Drug Analysis and Report Generation System

Sheetal. S. Patil[1], Rupali Phatak[2], Ayush Khandelwal[3], Supriya Kumari Mishra[4], Samuel Verghese[5]

Bharti Vidyapeeth Deemed to be University, College of Engineering, Pune

Abstract - *Pharmaceutical practices have evolved over time to become fully encompassed in all aspects of the pharmacy itself. The Pharmaceutical companies fill the form manually for testing of their medicines.*

This research paper provides a concept of digitalization for filling out the forms online at any geographical locations. The technology such as the Drug Analysis and Report Generation System is the platform designed with the help of Core Java and MySQL to help the drug regulation and to pacify all the firms involved.

The idea of this project may be used by various state governments in the future for providing the digital platform and enhance the transparency between parties.

Keywords: *digitalization, Drug analysis, Report Generation, Technology, Forms.*

I. INTRODUCTION

The pharmaceutical industry of India has a market size of $27.57 billion in 2016 and it is expected to be worth $50 billion by 2020. This shows how important the entire pharmaceutical market is for the entire nation. With this comes the challenge of regulating the market. This including keeping track of each product that has entered the market. Even before a product enters the market it has to be tested for safe human (or animal in case of vets) consumption because the drugs released by these companies can sometimes have harmful side effects or can be recreationally used by drug abusers[5].

The process starting from the release of a new drug, its subsequent testing and based on the result, its entry into the market should be digitalized. This will ensure that every detail of the process (From testing to deployment) is stored digitally in the form of 'FORMS' which in turn assures data integrity and transparency as anyone concerned with the particular data can look it up anywhere in the world provided an internet connection and a web browser[6].

Our proposed system comes under the category of software called Laboratory information management systems. It does the task of storage and management of information obtained in the experiments performed in the laboratory. These systems are performing the task of managing and controlling testing standards, equipment, samples, test results, and overall workflow automation.

The advantage of such a system is that all the data is available at one place and can be accessed by the concerned party at will through their computer.

One of the major challenges faced by the laboratory staff is the maintenance of a laboratory log. The introduction of Laboratory information management systems is to reduce the number of errors caused by 'human factors'.

Basically, our system is a place where the pharmaceutical firm will release a new product and its testing will be done by the laboratory. Once the tests are completed and if the drug is of the standard then the DCO (Drug Control Officer) alerts the market about the new drug.

All of these various processes are standardized through the introduction of various FORMS throughout the life cycle of the testing. Each of these FORMS has its own importance and is vital for the drug analysis process to complete successfully. The outcome of this process Thus determines whether the drug being tested is of quality or sub-standard.

II. PROBLEM DEFINITION

This project is aimed at developing a web application which is software developed for firms/manufactures for testing of medicines the firm produces. In the existing system of manually filling the forms is not feasible as there are high chances of error and fraudulent conduct. There are certainly other reasons for the development of the project which are stated below:

• Imprudent amount of paperwork. As the system for testing and analysis of drugs is not digitalized, it still takes a lot of paperwork to get a new drug into the market and Because of this huge amount of paperwork, errors or mistakes can occur anywhere in the process [3].

• Difficulty in filling the forms due to the spatial distribution of drug manufacturers across the state. Due to the reason that the drug manufacturers are distributed spatially across the state, the filling of the various forms becomes difficult. That's why this process of filling the various forms is completely digitalized in our project.

• The obfuscated channel of communication between the laboratory, manufacturing firm and the drug control organization. The process of communication between the

various departments have very little transparency and with this project, we aim that every entity will have the information concerning itself at any time they want at a click of a single button in the web application[3].

• Trifled promptness amongst the manufacturers, pharmacists, Doctors and retailers about the analysis of the Drug. With the use of this web application, the conduction of the drug Analysis process will become much more prompt than before and there will be an entire platform dedicated to connecting the drug manufacturers, lab analysts, drug control officials and the customer and this platform will, in turn, guarantee data integrity and transparency across the various entities.

