MODIFICATION OF LABORATORY INFORMATION MANAGEMENT SYSTEM PROGRAM (STARLIMS®) FOR COSMETIC MANUFACTURING

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MASTER OF SCIENCE
IN COSMETIC SCIENCE

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2008

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AN INDEPENDENT STUDY SUBMITTED TO
MAE FAH LUANG UNIVERSITY IN PARTIAL FULFILLMENT OF
THE REQUIREMENTS FOR THE DEGREE OF
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Independent Study Title Modification of Laboratory Information Management System Program (STARLIMS®) for Cosmetic Manufacturing

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ABSTRACT

StarLIMS® is software program designed as a laboratory information management system to increase the accuracy and speed of the manufacturing process. After reviewing the survey and relevant literature, as well as directly inquiring from the software owner, it has been established that there are currently no cosmetic manufacturers in Thailand that use StarLIMS® to manage and control quality in their processes. The objectives of this study were to modify the StarLIMS® Software Program as the primary operating system for the management and quality control of a laboratory in the cosmetics manufacturing industry as a means of standardizing the production process and quality levels to meet ASEAN's Good Manufacturing Practice (GMP) Guidelines as they relate to the production of cosmetics. In addition, the primary source of information in this study was the system user. Qualitative data was gathered through open-ended questions in one-on-one interviews that searched for both advantages and disadvantages in the system in terms of the management of production and quality control. Supporting data was researched from existing literature on the subject, from the company which owns the operating system, and from various other sources. The results of the study showed that modified StarLIMS®

Program for cosmetic manufacturing was supported, business operation, increased effectiveness and prevented the loss during the manufacturing process by improving the management of ingredients, inventory, accounting, personnel and budgeting. We have gain from a successful implementation of the system. By eliminating every possibility of human error within the manufacturing process, both time and money are saved for the manufacturer. Moreover, the customer benefits from having products of a guaranteed safe and consistently high standard as the system meets ASEAN's GMP Guidelines. The successful application of modified StarLIMS® program will be one of crucial steps in eventually developing high standard cosmetic products to the world market.

Keyword: Laboratory Information Management / System StarLims® Program / ASEAN's Good Manufacturing Practice Guidelines

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ABBREVIATION AND SYMBOL

BPR	=	Batch Product Record
GMP	=	Good Manufacturing Practice
ID	=	Identification
QC	=	Quality Control

CHAPTER 1

INTRODUCTION

1.1 Background of the Study

In our modern world, cosmetic products play an integral role in our daily lives. Everyone uses cosmetic products on a daily basis, whether for personal hygiene or for beautification. Indeed, it would be difficult to imagine a world without shampoo, soap, toothpaste, deodorants and lipstick. For this reason, the correct production of cosmetics is important because improper processing methods, use of low quality substances, or contamination could cause hypersensitive reactions (rashes), allergic reactions, dermatitis or toxicity, some of which can prove fatal in extreme cases. Due to the obvious danger to public health that a lack of regulations in the industry could lead to, the Ministry of Public Health has repeatedly expressed its concern through the consumer protection policy.[(1)] In order to prevent consumers being at risk, the Thai government's Food and Drug Agency (FDA), pays close attention to protecting the safety of consumers and monitoring the efficacy of the cosmetic products. To this end, the Thai FDA not only promotes standardized, high quality cosmetic products among all manufacturers within the industry, but also closely supervises these standards through inspections that cover every step of the manufacturing process.[(1)]

According to cosmetic product regulations as set out by the Ministry of Public Health, The Cosmetic Act 1992 (B.E. 2535) defines cosmetic products into two categories: controlled and specially-controlled. Cosmetic products that are not classified in either group will be regarded as general cosmetics. Moreover, the Cosmetic Committee with thirteen representatives from the government sector and six representatives from the private sector is appointed as the advisory board to the Minster of Public Health on regulatory and technical aspects of cosmetics. The Cosmetic Committee appoints 4 subcommittees: Standard and Pre-Marketing Approvals, Quality Improvement, Labeling and Advertising, and Good Manufacturing Practice (GMP) to assist it on

particular functions. The implementation of the GDP in the cosmetics industry is a Thai FDA policy aimed specifically at establishing and maintaining high production standards among producers. The cosmetic industry GMP is established by the GMP subcommittee and used as the primary reference by the FDA inspectors. (2)

Furthermore, as an Association of South-East Asian Nations (ASEAN) member, Thailand has complied with the Agreement of the ASEAN Harmonized Cosmetic Regulatory Scheme which was set up to provide conformity of assessments, harmonization of standards, and technical regulations to make an important contribution to the economic integration within ASEAN. Members of ASEAN are the Government of Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand and the Socialist Republic of Vietnam.(3) According to the Secretary General of ASEAN, Mr. Ong Keng Yong, the ASEAN Cosmetic Documents states that: "The operation of the ASEAN Harmonized Cosmetic Regulatory Scheme will, no doubt, assist regulators in networking for best practices and ensuring safety for consumers. In turn, this will assist the cosmetic industry in reducing the cost of doing business and gaining market access for its products in ASEAN and international markets." (3)

As stipulated during the 11th meeting on 26-27th of July 1993 in Manila, The Philippines, The ASEAN Harmonization of Cosmetic Regulation reached an agreement for the use of a new ASEAN Harmonized Cosmetic Regulatory scheme, Schedule B-ASEAN Cosmetic Directive for ASEAN Cosmetic GMP to start on January 1st 2008 (B.E. 2551)." (4) On this date, the Thai FDA implemented and enforced rules and regulations requiring all cosmetic manufacturing companies to meet the standard of Cosmetic Good Manufacturing Practice. However, so far only 66 cosmetic industries have become eligible to be GMP certified manufacturing plants. Many more failed to qualify due to problems of unacceptable building design or facilities which did not meet the ASEAN cosmetic GMP standard. (5)

The management and Quality Control of Cosmetic Laboratories are crucial factors for the production and quality of products before launch to the market or deliver to consumers. The manufacturers need to have the effective management process and quality control system that are aligned with the objectives of production under Good Manufacturer Production (GMP) Basic

Principle. The Thai FDA has cooperated with Asian countries to agree to follow the guidelines of ASEAN Cosmetic GMP since 1 January 2008. This has caused all manufacturers of cosmetic in Thailand to revise their manufacturing process according to the criteria of ASEAN Harmonization including the quality management system, personnel, location, machinery, tools, hygiene, manufacturing process, quality control, internal audit, documentary system, product complaints and product recall. [6]

StarLIMS[2] is user–friendly software designed as a laboratory information management system to increase the accuracy and speed of the manufacturing process. After reviewing the survey and relevant literature, as well as directly inquiring from the software owner, it has been established that there are currently no cosmetic manufacturers in Thailand that use StarLIMS to manage and control quality in their processes.

The Application of the StarLIMS Program as a Laboratory Information Management System of Cosmetic Manufacturer is to apply information technology to manage and control the processes in laboratories to increase the accuracy and speed of the manufacturing process. Therefore, we assume that the cosmetic manufacturers that apply the StarLIMS Program for their laboratories do so in order to improve cosmetic quality under ASEAN Cosmetic GMP Guidelines.

Moreover, the StarLIMS Program supports business operation, increases effectiveness and prevents the loss during the manufacturing process by improving the management of ingredients, inventory, accounting, personnel and budgeting.

This study will explain how to apply the StarLIMS Program in order to improve the management and quality control of cosmetic laboratories. The successful program application will be one of crucial steps in eventually developing high standard cosmetic products to the world market.

1.2 The Objective of Study

1. Modify the StarLIMS Program for the management and quality control of laboratories of cosmetic manufacturers.

2. Study a possibility to modify and apply the StarLIMS Program for management and quality control of laboratories under ASEAN Cosmetic GMP Guidelines.

1.3 The Scope of Study

The population in the study means the cosmetic manufacturers which have their own laboratory to control the cosmetics' quality. This study focuses on the sample size of one cosmetic manufacturer in Bangkok or sub-urban areas of Bangkok which has its own laboratory. The location of the study is the laboratory of the cosmetic manufacturer where I collect, analyze, improve and follow up program testing with the user by interview and questionnaire. The data that was used for this study involved qualitative data that was gathered by using the survey approach with open-ended questions asked in personal interview. This data is used as extensive information so as to improve the production and quality control including advantages and disadvantages that occurred in the company. The data in this study was also obtained from textbooks, websites (URL), primary publications, the StarLIMS Corporation Limited Company and other sources.

According to the StarLIMS program, this study is limited to only providing the implementation of the production process control. The program was applied to be easy to use for controlling the measurement of the amount of the product ingredient. According to ASEAN Cosmetic Good Manufacturing Practice (GMP), this study is limited to production and quality control which are 2 of 15 ASEAN Cosmetic GMP Guideline aspects.

The indicator or variable of the study refers to the satisfaction of the StarLIMS program user for Laboratory Information Management System of Cosmetic Manufacturer by the open-ended questionnaire and the evaluation form after using the program. Accordingly, the tools used in the study include:

1. StarLIMS Program by StarLIMS Corporation Limited
2. Evaluation form of StarLIMS Program application

1.4 Benefits of the Study

1.4.1 For cosmetic manufacturers to be able to apply the StarLIMS program effectively as a laboratory information management system for cosmetic manufacturer.

1.4.2 For cosmetic manufacturers to be able to achieve the good production procedure and quality control so that they are relevant to ASEAN GMP guidelines.

1.4.3 For cosmetic manufacturers to be able to achieve the good and high quality products following ASEAN GMP guidelines.

CHAPTER 2

LITERATURE REVIEWS

2.1 ASEAN GMP Guideline

The Cosmetic Good Manufacturing Practice (GMP) guidelines aim to ensure that a consistent level of quality is achieved during the manufacture of all products. All aspects of production and quality control are included in these guidelines. To guarantee the benefits of each product and safeguard the customers' health, the finished products must satisfy strict standards of quality that are appropriate to their specific intended use. The key criteria for product quality are the raw materials, the production and quality control process, the environment in which they are manufactured, the equipment involved in their manufacture and the personnel involved in their manufacture. [7, 8]

ASEAN Cosmetic GMP Guidelines are concerned with 15 aspects of production and quality control as follows:

1. Introduction
2. Personnel
3. Premises
4. Equipment
5. Sanitation and hygiene
6. Production
7. Quality control
8. Documentation
9. Internal audits
10. Storage
11. Contract manufacturing and analysis
12. Complaints

13. Product recalls
14. Glossary
15. References

In order to achieve stated policies and objectives, a quality control mechanism needs to be developed, established and implemented. This system should define the organizational structure, functions, responsibilities, procedures, instructions, processes and resources required for the application of quality management. The operation of this system should ensure that quality is maintained throughout the production process by the taking and testing of samples before, during and after production. Raw materials, materials in process, and the finished products would be either passed or rejected, dependent on their quality as ascertained through the sample testing and any other relevant evidence. This independent study is limited to the process of production, recommended appropriate procedures, and processing.

The Good Manufacturing Practices outlined here are only intended to provide rudimentary guidelines of general practices from which the manufacturers should develop their own management and control systems from the Laboratory Information Management System (LIMS) by applying the Star LIMS program. Above all else, protecting the consumers' health and providing the intended benefits by ensuring that the final product always meets the quality standards appropriate to its intended application remain the primary objectives. However, while achieving these objectives is of paramount importance, manufacturers of cosmetic products must also provide consistent control and monitoring in every stage of the manufacturing process to ensure that the consumers always receive products of a specified level of quality.

Production is the 6th aspect of the ASEAN's Cosmetic GMP Guideline and the details are as follow:

6. Production
    1) Starting Materials
        a) Water

Special attention should be paid to water, since it is an important raw material. Water production equipment and water systems should supply quality water. Water systems should be sanitized according to well-established procedures.

The chemical and microbiological quality of water used in production should be monitored regularly, according to written procedures and any anomaly should be followed by corrective action.

The choice of method for water treatment such as deionization, distillation or filtration depends on product requirement. The storage as well as delivery system should be properly maintained.

b) Verification of materials

All deliveries of raw materials and packaging materials should be checked and verified for their conformity to specifications and be traceable to the product.

Samples of raw materials should be physically checked for conformity to specifications prior to release for use. The raw materials should be clearly labeled. All goods must be clean and checked for appropriate protective packing to ensure no leakage, perforation or exposure.

c) Rejected materials

Deliveries of raw materials that do not comply with specification should be segregated and disposed according to standard operating procedures.

2) Batch Numbering System

a) Every finished product should bear a production identification number which enables the history of the product to be traced.

b) A batch numbering system should be specific for the product and a particular batch number should not be repeated for the same product in order to avoid confusion.

c) Whenever possible, the batch number should be printed on the immediate and outer container of the product.

d) Records of batch number should be maintained.

3) Weighing and Measurement

a) Weighing should be carried out in the defined areas using calibrated equipment.

b) All weighing and measurement carried out should be recorded and, where applicable, counterchecked.

4) Procedure and Processing

a) All starting materials used should be approved according to specifications.

b) All manufacturing procedures should be carried out according to written procedures.

c) All required in-process controls should be carried out and recorded.

d) Bulk products should be properly labeled until approved by Quality Control, where applicable.

e) Particular attention should be paid to problem of cross-contamination in all stages of processing.

5) Dry Products

Handling of dry materials and products should be given special attention. Where possible, dust-containing production system, central vacuum system or other suitable methods should be employed.

6) Wet Products

a) Liquids, creams and lotions should be produced in such a way as to protect the product from microbial and other contamination.

b) The use of closed systems of production and transfer is recommended.

c) Where pipe-lines are used for delivery of ingredients or bulk products, care should be taken to ensure that the systems are easy to clean.

7) Labeling and Packaging

a) Packaging line should be inspected for clearance prior to operation. Equipment should be clean and functional. All materials and products from previous packaging operation should have been removed.

b) Samples should be taken and checked at random during labeling and packaging operations.

c) Each labeling and packaging line should be clearly identified to avoid mix-up.

d) Excess labels and packaging materials should be returned to store and recorded. Any rejected packaging materials should be disposed off accordingly.

8) Finished Product: Quarantine and Delivery to Finished Stock

a) All finished products should be approved by Quality Control prior to release.

Quality control is the 7th aspect of ASEAN's Cosmetic GMP Guideline and the details are as follow:

7. Quality control

1) Introduction

Quality control is an essential part of GMP. It provides assurance that cosmetic products will be of consistent quality appropriate to their intended use.

a) A quality control system should be established to ensure that products contain the correct materials of specified quality and quantity and are manufactured under proper conditions according to standard operating procedures.

b) Quality control involves sampling, inspecting and testing of starting materials, in process, intermediate, bulk, and finished products. It also includes where applicable, environmental monitoring programs, review of batch documentation, sample retention program, stability studies and maintaining correct specifications of materials and products.

2) Reprocessing

a) The methods of reprocessing should be evaluated to ensure that they do not affect the quality of the product.

b) Additional testing of any finished product which has been reprocessed should be performed.

3) Returned Products

a) Returned products should be identified and stored separately either in allocated area or by moveable barrier such as rope or tape.

b) All returned products should be tested if necessary, in addition to physical evaluation before being released for distribution.

c) Returned products which do not comply with the original specification should be rejected.

d) Rejected products should be disposed according to appropriate procedures.

e) Records of returned products must be maintained.

In terms of the production process, it is crucial to manufacture products under the defined specification. If the manufacturing process deviated from the defined specification, the quality and customers' perception would change and damage customer loyalty. The customers may not trust in the products and change to use another trusted brand. Moreover, the changes of active ingredients in cosmetics products would lead to the loss of efficacy and adverse effects such as allergic reactions, rashes or irritations. One of the most likely errors during the manufacturing process is to err in mixing process by adding active ingredients different from the formula of the customer's order. This error may lead to a lawsuit or cancellation of orders that cause serious damage to the manufacturer.

Therefore, quality control is important for the manufacturing process in order to get the same quality product with the right formula and specifications. The good manufacturer who has its own laboratory should set up the quality control department and appoint the qualified personnel to run the laboratory. The small manufacturer should not run a laboratory without quality control.

In order to ensure precise results, a good cosmetic manufacturing system requires an effective laboratory information management system that can store information from every part of the processes. A good management system must be able to accurately check and present all relevant information clearly as well as being able to link to the other processes or documents to meet ASEAN's Cosmetic GMP requirement.[8] Applying the StarLIMS Program for the laboratory information management system of cosmetic manufacturers can lead to greater convenience, improved efficiency and increased production capacity.

2.2 StarLIMS Program

The “Laboratory Information Management System" (LIMS) is computer software used in laboratories to administrate laboratory users, instruments, samples, standards and other laboratory functions such as invoicing, plate management, and work flow automation. The LIMS performs similar functions to a Laboratory Information System (LIS). The main difference is that the LIMS is primarily used in environmental research or commercial analysis, such as in the pharmaceutical or petrochemical fields, whereas the LIS is designed for clinical markets, such as hospitals and clinical laboratories.

The StarLIMS Program has been adopted as the laboratory information management system by various organizations for pharmaceutical research and development and as a quality control system under various guidelines, including GMP, GLP, 21 CFR Part 11 etc. Major oil refineries and the laboratory of public health have also applied it in their work. The StarLIMS software is flexible enough that it can be adjusted according to individual laboratory’s specific purposes.

Therefore, the StarLIMS program should be an appropriate laboratory information management system for cosmetics manufacturers.

Nowadays, the trend is to take the whole process of information gathering, decision making, calculation, review and release out of the office and directly into the workplace with the aim of creating smoother operation whereby:

1. Laboratory instruments are integrated into a network from which they can receive instructions and work lists and to which they can return finished results including raw data back to a central repository where relevant information can then be updated to external systems such as a Manufacturing Execution System or Enterprise Resource Planning application.
2. Lab personnel will make calculations, complete documentation and analyze results using online information from a network of instruments, reference databases and other resources such as electronic lab notebooks (ELN's) all centrally connected to the LIMS.
3. Management can oversee the lab process, react to workflow bottlenecks and ensure regulatory demands are met.

4. External participants (department, company) can submit work requests and monitor progress, review results and print out analysis certificates and other documentation (perhaps even historically).

Indeed, with the cutting edge technologies of today, the LIMS is being touted as the complete enterprise resource planner (ERP) for the laboratory, no longer confined to simply monitoring samples and recording results. While it can be client-server or PC-based, it is now increasingly web browser-based with extensive functionality.[9]

StarLIMS is a powerful tool, allowing labs to manage complex processes, ensure regulatory compliance and promote laboratory and enterprise collaboration. StarLIMS is a web-based off-the-shelf LIMS (Laboratory Information Management System) flexible enough to adapt and function in a wide variety of laboratory environments in many scientific and industrial disciplines. StarLIMS consolidates disparate business functions into one compliant platform with comprehensive reporting, surveillance and networking capabilities, thus allowing greatly improved information management and sharing both within the laboratory and throughout the organization.[9]

StarLIMS has been successfully Future-Proofing Customer Investments for over 20 years. StarLIMS solutions are the perfect platform for both new implementations and simple conversions of older systems. Globally renowned as future-proof investments, the StarLIMS laboratory information management system preserves configuration efforts in all upgrades. Since its first appearance, StarLIMS has been dedicated to developing world-leading LIMS. The result of hundreds of man-years of focused research and development is a flexible LIMS platform that is easily configured to match the dynamic processes of virtually any lab. StarLIMS has a proven track record in public health, pharmaceutical, petrochemical, forensics, food and beverage, environmental, water and chemical industries. The company supports R&D and service-oriented organizations as well as processes, QA/QC and operations.

