Ontology-based Expert System for a Generic Drug Production of Pharmaceutical Dosage Forms

Project Plan

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Document History

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1

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¹ NS – Narangrit Saisuwan, PW – Panupak Wichaidit, CD- Chatchai Doungsa-ard

Table of Contents

Documen	it His	tory	. ii
Chapter 1	L	Introduction	. 1
1.1.	Iden	tification	. 1
1.2.	Proj	ect Overview	. 1
1.2.1	l.	Motivation	. 1
1.2.2	2.	Aim	. 1
1.2.3	3.	Objective	. 1
Chapter 2	2	System Architecture	. 2
2.1.	Syst	em Architecture	. 2
2.2.	Syst	em Architecture Overview	. 3
2.3.	Limi	t	. 4
Chapter 3	3	Deliverables	. 5
3.1.	Deli	verables	. 5
Chapter 4	1	Acronyms and Definitions	. 6
4.1.	Acro	nyms	. 6
4.2.	Defi	nitions	. 6
Chapter 5	5	Infrastructure	. 7
5.1.	Soft	ware Development Life Cycle	. 7
5.2.	Soft	ware Acquisition Plans	. 7
5.2.1	L.	Design Tools	. 7
5.2.2	2.	Development Tools	. 7
5.2.3	3.	Configuration Management Tools	. 7
5.2.4	1.	Document Tools	. 7
5.2.5	5.	Testing Tools	. 7
5.3.	Hard	dware and Material Resources	. 8
Chapter 6	5	Management Procedures	. 8
6.1.	Proj	ect Team Structure	. 8
6.2.	Mor	nitoring and Controlling Mechanisms	. 8
6.2.1	l.	Project Meeting	. 8
Chapter 7	7	Quality Standard	.9
7.1.	ISO 2	29110 for Very Small Entity (VSE)	.9
7.1.1	l.	Project Management (PM) process	.9
7.1.2	2.	Software Implementation (SI) process	۱1
Chanter 9	RΙ	Quality Planning	13

8.1. Qua	lity Factors	13
8.1.1.	Product operation factors	13
8.1.2.	Product revision factors	13
8.1.3.	Product transition factors	13
8.2. Revi	ews/Responsibility	14
Chapter 9	Schedule & Milestones	15
9.1. Sche	edule Plan	15
9.2. Mile	estones	17
Chapter 10	Version Control Strategy	20
10.1. Na	aming Conversion	20
10.2. Pr	oject Repository	21
10.3. Co	onfiguration Item Table	22
Chapter 11	Risk Management	23
11.1. Ri	sk Management Process	23
11.2. Ri	sk Identification and Solutions	24

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	iv / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

Chapter 1 | Introduction

1.1. Identification

Project Plan is the document for planning, scheduling activities and evaluating overall of the project so that the project will complete as successfully as possible in spite of all the risks. The Project Management will lead us to see specific project reach fruition and allow us to work with it and see a project through from start to finish.

1.2. Project Overview

1.2.1. Motivation

The price of original drugs, which is under patent protection, is always expensive because of research and development costs. So this reasons make poor people, in developing countries, cannot pay for curing their sickness or disease. For solve this problem, the local pharmaceutical corporations try to develop a new drug manufacturing that call reformulating drugs into a generic version after the patent protection expired.

The pharmaceutical formulation process is a highly specialize task requiring specific domain knowledge and often years of experience. Expert system derived from research into artificial intelligence support the efficient formulation of products and therefore increase productivity, consistency and quality.

Follow the issue above, OEGP can help an inexperienced industry pharmacists to reproduce a generic drug in the right way and the right time.

1.2.2. Aim

The aim of this project is to develop mobile application on Tablet computer. OEGP recommend a solution for reformulating an original drug into a generic version. The generic production receives a pharmaceutical value and shows result as a drug formula, manufacturing and excipients. The experience pharmacist can use OEGP for reformulating drug.