III. REVIEW OF LITERATURE

[1] "LABORATORY INFORMATION MANAGEMENT SYSTEMS IN THE WORK OF THE ANALYTIC LABORATORY"

D. O. Skobelev,1 T. M. Zaytseva,2 A. D. Kozlov,1 V. L. Perepelitsa,1 and A. S. Makarova1Measurement Techniques, Vol. 53, No. 10, 2011, UDC 681.142.37:543.08[1]

The author has described the system as the class of application software intended for storage and management of information obtained during the analysis in the laboratory. The system is used to regulate and preside over the samples, standards, test results, reports, laboratory staff, instruments, and workflow mechanization. The amalgamation of laboratory information management systems with the firm's information systems will make it viable to promptly address the required data to the laboratory and the company's administration[1].

[2] "ONLINE PHARMACEUTICAL MANAGEMENT SYSTEM"

Onuiri Ernest E., OyebanjiInalegwu G., Fayehun Solomon A., Chukwujioke Sam-David, European Scientific Journal April 2016 edition vol.12, No.12[2]

The author has described the system as a platform designed to help with drug regulation and to pacify all the firms involved. The channel used in the deployment of the software is the cumulative Model of System Development Life Cycle, which allows room for flexibility as time goes on. Creating an Online platform would help in pharmaceutical practices for all firms involved. It is prominent that the system provides a safe, shielded and substantiated platform for all firms which help to viaduct the communication gap and provide legitimate drugs. Therefore, if all commendations are strictly adhered to, There will be a stern examination of how drugs are circulated and a decrease in the spread of fake drugs [2].

IV. PROPOSED SYSTEM PLAN

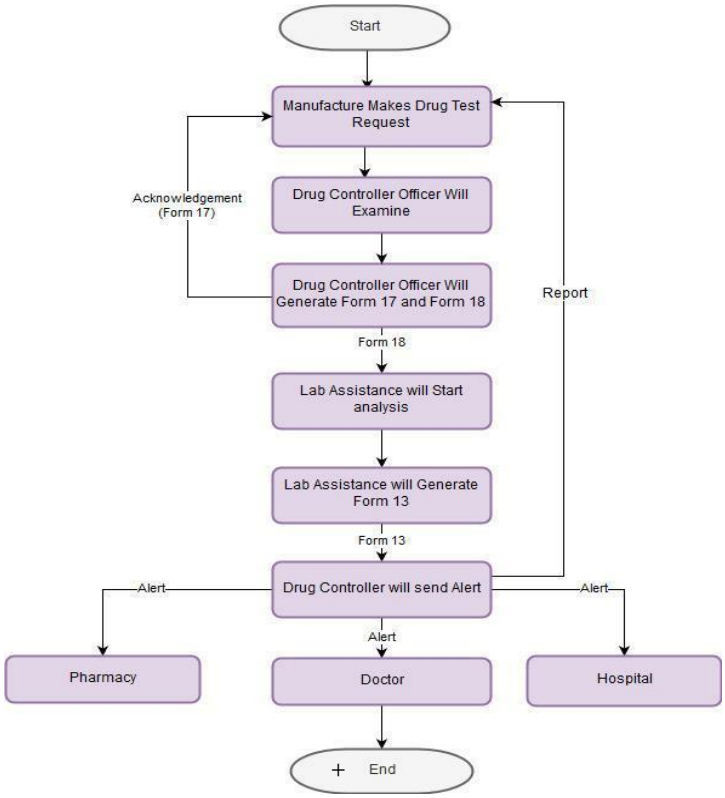


Figure 1.1 Flowchart Of Drug Analysis and Report Generation System

This project contains a very simple design and can be implemented on a commercial scale. The process starts with the DCO (Drug controller officer) who acknowledge the form filled by the manufacturer. The officer checks out the necessary details in the form and considers the medicines which manufacturers want to test.

The pharmaceutical companies will fill the form 17 for testifying of their manufactured medicine. These forms contain information about the company, the medicines they produced, license number, etc. This form is the base of this entire process.

At the second level, the DCO will fill the form 18 and submit to the lab along with form 17.

The laboratory tests the medicine and marks it as of standard or substandard. The labs perform the various tests on it and generate form 13 which contain all the relevant information about the results of medicines tested and pass to the DC (Drug Controller)

The third stage of this process is handled by the DC (Drug Controller).The report generated by the labs sent to the

DC which has the details of the medicine tested. The marks are given to the medicines and on the basis of this mark, the sustainability of medicines are identified. If the medicine is of standard, then it passes the test and can be used by patients and hospitals but if it is substandard then the medicine can't be used by patients and hospitals.