Figure 2.1 StarLIMS Dashboard automatically monitors the flow of data – providing targeted, real-time information personalized according toeach user's role and authorization level

StarLIMS was built from the ground up as an entirely web-based laboratory information management system. Leveraging XML and other advanced Internet technologies, StarLIMS enhances overall operational excellence in all types of laboratories and organizations.[10]

2.3 General Features of the StarLIMS Program

Monitoring and Tracking Traceability

1. System Statuses

Click the System Statuses Tab to check a different "Status". Each information set contains the status name, synonyms or status value and place to represent status values and places when using the information. Moreover, the status may be defined its background, screen and pictures including editing information at Synonym" and "Used In" menu.

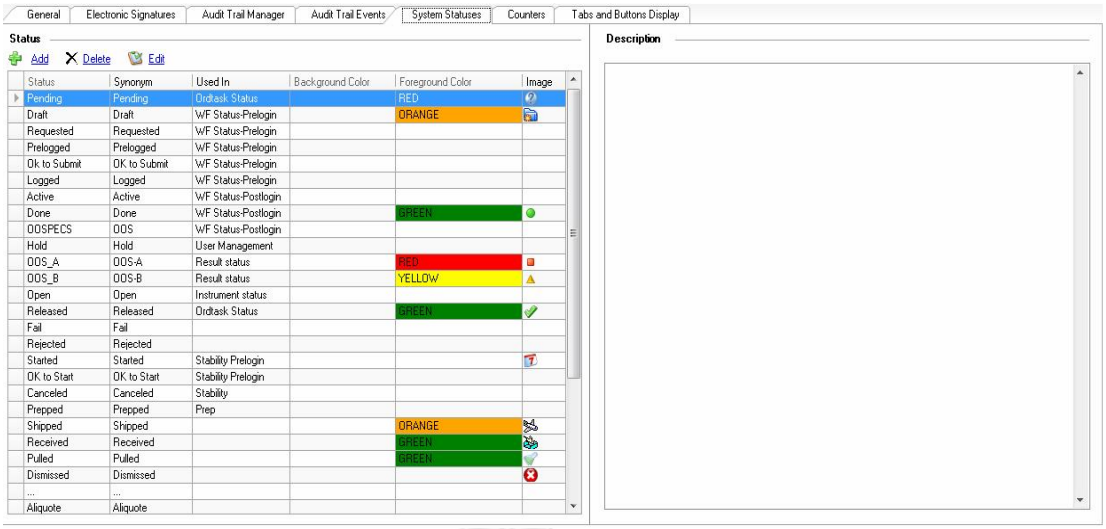


Figure 2.2 shows System Statuses

2. Using Approvals to Accept Actions

According to the criteria of GLP (Good Laboratory Practices), the system itself needs a Username and Password to edit and audit the information, if needed. The user can go to "Audit Trail Rules" in "Utilities", and then click on "Settings" in order to get the Approvals and Rejections for each specimen.

3. Using a Chain of Custody for Samples

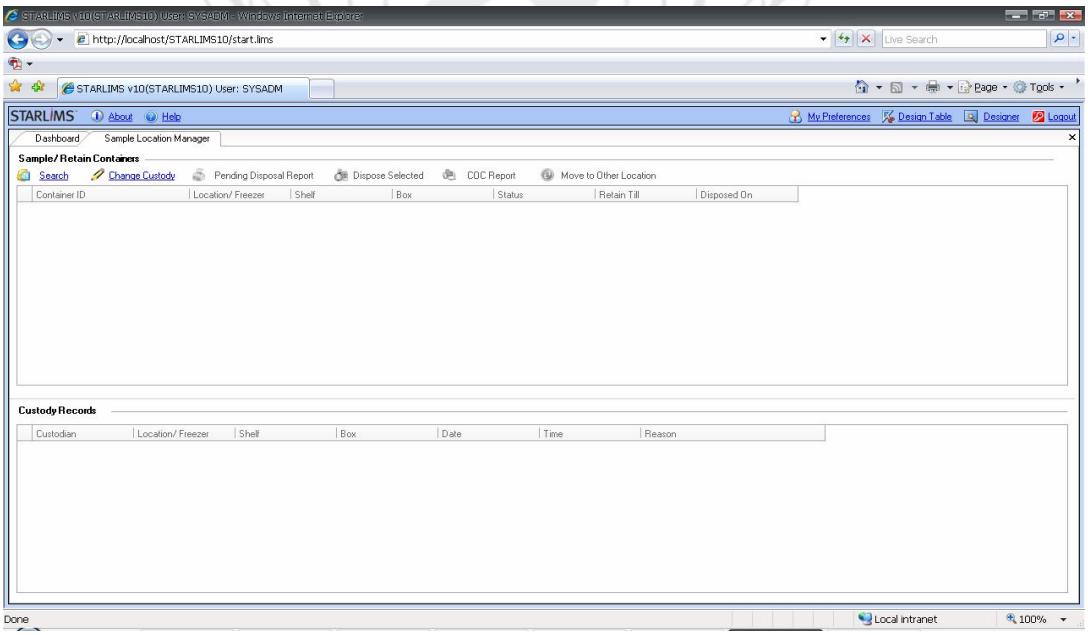


Figure 2.3 shows Sample Location Manager

In the “Chain of Custody” section, the user can observe the movements of a specimen in the laboratory. We can use the ”Sample Location Manager” feature to eliminate a specimen, move it from place to place, record its location, and also follow up the past records of the specimen.

4. Test Capacity Definitions

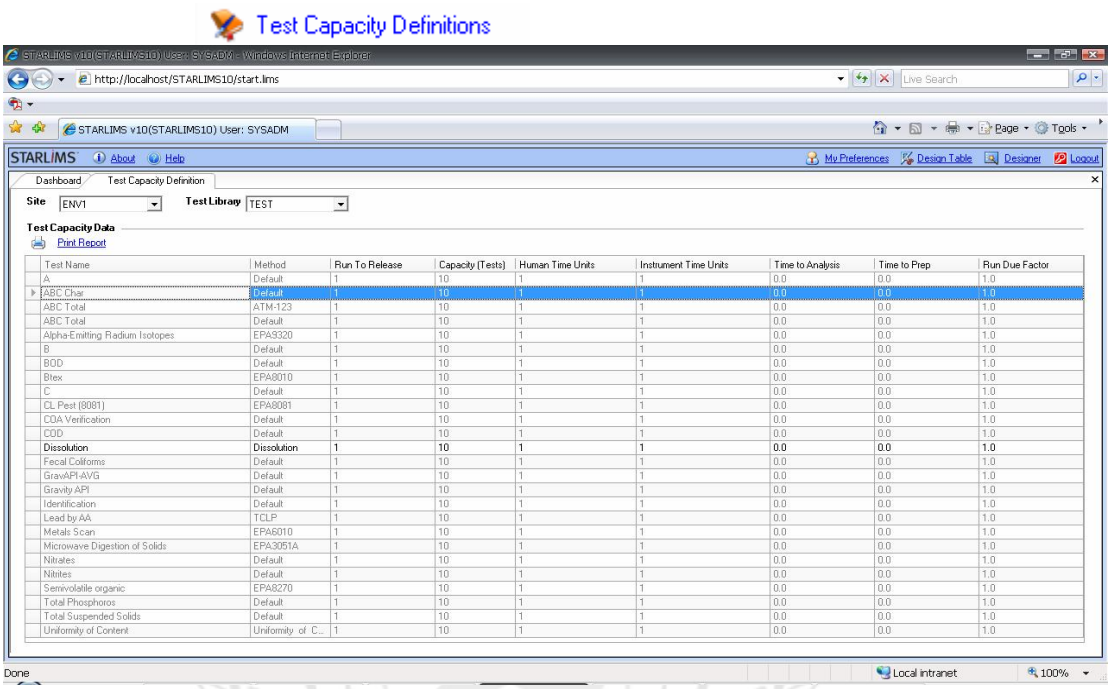


Figure 2.4 defines the type of test into the system

Preocess Management can manage the maximum capacity of specimens in the laboratory. The user can set the maximum capacity according to the number of specimens.

When the specimen has registered and defined the type of test into the system, the user will start testing and see the information of the specimen in “Console Branch”. The specimen will be categorized in “My Team’s Pending Tests” and “My Pending Tests”. If the number of tests exceeds the maximum capacity of the laboratory, the system will manage itself to test the specimen. To follow up “% of Capacity”, the user will use the report “Test as % of Capacity” on the StarLIMS Dashboard (Gauges for Management)

5. Viewing Auditing Information

StarLIMS's System can check the record of information, laboratory staff training, maintenance and tools calibration, specimen testing, and quality control standards including changing of testing record. The user can check information in "Traceability" that "Event" logs with signatures and "Audit Trail" also shows up on this menu.

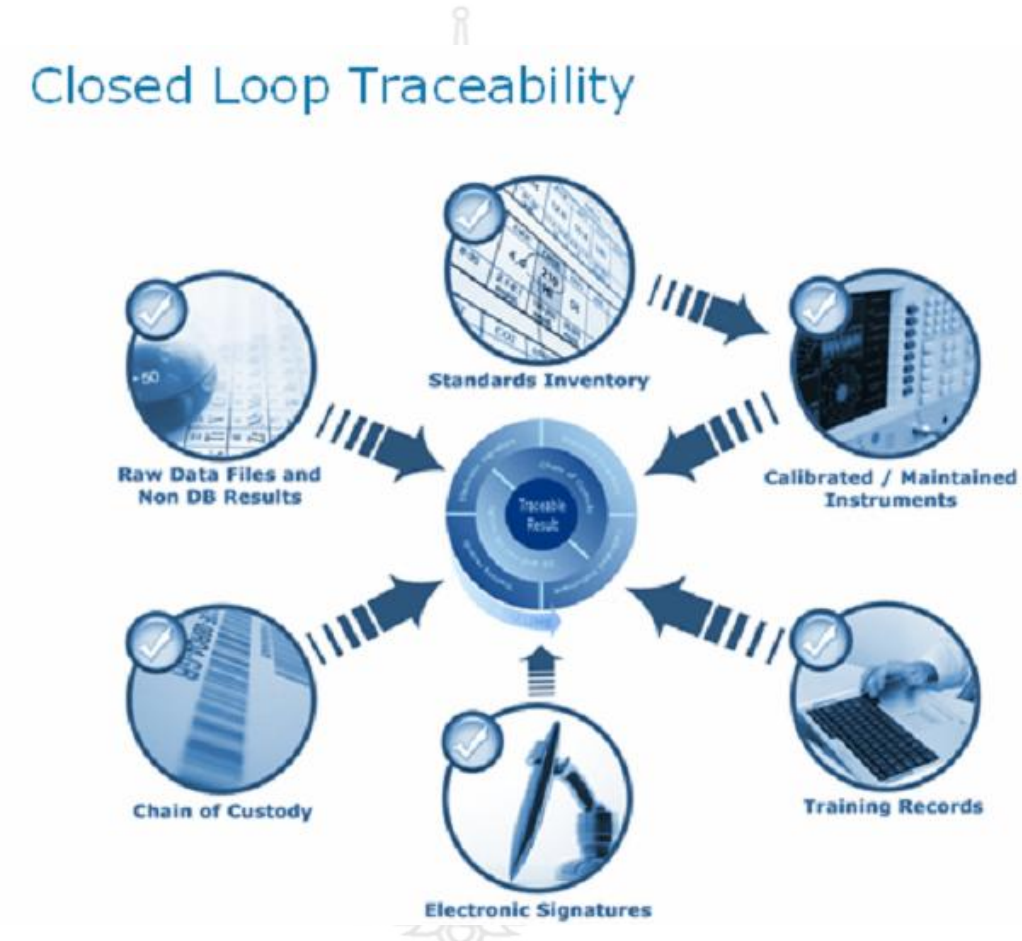


Figure 2.5 shows traceability of StarLIMS's System

At "Traceability", the information at the top of the samples is the old information that has not been updated. The updated information will be shown in the "Dynamic Folder Information" which has been retrieved from "Test Plan Manager" for "Test Definition". Furthermore, if the user clicks on "Toggle View" in "Samples", the format of information will change to be categorized "by test" or "by order". Number and click "View Retests" to show the status of revised or changed specimens after retesting.

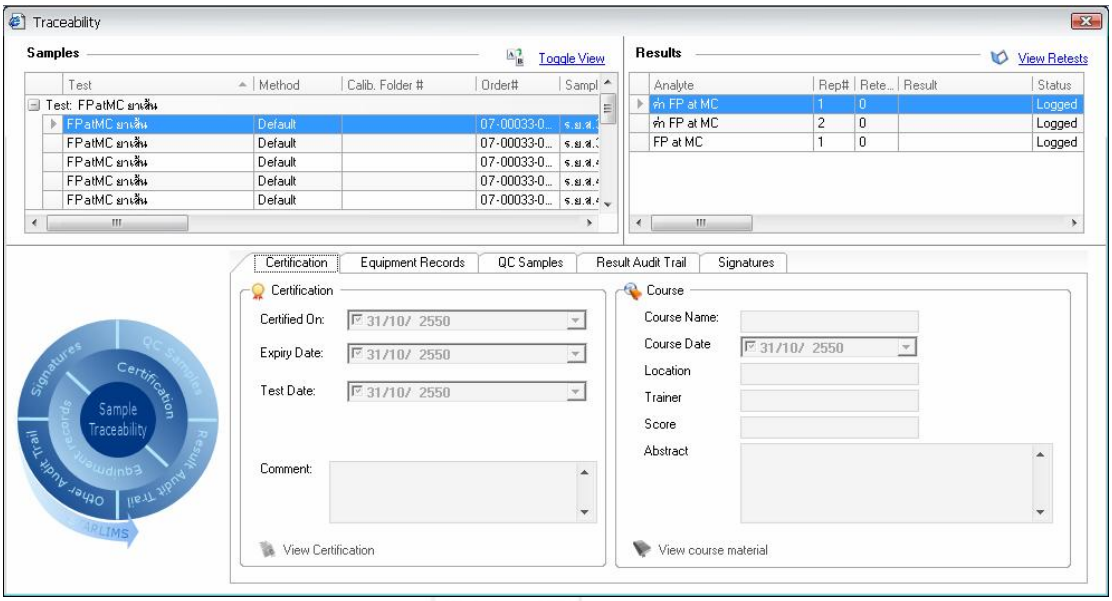


Figure 2.6 shows Sample Traceability

1) Analyst Certifications

The "Certification Tab" shows the record of training and certificates of laboratory staff. Some tests can only be run by certified laboratory staff so that the system will control that only certified laboratory can run the test. In this function, the system will show only the information of certified laboratory staff who can run the test.

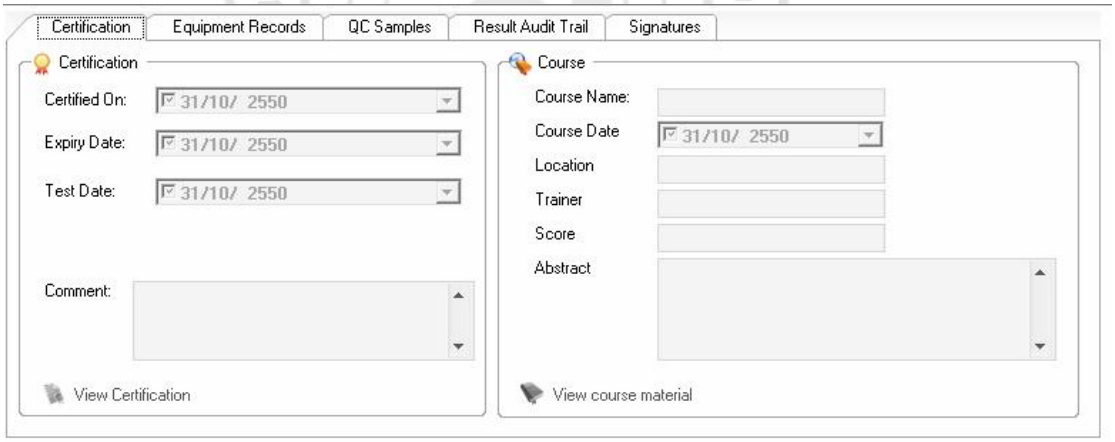


Figure 2.7 shows Analyst Certifications

2) Equipment Records

In this function menu, the system will show the information of tools, maintenance and tools calibration in the laboratory by clicking on “Static Tables” then choosing “Equipment Manager”.

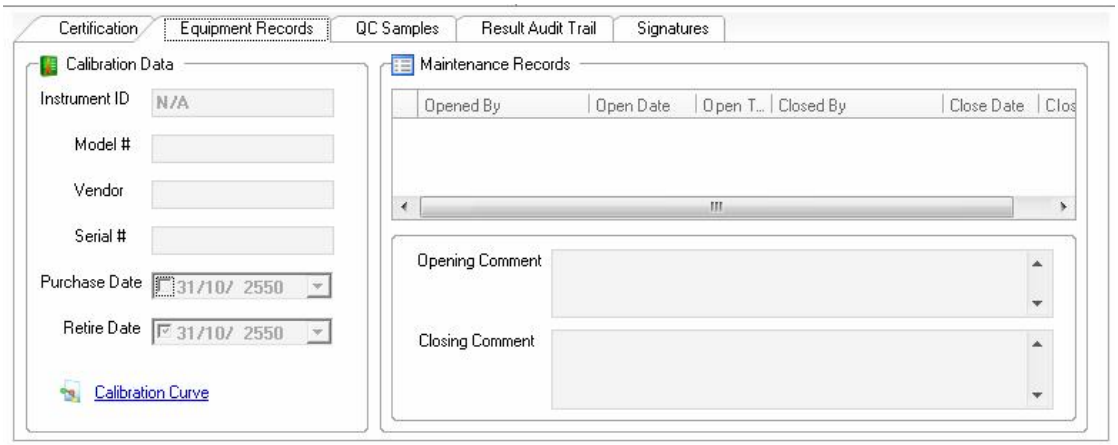


Figure 2.8 shows Equipment Records

3) QC Samples

In this function menu, the system will show standard and control testing substances.

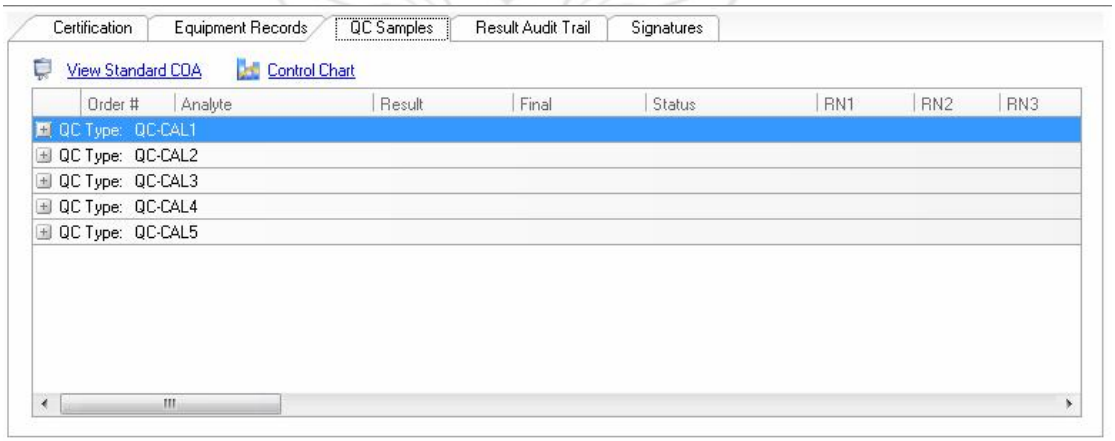


Figure 2.9 shows QC Samples

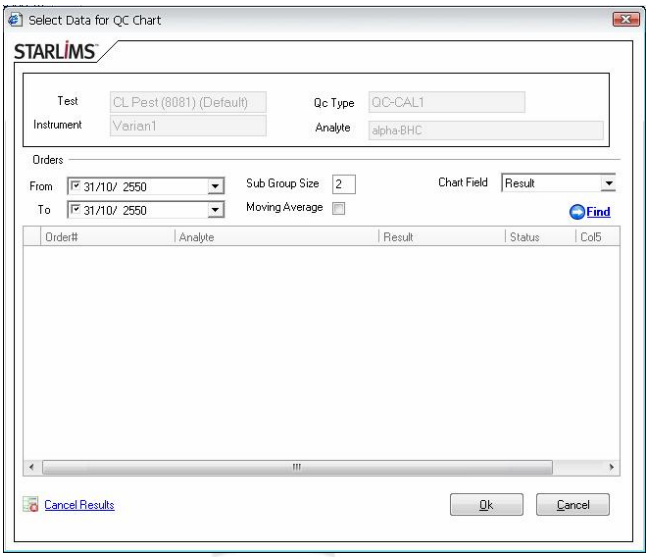


Figure 2.10 QC Chart

4) Result Audit Trail

This menu will show records of changing tests at "Results" comparing the old and new information including date and time of information changing.

