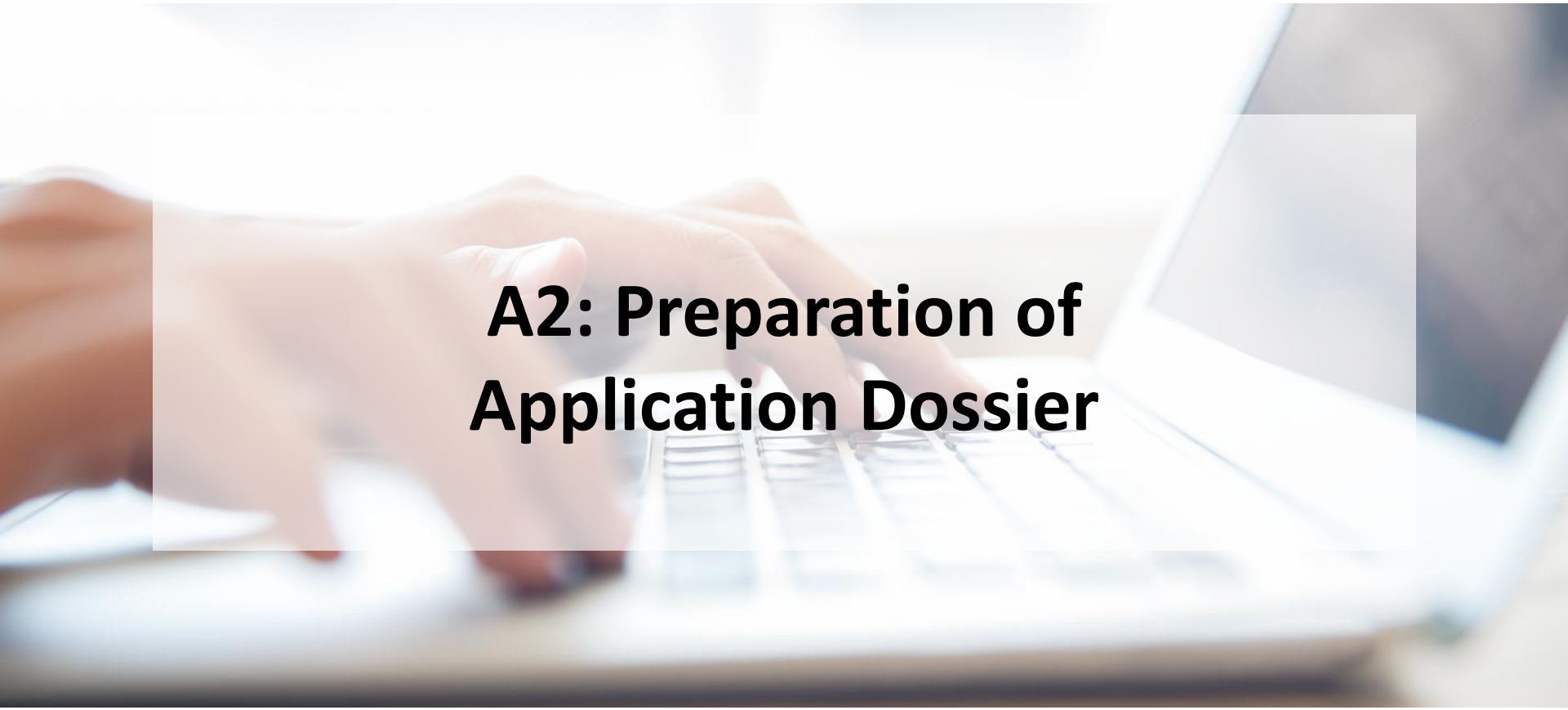


A2: Preparation of Application Dossier

Session Leader and Speaker

Speaker 1: Usanee Harnpramukkul, PReMA

Speaker 2: Wipada Rodtanaporn, PReMA

AGENDA

Time	Item
5 min	1. Introduction ・ Learning Objectives
10 min	2. Ice Breaker ・ Country specific requirements
60 min	3. Dossier Preparation 3-1. Lecture ・ Standard process of application dossier preparation 3-2. Lecture ・ Support tools (Template, Glossary, Checklist & Timeline table)
	Break
120 min	3. Dossier Preparation 3-3. Practice ・ Orientation (10 min) ・ Practice-1 (30 min) ・ Practice-2 (30 min) ・ Group discussion for presentation (10 min) ・ Group presentation (6 Gr x 3 - 5 min)

Day 2 Sessions A2

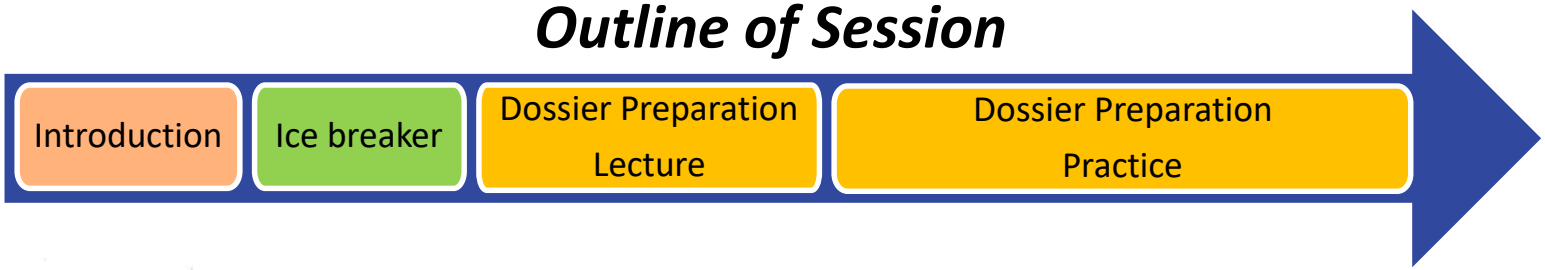
Preparation of Application Dossier

1. INTRODUCTION

LEARNING OBJECTIVES

1. To understand the standard processes for a **high-quality submission preparation**
2. To improve management of the **preparation process for application dossier**
3. **To improve the QC** processes/procedures for future application
4. To understand **importance of SOP**

Outline of Session



Day 2 Sessions A2

Preparation of Application Dossier

2. ICE BREAKER

"COUNTRY SPECIFIC REQUIREMENTS"

How to flight airplane safely

Please chat about key process/personnel/system/etc. in your group.