At the last stage of this process, the DC will generate an alert message and send to the hospitals, pharmacy; doctor stating that the medicines produced is of substandard and can't be used in near future. The officer also makes a report and sent to the manufacturer about what gone wrong in their manufactured medicines and how it can be corrected.

V. SYSTEM ANALYSIS AND DESIGN

The proposition used in the conception of the system is the Incremental Model of Software Development Life Cycle where the product being designed is implemented and tested incrementally.

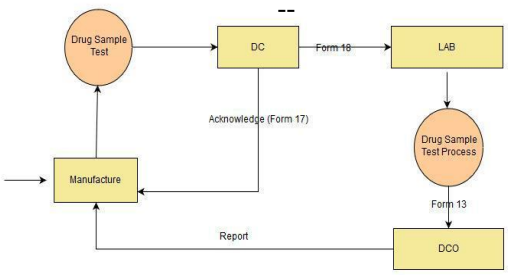


Figure 1.2 Data Flow Diagram Level 0

ADMIN:

• The admin is responsible to verify the various users of the system such as Drug Controller, Drug Control Officers, Lab Analysts, and Manufacturers/Firms.

• The admin can add/delete any user of the system.

• The admin is responsible to manage the Drug Controller, Drug Control Officers, Lab Analysts, and Manufacturers/Firms.

•The admin can modify any detail of the system.

MANUFACTURER/FIRMS

• Submit the samples to the Drug Control officer (DCO).

• Receive Form 17 on their portal filled by the Drug Control officer (DCO) as a memorandum upon collection of sample.

• Can see the progress of the drug sample analysis on the portal.

DRUG CONTROL OFFICER

• Collect the samples from the manufacturers/ firms and fill form 17.

• Submit the samples to the lab analysts

• Fill form 18 stating about the drug composition.

• Receive the report from the lab analyst in the form of form 13.

• Submit the analysis to the Drug Controller.

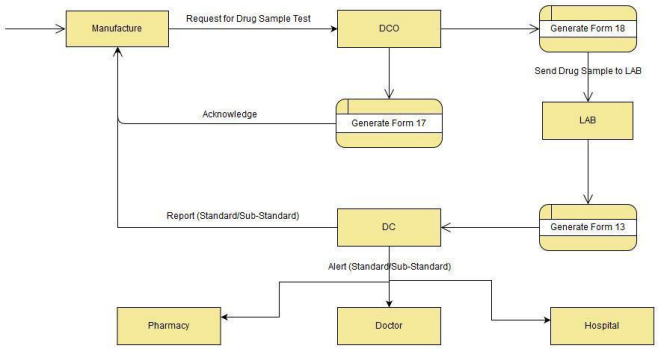


Figure 1.3 Data Flow Diagram Level 1

LAB ANALYST

• Receive the samples from the Drug Control Officer and form 18.

• Perform the test and generate a report in the form of form 13.

• Send the reports to Drug Controller and Drug Control Officer.

• Update about the status of Drug analysis and report generation.

DRUG CONTROLLER

• Receive the reports from the lab analyst in the form of form 13.

• Receive analysis about the samples from the Drug Control Officer.

• Deploy an Alert message to the firms/manufacturers, hospitals, pharmacists and Medical Representatives stating whether the drug is of standard or substandard.

