DigInspect: Android Mobile Application for the FDA Regulated Health Product and Establishment

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Introduction

Mobile phone's evolution is indeed fascinating that the latest of technology allowed it to be called a smartphone. The innovation to the mobile phone industry is becoming a trend every year as these popular phone manufacturers compete for a better smartphone to showcase. With the ongoing advancement of technology, the number of increasing capabilities of a smartphone can be compared to the growing number of population of a small country.

As the features of a smartphone become more helpful in our everyday lives, the usage of it substantially increase that's why more and more functions are now being added to smartphones. These mobile phones are now widely used in different kind of businesses such as for payments, distributing media and other contents, even tracking with the help GPS. This handheld computers are not only simply for text messaging nowadays but also for important transactions through the use of several applications.

Philippines ranked 12th worldwide based on the number of mobile phones in use. Three spots below Japan, an advanced country in terms of technology. This just means that the importance of mobile phone even in a third-world country is rapidly increasing. Even government offices can make use of this technology for faster transactions and seamless process.

Food and Drugs Administration, a bureau under the Department of Health, periodically inspects its regional field offices by designating an inspector in each region. Inspectors are tasked to monitor and regulate products such as cosmetics, drugs and food. With different manufacturers and business owners dispersed in every region, FDA designated a certain number of inspectors for each region. 70 inspectors for the NCR and 5 to 7 inspectors for the other regions. NCR with its economic power which made it the centre of finance and commerce deserves a large number of inspectors. This inspection helps to monitor all the products that are registered on their department to regularly check its status. They are currently conducting it by input of data in papers. After completing the inspection process the inspector must travel back to the agency to encode the result to the database system in the form of spreadsheets that will provide those reports for review.

Through the use of mobile phone portability and mobility, a snappy inspection for every regional field office will be attained. A better and safer storage of data will also be accomplished and immediate fast data transfer can be achieved, with the help of this technology efficient and accurate results can be attained. A digitalized process making the inspection less tedious and a lighter paraphernalia makes this mobile phone application suitable for the company's process because of its convenience to the target users.

DigInspect is a mobile application that will be developed for the use of Food and Drugs Administration inspection of foods, establishments and cosmetic products. It guides the user through the inspection process. The application provides a timestamp to monitor the real time of the inspection, automatic backup, and information of the inspectors that will be using the application. Once the checklist app is completed, a PDF is automatically generated that will be saved in the handheld device, eliminating paper forms and manual filing. Also forms are received back in the office once connected to the internet, forms can be checked by the supervisors immediately. A web-based application will be provided for the administrators to view automatically generated weekly and monthly reports. This application will serve as the inspection kit of the Regional Field Office's Inspectors, which has minimized inspector tasks, no more manual filing, scanning and driving back to the office.

References:

[1] Mr. Kenneth Dacallos (December 20, 2014), Food and Drugs Administration-IT Department, Information System Analyst II, Civic Drive, Filinvest Corporate City Alabang, Muntinlupa City.

I. Problem Domain

A. Statement of the Problem

a. General Problem Statement

- The manual inspection conducted in the field by inspectors of Food and Drugs Administration is time-consuming and requires too much resource to accomplish the task.

b. Specific Problem Statements

The general problem stated above can be furthered down into following specific problems.

- Manual inspection could take a minimum of half a day per warehouse of an establishment
- Analysing and creating of reports are delayed because inspection forms are not immediately delivered upon inspection.
- The resources used in conducting inspection such as papers

B. Objectives of the Study

a. General Objective

- The proponents aim is to develop both mobile application and web-based application that will not only improve the inspection process but also aims to aid the Food and Drugs Administration in regulating most of the products by increasing productivity.

b. Specific Objectives

With the general objective stated above, the proponent aim to achieve specific goals which include the following:

- To save up inspection time, no need to carry out paper forms since forms will be fill out electronically.
- Information from the mobile application will be automatically saved to the database; more immediate data means greater visibility for managers, earlier starts to evaluate results and to create reports.
- To reduce cost of paper processes and go green by 80%

C. Background of the Study

[1] FDA secures the wellness of each product that is basically consumed by each of our citizen. Every product that comes from the other countries and products that are process and produced locally. So in order to ensure every citizens safety, the Regional Field Office of FDA deploys an inspector weekly to asses each product produced by a certain manufacturer and also those products that is going to be sold on the market.

Each and every inspector needs to evaluate different types of products such as Cosmetic, Household and Hazardous Substances, Drug, Food and establishments. Each inspection has a series of process. So what are the procedures when conducting an inspection?

[3] Upon arrival at the facility, the inspector presents their appropriate credential and other authorizations to the management of the company/owner or person-in-charge. When the meeting is over, the inspector then proceeds, he may opt to do a quick tour of the facility before conducting detailed inspections of specific areas concern. For consistency and efficiency of inspection, the appropriate inspection guide is used. Although, the inspector is not forbidden from pursuing further interrogations outside of the guide as far as necessary and reasonable. He will be accompanied by a key technical personnel at all times to ensure that all questions raised during the inspection are discussed and addressed. All of the findings and observations of the inspector will be recorded too. The inspector can collect samples as well from the company when necessary, for example out of specification products. At the end of the inspection, the inspector finalizes the findings and observations and prepares a summary of observations then discusses matters to the management or to the person-in-charge also giving a copy of the inspection to the company. If deficiencies are found, the inspector will conduct a follow-up inspection not later than five (5) working days based from the company's submission of the CAPA where the same guidelines will be used. If the establishment have complied with the requirements in correcting the deficiencies, the inspector will file a report to exclude the deficiencies with the appropriate recommendation for their actions. But if ever the establishment has not performed any corrective measures the inspector recommends for the disapproval of the application of license, registration or authorization. If the establishment previously found with deficiencies, made effort to comply but the same is not satisfactory with the required corrective measures, the inspector records it and advise the company to submit another CAPA within fifteen (15) calendar days from the date of the follow-up inspection.

[2] The current estimated number of inspectors in the Food and Drugs Administration are 200. 70 inspectors are located in the NCR and 5-7 inspectors are located in each region. When conducting inspections, the minimum time for inspecting a

warehouse and the products in it is half a day. So upon inspection, the inspector will pay a visit to their supervisor to have each of the paper forms checked to approve the application of product. The inspectors will also encode the information collected into the computer for backup, so that they can provide monthly and annual summary reports regarding the inspections.

Imagine how many paper forms the inspector needs to carry and to fill manually and re-enter the information into the computer? The time that will be consumed in doing these task? DigInspect is a mobile application to be developed to help the inspectors of the Food and Drugs Administration. This application will help the inspectors finish their job less time consuming, secured and hustle free. The application will provide list of the checklist that will be used in inspecting different products and establishments, a timestamp to monitor the real time of the inspection, automatic backup, and information of the inspectors that will be using the application. This application will serve as the inspection kit of the Regional Field Office's Inspectors.

References:

[1] www.fda.gov.ph

[2] Mr. Kenneth Dacallos (December 17, 2014), Food and Drugs Administration-IT Department, Information System Analyst II, Civic Drive, Filinvest Corporate City Alabang, Muntinlupa City.