1.2.3. Objective

- To recommend a generic production that consist of a formula and its instructions.
- To evaluate the generic drug production comparing with the original drug.
- To suggestion the generic production, which is not equivalent to the original drug, until it equivalent to its original.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	1 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

Chapter 2 | System Architecture

2.1. System Architecture

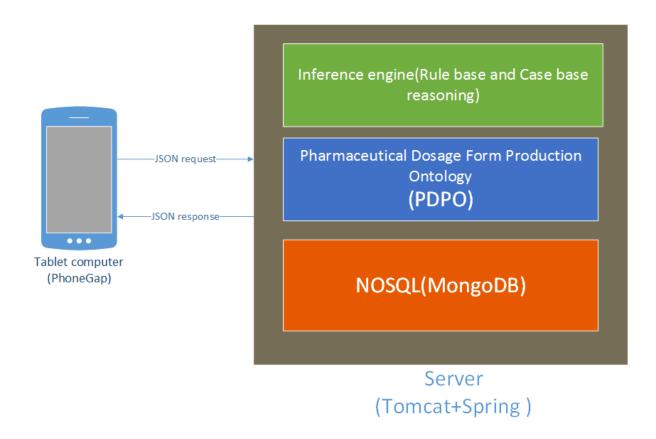


Figure 1 System Architecture.

Figure 1 shows the system architecture OEGP. Firstly, the system receives an input data from a user via tablet computer. Then it send the data to the server in JSON format. After that, the system on server will recommend an appropriate solutions using rule base technique and/or case base reasoning. Finally the system returns a drugs reformulation with manufacturing and excipients to the user.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	2 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

2.2. System Architecture Overview

From the system architecture on Figure 8, OEGP can be divided into many subsystem such as the user management system, the rule base system, the case base reasoning system, hybrid reasoning system and the pharmaceutical tablet production on ontology. The server side is develop on JAVA programming and with apache server. The structure of architecture overview is illustrated in Figure 10

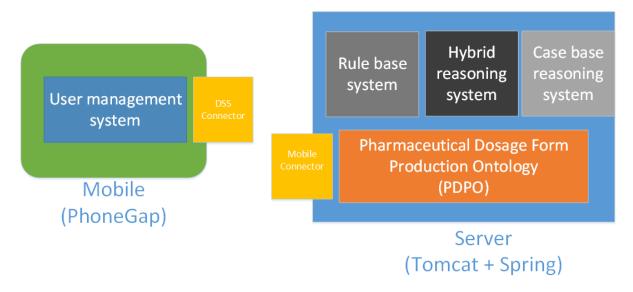


Figure 2: System Architecture overview

The subsystem can group into two main parts. The first one is a mobile part, and the second is a server part.

Mobile Part

• Feature 1 : User management system

There are two types of users in OEGP. The first one is experience pharmacists. This user uses the system for evaluating generic drugs production comparing with the original drug production. The experience pharmacists also use the system for suggested an appropriate manufacturing and excipients to reformulate a drug and they can create and/or add a new case by themselves. The second is inexperience pharmacists. This user uses the system similar with experience pharmacists, but they cannot add add/or create any of a new pharmaceutical case.

Server part

• Feature 2 : Rule base system

Rule base system is one part of inference engine that using for suggesting the reformulate an original drug as a generic version. Rule base system can decide a drug reformulating by "rule ". The rule is come from a set of pharmaceutical knowledge that call PDPO (Pharmaceutical dosage form production ontology). The rule base system receive a pharmaceutical value and show an appropriate result as a manufacturing and excipient to the user.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	3 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

• Feature 3 : Case base reasoning system

Case base reasoning system is one part of inference engine like a Rule base system. OEGP uses a case base reasoning system for reformulating an original drug and comparing the generic drug production with original drug production. The experience pharmacists can use the case base reasoning system for creating and adding a new case into the system. The new case base used to reformulate an original drug like existing case base.

Feature 4: Hybrid reasoning system

Hybrid reasoning system is an inference engine that combine with Case base reasoning and Rule base system. The system is suggest to reformulate an original drug into a generic version. The pharmacists can use the hybrid reasoning system for creating and adding a new case into the system like Case base reasoning system.

Feature 5 : Pharmaceutical Dosage Form Production Ontology system(PDPO system)

PDPO system is kept as set of knowledge. The rule base and the case base reasoning use PDPD for calculating an appropriate reformulate drugs the reformulate an original drug as generic version.

Feature 6 : DSS connector

DSS connector is a system at mobile part which sending and receiving a data between users and a server. DSS connector receive a data from a user interface and send data to PDPO for find a drug reformulation Additionally, DSS connector can receive a result from PDPO and show it to a user.