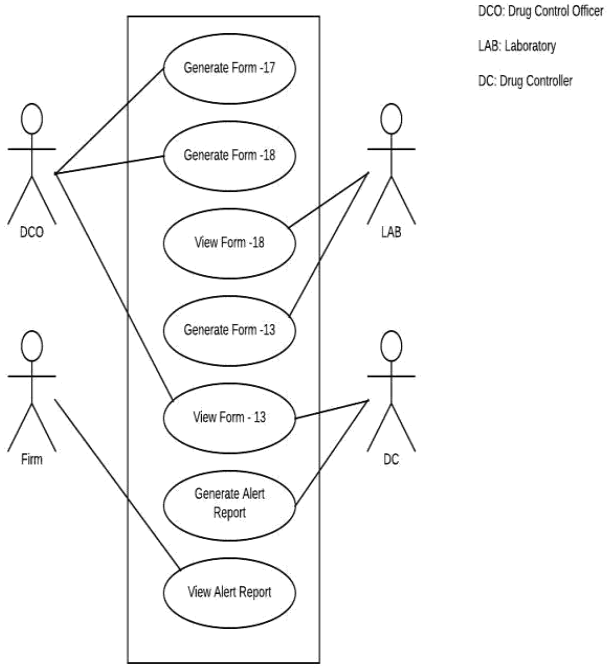


Figure 1.4 User Case Diagram

Hardware Requirement:

- A physical memory (RAM) of 512MB and above are required
- Intel, Celeron or AMD Pentium 3 processor
- Hard disk capacity: 2.4 GHZ, 80 GB HDD for installation

Software Requirement

- Operating system: Windows (98, 2000, ME, NT, XP, Vista, 7, 8, 10), Linux, Mac OS.
- JavaScript-enabled web browsers: Mozilla Firefox (Most suitable), Internet Explorer, Google Chrome, and Opera-mini.
- For front end development HTML, CSS ,JavaScript and JSP is used.
- For the Back End development Java and database by MySQL.
- The tools used are JDK 1.8, Eclipse and Apache Tomcat Server.

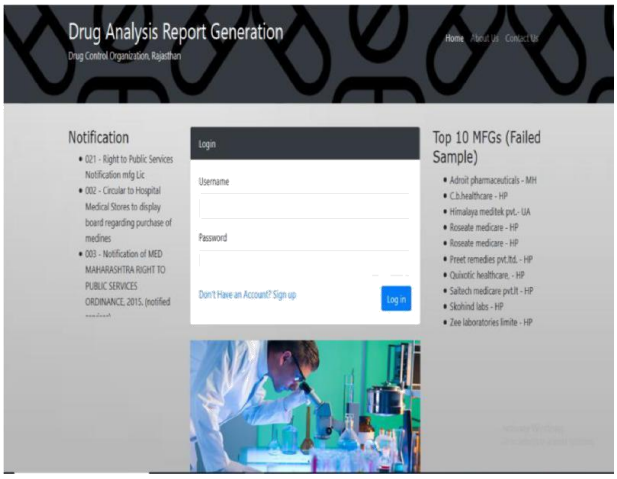


Figure 1.5 The login page for Manufacturer, Drug Control Officers, Drug Controllers , Lab Analyst and Admin

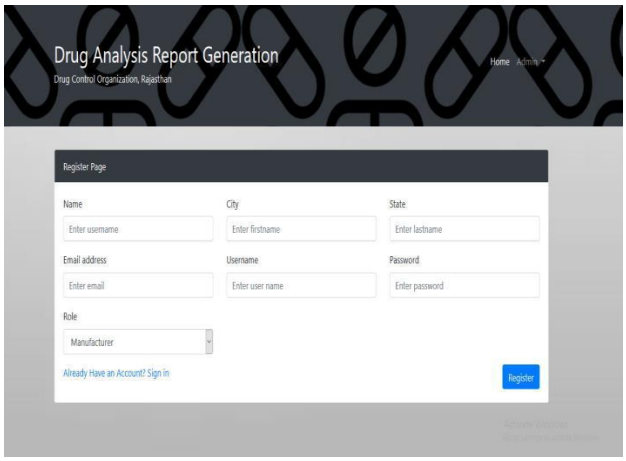
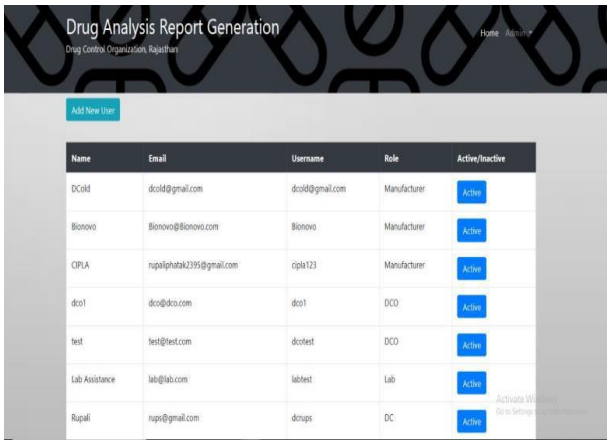