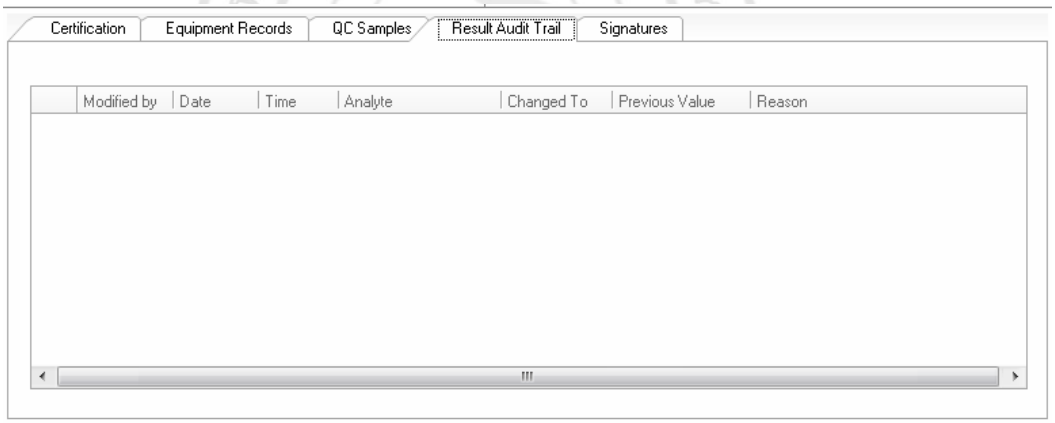


Figure 2.11 shows Result Audit Trail

5) Signatures

The "Signatures Tab" shows all operations with specimens such as registration and access of specimens to the system.

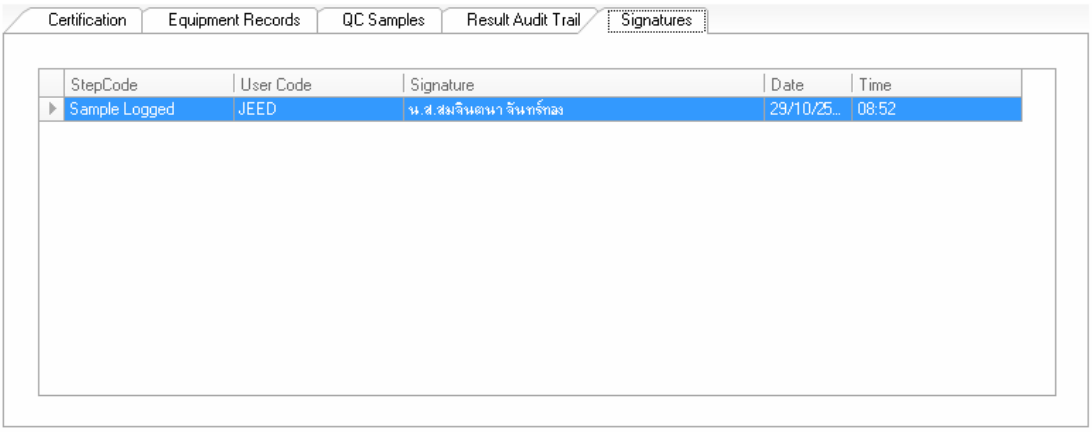


Figure 2.12 shows Signatures Tab

6) Tests/Standards Tab

The user can use the "Equipment Manager" selecting the tab "Tests/ Standard" to define the standard testing substance information, template and calibration curve. If the user needs to know the test of tools in laboratory, they can Click "Enter Calib. Results"

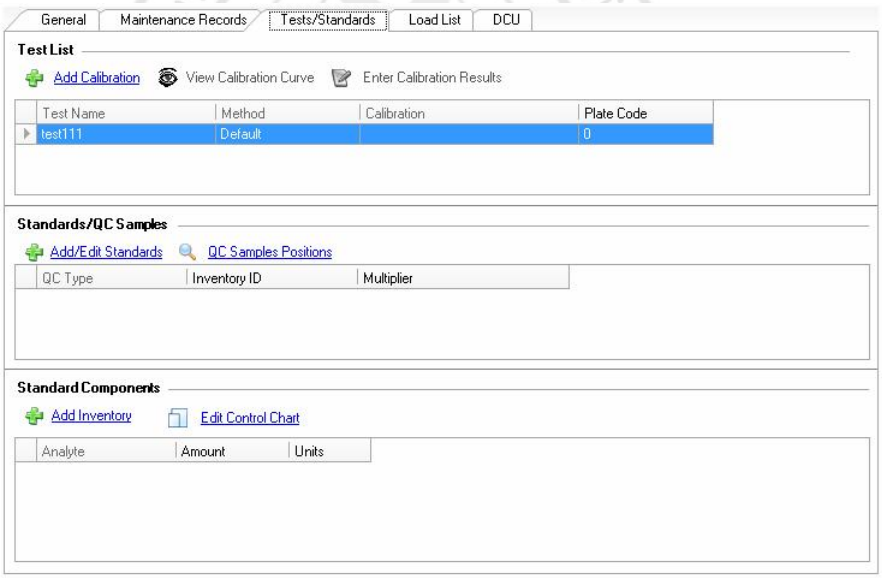


Figure 2.13 shows Tests/Standards Tab

1) Using Calibration Curves to Calibrate Instruments

User can calibrate instruments by using known concentration standard of the analyses. The concentration of standard will be ranked and plotted on “Calibration Curve”. If the line of calibration is aligned with the standard, it means that the instrument is valid. The user can compare the unknown sample with the liner curve to find out the concentration of unknown samples.

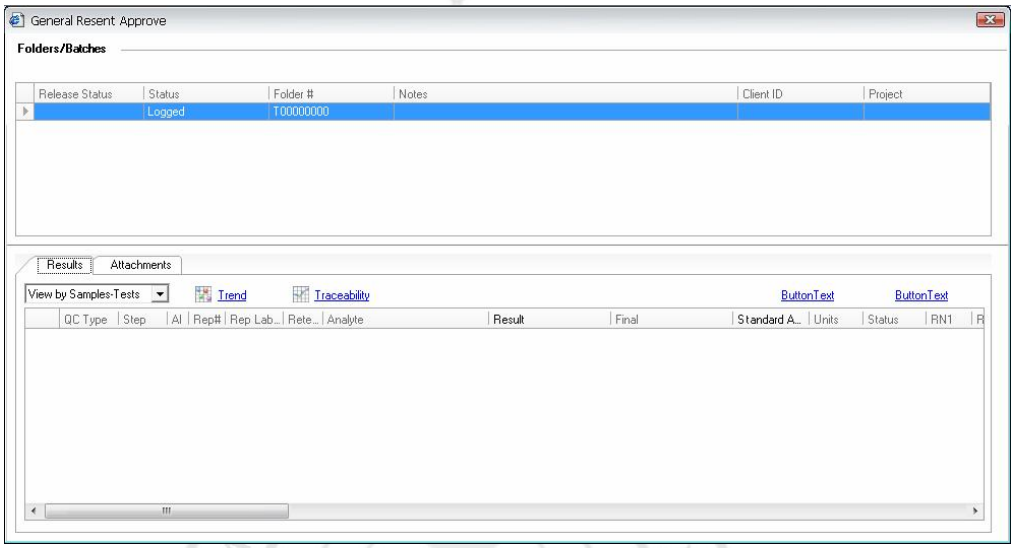


Figure 2.14 click “View by Sample – Tests” tab

Click “View Calibration Curve” to see the Calibration Curve as follows:

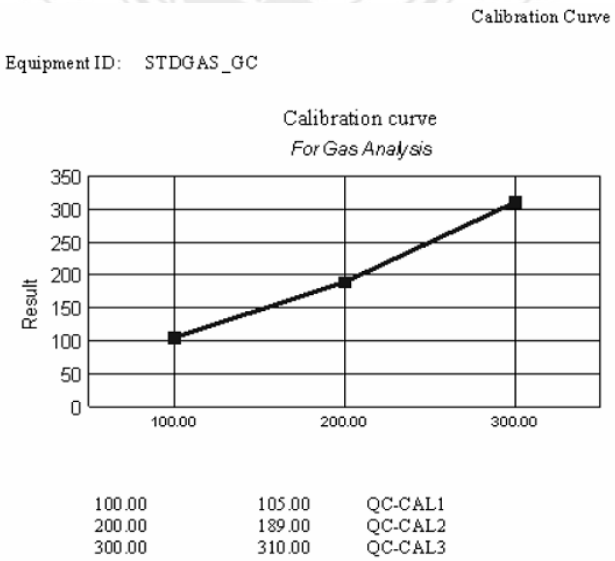


Figure 2.15 shows Calibration Curve

2) Creating Templates for Positioning Standards in Runs

Instead of defining the position of standard for instruments, User can define his owned template of standard substances called “Tray Layout” for instrument and test at “Equipment Manager”

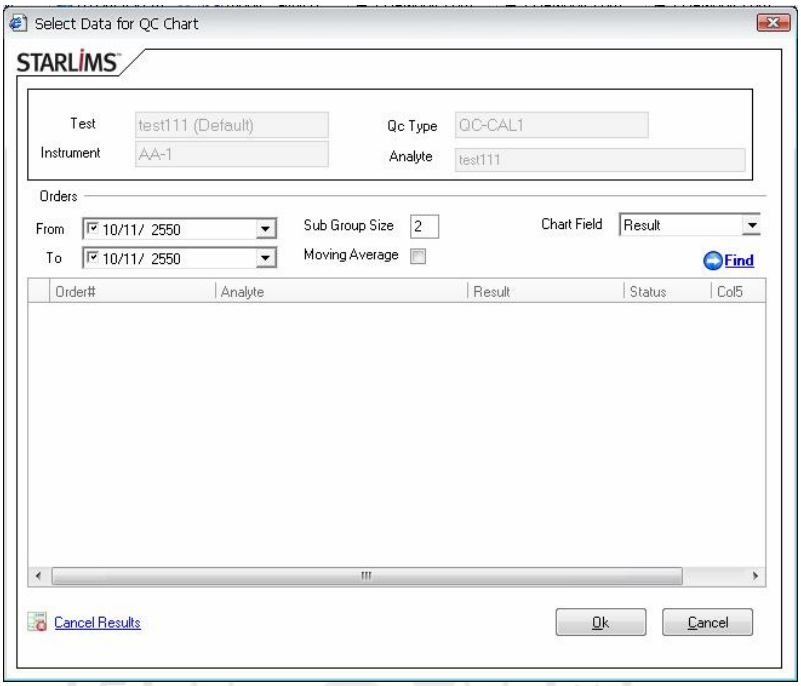


Figure 2.16 QC Chart

The “Equipment Control Chart” is at the “Tests/Standards” Tab in “Equipment Manager Module” The user can define the variables by clicking “Edit Control Chart” and browsing the menu to see information at “Pre-Calculated limits” or “Recalculate limits”

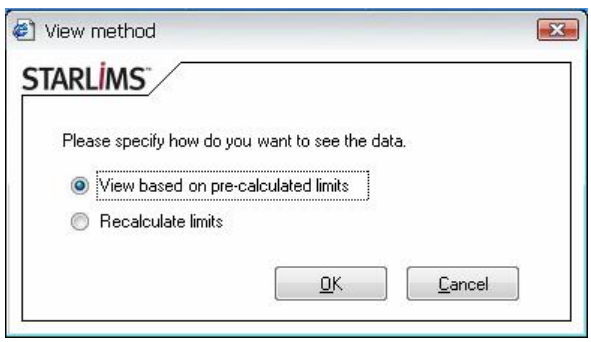


Figure 2.17 Edit Control Chart in “Equipment Manager Module”

If the user chooses “Recalculate limits”, the screen will show “QC Chart Parameters” which can search the ID of specimens as needed.

3) Load list Tab

In this part, the user can define the method for downloading the test information, for example, ID of specimen or instruments for testing, which can increase the effectiveness of specimen testing and manually decrease the number of errors.

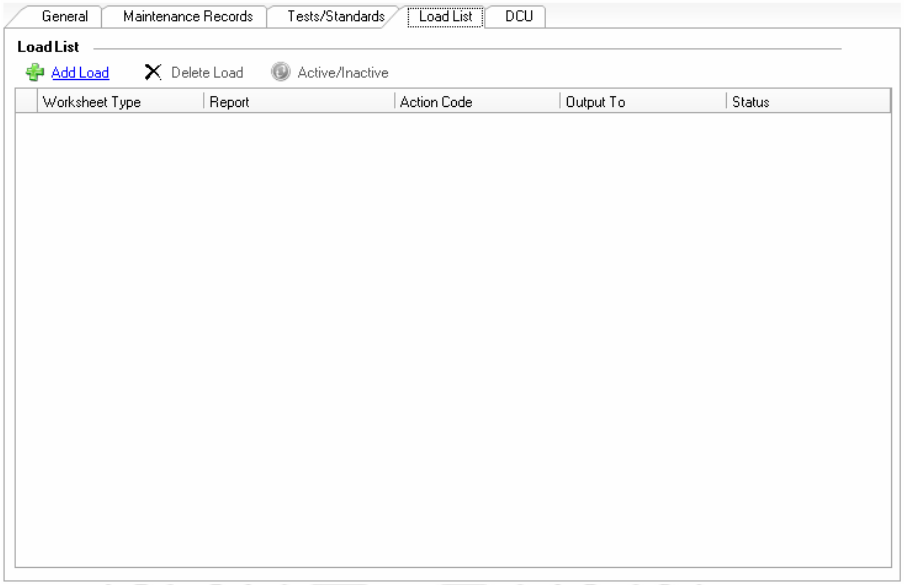


Figure 2.18 shows Load list Tab

The “Load List“ tab contains file or code to create the following items:

a) Formatted Form – The user can record details into the system manually.

b) Barcode Information – Number of specimens and testing instruments can be read at “Barcode” automatically.

c) Run Data - Data can be automatically imported into the system by saving as file or other electronic data transmission such as EMPOWER.

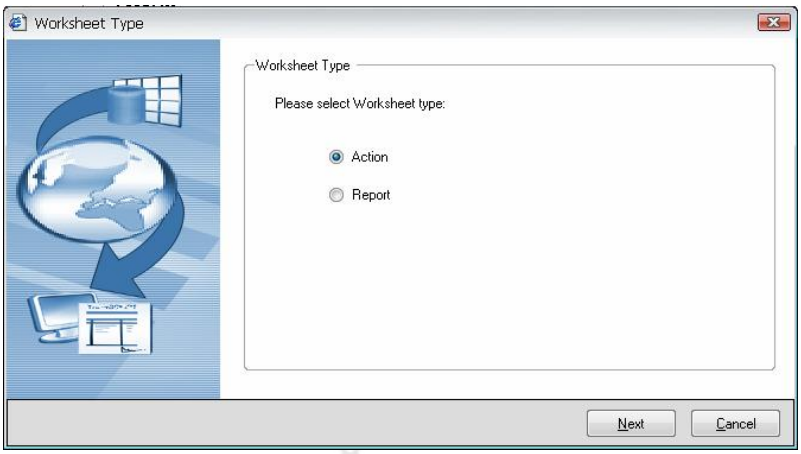


Figure 2.19 select "Worksheet Type"

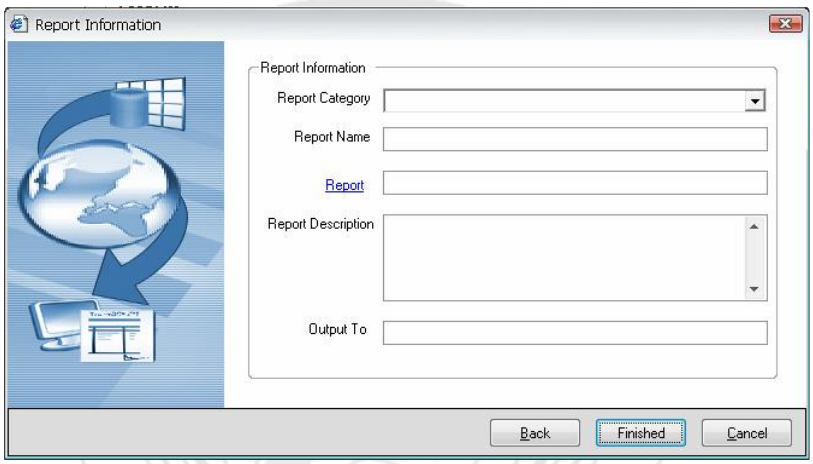


Figure 2.20 shows "Report Information"

CHAPTER 3

RESEARCH METHODOLOGY

This study incorporates design-demonstration research and applied research. The design-demonstration research aims to test and evaluate new programs or systems and to apply them into daily work in a laboratory [11]. Applied research is research accessing and using some part of the research communities' (the academy's) accumulated theories, knowledge, methods, and techniques, for a specific, often state, commercial, or client driven purpose. Applied research is often opposed to pure research in debates about research ideals, programs, and projects [12].