• Feature 7 : Mobile connector

Mobile connector is a system at server part which sending and receiving a data between users and a server. Mobile connector receive an input data from mobile part and send data to PDPO for suggesting a reformulate original drugs as generic drug production; furthermore Mobile connector sends a result to mobile part.

2.3. Limit

- The user require a Tablet computer and internet connection.
- OEGP is appropriated with a person who has a pharmacy knowledge.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	4 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

Chapter 3 | Deliverables

3.1. Deliverables

No.	Deliverables/Release	Media	Copies	Date
1	Project Proposal	Document	3	6 th Mar 2014
	 Proposal Version 			
2	Progress Report 1			7 th July 2014
	 Project Plan Version 1.0 	Document	3	
	 Software Requirement Specification Version 1.0 	Document	3	
	 Software Design Document Version 1.0 	Document	3	
	 Test Plan Version 1.0 	Document	3	
	 Traceability Record Version 1.0 	Document	3	
	 Software Version 1.0 	Source code	1	
3	Progress Report 2			12 rd October 2014
	 Project Plan Version 2.0 	Document	3	
	 Software Requirement Specification Version 2.0 	Document	3	
	 Software Design Document Version 2.0 	Document	3	
	 Test Plan Version 2.0 	Document	3	
	 Traceability Record Version 2.0 	Document	3	
	 Software Version 2.0 	Source code	1	
4	Progress Report 3			11 th December 2014
	 Project Plan Version 3.0 	Document	3	
	 Software Requirement Specification Version 3.0 	Document	3	
	 Software Design Document Version 3.0 	Document	3	
	 Test Plan Version 3.0 	Document	3	
	 Traceability Record Version 3.0 	Document	3	
	 Software Version 3.0 	Source code	1	
	Software Source Code	CD-ROM	1	22 rd December 2014
	Show Pro Event			19 th November 2014
	 Software Version 2.0 	File	1	
	o 30 Seconds Video	File	1	
	Poster size A1	Poster	1	
	 User Manual 	File	1	

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	5 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

Chapter 4 | Acronyms and Definitions

4.1. Acronyms

SRS **Software Requirement Specification** URS **User Requirement Specification** SDD Software Design Document OS **Operating System** VSE **Very Small Entity** PM **Project Management** SI Software Implementation Iterative and Incremental Development IID

SCI Software Configuration Item

OEGP Ontology Base Expert System For Generic Drug Production of Pharmaceutical dosage

Form

PDPO Pharmaceutical Dosage Form Production Ontology

4.2. Definitions

Name	Definition
Acceptance test	Test activities for sample checks to verify that a system (or product, solution) has the right quality for deployment or usage. Often acceptance test is done by the customer. [IEEE90]
Feature	Transformation of input parameters to output parameters based on a specified algorithm. It describes the functionality of a product in the language of the product. Used for requirements analysis, design, coding, testing or maintenance. [IEEE90]
IEEE	Institute for Electrical and Electronics Engineers. Biggest global interest group for engineers of different branches and for computer scientists. [IEEE90]
Plan	A documented series of tasks requires meeting an objective, typically including the associated schedule, budget, resources, organizational description and work breakdown structure. [IEEE90]
Project Management	The application of knowledge, skills, tools, and techniques to project activities in order to meet or exceed stakeholder needs and expectations from a project. [IEEE90]
Project Plan	A formal, approved document used to guide both project execution and project control. The primary uses of the project plan are to document planning assumptions and decision, to facilitate communication among stakeholders, and to document approved scope, cost, and schedule baseline. [IEEE90]
Risk	An uncertain event or condition that, if it occurs, has a positive or negative effect on a project's objectives. It is a function of the probability of occurrence of a given threat's occurrence. [IEEE90]
Risk Management	The systematic application of management policies, procedures and practices to the tasks of identifying, analyzing, evaluating, treating and monitoring risk. [IEEE90]

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	6 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

Chapter 5 | Infrastructure

5.1. Software Development Life Cycle

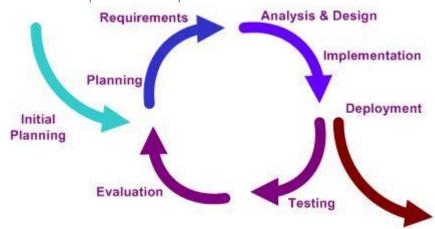


Figure 3: Iterative Development Model

Figure 1 presents a method of software development. Iterative development model is a cyclic software development process developed in response to the weaknesses of the Waterfall model. The model starts with planning and continues through iterative development cycles.