[3] FDA Controlled Document: Conduct of Inspection, Document No: QWP-ODDGFROO-3B.1-06

Issued by: Mr. Kenneth Dacallos, Food and Drugs Administration-IT Department, Information System Analyst II, Civic Drive, Filinvest Corporate City Alabang, Muntinlupa City.

Issued Date: (Jan 14, 2015)

D. Significance and Scope of the Study

a. Significance of the Study

The study has been made to resolve the above-mentioned problems that Food and Drugs Administration encountered using the manual system. The proponents listed the following benefits that the users will attain upon the implementation website and mobile-ready application.

FDA

Financial expenses will be lessened. Reports will be up to date since transferring of data will be real time.

Mobile Application Users (Inspectors on their respective Regions)

Less effort will be exerted in conducting inspections (e.g. bringing paper forms, copying out data then encoding in the database, ambiguous data will be avoided), thus improving the work flow.

Business Owner's and Manufacturers

With the Inspectors snappy inspection, approvals can be attained quickly for the firm to launch their products to the market. Licensing can be attained earlier by 60 percent.

b. Scopes of the Project

1. Mobile Application

The proponents will develop Inspection Application. This will be composed of the following modules:

1.1 Authentication Module - This will serve as the user log-in.

1.2 Category Module - This module displays the list of category of checklist that will be used in inspection.

1.2 Inspection Checklist Module - This module displays the form that will be used for inspecting. The form consist of questionnaires that will be answered by the users. Upon answering, the data will be stored in the devices in PDF format. Also, the data will be stored in the database which will be used in generating reports.

1.4 View Module
This module shows the data that has been provided by the user. The user will have to sign the form to verify its contents. Upon clicking Submit, the data will be saved in the device in PDF format.

2. Web-based Application

The proponents will develop a web-based application which will provide access to the database and is capable of the following:

2.1 Log-in Module - In this module, it basically asks for the username and password then check if such accounts exist.
2.2 Weekly Report Module - In this module, summary of reports will be display.
2.3 Search & Sort Module - In this module, it simply display search results based on the file name. Also, it is also capable of sorting based on category, region and name of inspector.
2.4 Inspection Log Module - In this module, it will display the current status of an inspector. The date of inspection it was performed, the name of inspector and the name of the region.

c. Limitation of the Project

The proposed project has the following limitations.

Mobile Application

- This application will only be developed for Android Platform.
- The proposed project will be made available only for the Food and Drugs Administration. Only the personnel that had been authorized will have the access to the application.

Web-based Application

- The proposed project will not be available for public. Only those that have authorized access will be able to use the web-based application.
- Only the summary of reports will be shown.

II. Review of Related Studies

A. Foreign Related Study

1. Safety Management

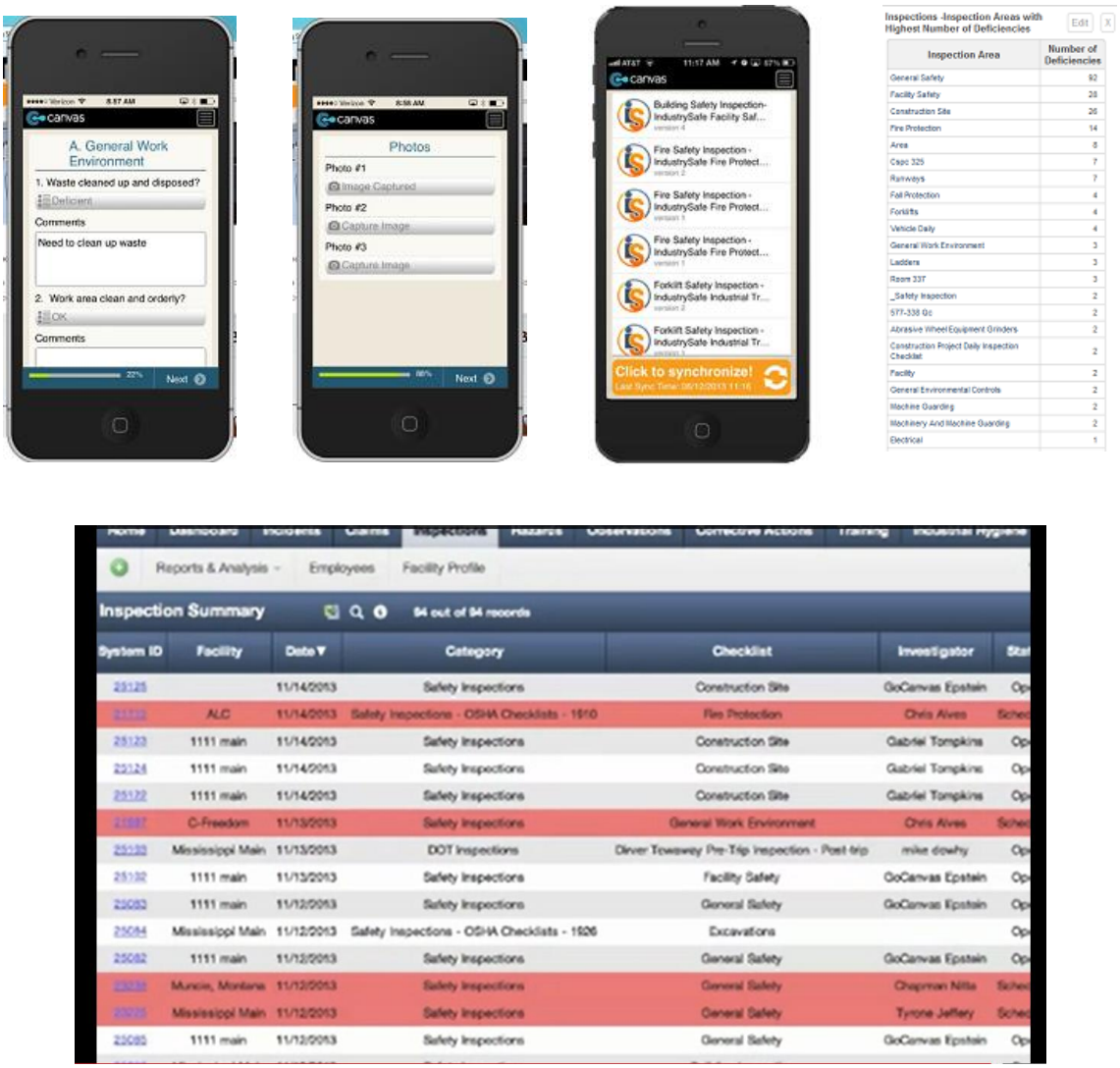


Figure 1. Industry Safe

Industry Safe allows individuals to conduct inspections from all types of mobile devices and then easily sync up their inspection results to the Industry Safe Software once they have Internet access. The Industry Safe Safety Software offers all types of detailed reporting, analytics and email notifications with these inspection checklists.

Comparison with the proposed Project

Industry Safe is a mobile application that is used in inspection. Also it has a web-based application which provide reports. This application is similar to the proposed project in terms of the process of transferring of data either online or offline and checklists are also pre-built. The difference is that Industry Safe is used in inspecting facility, site, building, vehicle, fire, forklift, ladder and more and the platforms where it can be used while DigInspect will be used in inspecting drugs, cosmetics, and etc. And unlike the DigInspect, the checklists provided cannot be downloaded from the web-based application.