- Airport
  -
  -
  -
  - etc.
- Airplane
  -
  -
  -
  -
  - etc.

How to flight airplane safely

Please chat about key process/personnel/system/etc. in your group

- Airport
  - Security check
  - Custom clearance
  - Immigration
  - etc.
- Airplane
  - Competency
    - Mechanic
    - Captain
    - Flight attendant
  - Control Tower
  - etc.

We can take similar photo around the world

Country A

Country B

The International Civil Aviation Organization (ICAO)

- ICAO works with the Convention's **191 Member States and industry groups**
  - To reach consensus on international civil aviation Standards and Recommended Practices (SARPs) and policies in support of a safe, efficient, secure, economically sustainable and environmentally responsible civil aviation sector.
- These SARPs and policies are used by ICAO Member States
  - To ensure that their local civil aviation operations and regulations conform to global norms, which in turn permits more than 100,000 daily flights in aviation's global network to operate safely and reliably in every region of the world.

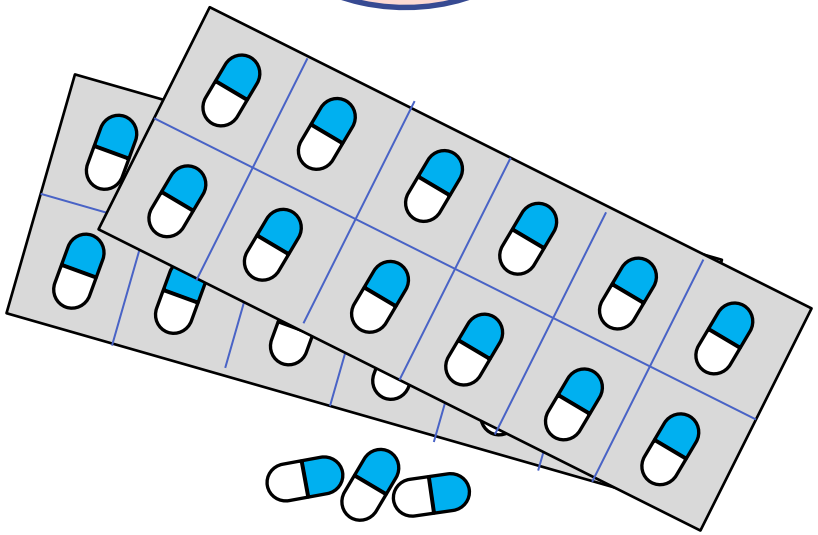
https://www.icao.int/Pages/default.aspx

How to prepare NDA dossier?

Requirements for NDA

- Documents template
  - ICH CTD/ACTD/Country specific CTD
- Quality information
  - Zone 2/Zone 4/Site specific stability data/etc.
- GMP
  - Site registration/GMP accreditation/etc.
- Clinical data
  - Local population data/Bridging evaluation/etc.

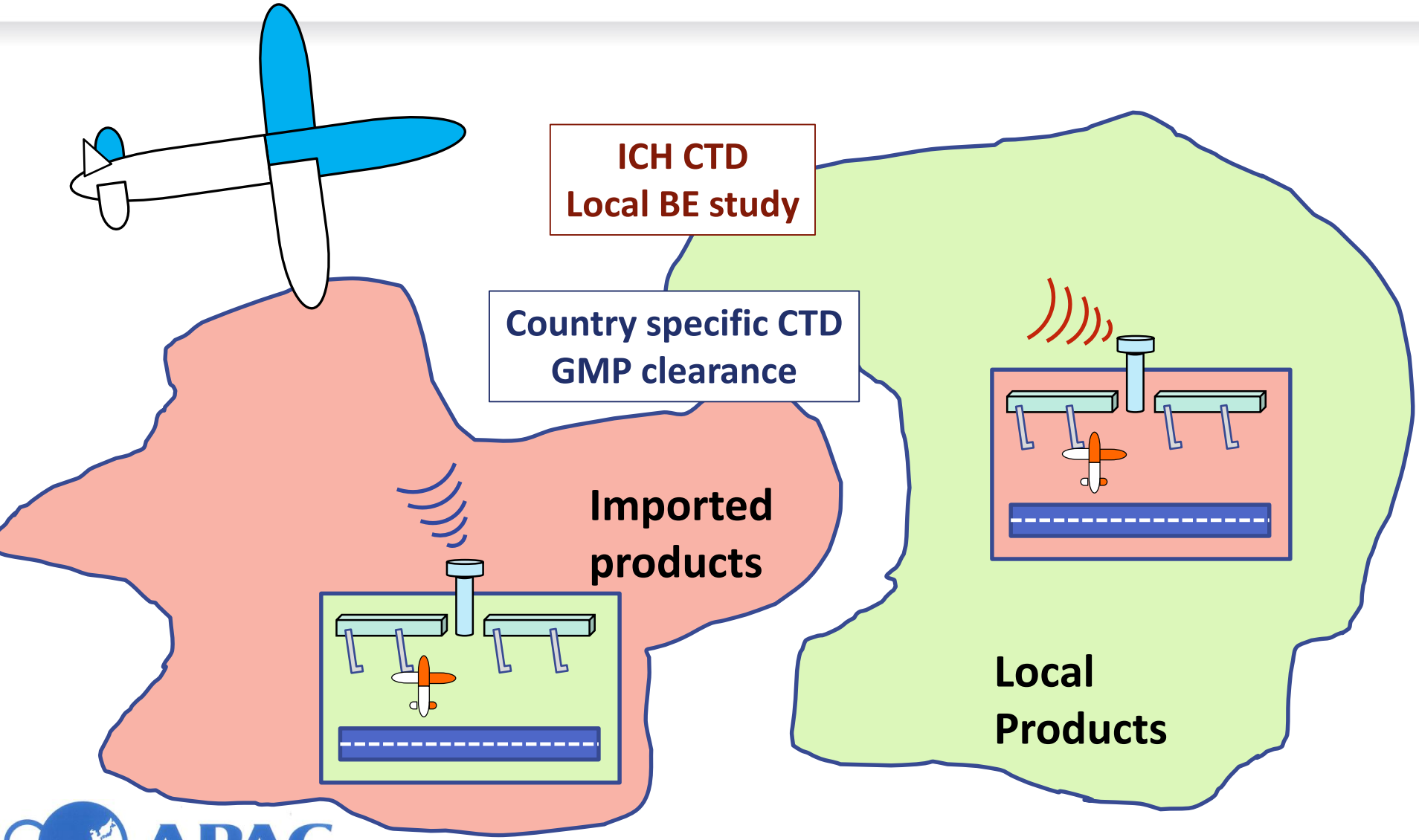
There are differences for evaluating one medicine depend on regulations