OEGP. Developer can use model to develop the iterative way to fulfill, change software and document for each development process.

5.2. Software Acquisition Plans

5.2.1. Design Tools

- Photoshop CS6
- Adobe Dreamweaver CS6

5.2.2. Development Tools

- Eclipse Kepler
- IntelliJ 12.1.6

5.2.3. Configuration Management Tools

• GitHub

5.2.4. Document Tools

Microsoft Word 2013

5.2.5. Testing Tools

- IPad 2
- Notebook with Google chrome or Firefox browser
- Host Server

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	7 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

5.3. Hardware and Material Resources

- Internet
- Computers
 - o Apple Macbook Pro mid 2013
 - Processor: Intel[®] Core[™] i7-3520M CPU @ 2.90GHz 2.90GHz
 - RAM: 8.00 GB
 - Operating System: Windows 7 Ultimate, OSX maverick
 - o Dell Inspiron n5110
 - Processor: Intel[®] Core[™] i5-2410M CPU @ 2.30GHz 2.30GHz
 - RAM: 4.00 GB
 - Operating System: Windows 8.1 Professional
- Tablet Computer
 - o Ipad 2

Chapter 6 | Management Procedures

6.1. Project Team Structure

Participants	Activities
	Feasibility Study
Mr. Panupak Wichaidit	Project Proposal
And	Project Requirements
Mr. Narongrit Saisuwan	Project Plan
	Project Design
	Implementation
	Testing

6.2. Monitoring and Controlling Mechanisms

6.2.1. Project Meeting

Participants	Roles
Mr. Panupak Wichaidit	Development team member
Mr. Narongrit Saisuwan	Development team member
Aj. Chartchai Doungsa-ard	Project advisor

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	8 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

Chapter 7 | Quality Standard

7.1. ISO 29110 for Very Small Entity (VSE)

ISO 29110 is the Software Life Cycle Profiles and Guidelines for Very Small Entities (VSEs) standards and technical reports are targeted at Very Small Entities (VSEs). A Very Small Entity (VSE) is an enterprise, organization, department or project having up to 25 people. ISO 29110 concerns on project management process and software implementation process.

7.1.1. Project Management (PM) process

Purpose

The purpose of the Project Management process is to establish and carry out in a systematic way the tasks of the software implementation project, which allows complying with the project's objectives in the expected quality, time and costs.

Objectives

- PM.O1. The Project Plan for the execution of the project is developed according to the Statement of Work and validated with the Customer. The tasks and resources necessary to complete the work are sized and estimated.
 - PM.O1. Tasks in this project:
 - 1. Create the Project Plan related with the Project Proposal.
- PM.O2. Progress of the project is monitored against the *Project Plan* and recorded in the Progress Status Record. Corrections to remediate problems and deviations from the plan are taken when project targets are not achieved. Appropriate treatment is taken to correct or avoid the impact of risk. Closure of the project is performed to get the Customer acceptance documented in the *Acceptance Record*
 - PM.O2. Tasks in this project:
 - 1. Record the project status in Project Status Record for each progress.
 - 2. Establish the Acceptance Record before submitting final progress.
- PM.O3. The Change Requests are addressed through their reception and analysis.
 Changes to software requirements are evaluated for cost, schedule and technical impact.
 - PM.O3. Tasks in this project:
 - 1. Analyzing the change.
 - 2. Setting the change request form.
 - 3. Approving the change request by project advisor.
 - 4. Change the project follow by approved change request.
- PM.O4. Review meetings with the Work Team and the Customer are held.