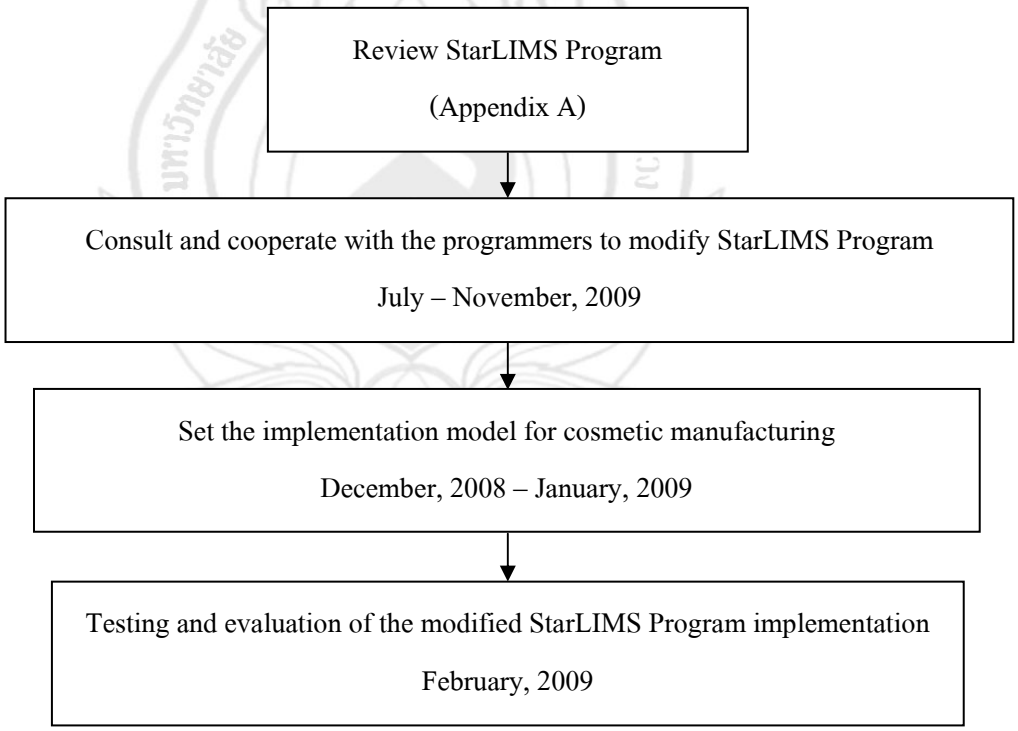


Figure 3.1 The research process is shown as the following steps:

The researcher reviewed the study of the modified StarLIMS program and applied the program to digital scales in a laboratory. In this study, we use scales of Mettler-Toledo International Inc. Model PB1502-L (Appendix B) which will be linked to the StarLIMS Program for automatic recording. The program itself will not allow users to edit any information or go to the next step unless the user puts in the information within an acceptable range of the scale linked to that program. The user needs to follow a step-by-step method in operating the system until finishing the final system.

Implementation of Modified StarLIMS Program to cosmetic manufacturing

After StarLIMS Program was modified, it was implemented and evaluated in laboratory of Doctor Cosmed Co., Ltd, Thailand. (Appendix C) The program was tested in the manufacturing process of three cosmetic products which were moisturizing cream, shampoo and liquid soap. The researcher provided closed and open-ended questionnaires for Ms. Boontaree Futrakul, Plant Manager, Ms. Prapatsorn Silapasatdumrong, R & D and Ms. Benjamas Muangchan, QC personnel.

Testing process was done at the laboratory room of Doctor Cosmed Co., Ltd. That presents as follow:

Figure 3.2 Laboratory Room

Figure 3.3 The researcher and Doctor Cosmed Co., Ltd. Staffs

From the right to the left:

Ms. Boontaree Futrakul Position : Plant Manager

Dr. Triyarith Temahivong, M.D. : Researcher

Ms. Prapatsorn Silapasatdumrong : R & D

Ms. Benjamas Muangchan : QC

Figure 3.4 Introduction of StarLIMS Program by the StarLIMS Program staff

Figure 3.5 Introduction for Application of StarLIMS Program by the programmer.

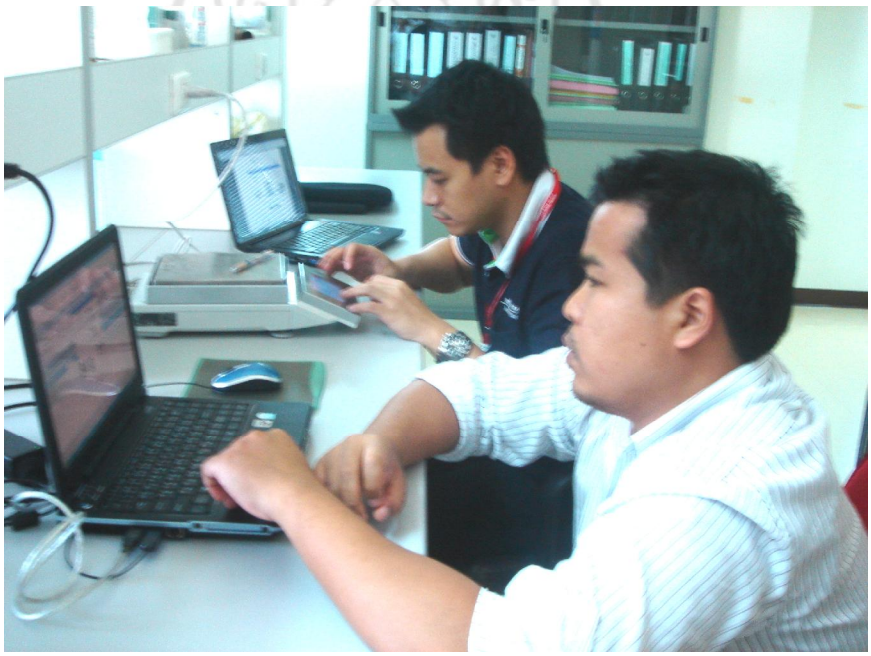


Figure 3.6 Connecting the digital scale to the computer

Figure 3.7 The substances measurement

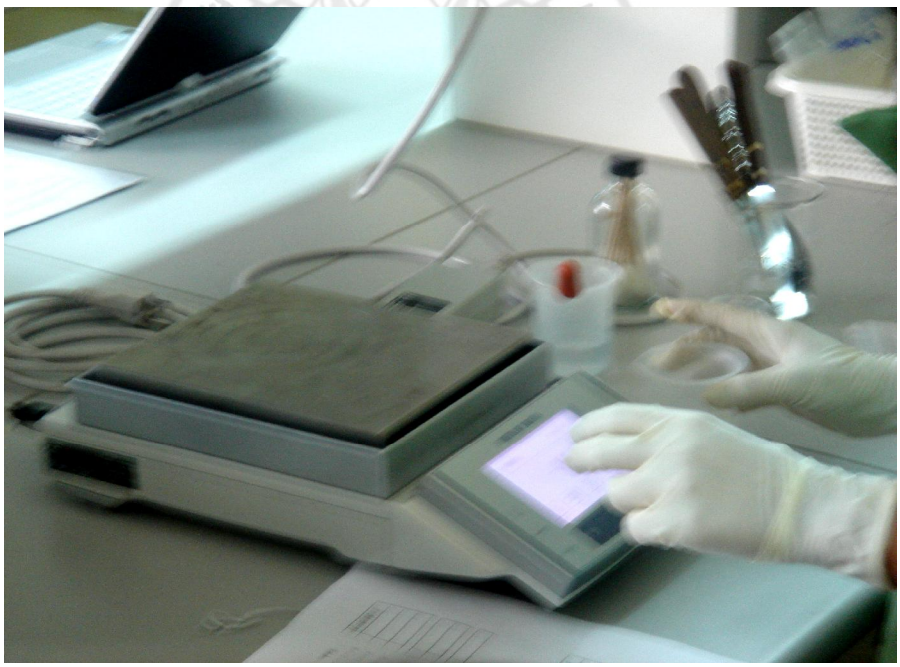


Figure 3.8 Transfer data from the digital scale to the connected computer

Figure 3.9 The data will be shown at the computer screen automatically which nobody can edit the data manually.

(a)

(b)

Figure 3.10 (a,b)After finishing the process of StarLIMS Program application for cosmetic manufacturing, Ms. Boontaree Futrakul, Plant Manager was interviewed and all staffs answered the questionnaire.

(Referenced by Boongit Eksupapan. E-mail address: Boongit.Eksupapan@mt.com)

Figure 3.11 Mr. Boongit Eksupapan, Application Engineer Laboratory Division of Mettler-Toledo International Inc. who supported the digital scale for the study testing joined to discuss that the applied StarLIMS Program was very useful and he had never seen the computerized program that could automatically recorded and applied to the cosmetic manufacturing like this program before. This is the innovative study for cosmetic manufacturing.

CHAPTER 4

RESULTS AND DISCUSSIONS

4.1 Modified StarLIMS Program

Regarding to the StarLIMS Program we can retrospective testing or traceability of the manufacturing but we cannot real time monitor the manufacturing process. In this study, the researcher designs and applies StarLIMS Program to use as real time control of cosmetic production process. If there is an error during the measuring each substance of cosmetic product formulation, the program will not permit to do the next step. The application of StarLIMS Program produces integrity system for cosmetic manufacturing.

To apply StarLIMS Program into the manufacturing process can be explained as the following steps:

Login to the system

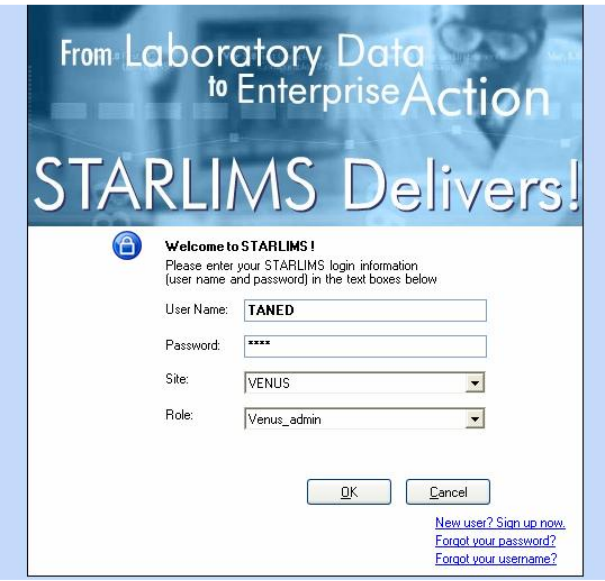


Figure 4.1 Login Menu

Fill in the information in all windows

User Name:

Password:

Site: - *Specific sites if there is more than one sites-*

Role: - *means to role of the user, please select one role-*

When registration completed, the user will see the following screen.

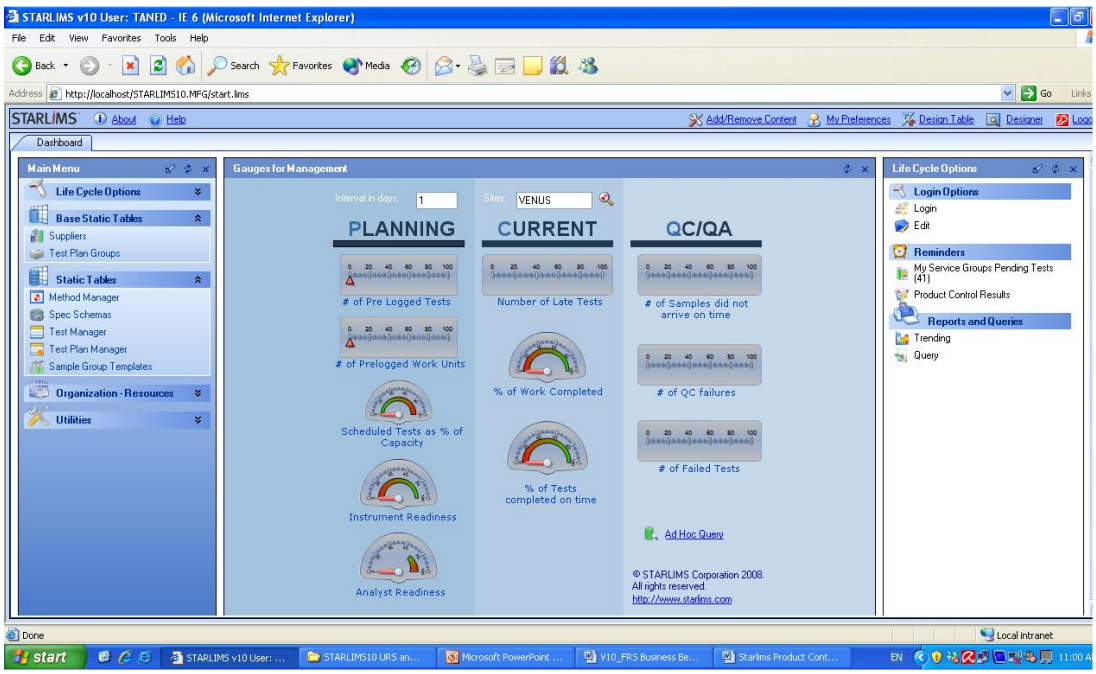


Figure 4.2 Registration Screen

Login Product Sample

To start the process, the user need to register the product, fill in the form of product sample, for example gel, cream, etc. the requester and contact details by click at “console login options” then choose “Login”

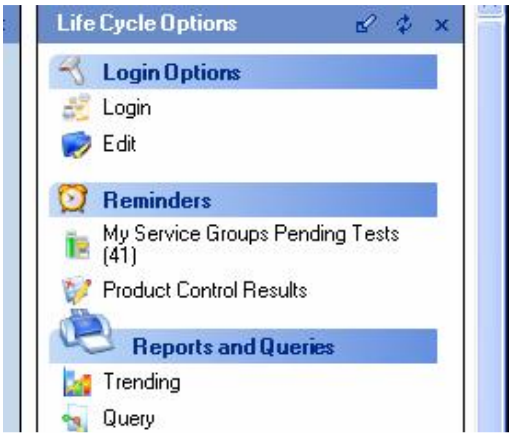


Figure 4.3 Console Login Options

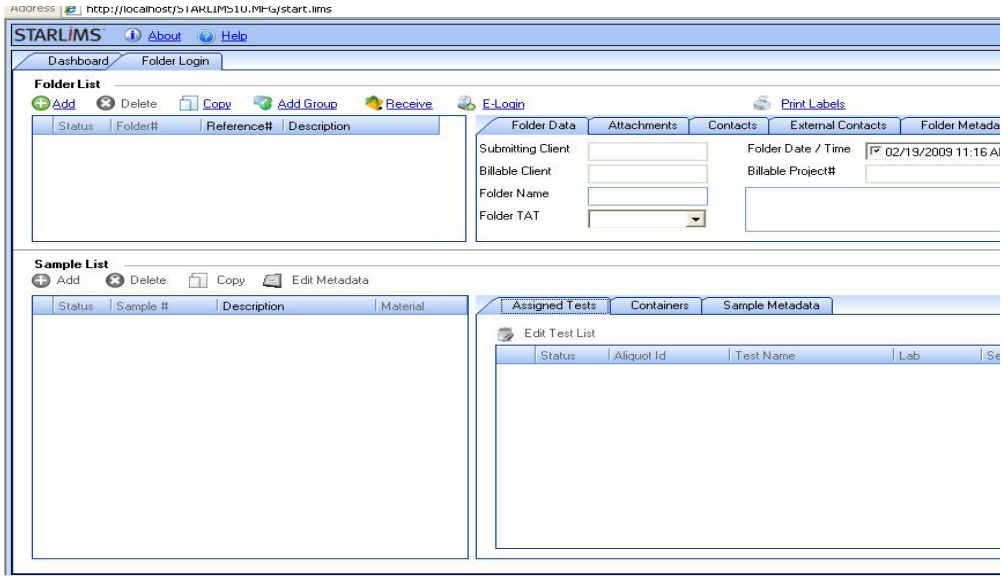


Figure 4.4 Folder Login Screen

Select Add

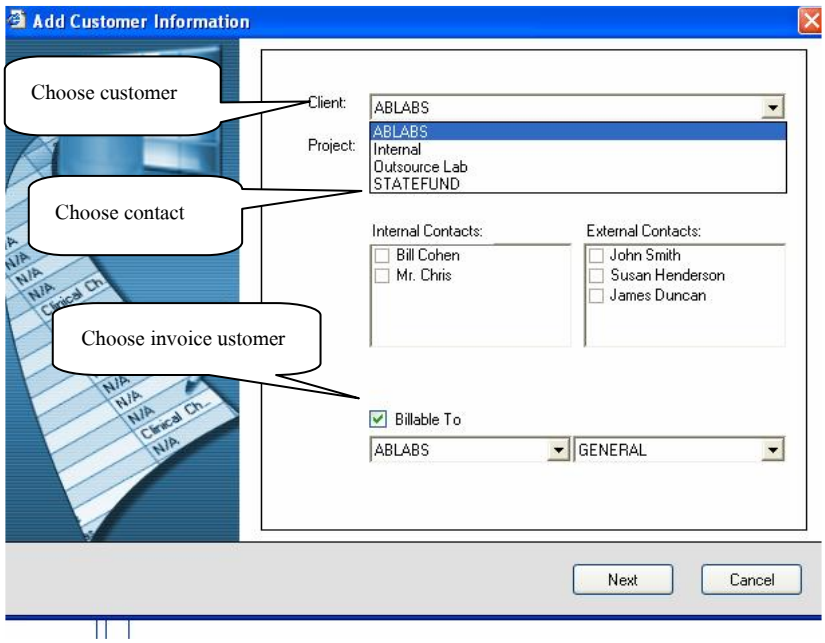
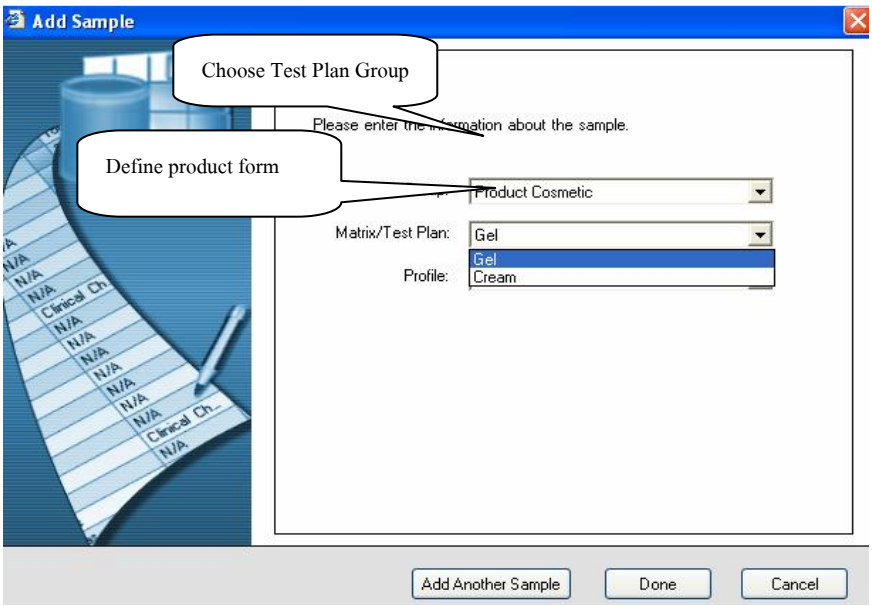


Figure 4.5 Customer Information

Choose Next to go for next step



Choose Done

Figure 4.6 Sample Information

after registration is completed. The user will get ID of sample test

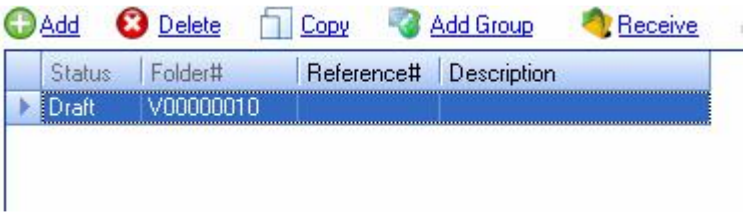


Figure 4.7 Sample ID Number Screen

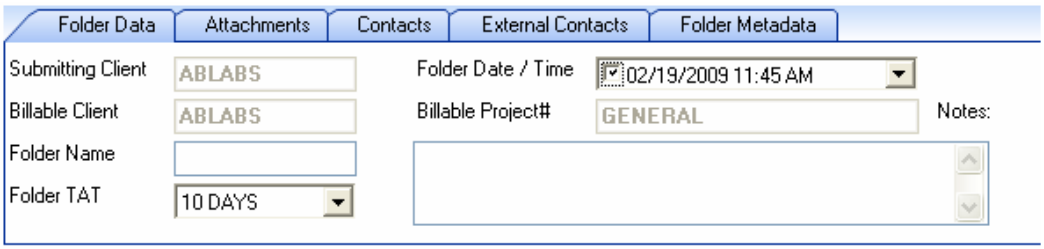


Figure 4.8 Folder Data Screen

The user can add more details, for example, Contact details or attach file

Product Control Results

When all information has already filled in, the user can start the process by click at "Console Reminders" then choose "Product Control Results"

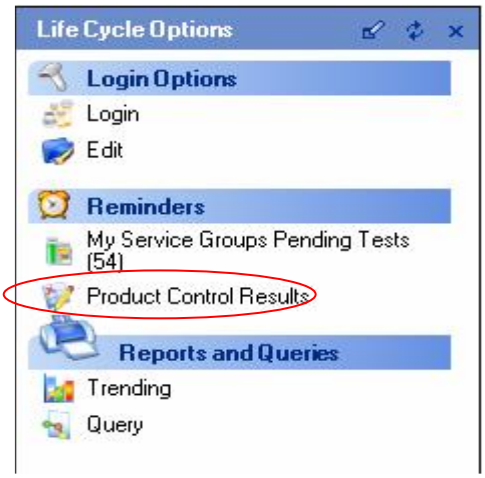
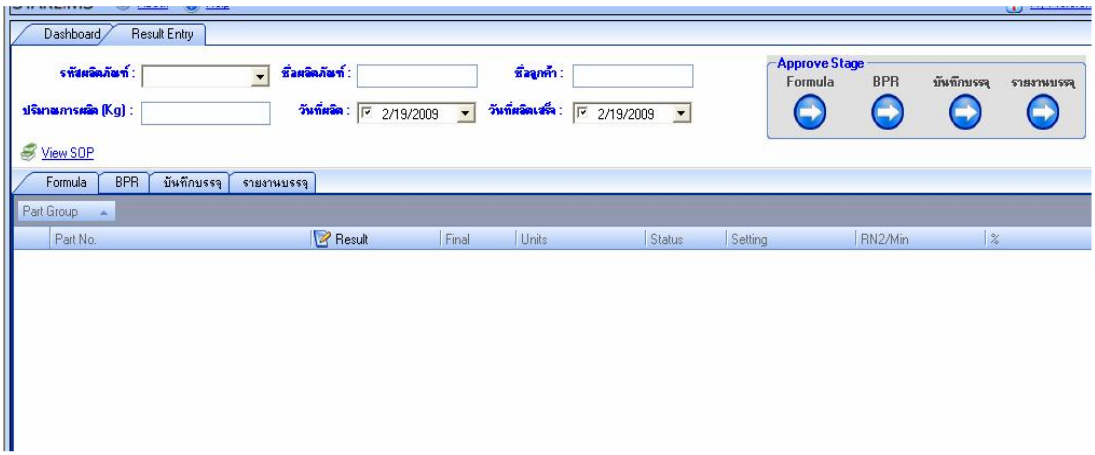


Figure 4.9 Life Cycle Options Screen



The manufacturing process will be divided into 4 steps. The system itself will approve the step by step. The user will not allow to across any step.