Group Chat

How to land your medicine in Thailand?

Plan Prepare SUBMIT Communi cate



Our expectation

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Preparation of Application Dossier

Today…

- Lectures
  - To learn fundamental dossier preparation
- Practices
  - To experience process of fundamental dossier preparation under virtual regulation

We believe we can run our training under harmonized regulation in near future…

Day 2 Sessions A2

Preparation of Application Dossier

3. DOSSIER PREPARATION

Day 2 Sessions A2

Preparation of Application Dossier

3-1. LECTURE

STANDARD PROCESS OF APPLICATION DOSSIER PREPARATION

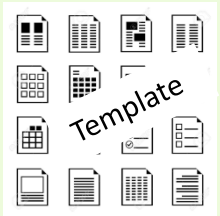
Preparation of Submission Dossier

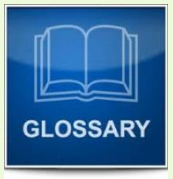
Plan

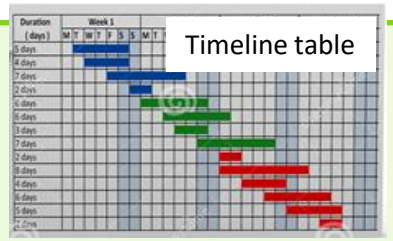
Preparation of each component

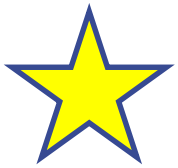
Compilation and assembling of submission dossier

Tools









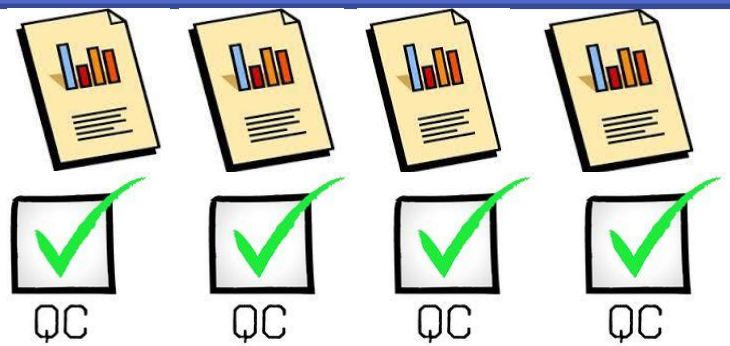
Authors

Experts in each scientific field or medical writers

Regulatory function

Standard Operating Procedures

Standard Operating Procedures



Submission dossier

Standard Operating Procedures

Submission

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Two main steps in preparation of application dossier

① Preparation of each component

– i.e. writing study reports and summaries, and preparing other required documents

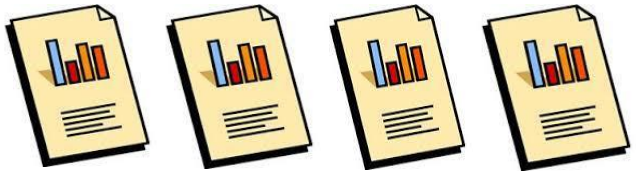
② Compilation and assembling of submission dossier

Two main steps in preparation of application dossier (cont'd)

① Preparation of each component

– Study Reports

- Strong rationale and robust data with scientific evidence
- Ensure reliability, integrity and traceability of data in the reports
- Refer to the relevant guidelines on the format and contents of study reports which can be accepted by the review authorities,
  - e.g. ICH M4 and E3



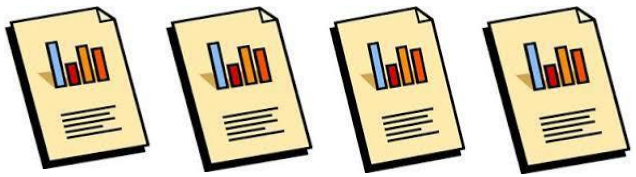
– Summary documents

- Clear rationale with justification based on study reports

Two main steps in preparation of application dossier (cont'd)

① Preparation of each component (cont'd)

- Fundamental of each component
  - Concise
  - Easy to read
  - Validity of scientific contents
  - Accuracy and validity of translation if needed



Two main steps in preparation of application dossier (cont'd)

② Compilation and assembling of submission dossier

- Follow the structure and format of dossier accepted by the authorities
  - e.g. ICH-CTD
- Collect and review of each component document
- Place each component document in the correct location of the format

Submission dossier

Submission of application

- Acceptable format, process and route of application submission
  - All the required information and materials using appropriate format
  - Proper category
  - Electronic dossier or hard copy
  - On-line, mailing or on-site submission

- Sometimes, pre-submission consultation with the review authorities is required to fix the date of submission.