2. ProntoForms – Mobile Forms

Figure 2. ProntoForms – Mobile Forms

ProntoForms – Mobile Forms is a solution that converts your inspection forms onto phones and tablets. Collect media rich field data on devices quickly, even without network coverage, and submit the mobile forms to the office in real time. Collect authorization via signature capture right on your device using the touch screen. Fill out and send forms with or without connectivity on site. Forms are auto-sent once network is restored. The ProntoForms App works on (almost) any device and operating system, including iOS, Android, BlackBerry, and Windows Phone or on a Web browser. Automatically generate PDFs and connect your data (XML, JSON, and CSV) to your preferred server or backend system with out-of-the-box integration options.

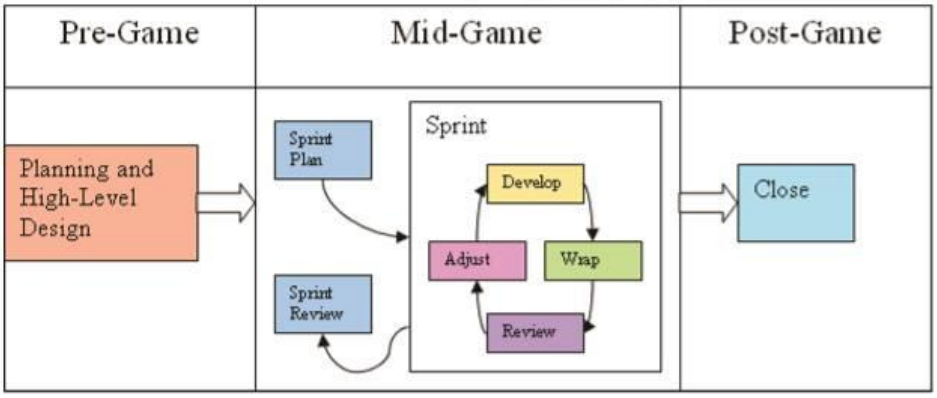
Comparison with the proposed Project

ProntoForms – Mobile Forms is an application that converts inspection forms onto mobile forms. The same concept will be found in the proposed project where inspection forms will be converted into mobile forms. Both application features collecting of signature in order to authenticate the data that will be stored in the database, generating PDFs and sending the data to a server or backend system. This will be almost exactly the DigInspect in the proposed project generated PDF will be saved to the device and only the raw data will be send to the server.

III. Approach to be taken in this Subject

A. Methodology

The Scrum development process concentrates on managing sprints. Before each sprint begins, the team plans the sprint, identifying the backlog items and assigning teams to these items. Teams develop, wrap, review, and adjust each of the backlog items. During development, the team determines the changes necessary to implement a backlog item. The team then writes the code, tests it, and documents the changes. During wrap, the team creates the executable necessary to demonstrate the changes. In review, the team demonstrates the new features, adds new backlog items, and assesses risk. Finally, the team consolidates data from the review to update the changes as necessary.



B. Theoretical Famework

Technology nowadays is very dynamic and change is inevitable to it. To help the team in developing the system our team, Team RJ45, chose a system design strategy called Top-Down/ Stepwise Refinement. The idea is to initially work on the top level computer program or the most important function of the system. Then to make it a better program other modules are attached making it bigger and better. A small program that gradually evolves into a much better program. The concept behind Top-Down is to start from Top to Bottom. This concept tells us to start developing first the top or most important function of the system and making it work, by then you can start go deeper by adding features, modules and other system requirements needed by the users. DigInspect is composed of different modules that are interconnected to each other so we decided that this strategy is the best for us to use.

C. Rationale of the Framework

Our chosen strategy (Top-Down) fits our system's flow thoroughly since the PDF Report Generation Module requires data from the Inspection Checklist Module. Without the data from the Inspection Checklist Module the administrator cannot release reports for the company's use. The data that are gathered and compiled by the Inspection Checklist modules are selected, arrange and used according to what information are needed by the reports generated by the PDF Report Generation Module. With the use of Top-Down Strategy, we can still improve the system especially when there are additional requirements and minor modifications found as we go deeper with the system.

D. Technologies you plan to consider or use

Listed here are the following hardware and software requirements needed to run the system and achieve the results that the client wants.

Requirements	Description
1. **Connectivity - Web Server**	Recommended internet speed Ping: Download speed: Upload speed: Based on:
2. **Software – Eclipse**	Juno SR2
3. **Software – MySql**	MySql 5.1 or above
4. **Software – Sqlyog**	Sqlyog v. 11 ultimate
5. **Software – Bluestacks App Player for Emulator**	Bluestacks v. 0.9.17.4138
6. **Software - Notepad ++**	Notepad ++ 6.7.7 or above
7. **Software – Chrome**	
8. **Software – Xampp**	Xampp 1.7.3 above
9. **Software – Java Development Kit**	Jdk 7 or above
10. **Software – Android Sdk Tools**	Sdk tools v. 24.2 or above
11. **Hardware Minimum and Recommended Specification**	Minimum Requirements Processor: RAM: System type: Operating system: Screen resolution: Recommended requirements Processor: RAM: System type: Operating system: Screen resolution:

IV. Project Plan

A. Concept

i. Description of the Design

The proponents will be developing a system design consisting of eight core processes (four in DigInspect Mobile and DigInspect WebApp)

ii. Process Model – Context Diagram

Figure 3. DFD Level 0 of DigInspect

iii. Data Model – Data Flow Diagram

a. Diagram 0

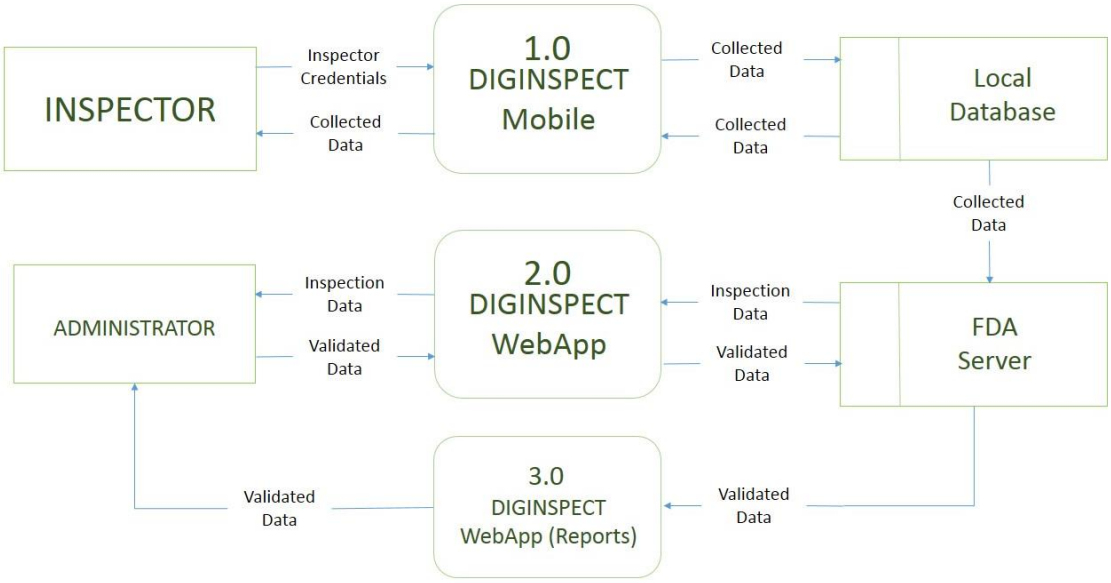


Figure 4. DFD, Level 1 of DigInspect

b. Child Diagram of Process 1.0 (DigInspect Mobile)