Figure 4.10 Manufacturing Process Monitoring Screen

1. Formula Measurement Process

Choose type of product to be tested

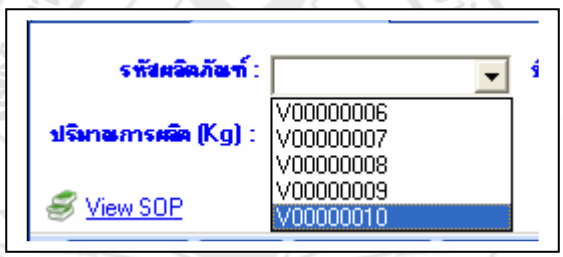
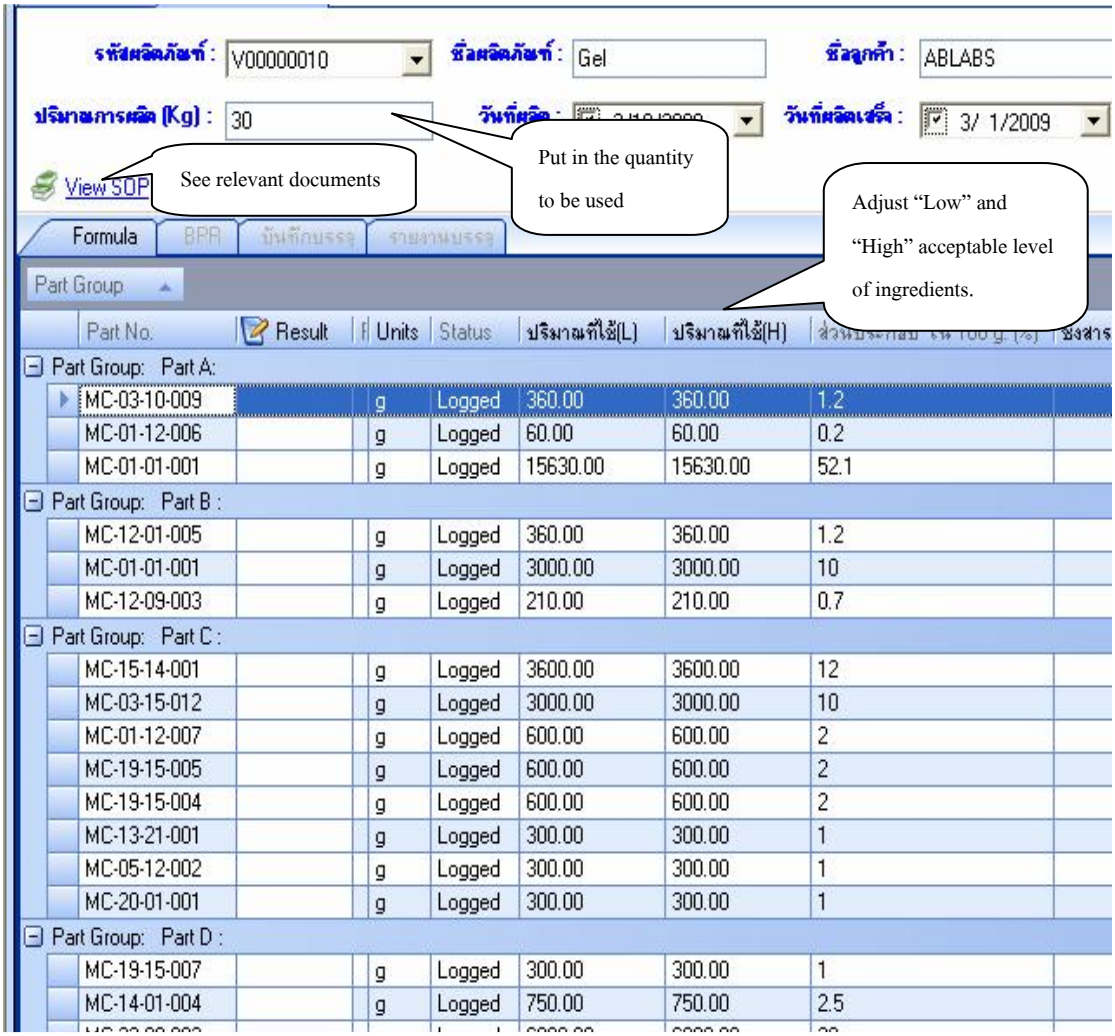


Figure 4.11 Product Type Screen

"Approve Stage" will be a green light showing the stage of approval

Figure 4.12 Approve Stage Button

At first stage “Formula”, the system will measure the substances or ingredients to manufacture by calculating in percentage of ingredients. The user can adjust “Low” and “High” acceptable level of ingredients.



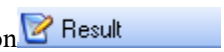
Select this icon  to measure the ingredients

Figure 4.13 Product Substance Measurement Screen

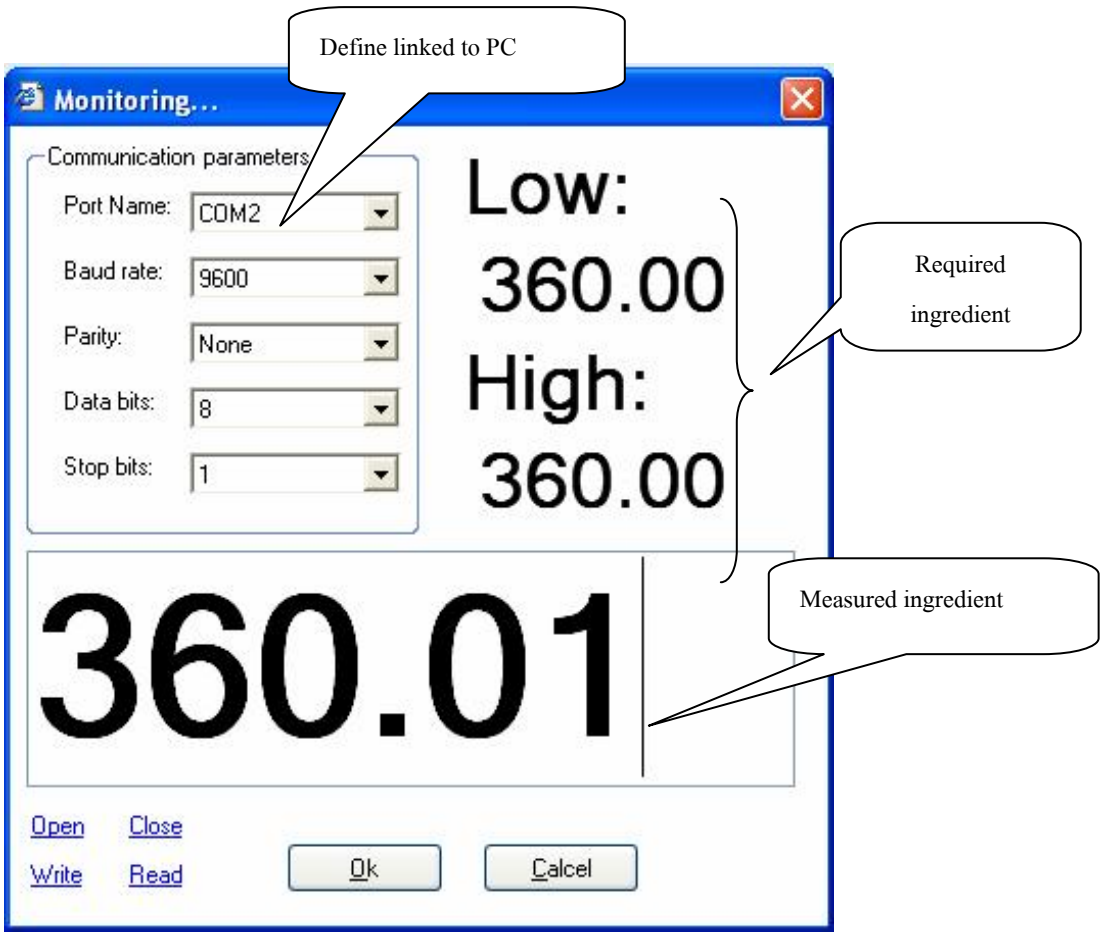


Figure 4.14 Monitoring Range of Acceptable Level of Ingredients

If the ingredients measurement is exceed than the acceptable limits, the system will not allow and “report out of spec” until the user adjust it into the acceptable limits.

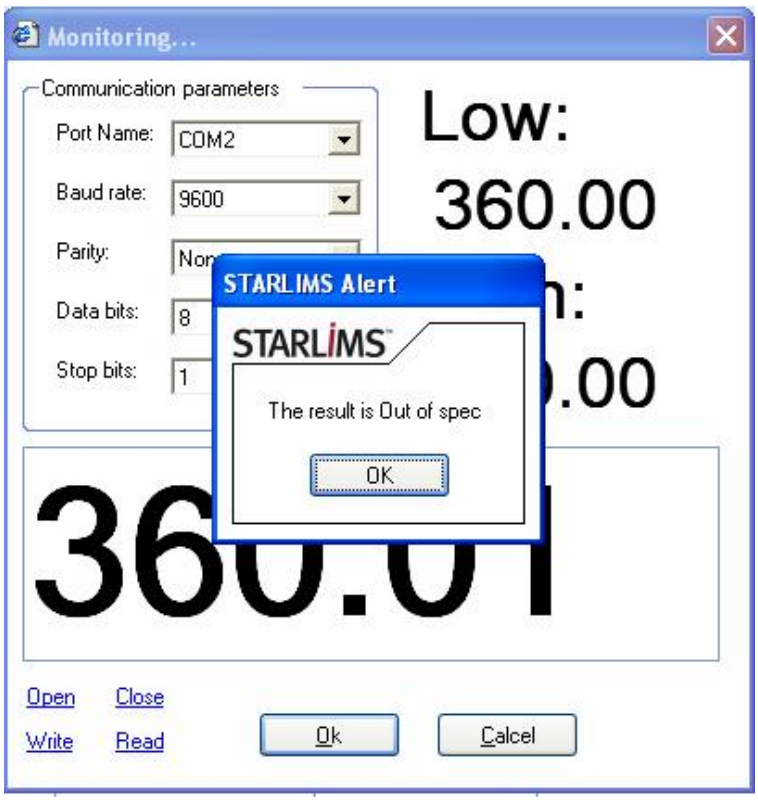


Figure 4.15 “Out of Spec” Screen

When measurement is under an acceptable limit, the status will report as “Done”

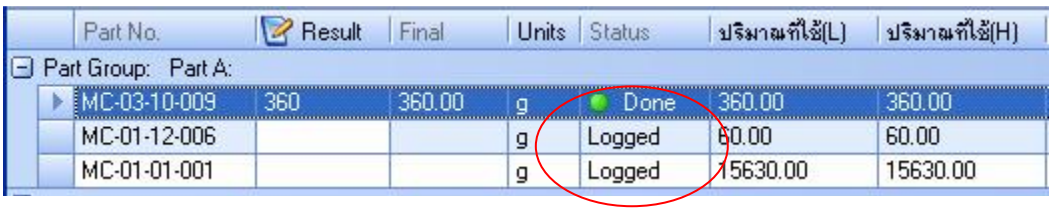


Figure 4.16 “Done” Button was automatically shown

All ingredients pass the measurement. Press “Approve” to go for a next step

2. BPR Process

Figure 4.17 BPR screen

3. Packaging Recording

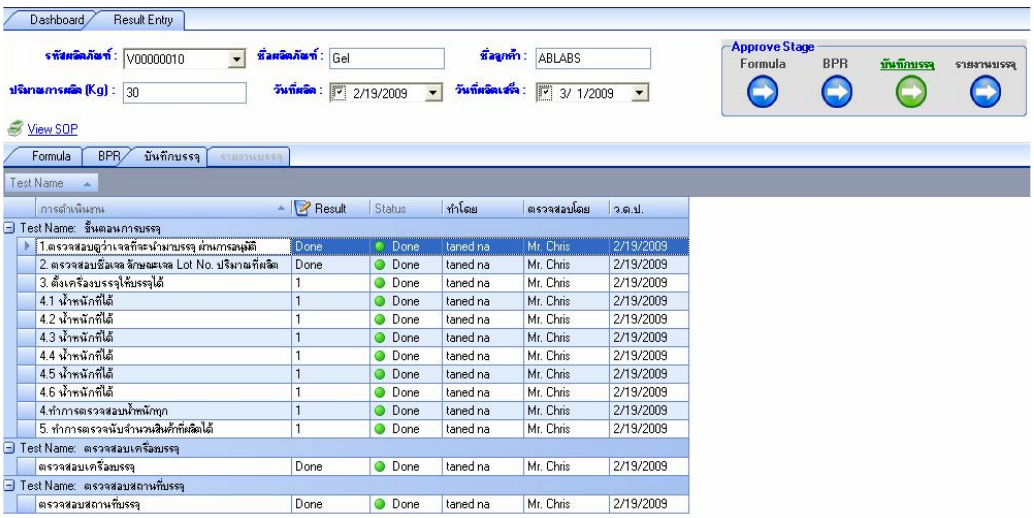


Figure 4.18 Packaging Recording screen

4. Packaging Reporting

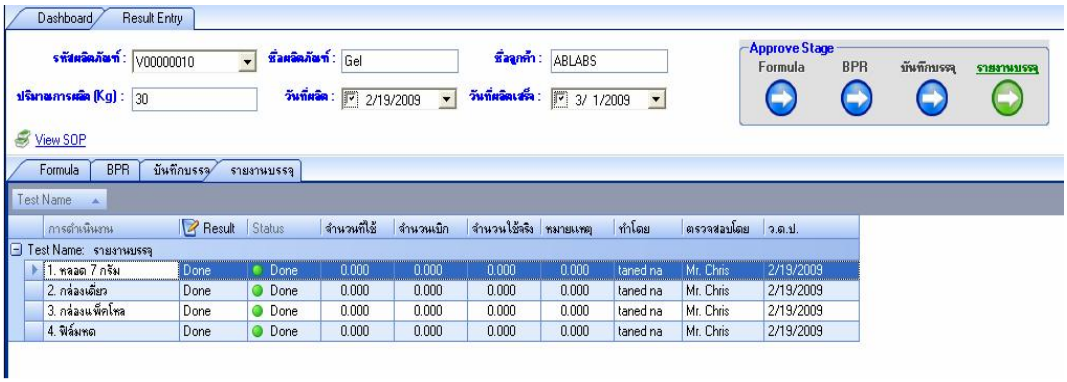


Figure 4.19 Packaging Reporting screen

Evaluation and result of the modified StarLIMS Program testing to cosmetic manufacturing

When finished all steps of implementation, the staffs in each function including laboratory testing, manufacturing, quality control and the manager evaluate the result and reply the questionnaires as attached in Appendix D and E.

The findings of modified StarLIMS Program application into the manufacturing process ware reported in 4 aspects as follows:

1. Benefit to staff in laboratory

The manager and staffs agreed that the application of modified StarLIMS Program into the manufacturing process was beneficial to manufacture good quality products according to the objective of production

2. Convenience for using aspect

The manager and staff agreed to use applied StarLIMS Program into the manufacturing process.

3. User satisfaction aspect

The manager and staffs were satisfied with the application of StarLIMS Program into the manufacturing process.

4. Advantage of StarLIMS Program

StarLIMS can be applied to improve the quality control and production process of cosmetic manufacturing that will produce the high quality standard and precise ingredients.

4.2 Discussion

4.21 StarLIMS Program is modifiable and applicable program. It can be apply to use in cosmetic manufacturing but it is not able to do by anyone except the StarLIMS programmers who have source code. The source code program is patent only for StarLIMS Co., Ltd. so it is not easy for users to apply the program by themselves.

4.2.2 StarLIMS Program is licentious software of StarLIMS Co., Ltd. Thus it limits the scope of studying all program functions or features.

4.2.3 StarLIMS Program is very expensive (more than one million baht), so the researcher designs the study from StarLIMS's manual and asking the StarLIMS programmers. The program was modified as the design only by the company programmers. So it disturbs the study flexibility.

4.2.4 This study is the first time for modification and application StarLIMS Program into Thai cosmetic manufacturing so it is quite difficult to communicate the programmers to understand the cosmetic manufacturing process and quality control.

CHAPTER 5

CONCLUSION AND SUGGESTION

5.1 Conclusion

The manufacturing process is important to on production of a good quality product. However, the measurement of ingredients or substances always finds some errors in this process and causes damages to the finished products. Therefore, the application of the StarLIMS Program will support the manufacturing process to ensure that all processes are under ASEAN Good Manufacturer Production (ASEAN GMP) guidelines.

The modification of the StarLIMS Program to the manufacturing process can support the manufacturer to control the production process and increase the effectiveness according to ASEAN's GMP. The specification of the finished goods will not deviate from an agreed standard formula and the manufacturer can guarantee the quality of goods in all production cycles. Therefore, the application of the StarLIMS Program will remarkably reduce human errors which are the most complicated issue to resolve if it has occurred in the manufacturing process.