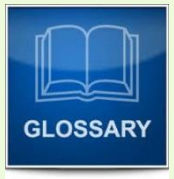
Preparation of Submission Dossier

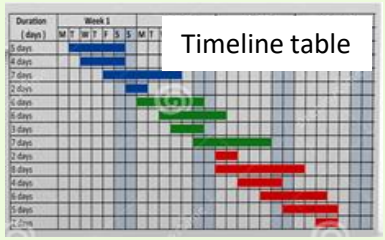
Plan

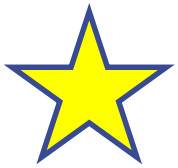
Preparation of each component

Compilation and assembling of submission dossier

Tools







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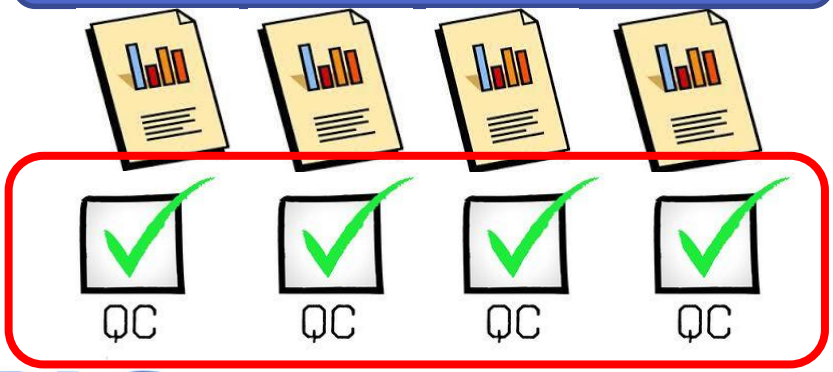

Regulatory function

Submission dossier

Submission

Standard Operating Procedures

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Quality Check (QC)

Purpose of QC

- To ensure information and data in submission dossier have sufficient quality
  - Accuracy, integrity and traceability of scientific data/information
- To check compliance to pre-defined format, template and structure

Types of QC

- QC of study reports and summary documents
- QC of submission dossier including electronic dossier

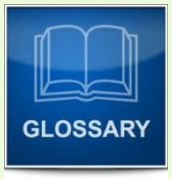
Preparation of Submission Dossier

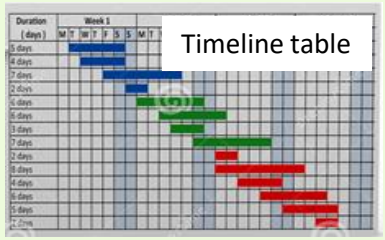
Plan

Preparation of each component

Compilation and assembling of submission dossier

Tools





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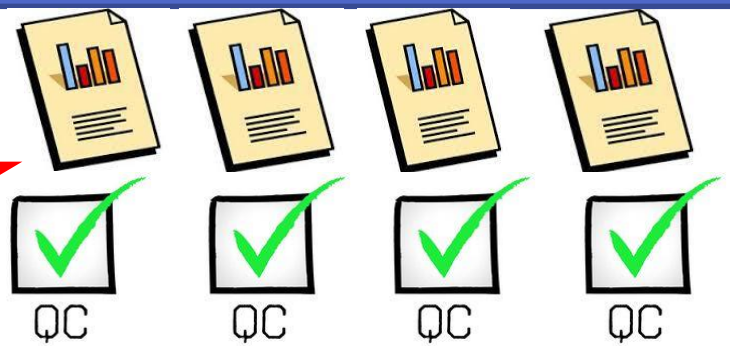

Submission dossier

Submission

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SOPs for submission preparation & management

Application submission is

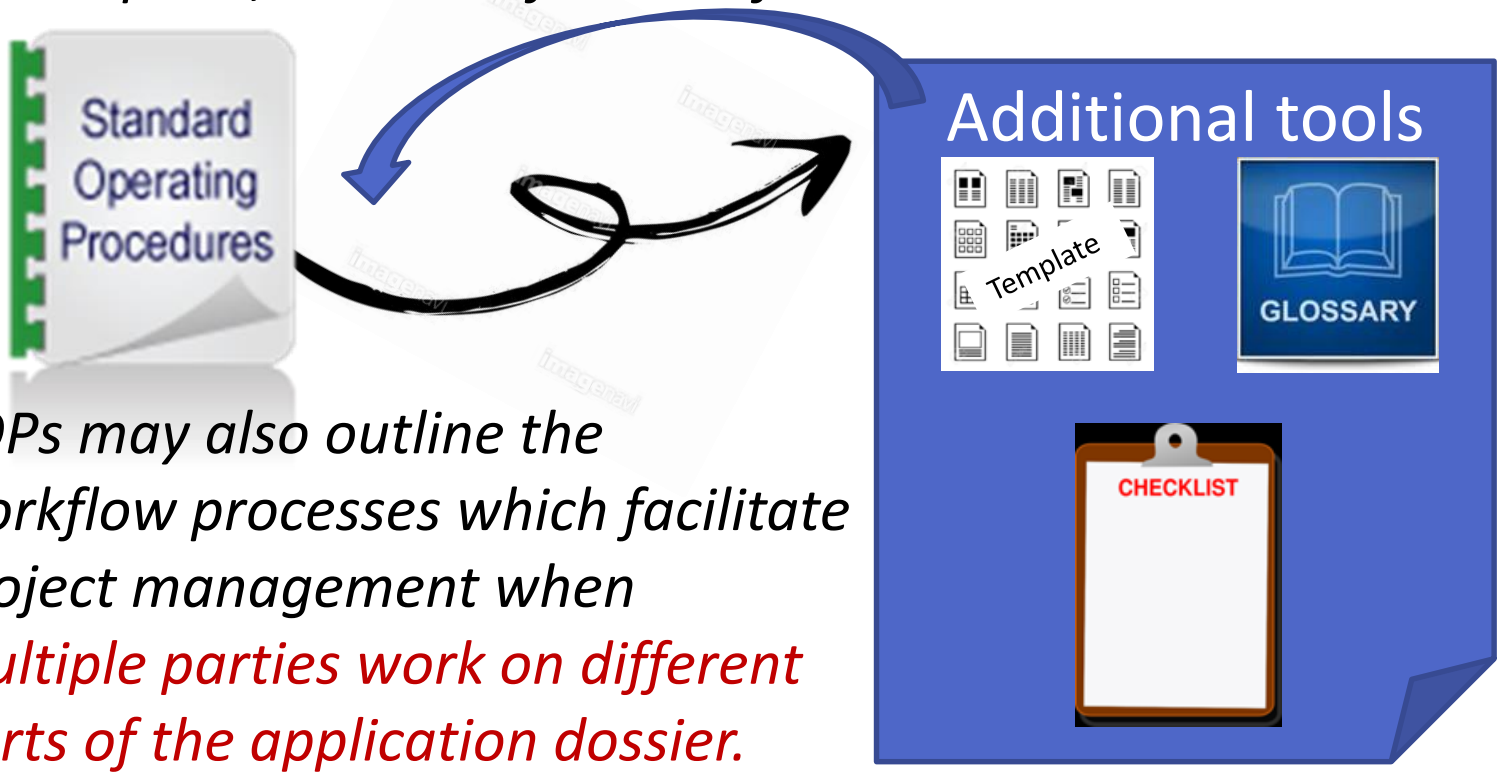
- Complicated and time-consuming process
- Often requires collaborations among applicants' parties or group of organizations locally and globally