Figure 1.6 The registration page for new users i.e. Manufacturer, Drug Control Officers, Drug Controllers and Lab Analysts

Figure 1.7 The admin page where he will activate and verify the user account for Manufacturer, Drug Control Officers, Drug Controllers and Lab Analysts



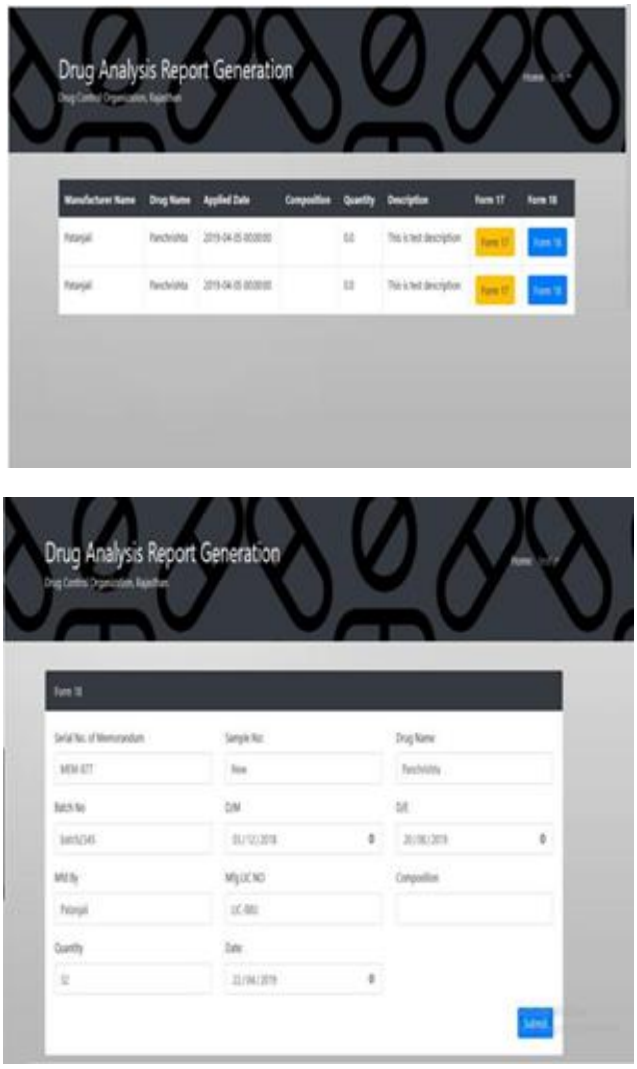


Figure 1.8 The Drug Controller page where he will receive the application for sample testing and will submit the memondrum to manufacturing firms in the form of Form 18 and thereafter the Form 18 will be activated. After the submission of Form 17, the form 18 will get activated and will be submitted to Lab Analyst

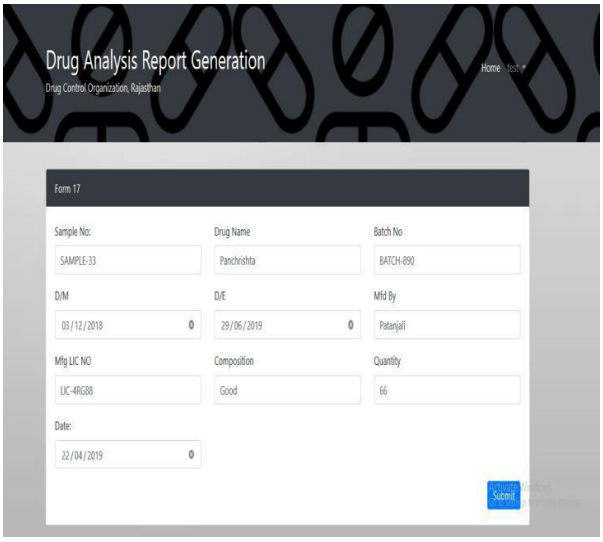


Figure 1.9 The view of Form 17 from Drug Control Officers Panel

VI. FUTURE SCOPE

Since this project deals with the digitalization of the manual process for testing of medicine it can be used by every state governments and central government for verifying the produced medicines. This project gives the vision to governments to implement it on a large scale under the ministry of health.