The findings of the study reported that the application of modified StarLIMS Program was very useful for management and quality control of laboratory in cosmetic manufacturer. The program is to apply information technology to manage and control the process in laboratory to increase accuracy and speed of manufacturing process. The initial objective of StarLIMS Program was to manage laboratory information system in the health, pharmaceutical, petrochemical, forensics, food and beverage, environmental, water and chemical industries only. By this study, it shows that StarLIMS Program can be modified and applied into cosmetic manufacturing for production process and quality control.

The two main principles of the modified StarLIMS Program for cosmetic manufacturing in this study are as follows:

1. Measurement of substances: The scales will be linked to the StarLIMS Program of StarLIMS Corporation Limited Company. The data will be seen on the computer screen and recorded automatically. The user can not fill in or edit the data manually.

2. The program has been set a desired acceptable level of errors in each measurement (dependent on the formula). For example, an acceptable set at 5% means the measurement may not deviate from the original formula more or less than 5%; otherwise, the program will not run the next step in each test.

The results showed that StarLIMS Program was supported business operation, increases effectiveness and prevents the loss during the manufacturing process by improving the management of ingredients, inventory, accounting, personnel and budgeting. The successful program modification will be one of crucial steps in eventually developing high standard cosmetic products to the world market.

5.2 Suggestion

1. StarLIMS Program is very expensive. We have to create the new program follows the same concept as the study to lower the cost that the small scale cosmetic manufacturers can afford. Exactly, it should be designed to be easily applied by users.

2. There should be further improvement of StarLIMS Program to support the whole aspects of cosmetic manufacturing.

REFERENCES

1. About Thai Food and Drugs Administration. [online]. [cited 2008 May 20] Available from URL: http://www.fda.moph.go.th/aboutthaifda43.htm.
2. Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme. [online] [cited 2008 May 20] Available from URL: http://www.thaicosmetic.org/.
3. Good Manufacturing Practice. [online]. [cited 2008 May 20] Available from URL: http://www.fda.moph.go.th/fda-net/html/product/cosmetic/cosmetic/dat/gmp/gmp.htm.
4. E-Cosmetic, Current Laws and Regulations. [online]. [cited 2008 May 20] Available From URL: ttp://www.fda.moph.go.th/fdanet/html/product/cosmetic/cosmetic/ page/index-en.htm.
5. สถานที่ผลิตที่ได้รับการรับรอง 66 แห่ง. [online]. [cited 2008 Feb 04] Available from URL: http://www.app1.fda.moph.go.th/cosmetic/GMPC.asp?nPage=1.
6. StarLIMS Program. [online]. [cited 2008 Feb 09] Available from URL: http://www.starlims.com/.
7. ASEAN GMP Guideline. [online]. [cited 2008 Feb 04] Available form URL: http://www.fda.moph.go.th/fda-net/html/product/cosmetic/cosmetic/dat/tr-gmp.htm.
8. Thai FDA Notification on ASEAN Cosmetic GMP Practices. [online]. [cited 2006 Jul 14] Available form URL: http://www.fda.moph.go.th/fda-net/html/product/cosmetic/ cosmetic/dat/ harmoniz/harmoniz.htm.
9. Laboratory Information Management System. [online]. [cited 2008 Apr 12] Available from URL: http://www.starlims.com/solutions/.
10. Laboratory Information Management System. [online]. [cited 2008 Apr 12] Available from URL: http://en.wikipedia.org/wiki/laboratory_information_management_System.
11. Design-demonstration Research. [online]. [cited 2008 Oct 05] Available from URL: http://www.languages.ait.ac.th/el21meth.htm.
12. Applied Research. [online]. [cited 2008 Oct 05] Available from URL: http://en.wikipedia.org/wiki/Applied_research.

APPENDIX A

STARLIMS PROGRAM VERSION 10

BROCHURE

STARLIMS
LAB DATA/ENTERPRISE ACTION

STARLIMS Version 10

Configurable Off-the-Shelf LIMS for Laboratory and Enterprise Collaboration

STARLIMS is the most powerful tool labs have to manage complex processes, ensure regulatory compliance and promote laboratory and enterprise collaboration.

STARLIMS V10 is a high-performance, truly web-based Laboratory Information Management System (LIMS). It provides all the features required to manage the workflow and resources of the laboratory, while providing enterprise-wide access to lab data. STARLIMS V10 helps optimize laboratory efficiency levels, while also ensuring that laboratory information is available throughout the organization in a timely way. STARLIMS V10 sets the standard for LIMS by offering a future-proof web architecture, rapid global deployment, minimal learning curves and unlimited browser-based access.

STARLIMS V10 can be deployed with the STARLIMS fully integrated Scientific Data Management System (SDMS), to create a single multi-purpose platform that manages not only structured lab data, but also unstructured information largely inaccessible to other LIMS (documents, instrument data files, PDFs, product specifications, etc). Such integration leads to optimal use of valuable lab data, and protects the value of historical data. It enables organizations to create knowledge, and make decisions, based on a combination of accurate, up-to-the-minute data and relevant historical information.

Based on two decades of experience in hundreds of organizations, STARLIMS supports most lab requirements straight out of the box with a rich true-to-life GUI, while powerful configuration tools are available to help meet specific needs. STARLIMS has a proven track record in R&D, Analytical Services, Process Operations and QA/QC environments; and operates in the public health, pharmaceutical, petrochemical, forensics, food and beverage, environmental, water and chemical industries.

STARLIMS was built from the ground up as an entirely web-based solution. Leveraging XML and other advanced Internet technologies, STARLIMS enhances overall operational excellence in all types of laboratories and organizations.

An Integral Part of Enterprise Systems

STARLIMS is a collaborative web-based tool which is an integral part of enterprise-level business systems. Seamlessly interoperating with other systems, STARLIMS generates and disseminates quality data that is used by other software systems or personnel to make business decisions. Depending on the type of organization, timely STARLIMS data can help an organization to:

- Procure additional raw materials when incoming lots fail inspections;
- Accelerate shipments after final quality control;
- Implement timely product recalls; or
- Raise alerts to officials responsible for managing Public Health threats.

The Flexibility Dynamic Labs Require

STARLIMS' flexibility is manifested in multiple levels of the system--from automated workflow and records management to closed-loop traceability. STARLIMS offers multiple ready-made tools and wizards, vastly reducing reengineering requirements. Fine-tuning STARLIMS to meet the needs of any lab is easy and convenient, thanks to a rich true-to-life GUI based on intuitive drag&drop functions. STARLIMS guides operators through defined steps and makes appropriate recommendations based on entered data, raw data or a resource reference. STARLIMS mimics manually implemented procedures, recording business logic within the automated system.

Advanced Document Management Capabilities

In addition, STARLIMS offers exceptionally flexible electronic document management capabilities. STARLIMS securely stores textual and graphical documents (instrument-generated graphics such as chromatograms or spectra; raw data files; standard operating procedures (SOPs); analyst certifications; electronic training materials; investigation reports and others). With full documentation readily available, organizations can ensure the integrity and validity of results, enjoying a high degree of confidence in the analysis process.

The quest for a true web-based application came about from real needs for increased efficiency and remote global access.

Limited resources in IT departments have driven demand for systems with zero client-side installation and maintenance.

Redesigning STARLIMS as an entirely web-based application is a major step in meeting these challenges.

The Road to a True Web-based Experience

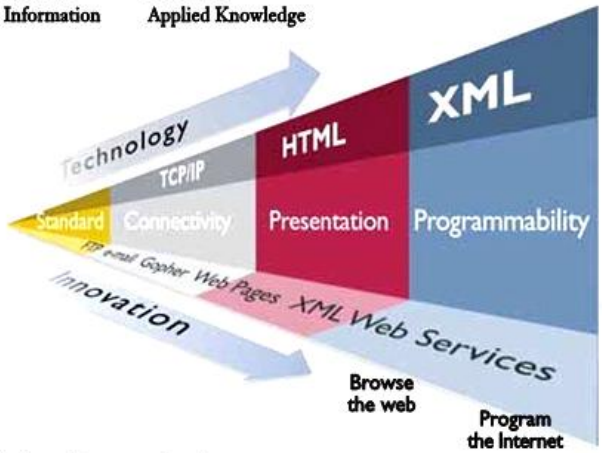
Over the last decade, laboratory regulations have become far more stringent, requiring laboratories to record dramatically larger volumes of data. In addition, laboratories and companies are seeking to accelerate response times, improve profitability and enhance decision-making processes. To achieve these aims, vast amounts of generated data must be converted into useful information—and effectively distributed throughout the organization.

With the advent of new technologies, better security and leaner systems, LIMS has moved out of the laboratory and on to the desktops of laboratory data consumers, such as research personnel, process engineers, satellite laboratories and field workers. At the same time, web service applications facilitate a paradigm shift that enables interconnection and integration of disparate business applications, resulting in shared functionality across different systems and platforms.

Going beyond traditional web-enabled solutions, STARLIMS is built from the ground up as an entirely web-based application. STARLIMS leverages XML and other advanced Internet technologies to facilitate data management and decision-making within the lab, throughout the plant and across the enterprise. At the same time, it offers a 'rich' true-to-life GUI that vastly streamlines configuration and deployment. STARLIMS requires no client-side installation or maintenance, and offers an accelerated learning curve.

STARLIMS advanced features, including the dashboard, are changing the way data is utilized and the way processes are executed.

From	To
Monitored	Optimized
Reactive	Proactive
Information	Applied Knowledge



Evolution of Internet technology

Web-Based Architecture

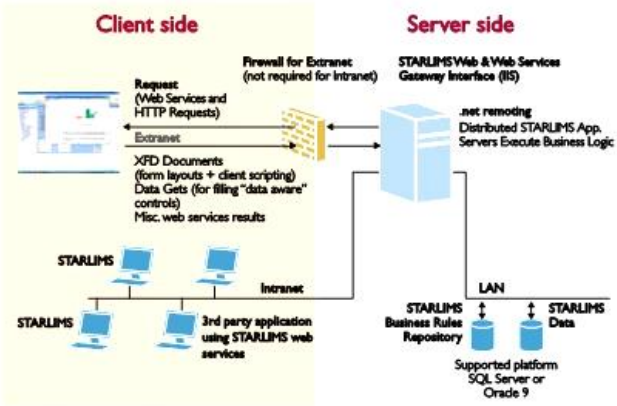
Benefits of STARLIMS Web-based Architecture

- Intuitive true-to-life GUI for a rich user experience
- Built according to Internet standards for an accelerated learning curve
- No client-side software installations
- Scalable for easily configured hardware resources and load balancing algorithms
- Unified application for design and runtime
- Full enterprise integration
- Full separation of user interface from business logic
- Predictable response times
- Easy-to-use tools for enhancing and modifying system functionality

STARLIMS architecture incorporates standard web-based features, with a scalable and extendable web browser client-side application and a database server "farm." Communications between client and server are achieved through standard web service messaging over hypertext transfer protocol (HTTP). Alternatively, a secure HTTP (HTTPS) can be used for a more secure environment.

To take advantage of all the available processing power and allow for a rich user experience, STARLIMS splits code into business logic (which is executed on the server side), and presentation code (run by a .NET control on the web client). The result is predictable response times and a far superior user experience.

The STARLIMS application servers provide true scalability, allowing the LIMS to grow and meet the changing demands of the laboratory and organization. STARLIMS provides fail-safe capabilities to help ensure 100% availability of the LIMS.



STARLIMS Version 10 architecture

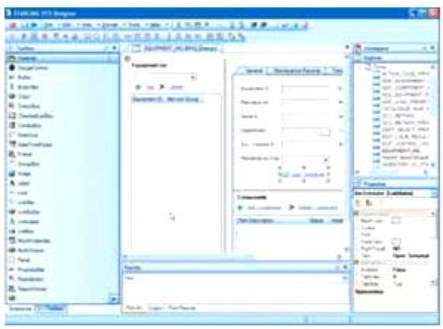
The STARLIMS client is a standard web browser that hosts a .NET control that dynamically presents the user interface. The STARLIMS XFD Renderer Controls are automatically deployed on the client when a new version is released. In addition to the classic GUI controls (labels, buttons, textboxes), this technology supports more complex controls, such as hierarchical data grids, tab controls, and selection boxes. For data-aware components, special business actions, termed data providers, are used to interface between the GUI and the data model residing on the server. For increased security, client-side scripting code is run in an isolated ("sand-boxed") environment, and the server-side business logic code is separated from the client-side. The STARLIMS XFD Renderer uses the local machine's computational capabilities, resulting in reduced server and network load.

Web-Based Architecture

STARLIMS XFD Designer

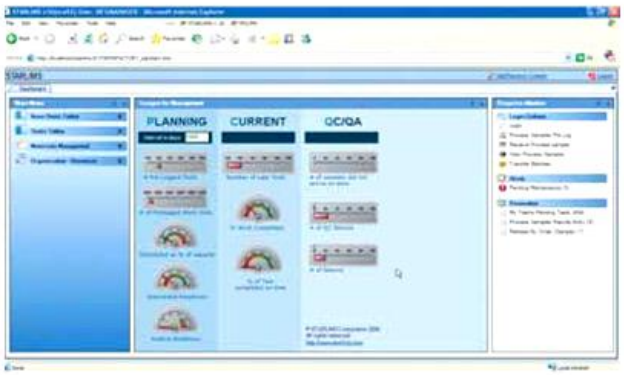
The STARLIMS XFD Designer enables authorized users to configure, enhance and modify the system as business requirements change. Designed to make GUIs and Internet protocols entirely transparent to the user, STARLIMS allows users to focus solely on creating optimized business rules.

Using intuitive graphic drag & drop design tools, authorized users define the processes they need. . XML forms containing layout tags are used in a declarative way to describe the user interface. JScript.NET code is used to programmatically handle these elements and corresponding events, and to make remote calls to business logic services located on the server. Communications between the GUI and the business logic are achieved via standard web services. The STARLIMS XFD Designer is also used to create web services made available to third-party client applications, for seamless interoperability between STARLIMS and a host of enterprise applications.



Sampling to Reporting

STARLIMS' flexible configuration tools allow system administrators to easily establish and maintain their laboratory's unique workflow and business rules through ad hoc or pre-defined lifecycles. The STARLIMS Dashboard automatically monitors the flow of data—providing targeted, real-time information personalized according to each user's role and authorization level.



THE STARLIMS DASHBOARD

GOOD LABORATORY PRACTICES CONTINUOUSLY MONITORED

Sample Login
- Login by Sampling Program
- Double Data Entry
- Barcode Labels - Printed
- Sample Receipts – Issued

Work Assignment
- Samples - Organized
- Work Lists - Issued
- Instrument Parameters – Sent

Results Entry
- Manual or Automatic Calculations
- Integrated Data Capture Utility
- Non-Numeric Data Archival
- Online Validation and Flagging

Review and Approval
- Resubmit for Testing
- Re-sample / Investigate
- Release with Electronic Signature

Reports and Queries
- Intuitive Query by Example
- Integrated SQC
- Trend Analysis
- Performance Testing
- Integrated Crystal Reports
- Export to Desktop Application
- Enterprise Updates

SAMPLE COLLECTION AND STORAGE MANAGEMENT
SAMPLE RECEIPT AND PREPARATION
SAMPLE TESTING
QUALITY ASSURANCE
ELECTRONIC DATA DELIVERABLES

Traceability

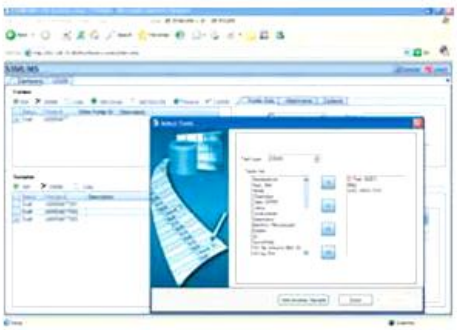
STARLIMS' flexible workflow tools provide complete traceability in a manner compliant with the strict standards of the US Food and Drug Administration Regulation 21 CFR Part 11. All this is possible with no compromise in process versatility.

The core of the STARLIMS application is the automated electronic record-keeping function. An electronic signature is maintained in a relational database--encompassing test results, equipment settings, and all movements and activities.

STARLIMS also implements very strict controls including: stringent access rules, document and data change controls, transactional or silent audit trails and password security.

Sample Login

During Sample Login, users describe each sample using a set of meta-data fields and request tests. Test assignments and meta-data vary according to the sample type. The sample login process is extremely flexible. All meta-data fields, their pop-up list properties and test assignment methods are easily configured and associated with the sample type.



STARLIMS offers several sample login methods to accommodate diverse testing protocols: batch, routine, time-based, event-based, calendar and ad hoc. STARLIMS facilitates assigning disparate workflows and testing protocols based on login content.

Pre-Log Samples

Lab efficiency is enhanced through the ability to pre-log samples, alerting the lab and enabling it to prepare for rapid sample processing upon arrival. This eliminates errors and confusion due to misinterpretation of hand-written login forms

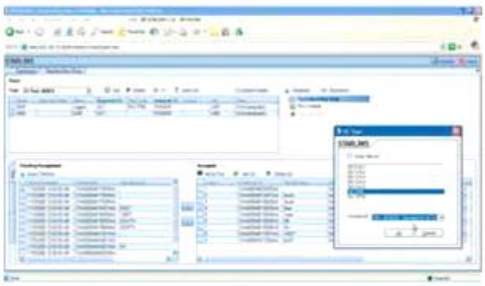
Several pre-login methods are available:

- Via a Pre-login screen accessed via Microsoft™ Internet Explorer
- Via portable devices that use active synchronization services
- Via web services that are accessible from third-party systems (ERP, MES, Clinical Trial Management Systems, PIMS, etc.)

Receive in Lab

Barcodes and handheld devices can be utilized to generate sample labels and receive samples in a rapid error-free manner.

The Workflow



Work Assignment

Depending on laboratory-specific business rules, tasks are assigned to analysts and teams. The Test Design Wizard enables configuring some tests so they will be assigned solely to certified analysts. Samples can be grouped into runs (batches of samples intermingled with QC samples). Utilizing the STARLIMS Instrument Work Assignment interface, work lists and instrument control parameters can be sent to analytic instruments or laboratory robotics systems.

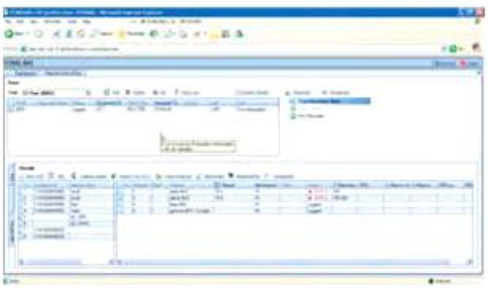
The built-in Work Scheduler calculates the time needed to complete the tests on the work list. The STARLIMS Dashboard dynamically displays Key Performance Indicators (KPI) that indicate current capacity, percent of work completed and other critical parameters.

Results Entry

The type of result patterns that may be stored range from simple single-number or text responses, to arrays of data such as Elisa and chromatography data sets. STARLIMS' tight integration with Microsoft Office™ also supports unstructured results (e.g., notes describing an electron microscope image).

Built-in calculations, including QC calculations, automatically determine bias, precision, accuracy, sensitivity and other pre-determined parameters. Validations based on specific QC requirements can automate "reflex testing" or retesting.

Automatic Data Capture Utility (DCU)



Automatic result entry of test data is facilitated through the DCU, a built-in parsing utility that enables data capture from multiple instruments or systems. Virtually any lab or enterprise system can place result files onto the network, or communicate with STARLIMS via a standard API. Upon bench approval, results are transmitted to the DCU, triggering additional calculations and validations prior to final database storage.