..... It is therefore beneficial for applicants to generate SOPs and share them within the parties or organizations ***for proper management of the whole process of submission preparation.***

- SOP is not a regulatory requirement
- SOP in GSubP Guideline means procedure/operation manual for submission and not subject of strict compliance like SOPs in GCP, GMP

How to write SOP for submission preparation

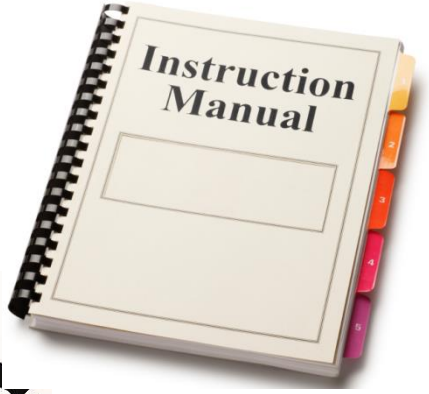
- *SOPs may be structured to contain or refer to additional tools that could assist in performing the procedure for submission, e.g. template, standard format of checklist.*



- *SOPs may also outline the workflow processes which facilitate project management when multiple parties work on different parts of the application dossier.*

Other procedure documents

Additional working procedure documents may also be created to give more detailed instruction and structure in support of SOPs. These documents can describe in detail how a particular process is performed, e.g. procedure for drafting, reviewing and finalization of each study report and summary.



Update for SOP

These SOPs need to be updated depending on the change in applicant's working environment, e.g. change in organization, scheme of work-sharing etc.

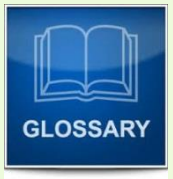
Preparation of Submission Dossier

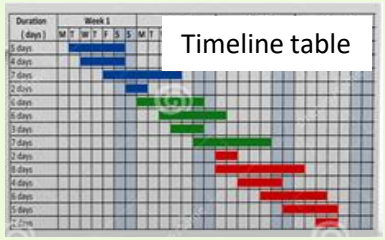
Plan

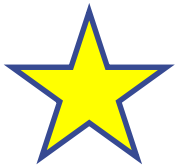
Preparation of each component

Compilation and assembling of submission dossier

Tools







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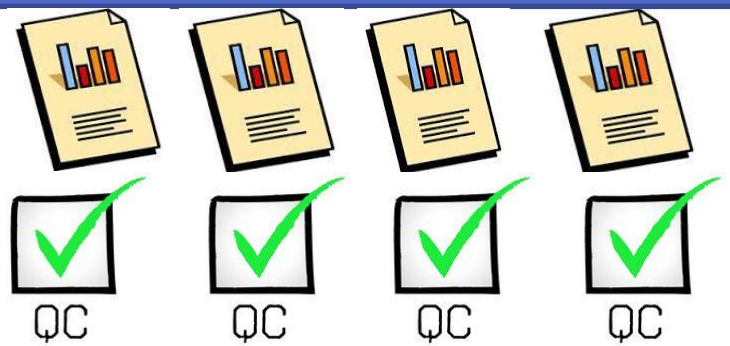

Submission dossier

Standard Operating Procedures

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Day 2 Sessions A2

Preparation of Application Dossier

3-2. LECTURE

SUPPORT TOOLS (TEMPLATE, GLOSSARY, CHECKLIST & TIMELINE TABLE)

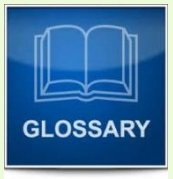
Preparation of Submission Dossier

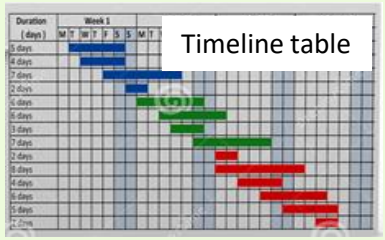
Plan

Preparation of each component

Compilation and assembling of submission dossier

Tools





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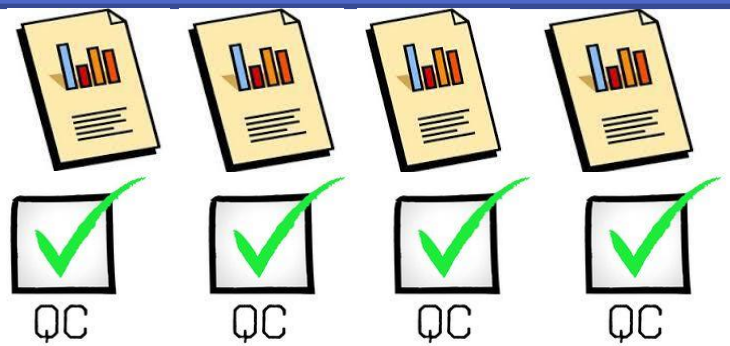

Submission dossier

Standard Operating Procedures

Submission

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Introduction

2. PRINCIPLES OF GOOD SUBMISSION

1. *Strong Scientific Rationale and Robust Data with Clarification of Benefit-Risk Profile*
2. *Compliance to Up-to-date Regulatory Requirements*
3. *Well-Structured Submission Dossier with Appropriate Cross-references*
4. *Reliability, Quality, Integrity and Traceability of Submission Documents and Source Data*
5. *Effective and Efficient Communications*

Introduction

2. PRINCIPLES OF GOOD SUBMISSION

How do you prepare Well-structured **Submission Dossier** and **Submission Documents** with Good Quality?