Agreements are registered and tracked.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	9 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

- PM.O4. Tasks in this project:
 - 1. Meeting with team members and project advisor.
 - 2. Evaluate meeting results.
- o **PM.O5.** Risks are identified as they develop and during the conduct of the project.
 - PM.O5. Tasks in this project:
 - 1. Identify the risks.
 - 2. Analyse the risks.
 - 3. Plan for managing the risksin the Project Plan.
- PM.O6. A Software Version Control Strategy is developed. Items of Software
 Configuration are identified, defined and base lined. Modifications and releases of
 the items are controlled and made available to the Customer and Work Team
 including the storage, handling and delivery of the items.
 - PM.O6. Tasks in this project:
 - 1. Identify SCI.
 - 2. Create SCI table.
 - 3. Record the change of each SCI in the SCI table.
- PM.O7. Software Quality Assurance is performed to provide assurance that work products and processes comply with the *Project Plan* and *Requirements* Specification.
 - PM.O7. Tasks in this project:
 - 1. Create tasks follow ISO29110 for VSE to the Project Plan and Requirements Specification.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	10 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

7.1.2. Software Implementation (SI) process

Purpose

The purpose of the Software Implementation process is the systematic performance of the analysis, design, construction, integration and tests activities for new or modified software products according to the specified requirements.

Objectives

 SI.O1. Tasks of the activities are performed through the accomplishment of the current Project Plan.

SI.O1. Tasks in this project:

- 1. Develop software comply with the current Project Plan.
- SI.O2. Software requirements are defined, analysed for correctness and testability, approved by the Customer, base lined and communicated.

SI.O2. Tasks in this project:

- 1. Analyse the requirements.
- 2. Accomplish the Software Requirements Specification.
- SI.O3. Software architectural and detailed design is developed and base lined. It
 describes the software items and internal and external interfaces of them.
 Consistency and traceability to software requirements are established.

SI.O3. Tasks in this project:

- 1. Create Software Design Document that covers all of Software Requirements.
- 2. Create Traceability Record to trace the items in Software Design Document with the software requirements.
- S1.04. Software components defined by the design are produced. Unit test are
 defined and performed to verify the consistency with requirements and the
 design. Traceability to the requirements and design are established.

SI.O4. Tasks in this project:

- 1. Create Unit test that is comply with requirements and design after software components are produced.
- 2. Perform the unit test.
- 3. Traceability record is created for tracing Unit test with the requirements and design.
- SI.O5. Software is produced performing integration of software components and verified using Test Cases and Test Procedures. Results are recorded at the Test Report. Defects are corrected and consistency and traceability to Software Design are established.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	11 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

SI.O5. Tasks in this project:

- 1. Design Test Cases from Software Design.
- 2. Test the software components.
- 3. Record the Test Cases results at the Test Report.
- 4. Create traceability record.
- SI.O6. A Software Configuration, that meets the Requirements Specification as agreed to with the Customer, which includes user, operation and maintenance documentations is integrated, base lined and stored at the Project Repository.
 Needs for changes to the Software Configuration are detected and related Change Requests are initiated.

SI.O6. Tasks in this project:

- 1. Analyze the change.
- 2. Create the change request form.
- 3. Approve the change request by project advisor and upload in our repository that is Dropbox.com.
- 4. Change the project complies with approved change request.
- S1.07. Verification and Validation tasks of all required work products are
 performed using the defined criteria to achieve consistency among output and
 input products in each activity. Defects are identified, and corrected; records are
 stored in the Verification/Validation Results.

SI.O7. Tasks in this project:

1. All works are traceable and have tested.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	12 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

Chapter 8 | Quality Planning

8.1. Quality Factors

8.1.1. Product operation factors

Reliability

 The software should able to handle more than 80% of traditional activity with less than 10% of software's failure.

Correctness

 The software product should able to provide more than 80% correctness of data from user traditional request.

Usability

 The people who use software product, as his first time should be able to estimate complacency of the product more than 70%

Efficiency

 The software product should able to provide more than 80% of efficiency data from user traditional request.

Integrity

o The software should able to limit a group of person who can modify the data.

8.1.2. Product revision factors

Testability

 The software should able to be tested 100% of it defined routine and functionality.

8.1.3. Product transition factors

Flexibility

• The software product should able to be flexibility more than 60%.