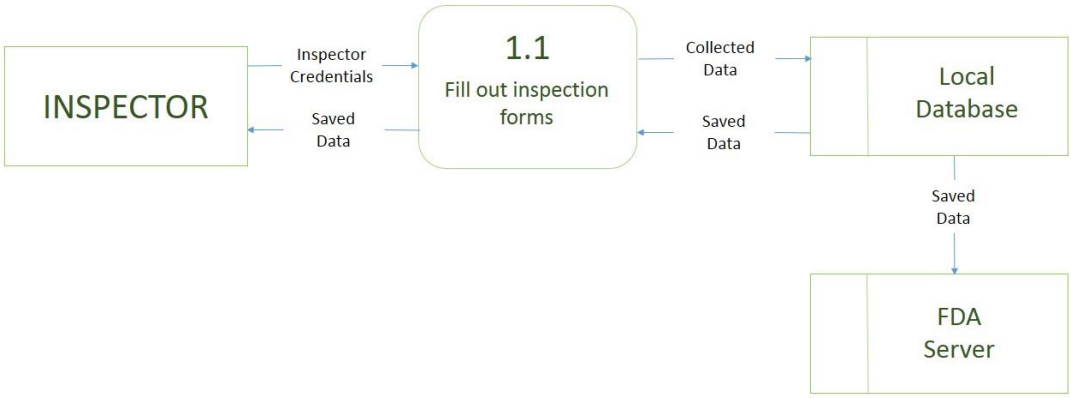


Figure 5. Mobile Application: Child Diagram, Process 1.0

c. Child Diagram of Process 1.0 (DigInspect WebApp)

Figure 6.Web-based Application: Child Diagram, Process 2.0

iv. Logical Model - Structured English

a. DigInspect Web Portal

Process 1.0 - View Inspection Records

If Administrator View Inspection Records

Administrator views fetched inspection record from the database.

Process 1.1 Sort Inspection Records

Administrator views sorted inspection records by type of checklist and date of inspection.

Process 1.2 Search Inspection Record

Administrator views fetched data based from the query string from the database.

b. DigInspect Mobile App

Process 1.0 Set Inspection Checklist Information

If Inspector validated collected data

Synced collected data to DigInspect if online

Process 2.0 Saved Collected Data to PDF Form

If collected data was synced to online database

Saved collected data to pdf form

v. Conceptual Model – Entity Relationship Diagram

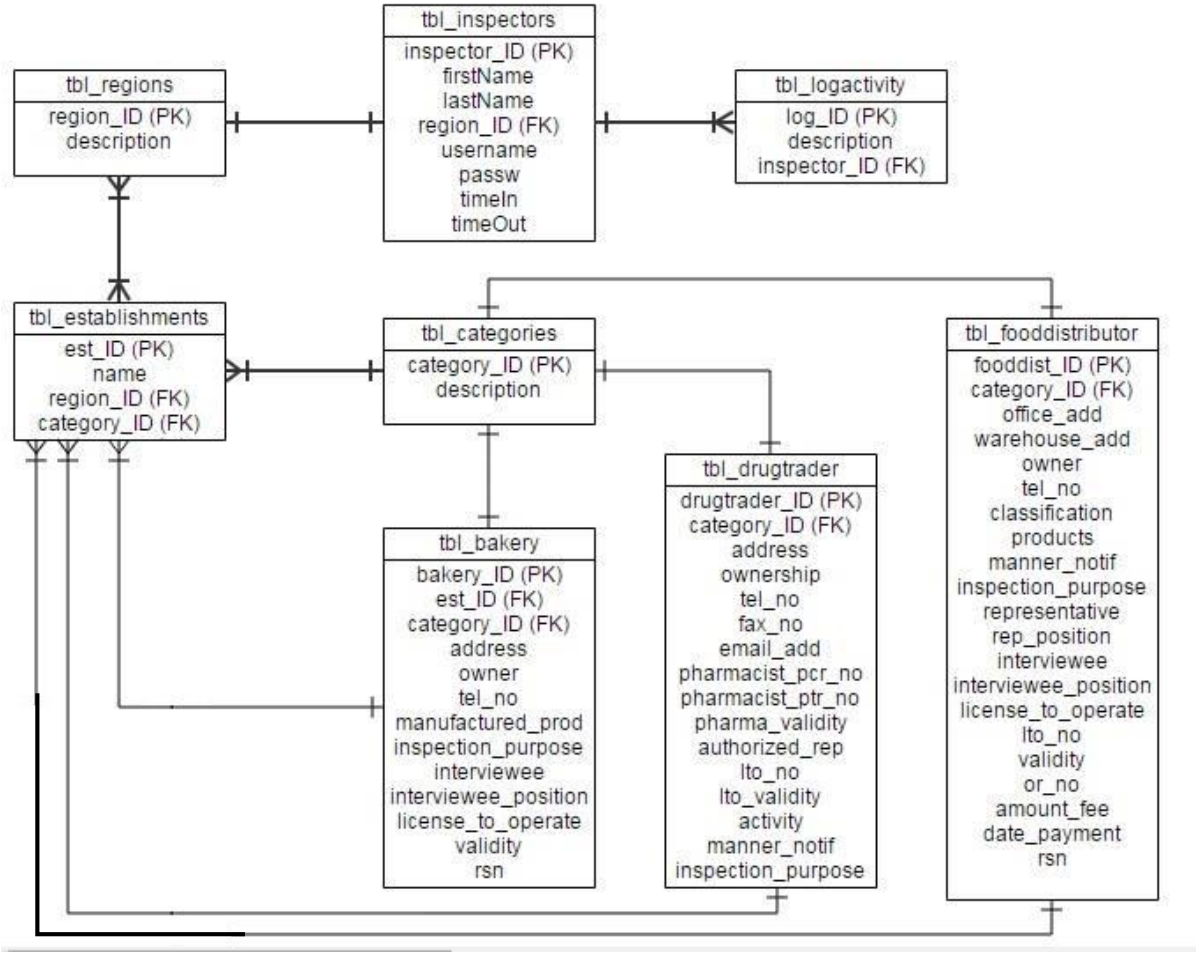
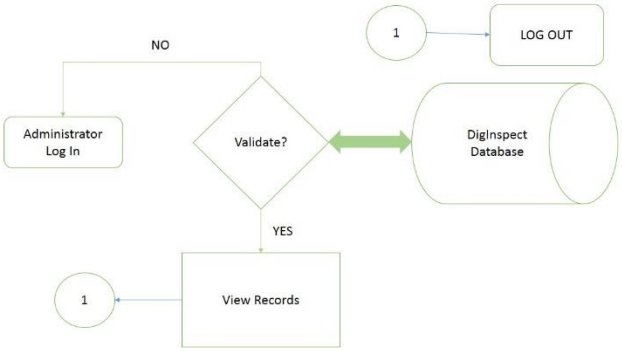
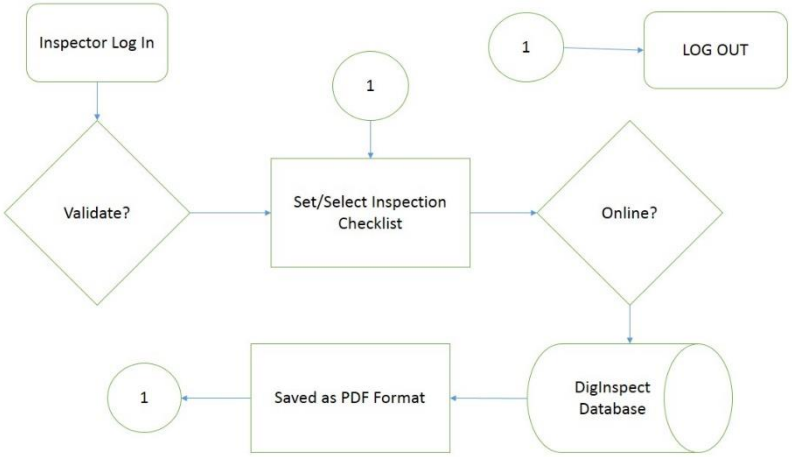