The STARLIMS Data Capture Utility efficiently eliminates transcription errors, creates a traceable closed-loop environment, and makes lab data available throughout the enterprise.

Manual Data Capture

In manual mode, result-entry screens lead the analyst through the required workflows. STARLIMS automatically prompts the analyst to record the necessary data at each step of the preparation and testing workflow. The screens are easily configured to reflect the specific test workflow and the information that needs to be captured.

The STARLIMS Dashboard dynamically provides the analyst KPIs regarding the workload, as well as QC KPI's (e.g., reflex tests, retest, and QC rejects.

Customer Access

Based on a secure web services layer, STARLIMS enables authorized users to obtain virtually any type of lab data over the Intranet—from results of analytical services to sample status and billing information.

By giving lab data consumers direct access to the information they need, STARLIMS helps labs:

- Accelerate response times
- Minimize status queries
- Reduce manual handling of analytical services
- Lower costs
- Improve customer satisfaction

Review & Approval

When all results have been entered and approval is required, the STARLIMS Dashboard Workflow console alerts the appropriate personnel to review and approve pending results. Laboratory-specific business rules determine what electronic signatures are required before final release. During the release process, all information related to the reviewed samples is accessible via the Traceability viewer. This includes:

- Instrument maintenance records,
- Analyst training records
- Records pertaining to the standards that were used
- Audit trail records and signatures gathered at the different workflow steps

Reports & Queries

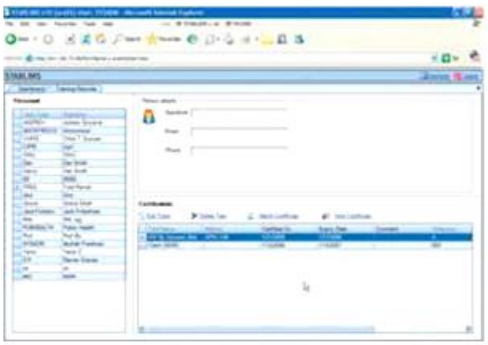
Many laboratories are facing increasing demand for more and more personalized, services. Typically, customers are demanding improvements in:

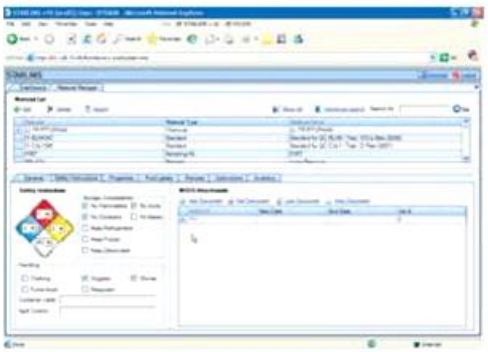
- Report formatting
- Rates, terms and conditions
- Turnaround times
- Sample collection services
- Kit management
- QC requirements

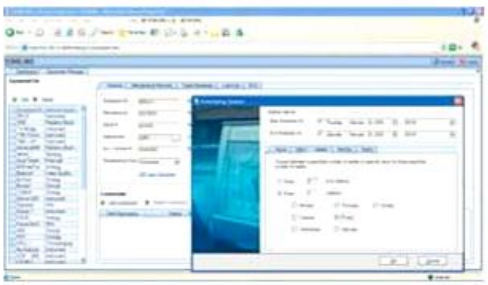
The exceptional flexibility and data filtering capabilities of STARLIMS are important factors that enable laboratories to meet these requirements. Depending on their authorization level, data consumers can obtain any type of lab data: trend analysis, proficiency testing, turnaround time, laboratory resource planning, QC charting, laboratory output, billing and invoices, and more. STARLIMS can issue reports that are personalized for a specific user, role, instrument, group, laboratory, or location. Any report can be sent to a workstation screen, routed to a network printer, sent via fax or e-mail, or published on the organization's Intranet.

STARLIMS uses Business Objects' Crystal Reports, an industry standard SQL reporting tool offering complete flexibility in report design and layout. Other off-the-shelf desktop applications such as Microsoft Office™ can also be used to create reports.

Good Laboratory Practice







STARLIMS helps lab establish and maintain Good Laboratory Practice (GLP) documentation procedures for closed-loop traceability and regulatory compliance. Among other functions, STARLIMS facilitates maintaining versions of test methods, training certifications for analysts, logbooks for instruments and standards, control charts, MSDS and more.

The Materials Manager maintains the inventory of standards, reagents, containers and other materials used in the sampling and testing processes. In addition, the system provides tabs to maintain additional information such as links to MSDS, material recipes, etc.

The Instrument Management Module helps ensure regular ongoing maintenance, by establishing schedules, tracking completed tasks (including real-time annotations on actions taken) and flagging incomplete tasks. Depending on lab-specific configurations, certain requests may be disabled until the required maintenance task is completed.

STARLIMS ensures the highest standards of integrity and quality, in conformity with GAMP, ISO 17025, GLP, EN requirements for audit trails, security, data integrity and data archiving. This includes customer compliance with 21 CFR Part 11 requirements for electronic records and signatures.

Security

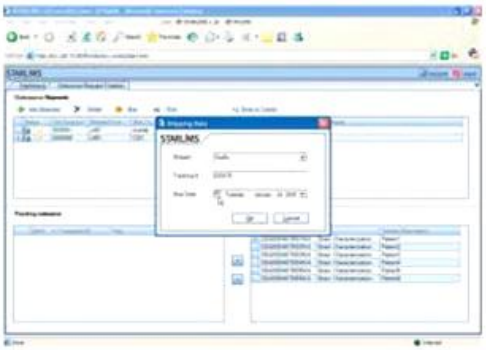
STARLIMS' security configurations allow users to determine the functions and content accessible for a given role. For instance, the functions of analysts would typically include entering results and performing peer approval. Using the STARLIMS Role Design Wizard, system administrators rapidly create multiple roles, and assign them to various users.

Likewise, access to content can also be limited to specific groups and individuals within the organization. For instance, members of the chromatography group may only be able to view their own group's data, but a lab manager may access data from various groups.

The Dashboard Parts Manager provides tools to configure different dashboards for different roles, so the appropriate content is delivered according to each person's job description and organizational affiliation.

Audit Trail

The automatic audit trail function records all changes in the audit log, indicating the nature, user and reason for the change. The system administrator can limit the fields subject to the audit trail, and the conditions required to implement changes.



Version Control

STARLIMS safeguards data integrity by disallowing changes to critical information such as test plans, specifications, test methods and other controlled procedures. Critical information can only be modified by creating new versions.

Document Management

STARLIMS offers laboratory document and scientific data management in a single platform that fully complies with 21 CFR Part 11. STARLIMS Document Management functions are fully integrated into the STARLIMS workflow, for automatic simultaneous presentation of STARLIMS content and captured documents enterprise-wide. Routed content and documents may include SOPs, analyst certifications, electronic training materials, investigation reports, captured instrument outputs, COAs (Certificates of Analysis) generated by the laboratory for users, scanned COAs received from suppliers, and more.

Altogether, STARLIMS provides scientists and lab users the ability to securely store and share complete scientific reports in various textual, graphic and audio visual formats. This provides rich and complex data extraction during data querying and analysis.

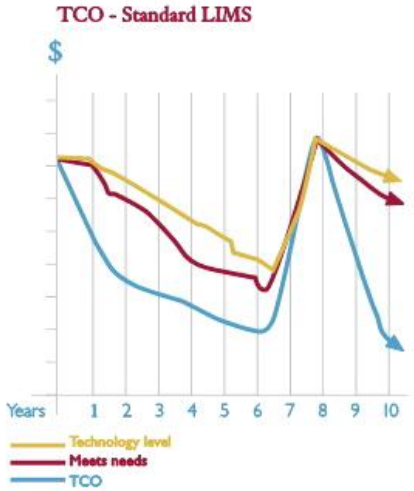
Multi-Lab Capabilities

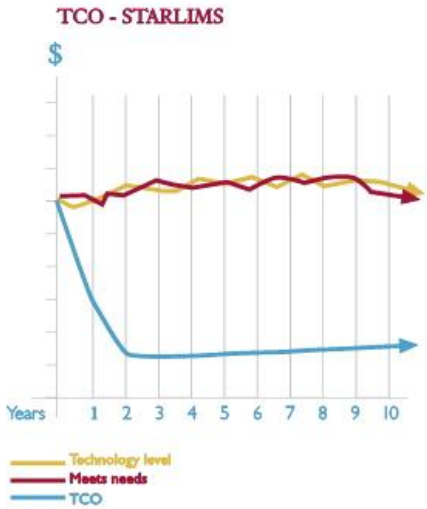
As an Internet-based system, STARLIMS V10 enables using a single database to run multiple laboratories operating at different geographical sites. Access to data is defined for each user. Some users may only view local data, while management may access a wider view spanning multiple sites and labs. Alongside these functions are capabilities that allow for transfer of samples between labs to accommodate for conditions such as capacity overflows, etc.

Add-On Modules

Stability Studies – The stability studies module provides a workflow for the creation, review and approval of stability study protocols, which are converted to studies. The Pull stability studies functions provide reminders as to when samples need to be pulled from storage and sent to testing. Built-in inventory management capabilities provide real-time information about the stored samples, their location and storage conditions. The reporting and analysis module provides tools to extract stability data and perform calculations (expected shelf life, etc.)

Future-Proof Investment



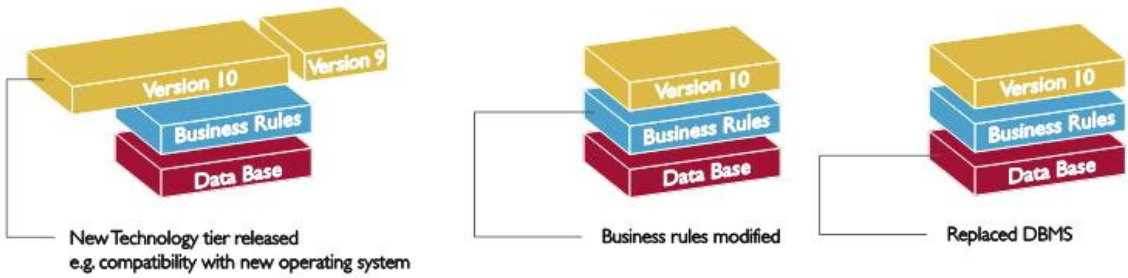


In most legacy and first-generation LIMS systems, the technology and the business rules components are compiled together and cannot be separated. Often, custom code is developed to meet dynamically changing lab and business needs. In parallel, vendors make modifications to their product code to incorporate new IT technology.

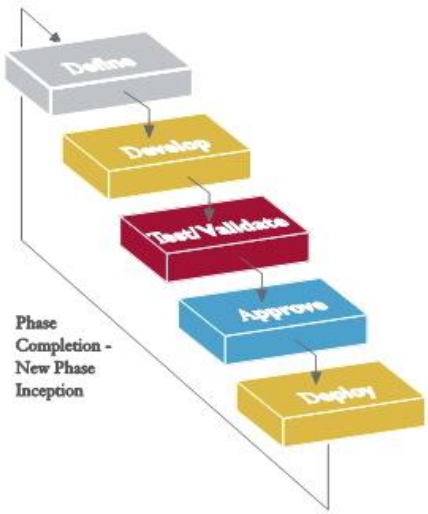
These parallel developments are normally incompatible, so users must forgo their customized applications if they wish to upgrade to newer versions of the vendor's LIMS. Deviation from the vendors' development path makes it more difficult to modify business rules. Over time, the laboratory finds itself using a system that is far behind the latest technologies, and also falls short of the laboratory's own requirements. STARLIMS Corporation believes that the long-term effectiveness and ROI of LIMS solutions can only be improved by using a single technological platform, which preserves existing business rules while allowing for ongoing configuration.

STARLIMS does just that, by using a multi-tier system that partitions development and maintenance tasks. The new and advanced features developed by STARLIMS Corporation are rapidly integrated, validated and distributed enterprise-wide, without compromising business rules or database components. In this way, we help ensure a high level of technological adoption. Conversely, users modify business rules to meet evolving requirements, without departing from STARLIMS's overall development path. This approach increases adoption of ongoing upgrades, while bringing annual ownership costs down to the level of ongoing maintenance costs.

STARLIMS represents a new paradigm for LIMS cost/performance. Easier to implement, validate, certify and maintain than comparable solutions, it lowers total cost of ownership throughout the LIMS life cycle.



Delivery



Based on twenty years of LIMS-only development, STARLIMS provides hundreds of ready-made rules and wizards for rapid deployment of common business processes. Nevertheless, each lab has individual requirements—and each STARLIMS application requires its own configuration, validation and testing cycle.

Implementation is a site-specific process, involving several iterations between the client and the STARLIMS professional services team. Issues typically addressed include: Modifications to existing test workflows, instrument interfacing for automated run scheduling and data collection, site-specific reporting, and interfacing LIMS with internal or external business systems and applications.

The STARLIMS professional services team follows industry best practices, as defined by the Project Management Institute's 'Project Management Body of Knowledge' (PMBOK 2000) and the ISPE's Good Automated Manufacturing Process (GAMP4) guide for validation of automated systems.

STARLIMS has built a reputation not only for providing first-time LIMS users with successful implementations, but also for straightforward conversions and migrations from legacy LIMS systems.

Project Definition

The project definition phase involves a kickoff meeting to define project goals, objectives and staffing requirements. The STARLIMS professional services team prepares detailed documents to define the project scope (Statement of Work, Project Plan and Work Breakdown Schedule).

Delivery

STARLIMS Corporation is entirely committed to quality processes. The company holds ISO 9001:2000 certification, reflecting our continuing efforts to offer laboratory information management systems that consistently exceed our customers' expectations.

Iterative Development

In each phase of the project, STARLIMS

- Gathers end-user requirements and develops a detailed User Requirements Specification.
- Develops a detailed Functional Specification that shows how the application will meet end-user requirements.
- Establishes a test plan and a documented Factory Acceptance Test.
- Assists the customer to develop a site-specific Site Acceptance Test to ensure the application is working correctly onsite.
- Develops a Traceability Matrix that will trace requirements through functional specification to testing.

This development cycle is repeated at each phase, depending on the scope of the application.

Project Wrap-Up

Once the project is completed, a wrap-up meeting is conducted to review the project and to evaluate its success in meeting all goals and objectives.

Ongoing Maintenance

A STARLIMS Support and Update Contract provides customers unlimited remote support and software updates on a regular basis, ensuring that systems remain current and equipped with the latest technological and functional developments. STARLIMS has built-in backward compatibility, so that customers' investment in internal logic is never compromised.

Global Support

A global network of experienced specialists deliver STARLIMS state-of-the-art solutions directly to customers, with professionals located in the US, Canada, Europe, Asia, Africa and Latin America.

About Us

STARLIMS Corporation delivers cost effective, easy-to-use collaborative LIMS solutions to organizations within the public health, pharmaceutical, forensics, food and environmental industries.

The STARLIMS full featured, flexible, multilingual laboratory information management system provides complete traceability leading to regulatory compliance, without compromising process versatility.

The company's 20-year track record together with STARLIMS' architecture have earned us recognition for "future proofing" our customers' investments in internal know-how and for straightforward conversions of disparate legacy systems.

STARLIMS

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APPENDIX B

THE DIGITAL SCALE (BALANCE)

METTLER-TOLEDO INTERNATIONAL INC.MODEL PB1502-L

Features and Benefits

Adjustment: Adjustment at a keystroke with an external weight.

Brilliant backlit display: Correct reading of results under any light condition.

Robust quality: Full metal housing.

MonoBloc weighing technology: Including permanent shock and overload protection.

Easy operation: Large, ergonomic touch-sensitive keys.

Standard Features:	All models
Protective in-use cover	are available as certified version
RS232 interface	can be adjusted in a frequently used weighing range with external weights
Hook for weighing below the balance	have piece counting, percent weighing and dynamic weighing as standard built-in application programs
	are able to show weighing results in different units: g, mg, lb, oz, ozt, GN, dwt, mo, m, tl

Specifications - PB1502-L Precision Balance	
Search Capacity	1510 g
Search Readability	0.01 g
Repeatability	
Linearity	
Settling time (typical)	
Adjustment with internal weights	
Adjustment with external weights	
Sensitivity temperature drift	
Interfaces	
Size of weighing pan	
Dimensions	

Product Documentation

Datasheets

Classic Selection Guide Light (pdf)
Free your mind - Classic weighing from METTLER TOLEDO (pdf)
Selection Guide Classic Balances (pdf)

APPENDIX C

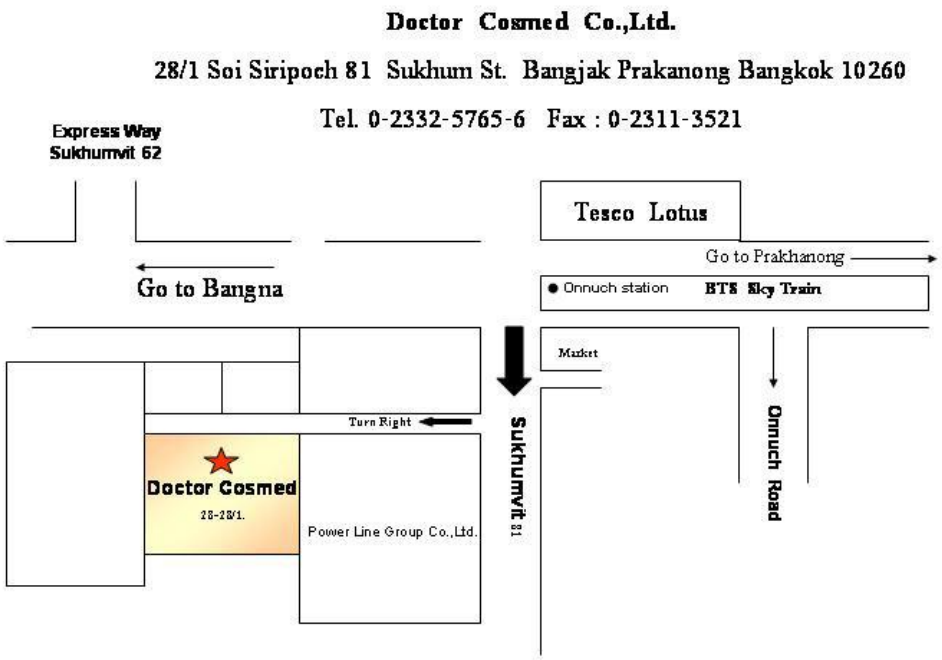
DOCTOR COSMED Co.,Ltd.

General Information

Doctor Cosmed Co., Ltd was established in 1997 to fulfill requirement of cosmetic, toiletries, spa, food supplement and herbal medicinal products. Years of experience of our company make us a manufacturer of professional products with high standard manufacturing equipment and professional staffs both in research and development and manufacturing.

Doctor Cosmed is certified as a Good Manufacturing Practice Company (GMP) by Thai Food and Drug Administration since 2004 which can guarantee the quality of products in standard level. We aim in product development to meet the most customer satisfaction as well as developing product qualification to improve people well being.