3. *Well-Structured Submission Dossier with Appropriate Cross-references*
4. *Reliability, Quality, Integrity and Traceability of Submission Documents and Source Data*

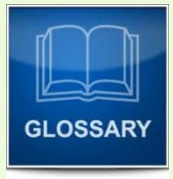
You should use **Support tools** effectively.

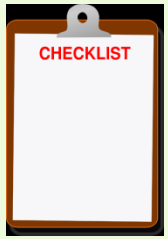
Objective

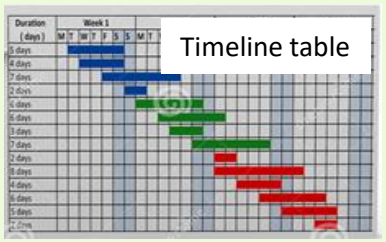
To learn how to use the following support tools effectively to prepare good quality Submission Dossier and Submission Documents.

- Template
- Glossary
- Checklist
- Timeline table

Tools



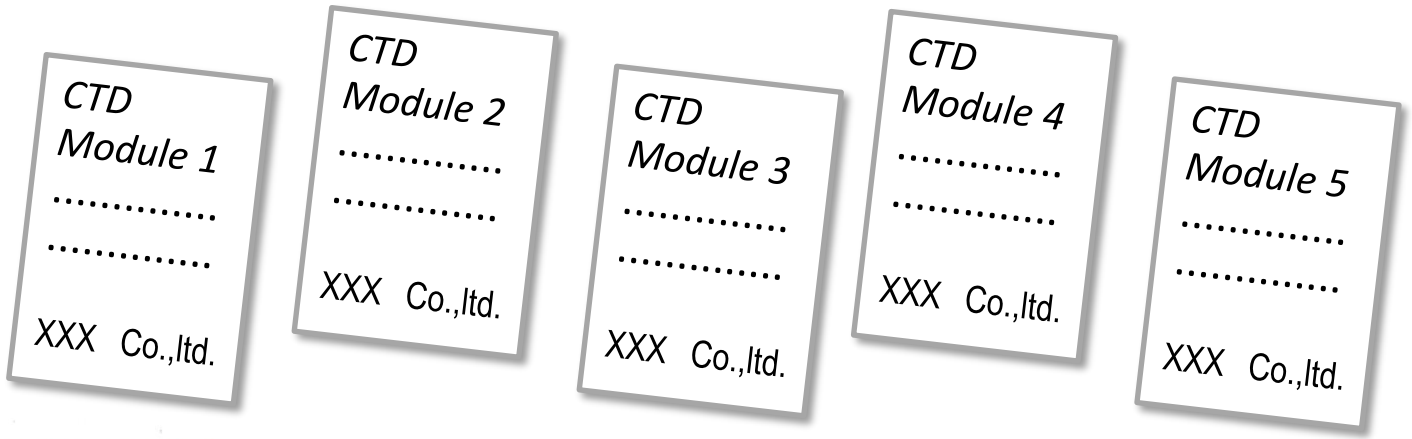




What's tool

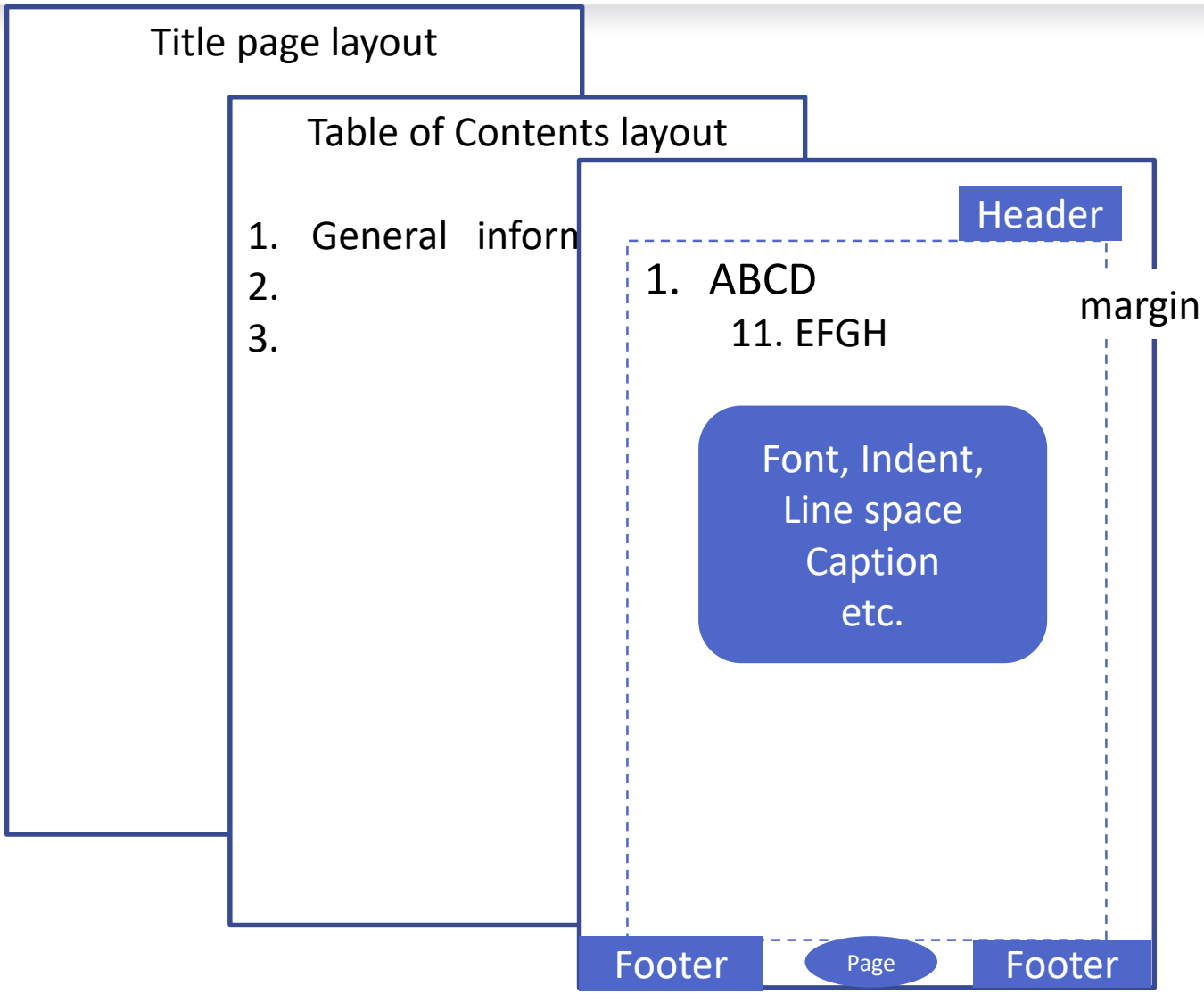
Template:

..... help authors to prepare each component document in structured and consistent manner complying with the required format and contents.... It will also enhance efficiency of preparation. Submission with a unified format of study reports and summaries also enables reviewers to perform review smoothly.



Examples of Template (1)

Software Version
Paper size
File naming rules
etc.



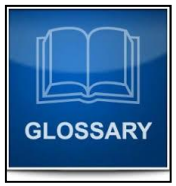
Examples of Template (2)

- Meet the regulatory requirement
  - Items, details and any contents defined by regulation
  - Numbering, font, page's font
  - Adjust e-CTD requirement if have
- Numbering, font, page's font even if no above requirement
- Integration of session title, caption, index, etc.
- File name and draft version rule
- Distribute them to all authors related dossier preparation in the project in advance

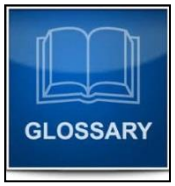
What's tool

Glossary:

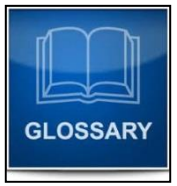
It is important to keep consistency of terminology used throughout a submission dossier. .... recommended to create a list of general glossary before initiating preparation of study reports and summaries.



For abbreviations



For project specific terminology



For translation

Examples of Glossary (1)

Project-specific terminology

		Note	Inappropriate
Product Name	ABCDE™	All capital letters	Abcd
Generic Name	wxyz	All lower case	Vwxyz
Deveropment No.	AB-1234	Hyphen	AB1234

Item	Unified format
Manufacture Site Name	Flour Phrm Co., Forest Plant
Manufacture Site Address	123-4, Woods Str. Hill Prrf. Green Country

Examples of Glossary (2)

Abbreviations

Abbreviation	Formal name
GSubP	Good Submission Practice

Abbreviation	Formal name	Note	Inappropriate
HER2	human EGFR-related 2	All capital letters	Her2
cDNA	chromosomal DNA	"c" lower case	CDNA,cdna

Examples of Glossary (3)

For Translation

English	Chinese	Inappropriate
ethyl acetate	醋酸乙酯	乙酸乙酯、醋酸乙基
rat	大鼠	鼠、白鼠

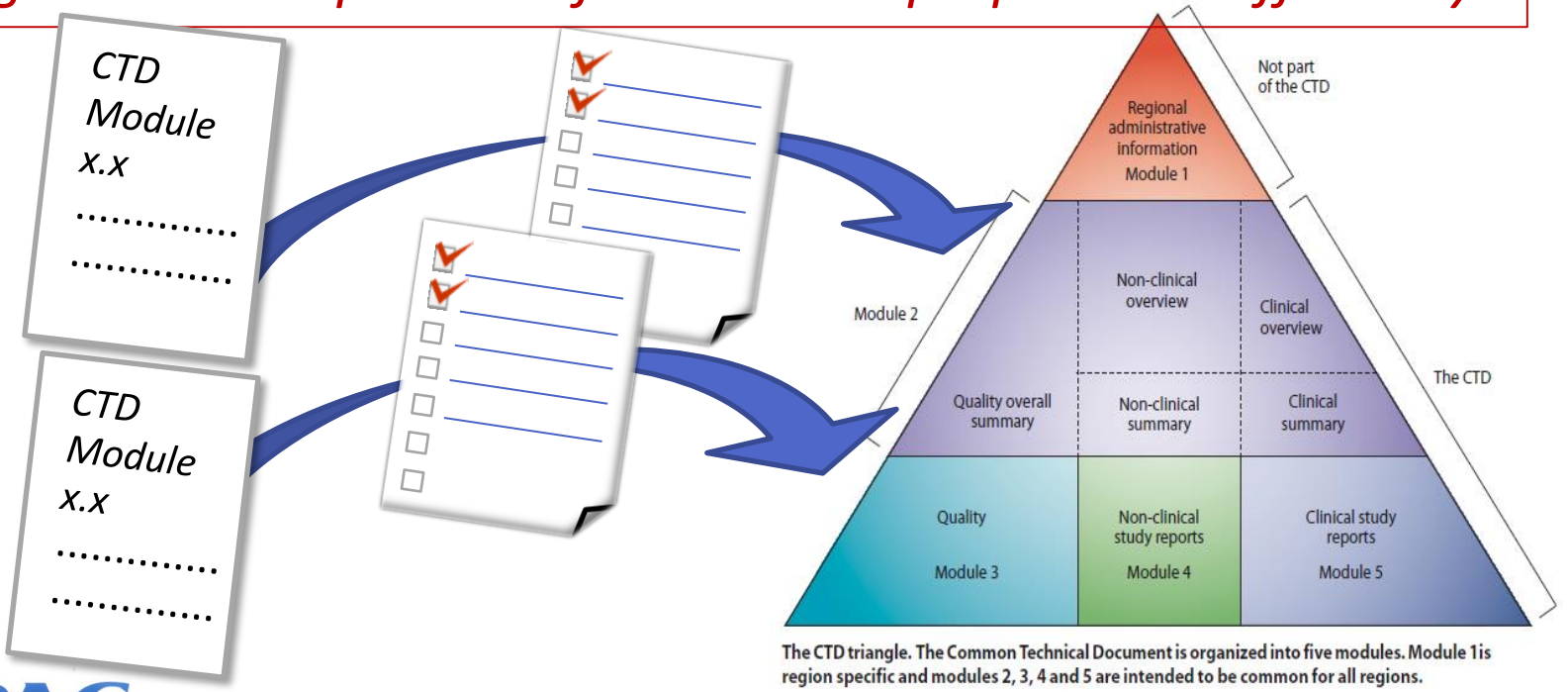
Examples of Glossary (4)