Figure 7. Entity Relationship Diagram

Conceptual Flowcharts – DigInspect Web Portal



Conceptual Flowcharts – DigInspect Mobile App



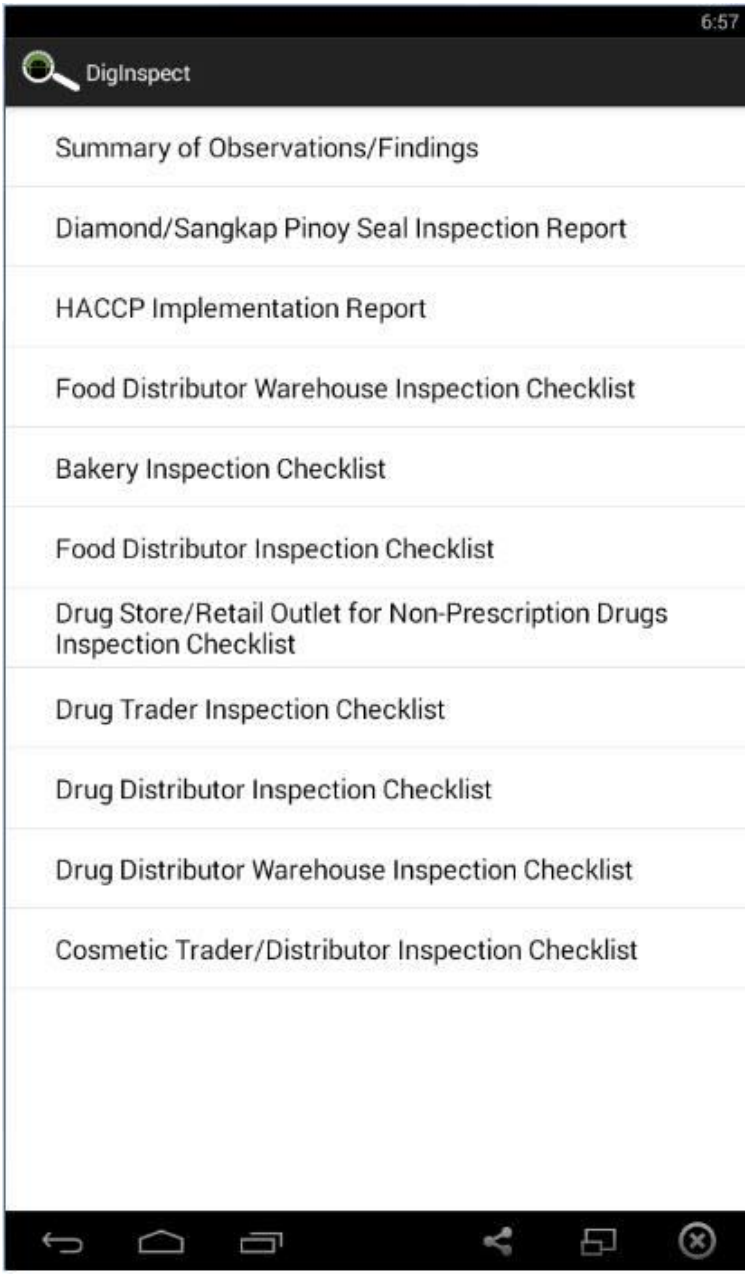
vi. List of Modules

a. DigInspect Mobile

i. Authentication Module

ii. Category Module

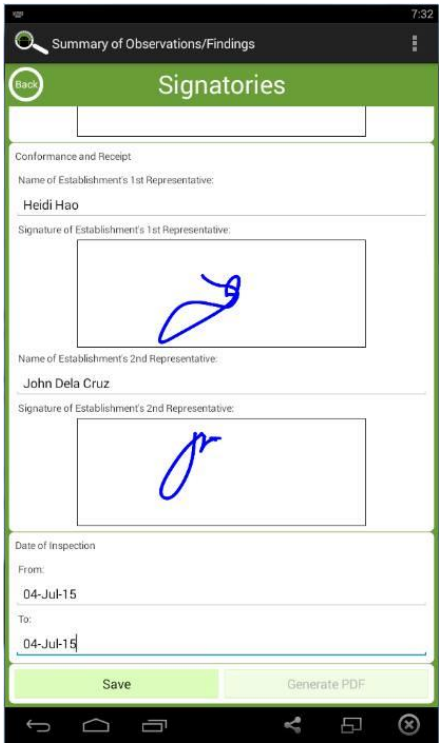
s



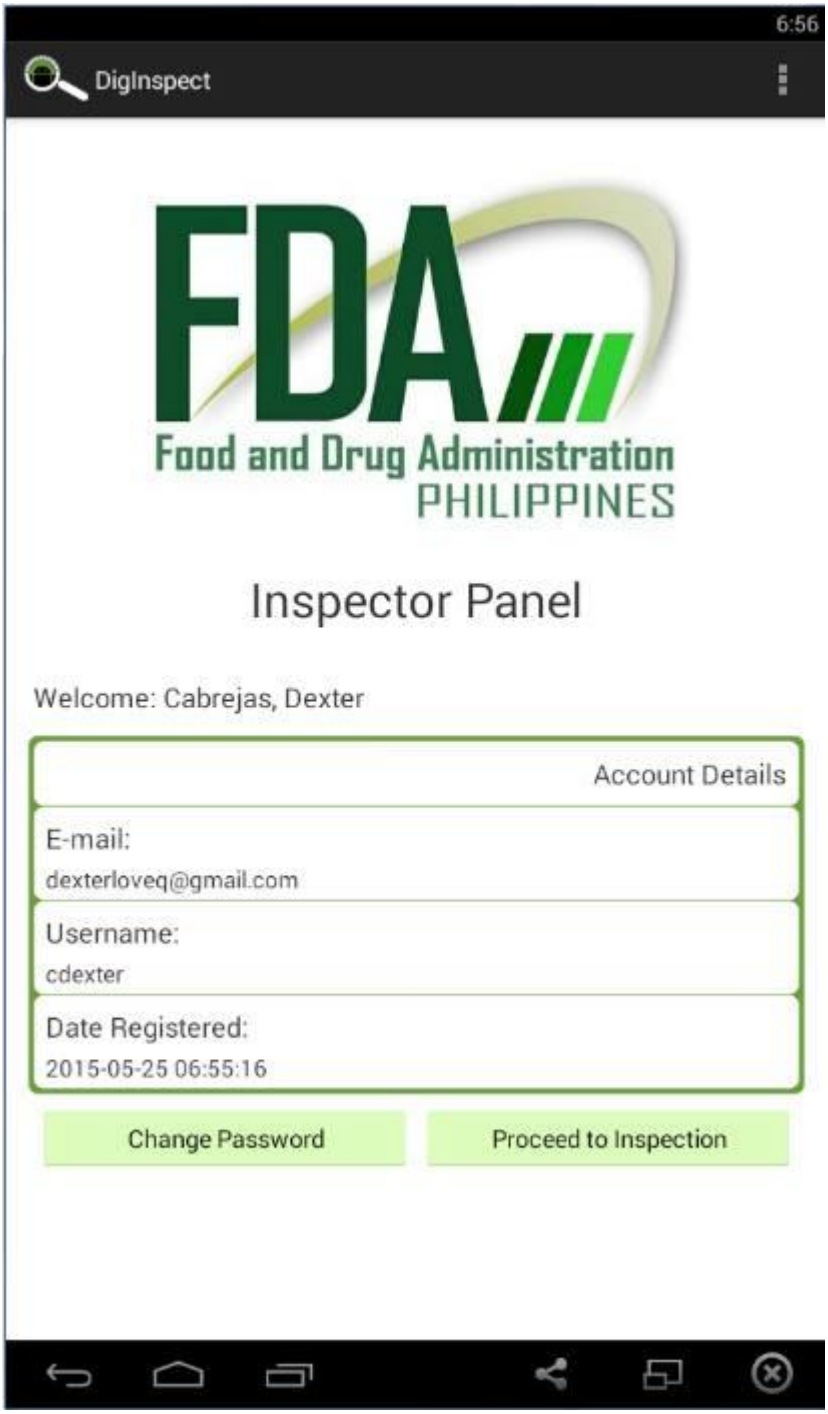
iii. Inspection Checklist Module


7:24
Summary of Observations/Findings
General Information
Next
Name of Establishment:
2 Sisters
Plant/Office Address:
UK
GPS Coordinates(Latitude, Longitude):
143,123
Warehouse Address:
France
GPS Coordinates(Latitude, Longitude):
-23, 782
Owner:
Anjo Farms
Telephone Number:
8699811
Fax Number:
123401
Classification:
Food
Distributor
Exporter/Importer
Product/s:

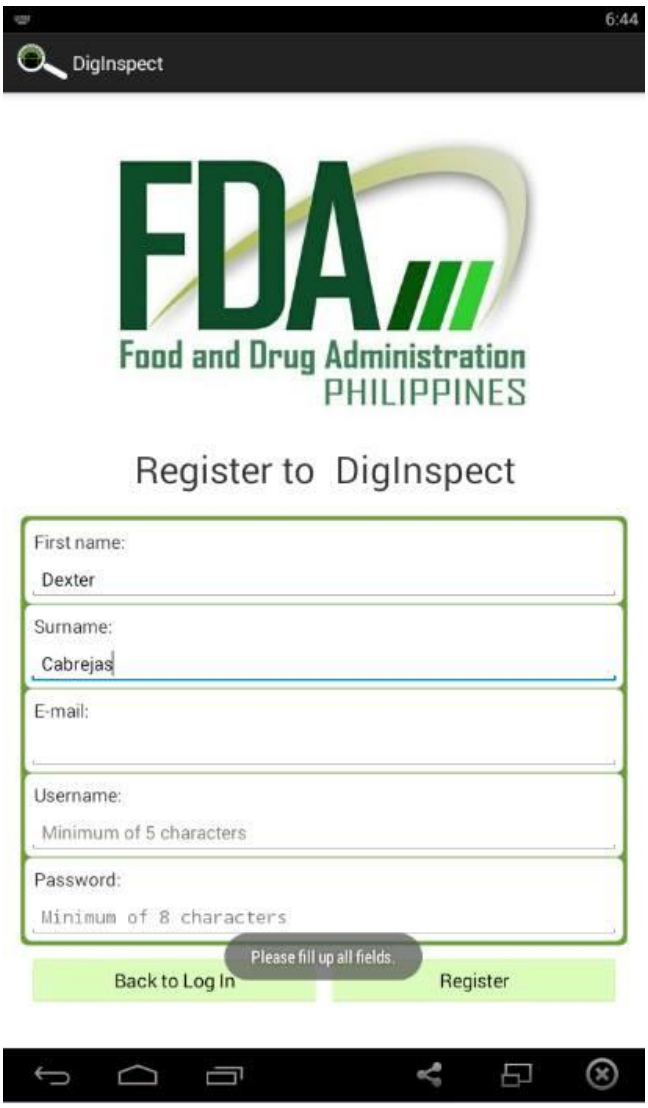

7:26
Summary of Observations/Findings
Back
Others Directiv
Clear
Save
OBSERVATION FINDINGS:
Clean facility, regular maintenance needed.
Overall needs improvement as an establishment.
DIRECTIVES:
To always observe Good Distribution Practice / Good Storage Practice
For Critical findings
1. Stop production, suspend the line outright or in case of distributor stop further importation and/or distribution, if applicable; inventory and sealing of products found within the premises.
2. Undertakes or causes company recall of affected batches following existing FDA rules and procedure for product recall.
For Warehouse Inspection
For Follow-up Inspection
For Corrective Action/Preventive Action (CAPA) plan
Address the deficiencies and submit CAPA Plan through FDA Central Receiving Unit including submission of objective evidence of compliance within the specified timeline reckoned on the following day of receipt of summary of observation/finding:
Forty-five (45) calendar days for major deficiencies & other deficiencies


7:32
Summary of Observations/Findings
Back
Signatories
Conformance and Receipt
Name of Establishment's 1st Representative:
Heidi Hao
Signature of Establishment's 1st Representative:
Name of Establishment's 2nd Representative:
John Dela Cruz
Signature of Establishment's 2nd Representative:
Date of Inspection
From:
04-Jul-15
To:
04-Jul-15
Save
Generate PDF