Reusability

 More than 20% part of finished software product should able to be reused in future development.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	13 / 28
Document Type Project Plan		Release Date	October 21, 2014	Print Date	October 21, 2014

8.2. Reviews/Responsibility

	Stage Exit Review								
No.	Stage	Review Item	Responsibility						
1	Project Planning	Project Plan	Panupak and Narongrit						
2	Requirement Specification	Software Requirement Specification	Panupak and Narongrit						
3	Architecture and Detailed Design	Software Design Document	Panupak and Narongrit						
4	Software Testing	Software Testing Documents	Panupak and Narongrit						
5	Project Monitoring and Control	Traceability Record	Panupak and Narongrit						

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	14 / 28
Document Type Project Plan		Release Date	October 21, 2014	Print Date	October 21, 2014

Chapter 9 | Schedule & Milestones

The schedule and milestones of OEGP. During period of time, there are work terminologies. And the description is shown below that:

9.1. Schedule Plan

Task	Feature	Sub-feature	URS	Date
			URS-09: The user adds a new substance into	21 st April 2014 –
			the system.	29 th April 2014
			URS-10: The user updates an existing	30 th April 2014 –
			substance into the system.	2 nd May 2014
		Manage the drug	URS-11: The user deletes an existing	3 rd May 2014 –
		substance	substance from the system.	7 th May 2014
			URS-12: The user views the substance in the	13 th May 2014 –
			system.	20 th May 2014
			URS-13: The user adds a new excipient to the	21 st May 2014 –
			system.	23 rd May 2014
			URS-14: The user updates an existing drug	24 th May 2014 –
			excipient in the system.	28 th May 2014
		Manage the drug	URS-15: The user delete an existing drug	29 th May 2014 –
0	Feature 5:	excipient	excipient in the system.	2 nd June 2014
Report I	PDPO System		URS-16: The user views all the drug excipient	3 rd June 2014 –
			in the system.	7 th June 2014
			URS-17: The user adds a new drug	8 th June 2014 –
			formulation case into the system.	12 th June 2014
			URS-18: The user updates an existing drug	13 th June 2014 –
		Manage the drug	formulation case in the system.	18 th April 2014
		formulation	URS-19: The user deletes an existing drug	19 th June 2014 –
		Torritalation	formulation case in the system.	25 th June 2014
			URS-20: The user views all of the formulation	25 th June 2014 –
			in the system.	30 th June 2014
Progress	Feature 2:	Calculate the drug		22 th July 2014 –
Report II	Rule Base	reformulation by	URS-06: The user calculates a drug	20 th August
	System,	using the inference	reformulation by using an inference engine.	2014
	Feature 3	engine.		
	:case base	View the drug	URS-07: The user views their drug	21 th August
	reasoning	reformulation history	reformulation history.	2014 -19
	system			September
				2014

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	15 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

Task	Feature	Sub-feature	URS	Date
	Feature 2: Rule Base System, Feature 3: case base reasoning system	Make the drug reformulation evaluation	URS-08: The user makes the drug reformulation evaluation.	22 th October 2014 – 29 th October 2014
			URS-01: The user registers as a member.	30 th October 2014 – 6 th November 2014
			URS-02: The user updates their information.	6 th November 2014 – 12 th November 2014
Progress		Manage the user account	URS-03: The Administrator deletes the member account.	12 th November 2014 – 18 th November 2014
Repost	Feature 1 : User Management	eature 1 : User nagement	URS-04: The Administrator approves a general pharmacist registration.	19 th November 2014 – 22 th November 2014
	system		URS-05: The Administrator changes an authorized person status.	22 nd November 2014 – 28 th November 2014
	Login to the system	Login to the system	URS-24: The user logins to the system.	28 th November 2014 – 30 th November 2014
		Logout from the system	URS-25: The user logouts from the system.	1 st December 2014 – 5 th December 2014
	Feature 4: Hybrid reasoning system	Hybrid reasoning system	URS-06: The user calculates a drug reformulation by using an inference engine.	5 th December 2014 – 10 th December 2014

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	16 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

