2780596	4.243694517	0
	22	922754	2.384167395	0

Total sums for the three products together

305	9494584	3.212357698
-----	---------	-------------

Complaint Rate	Factory Name
3.212357698	Bar Soap

Difference in rates 0

January 2005 data.

qryResults : Select Query						
Complaint Date	Product Code CSR	Complaint Total	Production Tota	Complaint Rate	Message	
January 2005		85	3075466	2.76380880166		
January 2005		56	1428440	3.92036067318		
January 2005		7	462562	1.51331064809		

February 2005 data.

qryResults : Select Query						
Complaint Date	Product Code CSR	Complaint Total	Production Tota	Complaint Rate	Message	
February 2005		80	2715768	2.94575972616		
February 2005		62	1352156	4.58526974698		
February 2005		15	460192	3.25950907447		

Aggregate result for both January and February 2005.

qryResults : Select Query						
Product Code CSR	Complaint Total	Production Tota	Complaint Rate	Message		
	165	5791234	2.84913370795			
	118	2780596	4.24369451729			
	22	922754	2.38416739456			

Verification of Calculations – Part 4

Method comparison to validate import of data and calculation methods

Step 1. Obtain data from monthly KPI reporting

Step 2. Run a query in the application to retrieve a the same information

Step 3. Compare the results/data from diferent systems

Data from application report

Complaint Date	Product Code CSR	Complaint Rate
January 2005		36.730293013
January 2005		7.86400644251
January 2005		13.1884879154
January 2005		7.90209558477
February 2005		31.008975689
February 2005		7.25712361114
February 2005		10.6016031138
February 2005		6.89921624903
March 2005		21.8430384951
March 2005		14.3245820919
March 2005		10.1432002521
March 2005		8.69484732129
April 2005		22.0157228954
April 2005		11.9246362986
April 2005		9.86035275412
April 2005		10.7149814923
May 2005		12.7781045972
May 2005		10.7466472589
May 2005		7.72320049428
May 2005		9.50017670329

Screenshot form application output.

Complaint Date	Product Code CSR	Complaint Rate
January 2005		36.73029301
January 2005		7.864006443
January 2005		13.18848792
January 2005		7.902095585
February 2005		31.00897569
February 2005		7.257123611
February 2005		10.60160311
February 2005		5.749346874
March 2005		21.8430385
March 2005		14.32458209
March 2005		10.14320025
March 2005		8.694847321
April 2005		22.0157229
April 2005		11.9246363
April 2005		9.860352754
April 2005		10.71498149
May 2005		12.7781046
May 2005		10.74664726
May 2005		7.723200494
May 2005		9.500176703

Data from Monthly KPI (old method)

PRODUCT	Jan-05	Feb-05	Mar-05	Apr-05	May-05
LEMON	7.86	7.26	14.42	11.92	10.75
SPRNG BLSSM	7.90	5.75	8.69	10.71	9.50
BAK SODA FSH	36.73	31.01	21.84	22.02	12.78
MTN FRSH	13.19	10.60	9.78	9.86	7.72

Side by side comparison

	Jan-05
	7.86
	7.90
	36.73
	13.19

From CC app	Difference	
7.86400644	0.00	
7.90209558		0.00
36.730293	0.00	
13.1884879	0.00	

	Feb-05
	7.26
	5.75
	31.01
	10.60

From CC app	Difference	
7.26	0.00	
5.75	0.00	
31.01		0.00
10.60	0.00	

	Mar-05
	14.42
	8.69
	21.84
	9.78

14.32	0.09	see explanation below (1)
8.69	0.00	
21.84	0.00	
10.14	-0.36	see explanation below (2)

	Apr-05
	11.92
	10.71
	22.02
	9.86

11.92	0.00
10.71	0.00
22.02	0.00
9.86	0.00

	May-05
	10.75
	9.50
	12.78
	7.72

10.75	0.00
9.50	0.00
12.78	0.00
7.72	0.00

(1) The discrepancy is in the number of complaints. The original data file and the application report 155 complaints. The KPI data reports 156. This may be due to a data entry error or manual adjustment in the KPI data. See the next note for an example.

(2) The discrepancy is due to using different data. The monthly KPI reported 27 complaints whereas the database has 28 complaints, the same number as in the original CRS data. Due to a judgement call the data had to be adjusted in the monthly KPI. The table below show the calculation based on both numbers. Based on 28 complaints the CC Application is correct.

	# of complaints	
	27	28
production		
276047	9.78	10.14