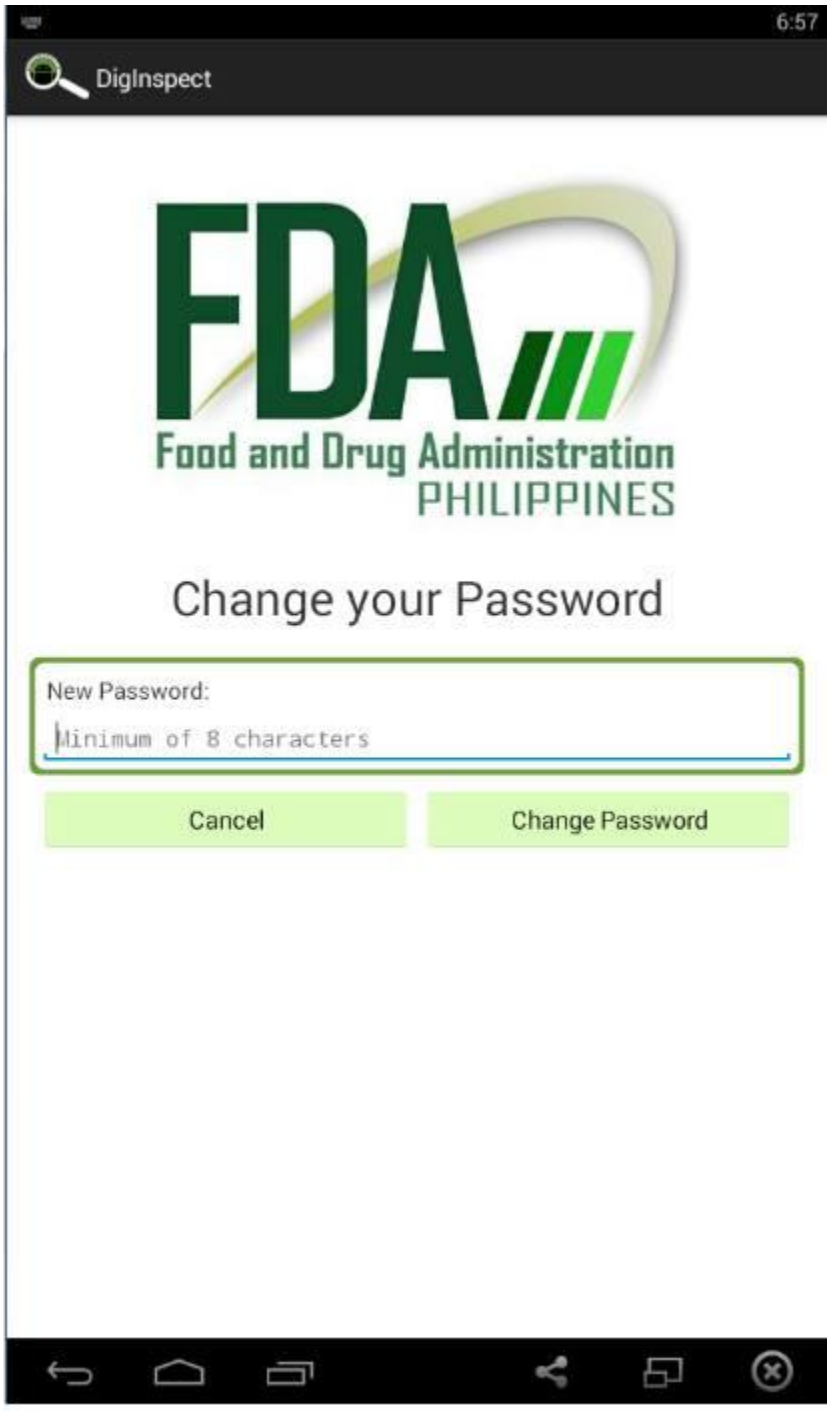
iv. Inspector's Module



a. Create Account

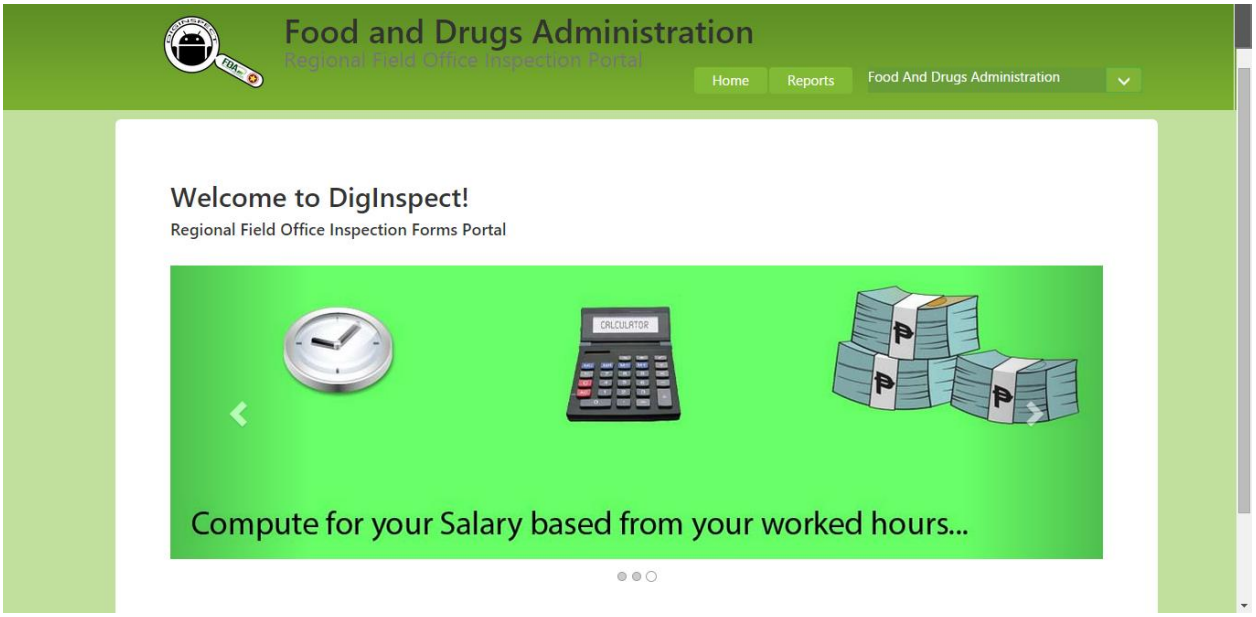


b. Change Password

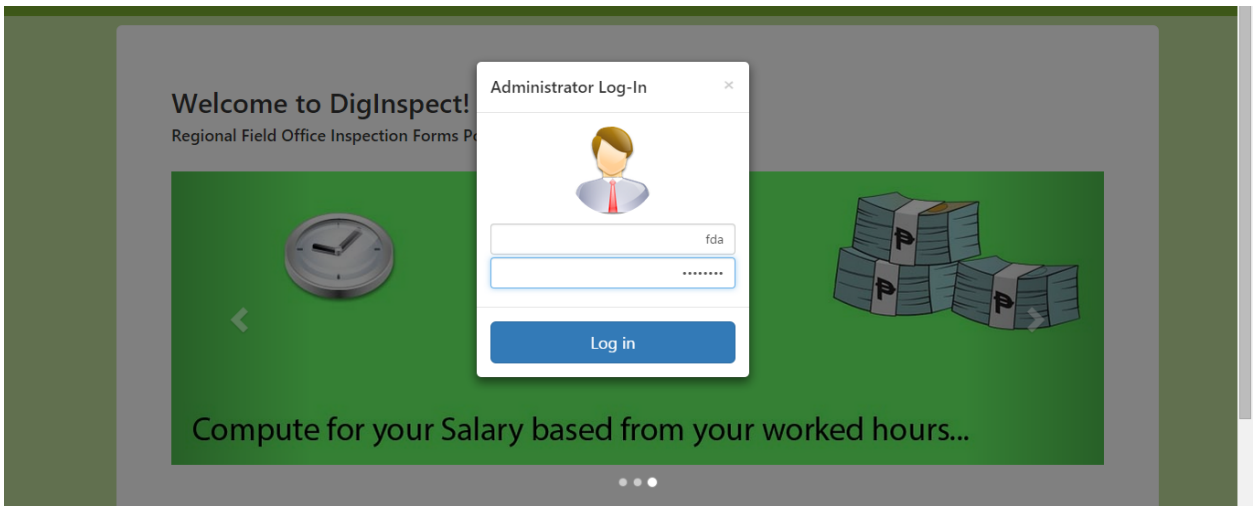


b. DigInspect Portal

i. Home Page

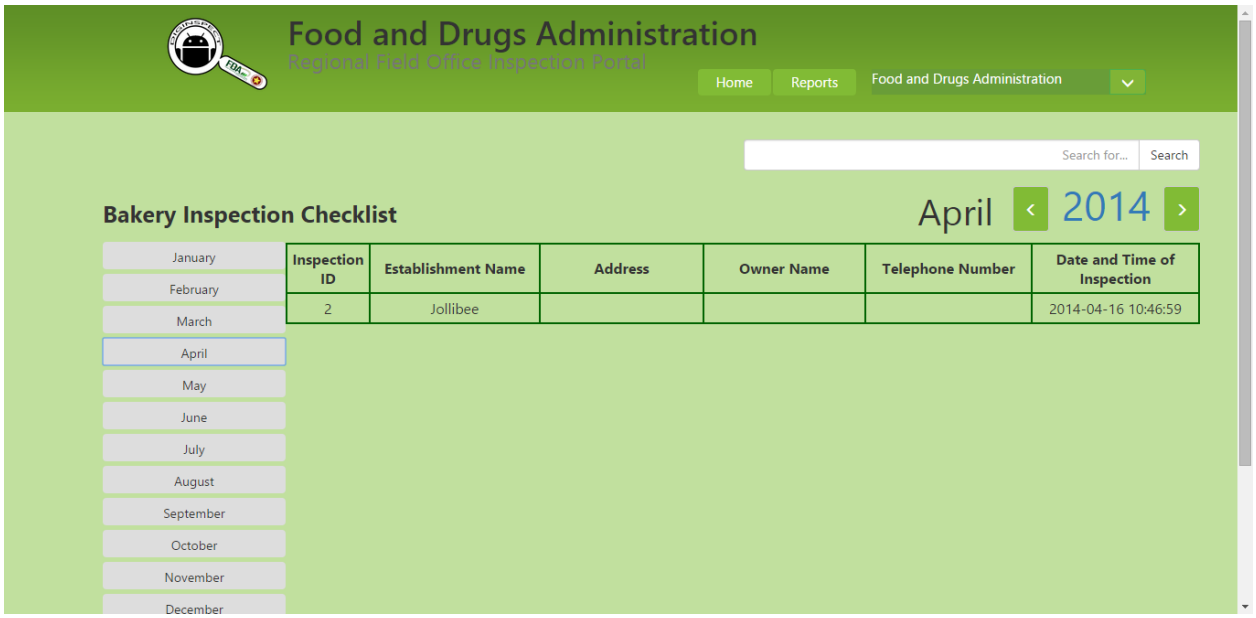


ii. Administrator Log-in Page

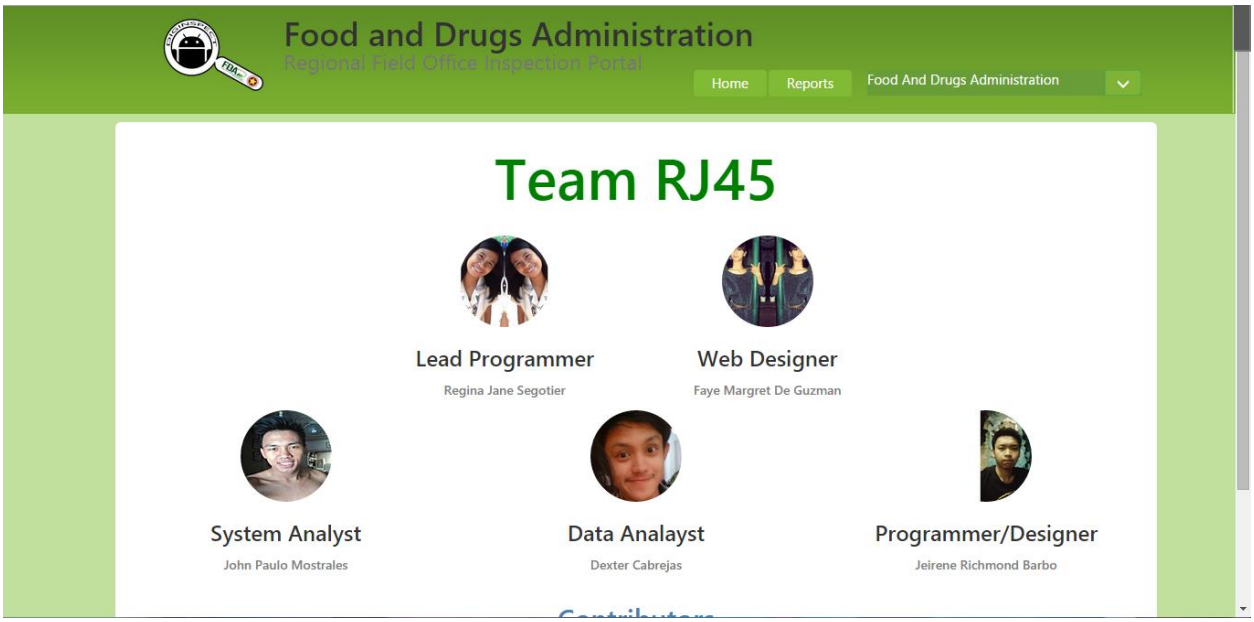


iii. Checklist Page

v. Sort per month/year Page



vi. Developer's Page



vii. Search Page

B. Methods

a. Design Studies

The team has studied the color scheme to be used. Our client has shades of green in their logo and since this project is aiming a paperless job and go green.

b. Production of Prototypes

The team accommodated the ideas from each individual we also did adapted some tips from some of our colleagues in order to accomplish a nice output design; from the logo, color scheme used, navigation, function and especially the name used, DigInspect. After several interviews and researches with the client about the inspection process, we together with their IT Department head came up with various ideas; how the data will flow from one point to another, what technology to use and every small detail needed to develop the system. Generating the prototype was uncomplicated since a portion of it was created by the client, giving our team a fresh start. As the development goes deeper the system ended up into pleasant, efficient and effective modules that can be soon implemented and enhanced as the time goes on.

c. Plan for user testing and project assessment

To be able to give our client an efficient project and receive their satisfaction, the team conducted research, interviews and brainstorming, for the team to identify all requirements, adjustments and additional functions for the project. All gathered information are evaluated and observed giving the team satisfying results.

d. Plan for collaboration

Name	Position
Regina Jane Segotier	Project Leader, Web Developer, Designer
Jeirene Richmond Barbo	Mobile Developer, Designer
Dexter Cabrejas	Document Analyst
Faye Margret De Guzman	Document Analyst
John Paulo Mostrales	Data Gatherer