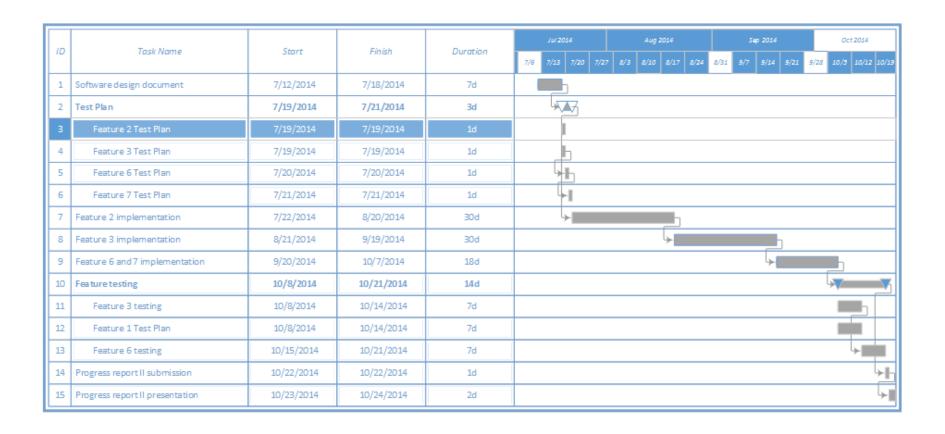
9.2. Milestones

ID	Task Name	Start	Finish	Duration	3/23 3/30 4/6 4/13 4/20 4/27 5/4 5/11 5/18 5/25 6/1 6/8 6/15 6/22 6/29 7/6
1	Software requirement specification	4/1/2014	4/15/2014	11d	
2	Software design document	4/16/2014	5/1/2014	12d	<u> </u>
3	Test Plan	5/6/2014	5/20/2014	11d	₩
4	Feature 5 Test Plan	5/6/2014	5/20/2014	11d	
5	Feature 5 implementation	5/23/2014	6/13/2014	16d	\
6	Feature testing	6/16/2014	6/30/2014	11d	- T
7	Feature 5 testing	6/16/2014	6/30/2014	11d	
8	Progress report I submission	7/7/2014	7/7/2014	1d	├ -
9	Progress report I presentaion	7/10/2014	7/11/2014	2d	→Ⅲ

Progress Report I Milestone

Figure 4 : Progress Report I Milestone.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	17 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014



Progress Report II Milestone

Figure 5: Progress Report II Milestone.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	18 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

ID	Task Name	Start	Finish	Duration	Sep 2014 9/7 9/14 9/21 9/2	Oct 2014	Nov 2014 5 11/2 11/9 11/16
1	Progress Report III	10/22/2014	12/11/2014	51d			
2	Software design document	10/22/2014	10/25/2014	4d			
3	Test Plan	10/26/2014	10/27/2014	2d		₩.	
4	Feature 1 Test Plan	10/26/2014	10/27/2014	2d			
5	Feature 4 Test Plan	10/26/2014	10/27/2014	2d			
6	Feature 4 and Feature 1 implementation	10/28/2014	11/13/2014	17d		+	
7	Feature testing	11/14/2014	11/26/2014	13d			7
8	Feature 1 testing	11/14/2014	11/16/2014	3d			
9	Feature 4 testing	11/14/2014	11/16/2014	3d			
10	System testing	11/17/2014	11/26/2014	10d			-
11	Review Document	11/27/2014	12/9/2014	13d			→ II
12	Progress report II submission	12/10/2014	12/10/2014	1d			
13	Progress report II presentation	12/11/2014	12/11/2014	1d			

Progress Report III Milestone

Figure 6 : Progress Report III Milestone.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	19 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

Chapter 10 | Version Control Strategy

10.1. Naming Conversion

For naming conversion OEGP, the name of document and software will be named as following format:

"[Project Name]-[Document Name] _ [Version]. [File Type]"

• Project Name

This part will be the name of this project that is "OEGP"

Document Name

This part will depend on substance of that file. In each file will has its certain name as following:

- Proposal
- Project Plan
- Software Requirement Specification (SRS)
- Software Design Document (SDD)
- Test Plan
- Test Record
- Traceability Record(TR)
- Software Source Code
- Show pro video
- Poster

Version

This part is the version of document. Version number will be in the following format:

"V.[Main version].[Sub version]"

- Main version is the main of version software and document. For example
 V.1.0, the number 1 is the main version. It might refer to feature of software.
- Sub version is a part of main for developing. Subversion will has update more than the main version.

• File Type

This part is the type of file or the file extension. For example, .docx, .pdf.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	20 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

10.2. Project Repository

• GitHub

GitHub is a tool that can help to manage the version of document and software. Developers can share file or update version of file anytime that they want. Developers have to have their own account of GitHub. Then the developers can create project file and can share it with anyone they want.