Address: Pimollak Wattanaporn 28/1 Soi Siripoj 81, Sukhumvit, Bangjak, Prakhanong, Bangkok,10250, Thailand Tel : 02 332-765-6 Fax :02 311-3521



Map of Doctor Cosmed Co., Ltd

Front of Doctor Cosmed Co., Ltd

APPENDIX D

QUESTIONNAIRE

แบบประเมินผลการใช้งานโปรแกรม StarLIMS

(เพื่อประกอบการทำ Independent Study สำนักวิชาวิทยาศาสตร์เครื่องสำอาง มหาวิทยาลัยแม่ฟ้าหลวง)

หมวด 1 ข้อมูลทั่วไปของผู้ตอบแบบสอบถาม

เพศ ชาย หญิง

อายุ.....ปี

การศึกษาระดับสูงสุด

ปริญญาตรี

ปริญญาโท

ปริญญาเอก

อื่นๆ (ระบุ) .....

สาขาวิชา (ระบุ) .....

ตำแหน่งงานปัจจุบัน .....

ลักษณะงาน (เลือกได้มากกว่า 1 ข้อ)

- ☐ ผู้บริหาร
- ☐ หัวหน้างาน
- ☐ ผู้ปฏิบัติงานในห้องปฏิบัติการ
- ☐ ผู้ควบคุมคุณภาพ
- ☐ อื่นๆ (ระบุ) .....

หมวด 2 ความรู้ทั่วไปเกี่ยวกับระบบ Laboratory Information Management System (LIMS) ก่อนทำการทดลองใช้โปรแกรม StarLIMS

2.1 หน่วยงานที่ท่านปฏิบัติงานอยู่มีการใช้ระบบ LIMS หรือไม่

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2.2 ท่านรู้จักระบบ LIMS มากน้อยอย่างไร

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2.3 ท่านคิดว่าระบบ LIMS ช่วยในการควบคุมคุณภาพการผลิตในอุตสาหกรรมเครื่องสำอาง

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2.4 ท่านคิดว่าระบบ LIMS มีความจำเป็นในการควบคุมคุณภาพการผลิตในอุตสาหกรรมเครื่องสำอางสำหรับหน่วยงานท่าน มากน้อยอย่างไร

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หมวด 3 หลังจากทดสอบการใช้งานโปรแกรม StarLIMS

3.1 สำหรับผู้บริหาร และ หัวหน้างาน

3.1.1 ท่านคิดว่าโปรแกรม StarLIMS ซึ่งได้รับการประยุกต์ใช้กับการผลิตเครื่องสำอางมีประโยชน์ต่อการปฏิบัติงานของหน่วยงานที่ท่านปฏิบัติงานอยู่หรือไม่ อย่างไร

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3.1.2 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยแก้ปัญหาหรือช่วยให้กระบวนการผลิตเครื่องสำอางดีขึ้นหรือไม่ อย่างไร

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3.1.3 ท่านมีความรู้สึกพอใจกับการใช้โปรแกรม StarLIMS ในกระบวนการผลิตเครื่องสำอางหรือไม่อย่างไร

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3.1.4 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยให้กระบวนการผลิตเครื่องสำอางได้มาตรฐานตาม ASEAN GMP หรือไม่ อย่างไร

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3.1.5 ท่านมีความประสงค์ที่จะนำโปรแกรมดังกล่าวมาใช้ในการบริหารจัดการและควบคุมคุณภาพการผลิตเครื่องสำอาง หรือไม่ มากน้อยเพียงใด

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3.1.6 ข้อเสนอแนะอื่นๆ

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3.2 สำหรับผู้ปฏิบัติงานในห้องปฏิบัติการ

3.2.1 ท่านคิดว่าโปรแกรม StarLIMS ซึ่งได้รับการประยุกต์ใช้กับการผลิตเครื่องสำอางมีประโยชน์ต่อการปฏิบัติงานของหน่วยงานที่ท่านปฏิบัติงานอยู่หรือไม่ อย่างไร

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3.2.2 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยแก้ปัญหาหรือช่วยให้กระบวนการผลิตเครื่องสำอางดีขึ้นหรือไม่ อย่างไร

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3.2.3 ท่านคิดว่าโปรแกรม StarLIMS เป็นโปรแกรมที่สะดวกต่อการใช้งานหรือไม่ อย่างไร

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3.2.4 ท่านมีความรู้สึกพอใจกับการใช้โปรแกรม StarLIMS ในกระบวนการผลิตเครื่องสำอางหรือไม่อย่างไร

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3.2.5 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยให้กระบวนการผลิตเครื่องสำอางได้มาตรฐานตาม ASEAN GMP หรือไม่ อย่างไร

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3.2.6 ท่านประสงค์ให้หน่วยงานท่านนำโปรแกรม StarLIMS มาใช้ในการผลิตเครื่องสำอางหรือไม่มากน้อยเพียงใด

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3.2.7 ข้อเสนอแนะอื่นๆ

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ขอขอบคุณสำหรับการตอบแบบสอบถาม

APPENDIX E

ANSWERS OF THE QUESTIONNAIRES

หมวด 3 หลังจากทดสอบการใช้งานโปรแกรม StarLIMS

3.1 สำหรับผู้บริหาร และ หัวหน้างาน

3.1.1 ท่านคิดว่าโปรแกรม StarLIMS ซึ่งได้รับการประยุกต์ใช้กับการผลิตเครื่องสำอางมีประโยชน์ต่อการปฏิบัติงานของหน่วยงานที่ท่านปฏิบัติงานอยู่หรือไม่ อย่างไร

มี ช่วยลดความผิดพลาดที่เกิดขึ้นจากการชั่งสาร ชั่ง น.น. ผลิตภัณฑ์ ได้

หัวหน้างานสามารถตรวจเช็คความถูกต้อง ของการปฏิบัติงาน ของพนง. ได้ ง่ายขึ้น และได้ข้อมูลที่เป็นจริง

3.1.2 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยแก้ปัญหาหรือช่วยให้กระบวนการผลิตเครื่องสำอางดีขึ้นหรือไม่ อย่างไร

ลด Human error ได้

3.1.3 ท่านมีความรู้สึกพอใจกับการใช้โปรแกรม StarLIMS ในกระบวนการผลิตเครื่องสำอางหรือไม่อย่างไร

พอใจ ในหลักการการทำงาน แต่ถ้าเข้ามาใช้งานจริง คงจะต้องมีการลองทดสอบระบบ

การ key ข้อมูลต่างๆ ให้มากขึ้น และปรับให้เข้ากับระบบการทำงาน ของโรงงานนั้นๆ

3.1.4 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยให้กระบวนการผลิตเครื่องสำอางได้มาตรฐานตาม ASEAN GMP หรือไม่ อย่างไร

ช่วยได้ในระดับหนึ่ง เกี่ยวกับขบวนการผลิต แต่ ASEAN GMP ยังมีกฎเกณฑ์อื่นๆ ที่ต้อง

ปฏิบัติตาม เพิ่มเติมนอกจากการผลิตด้วย

3.1.5 ท่านมีความประสงค์ที่จะนำโปรแกรมดังกล่าวมาใช้ในการบริหารจัดการและควบคุมคุณภาพการผลิตเครื่องสำอาง หรือไม่ มากน้อยเพียงใด

ถ้าขนาดการผลิต มีขนาดใหญ่มากขึ้น การนำโปรแกรม มาใช้ น่าจะมีประโยชน์ และคุ้มทุนมากกว่า

3.1.6 ข้อเสนอแนะอื่นๆ

3.2 สำหรับผู้ปฏิบัติงานในห้องปฏิบัติการ

3.2.1 ท่านคิดว่าโปรแกรม StarLIMS ซึ่งได้รับการประยุกต์ใช้กับการผลิตเครื่องสำอางมีประโยชน์ต่อการปฏิบัติงานของหน่วยงานที่ท่านปฏิบัติงานอยู่หรือไม่ อย่างไร

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3.2.2 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยแก้ปัญหาหรือช่วยให้กระบวนการผลิตเครื่องสำอางดีขึ้นหรือไม่ อย่างไร

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3.2.3 ท่านคิดว่าโปรแกรม StarLIMS เป็นโปรแกรมที่สะดวกต่อการใช้งานหรือไม่ อย่างไร

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3.2.4 ท่านมีความรู้สึกพอใจกับการใช้โปรแกรม StarLIMS ในกระบวนการผลิตเครื่องสำอางหรือไม่อย่างไร

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3.2.5 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยให้กระบวนการผลิตเครื่องสำอางได้มาตรฐานตาม ASEAN GMP หรือไม่ อย่างไร

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3.2.6 ท่านประสงค์ให้หน่วยงานท่านนำโปรแกรม StarLIMS มาใช้ในการผลิตเครื่องสำอางหรือไม่มากน้อยเพียงใด

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3.2.7 ข้อเสนอแนะอื่นๆ

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ขอขอบคุณสำหรับการตอบแบบสอบถาม

แบบประเมินผลการใช้งานโปรแกรม StarLIMS

(เพื่อประกอบการทำ Independent Study สำนักวิชาวิทยาศาสตร์เครื่องสำอาง มหาวิทยาลัยแม่ฟ้าหลวง)

หมวด 1 ข้อมูลทั่วไปของผู้ตอบแบบสอบถาม

เพศ ☐ ชาย ☑ หญิง

อายุ 25 ปี

การศึกษาระดับสูงสุด

☑ ปริญญาตรี

☐ ปริญญาโท

☐ ปริญญาเอก

☐ อื่นๆ (ระบุ) .....

สาขาวิชา (ระบุ) เทคโนโลยีเครื่องสำอาง

ตำแหน่งงานปัจจุบัน ฝ่าย ควบคุมคุณภาพ

ลักษณะงาน (เลือกได้มากกว่า 1 ข้อ)

☐ ผู้บริหาร

☐ หัวหน้างาน

☑ ผู้ปฏิบัติงานในห้องปฏิบัติการ

☐ ผู้ควบคุมคุณภาพ

☐ อื่นๆ (ระบุ) .....

หมวด 2 ความรู้ทั่วไปเกี่ยวกับระบบ Laboratory Information Management System (LIMS) ก่อนทำการทดลองใช้โปรแกรม StarLIMS

2.1 หน่วยงานที่ท่านปฏิบัติงานอยู่มีการใช้ระบบ LIMS หรือไม่

ไม่มี

2.2 ท่านรู้จักระบบ LIMS มากน้อยอย่างไร

ไม่รู้จัก

2.3 ท่านคิดว่าระบบ LIMS ช่วยในการควบคุมคุณภาพการผลิตในอุตสาหกรรมเครื่องสำอาง

น่าจะมีส่วนในการควบคุมคุณภาพ ช่วยลดการผิดพลาด

2.4 ท่านคิดว่าระบบ LIMS มีความจำเป็นในการควบคุมคุณภาพการผลิตในอุตสาหกรรมเครื่องสำอางสำหรับหน่วยงานท่าน มากน้อยอย่างไร

สิ่งจำเป็นเป็นปานกลาง

หมวด 3 หลังจากทดสอบการใช้งานโปรแกรม StarLIMS

3.1 สำหรับผู้บริหาร และ หัวหน้างาน

3.1.1 ท่านคิดว่าโปรแกรม StarLIMS ซึ่งได้รับการประยุกต์ใช้กับการผลิตเครื่องสำอางมีประโยชน์ต่อการปฏิบัติงานของหน่วยงานที่ท่านปฏิบัติงานอยู่หรือไม่ อย่างไร

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3.1.2 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยแก้ปัญหาหรือช่วยให้กระบวนการผลิตเครื่องสำอางดีขึ้นหรือไม่ อย่างไร

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3.1.3 ท่านมีความรู้สึกพอใจกับการใช้โปรแกรม StarLIMS ในกระบวนการผลิตเครื่องสำอางหรือไม่อย่างไร

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3.1.4 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยให้กระบวนการผลิตเครื่องสำอางได้มาตรฐานตาม ASEAN GMP หรือไม่ อย่างไร

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3.1.5 ท่านมีความประสงค์ที่จะนำโปรแกรมดังกล่าวมาใช้ในการบริหารจัดการและควบคุมคุณภาพการผลิตเครื่องสำอาง หรือไม่ มากน้อยเพียงใด

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3.1.6 ข้อเสนอแนะอื่นๆ

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3.2 สำหรับผู้ปฏิบัติงานในห้องปฏิบัติการ

3.2.1 ท่านคิดว่าโปรแกรม StarLIMS ซึ่งได้รับการประยุกต์ใช้กับการผลิตเครื่องสำอางมีประโยชน์ต่อการปฏิบัติงานของหน่วยงานที่ท่านปฏิบัติงานอยู่หรือไม่ อย่างไร

มีประโยชน์ต่องานชั่งสาร ผลิตภัณฑ์ ใช้ได้ตามชนิด แม่นยำมากขึ้น

3.2.2 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยแก้ปัญหาหรือช่วยให้กระบวนการผลิตเครื่องสำอางดีขึ้นหรือไม่ อย่างไร

ช่วยลดปัญหา ความผิดพลาดในการที่ต้องลงข้อมูล และการคำนวณ ค้นหา ข้อมูลยังไง

3.2.3 ท่านคิดว่าโปรแกรม StarLIMS เป็นโปรแกรมที่สะดวกต่อการใช้งานหรือไม่ อย่างไร

สะดวกต่อการใช้งาน แต่ต้องศึกษาโปรแกรม ก่อน การใช้งาน

3.2.4 ท่านมีความรู้สึกพอใจกับการใช้โปรแกรม StarLIMS ในกระบวนการผลิตเครื่องสำอางหรือไม่อย่างไร

มีความพอใจ

3.2.5 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยให้กระบวนการผลิตเครื่องสำอางได้มาตรฐานตาม ASEAN GMP หรือไม่ อย่างไร

มีโปรแกรม StarLIMS สามารถช่วยให้ กระบวนการผลิตเครื่องสำอางได้ตามตาม GMP ในเรื่องของการตรวจสอบความเที่ยงตรง และความแม่นยำ ในการผลิต มากขึ้น

3.2.6 ท่านประสงค์ให้หน่วยงานท่านนำโปรแกรม StarLIMS มาใช้ในการผลิตเครื่องสำอางหรือไม่มากน้อยเพียงใด

ต้องการนำมาใช้

3.2.7 ข้อเสนอแนะอื่นๆ

ขอขอบคุณสำหรับการตอบแบบสอบถาม

แบบประเมินผลการใช้งานโปรแกรม StarLIMS

(เพื่อประกอบการทำ Independent Study สำนักวิชาวิทยาศาสตร์เครื่องสำอาง มหาวิทยาลัยแม่ฟ้าหลวง)

หมวด 1 ข้อมูลทั่วไปของผู้ตอบแบบสอบถาม

เพศ ☐ ชาย ☑ หญิง

อายุ.....24.....ปี

การศึกษาระดับสูงสุด

☑ ปริญญาตรี

☐ ปริญญาโท

☐ ปริญญาเอก

☐ อื่นๆ (ระบุ).....

สาขาวิชา (ระบุ).....วิทยาศาสตร์ เคมี.....

ตำแหน่งงานปัจจุบัน .....RD.....

ลักษณะงาน (เลือกได้มากกว่า 1 ข้อ)

☐ ผู้บริหาร

☐ หัวหน้างาน

☑ ผู้ปฏิบัติงานในห้องปฏิบัติการ

☐ ผู้ควบคุมคุณภาพ

☐ อื่นๆ (ระบุ).....

หมวด 2 ความรู้ทั่วไปเกี่ยวกับระบบ Laboratory Information Management System (LIMS) ก่อนทำการทดลองใช้โปรแกรม StarLIMS

2.1 หน่วยงานที่ท่านปฏิบัติงานอยู่มีการใช้ระบบ LIMS หรือไม่

.....ไม่.....

2.2 ท่านรู้จักระบบ LIMS มากน้อยขอย่างไร

.....น้อยมาก.....

2.3 ท่านคิดว่าระบบ LIMS ช่วยในการควบคุมคุณภาพการผลิตในอุตสาหกรรมเครื่องสำอาง

.....ช่วยลดขั้นตอนในการทำงานของ งานบริการตามงาน ตรวจเร็วได้.....

2.4 ท่านคิดว่าระบบ LIMS มีความจำเป็นในการควบคุมคุณภาพการผลิตในอุตสาหกรรมเครื่องสำอางสำหรับหน่วยงานท่าน มากน้อยขอย่างไร

.....ปานกลาง.....

หมวด 3 หลังจากทดสอบการใช้งานโปรแกรม StarLIMS

3.1 สำหรับผู้บริหาร และ หัวหน้างาน

3.1.1 ท่านคิดว่าโปรแกรม StarLIMS ซึ่งได้รับการประยุกต์ใช้กับการผลิตเครื่องสำอางมีประโยชน์ต่อการปฏิบัติงานของหน่วยงานที่ท่านปฏิบัติงานอยู่หรือไม่ อย่างไร

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3.1.2 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยแก้ปัญหาหรือช่วยให้กระบวนการผลิตเครื่องสำอางดีขึ้นหรือไม่ อย่างไร

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3.1.3 ท่านมีความรู้สึกพอใจกับการใช้โปรแกรม StarLIMS ในกระบวนการผลิตเครื่องสำอางหรือไม่อย่างไร

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3.1.4 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยให้กระบวนการผลิตเครื่องสำอางได้มาตรฐานตาม ASEAN GMP หรือไม่ อย่างไร

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3.1.5 ท่านมีความประสงค์ที่จะนำโปรแกรมดังกล่าวมาใช้ในการบริหารจัดการและควบคุมคุณภาพการผลิตเครื่องสำอาง หรือไม่ มากน้อยเพียงใด

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3.1.6 ข้อเสนอแนะอื่นๆ

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3.2 สำหรับผู้ปฏิบัติงานในห้องปฏิบัติการ

3.2.1 ท่านคิดว่าโปรแกรม StarLIMS ซึ่งได้รับการประยุกต์ใช้กับการผลิตเครื่องสำอางมีประโยชน์ต่อการปฏิบัติงานของหน่วยงานที่ท่านปฏิบัติงานอยู่หรือไม่ อย่างไร

มีประโยชน์ โดยการช่วยลดข้อผิดพลาดในการบันทึก ในส่วนของการชั่ง, การผสม ๆ ทำให้ผลิตภัณฑ์ที่ได้มีคุณภาพ

3.2.2 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยแก้ปัญหาหรือช่วยให้กระบวนการผลิตเครื่องสำอางดีขึ้นหรือไม่ อย่างไร

เนื่องจากความผิดพลาดในการผลิตสามารถ recheck ได้

3.2.3 ท่านคิดว่าโปรแกรม StarLIMS เป็นโปรแกรมที่สะดวกต่อการใช้งานหรือไม่ อย่างไร

โปรแกรม StarLIMS จะต้องมีการศึกษาเบื้องต้นก่อนใช้งาน คิดว่าน่าจะไม่สะดวกต่อการใช้งาน

3.2.4 ท่านมีความรู้สึกพอใจกับการใช้โปรแกรม StarLIMS ในกระบวนการผลิตเครื่องสำอางหรือไม่อย่างไร

พอใจ เพราะโปรแกรมนี้สามารถลดขั้นตอนการควบคุมคุณภาพการผลิต ถ้าเรียนรู้ความถูกต้อง

3.2.5 ท่านคิดว่าโปรแกรม StarLIMS จะช่วยให้กระบวนการผลิตเครื่องสำอางได้มาตรฐานตาม ASEAN GMP หรือไม่ อย่างไร

น่าจะช่วยได้ เนื่องจากช่วยให้การผลิตมีมาตรฐานมากขึ้น

3.2.6 ท่านประสงค์ให้หน่วยงานท่านนำโปรแกรม StarLIMS มาใช้ในการผลิตเครื่องสำอางหรือไม่มากน้อยเพียงใด

ต้องการปานกลาง

3.2.7 ข้อเสนอแนะอื่นๆ

ขอขอบคุณสำหรับการตอบแบบสอบถาม

CIRRICULUM VITAE

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