This project also serves the purpose of transparency and integrity between the entities (DCO, manufacturer, DC, labs).

VII. CONCLUSION

The main objective of this web application is to provide the digitalization to the drug and health department for filling forms. The DCO fills the form 17 as a memorandum on behalf of manufacturers to avoid any conspiracy. With this application, all the firms producing medicines in the country can fill form situated in any geographical locations. It also solves the problem as the manufacturer can easily fill the forms online. In this project, there is scope for integrity, availability that the reports are generated. Also, since the drugs are tested by filling the form through this platform are for pharmaceutical a purpose, who then confirms the order from the pharmacy to ensure that an intruder has not obtained their login details. This project has given the opportunity, to government bodies to make it digitally filling the form and help in alerting the entities by generating mail that the medicines are of standard and substandard and must be distributed in the market if it comes out to be standard otherwise not.

VIII. REFERENCES

[1]. D. O. Skobelev and T. M. Zaytseva, "Laboratory information management systems (LIMS).
[2]. Onuiri Ernest E., OyebanjiInalegwu G. Fayehun Solomon A., Chukwujioke Sam David," Online Pharmaceutical Management System "
[3]. GOST R ISO 5725-6-2002, Accuracy (correctness and precision) of Methods and Results of Use of Accuracy Values under Practical Conditions.
[4]. G. A. Gibbon, "Brief history of LIMS," Lab. Autom.Inform. Manag., Iss. 32, 1–5 (1996).
[5]. GOST R ISO/MEC 17025-2006, General Requirements and Jurisdiction of Testing and Calibration Laboratories.
[6]. ASTM E 1578-06, Standard Guide for Laboratory Information Management Systems (LIMS).
[7]. GOST 53798-2010, Standard Manual for Laboratory Information Management Systems.
[8]. B. Hillhouse, "Integration of LabWare LIMS and SAP R/3 QM," in Laboratory Information Management Systems and Management Enterprise Control Systems, Izd. OOO MIT, Moscow (2008).
[9]. Strategic Directions International, Inc, World survey of LIMS users, 2007.
[10]. GOST R ISO 5725-1-2002, Accuracy (correctness and precision) of Methods and Results of Measurements.
[11]. Turner S, Longwith A, Nunn AJ, Choonara I. Unlicensed and off-label drug use in pediatric wards: prospective study. BMJ. 1998;316:343–345. [PMC free article] [PubMed] [Google Scholar]
[12]. McIntyre J, Conroy S, Avery A, Corns H, Choonara I. Unlicensed and off label prescribing of drugs in general

practice. Arch Dis Child. 2000;83:498–501. [PMC free article] [PubMed] [Google Scholar]
[13]. Carlos Correa "Ownership of Knowledge - the role of patents in pharmaceutical R&D", WHO Bulletin, Volume 82, Number 10, October 2004, 719-810
[14]. CIPIH Report (2006), p. 187.
[15]. Forman. L., "Desk review of the intergovernmental working group on public health, innovation, and intellectual property from a right to development perspective" unpublished paper, Geneva, March 2009 16. Frederick M. Abbott and Jerome H. Reichman, "Strategies for the Protection and Promotion of Public Health Arising out of the WTO TRIPS Agreement Amendment Process", Florida State University and Duke University
[16]. OMS, "Public Health, innovation and intellectual property" Geneva 2006, op. cit. P.35
[17]. P. Trouiller, et al., ''Drug Development for Neglected Diseases: A Deficient Market and a Public Health Policy Failure'', The Lancet 359 (2002): p. 2188. 19.Richard D. Smith, Carlos Correa and Cecilia Oh, "Trade, TRIPS and Pharmaceuticals", (2009) The Lancet 373, p. 687.
[18]. Seuba, X. "La protección de la Salud ante la regulación Internacional de Los Productos farmacéuticos" doctoral thesis p.92 and following Barcelona 2008.