For OEGP, we will create folders to be the project repository as following:

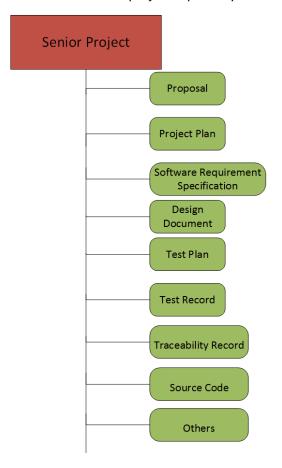


Figure 7: Repository of OEGP

List of related document and description

- Proposal: contain involving proposal files.
- Project plan: contain project plan document files.
- Software Requirement Specification : contain a software requirement specification document file
- Design Document: contain design and diagram document files.
- Test Plan: contain test plan document files.
- Test Record: contain test record document files.
- Traceability record: contain traceability record document
- Source code: contain source code of project.
- Others: contain kind of picture, server information, interesting web site and etc.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	21 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

10.3. Configuration Item Table

No.	Item	File Name	File Type	Owner	Path	Baseline
1	Project Proposal	OEGP –ProjectProposal_V.2.0	.docx	Panupak, Narongrit	Proposal	2.0
2	Development and Quality Plan	OEGP -Project Plan_V.2.0	.docx	Panupak, Narongrit	Project Plan	2.0
3	Software Requirement Specification	OEGP –Software requirement specification _V.2.0	.docx	Panupak, Narongrit	Software Requirement Specification	2.0
4	Software Design Document	OEGP –Software design document-V.2.0	.docx	Panupak, Narongrit	Design	2.0
5	Test Plan	OEGP -Test Plan_V.2.0	.docx	Panupak, Narongrit	Testing	2.0
6	Test Record	OEGP -Test Record_V.2.0	.docx	Panupak, Narongrit	Test Record	2.0
7	Traceability Record	OEGP -Traceability Record_V.2.0	.docx	Panupak, Narongrit	Traceability Record	2.0
8.	Software Source Code	OEGP-Software source code _V.2.0	.zip	Panupak, Narongrit	Source code	2.0
9.	30 seconds video	OEGP- Show pro Video_V.1.0	.avi	Panupak, Narongrit	Others/Showpro video	1.0
10.	Poster size A1	LTAS-Poster_V.1.0	.png	Panupak, Narongrit	Others/Poster	2.0

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	22 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

Chapter 11 | Risk Management

Risk management is concerned with identifying risks and drawing up plans to minimize their effect on the project.

A risk is probability that some adverse circumstance will occur.

- Project risks affect schedule or resources.
- Product risks affect the quality or performance of the software being developed.
- Business risks affect the project team during developing or procuring the software.

Identified risks at the start of project and at the start of development phase. All identified risks are documented and assessed in the Risk Management Process by the Project Team. In the Risk Management Process defines the possible risks and solution of them, and who is responsible for.

11.1. Risk Management Process

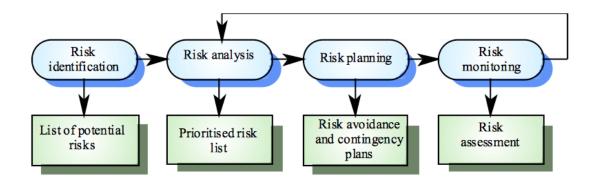


Figure 8: Risk Management Process Model

- 1. Risk identification: identify project, product and business risks.
- 2. Risk analysis: Assess the likelihood and consequences of the risks.
- 3. Risk planning: Draw up plans to avoid or minimize the effects of the risks.
- 4. Risk monitoring: Monitor the risks throughout the project.

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	23 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014

11.2. Risk Identification and Solutions

No.	Risk statement	Risk Solution		
1.	The requirements are change.	 Meeting and discuss and do a priority of changed requirements. Design system with flexible requirements and related with the other requirements. 		
2.	The deliverables are delay.	 Try to study more hard than previous work. Ask a professional to make faster understand. 		
3.	Budget of developing are not enough.	Ask for more budgets from project advisor.		
4.	Work products are not submitted on time.	Establish the project plan.Develop project follow the project plan.		

Document Name	OEGP-Project Plan _ 1.2.docx	Owner	NS,PW	Page	24 / 28
Document Type	Project Plan	Release Date	October 21, 2014	Print Date	October 21, 2014