- It is important to decide the word role to prepare submission dossier from initial step.
- Update is acceptable. Inform it to all members.
  - proper name: how to describe
    - Companies' English name and address
  - uppercase letter and lower case letters
    - Ex. Product name: how to using uppercase letter
  - word list for translation (English vs. local word)
    - In particular, pay attention to use translation agency

What's tool

Check-list:

……. may include name of each document with information such as responsible person/party, target date and status. Such list will be useful not only to check if there is any missing component but also to manage the whole process of submission preparation efficiently



The CTD triangle. The Common Technical Document is organized into five modules. Module 1is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

Examples of Checklist (1)

Checklist: Module 1 2016/11/17

No.	Items	#	Responsible	Deadline	Meet requirement	Status
1	Original and Copy of Registration Application of Drug Inspection	1	HQ RA	2016/9/30	OK	closed
2	Patent Statement	1	HQ RA	2016/9/30	OK	closed
3	Worldwide status	1	HQ RA	2016/9/30	OK	closed
4	Proposed design of vial label and outer box	2	Local RA	2016/10/30	OK	closed
5	Proposed Package Insert (6 pages) in local language based on translation of EU SmPC	2	Local RA	2016/11/30	OK	QC
6	CPP with notarization, legalization (original)	1	HQ RA	2016/12/30		Request to HA
7	Site Master File	1	HQ RA	2016/9/30	OK	closed
8	Risk Management Plan (original country)	1	HQ RA	2016/10/30	OK	closed
9	Risk Management Plan for local	1	Local RA	2016/12/15		Under preparation

Examples of Checklist (2)

- All items to be submitted are listed based on the latest Regulatory requirement from your authorities
- Submission team members and all related persons including agencies are shared the latest Check list until finalization of dossier
- Check list can also use the quality check

What's tool

Timeline table:

……. is one of the most important tasks in submission planning phase especially when the submission is performed by collaborations among multiple parties of applicants. It is recommended that applicants generate and keep updating a timeline table or a Gantt chart including the role and responsibility of each person/party to manage the whole process of submission preparation efficiently

Timeline table for Project F

Timeline				2015/2Q	2015/3Q	2015/4Q	2016/1Q	2016/2Q	2016/3Q	2016/4Q
Preparation of Documents		Responsibility	Done by							
Module 1	Module 1 Table of Contents									NDA Submission
	Application form									
	Letter of Authorization by HQ office									
	Patent Statement									
	Worldwide status									
	CPP with notarization, legalization (original)									
	CPP with notarization, legalization, translation									
	GMP certificate with notarization, legalization (original)									
	GMP certificate with notarization, translation									
	Plant Master File									
	Proposed Package Insert & Patient Information Leaflet									
	Proposed artwork for PTP/aluminium pillow, outer box									
	Risk Management Plan									
	Assesment report									
	Report for HA consultsion									

Examples of Timeline table (1)

Timeline table for Project F

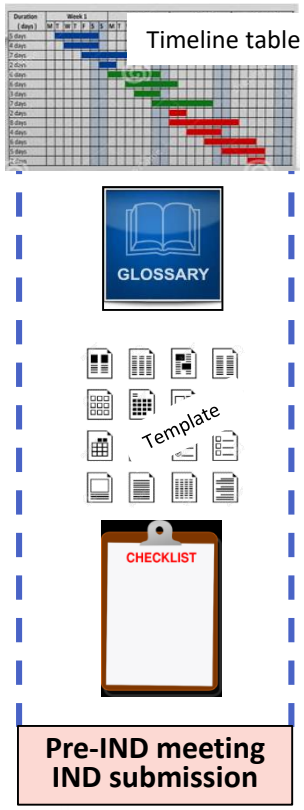
Timeline				2016/2Q			2016/3Q			2016/4Q			2017/1Q		
Preparation of Documents		Responsibility	Done by		KoM		Approval in orinal country								
Module 1	Module 1 Table of Contents	Local RA	30/11/2016												
	Application form	Local RA	31/10/2016												
	Application form, review & QC	Tram leader	15/11/2016												
	Letter of Authorization by HQ office	Head office RA	30/09/2016												
	Patent Statement	Head office RA	30/09/2016												
	Worldwide status	Head office RA	30/09/2016												
	CPP with notarization, legalization (original)	Head office RA	30/09/2016												
	CPP with notarization, legalization, translation	Local RA, CRO	31/10/2016												
	GMP certificate with notarization, legalization (original)	Head office RA	30/09/2016												
	GMP certificate with notarization, translation	Local RA, CRO	31/10/2016												
	Plant Master File	Head office RA	31/07/2016												
	Package Insert & Patient Information Leaflet, (original country)	Head office RA	15/08/2016												
	Proposed Package Insert & Patient Information Leaflet for local, prepration	Local RA	15/09/2016												
	Proposed artwork for PTP/aluminium pillow, outer box	Head office RA	15/08/2016												
	Risk Management Plan (original)	Head office RA	15/07/2016												
	Risk Management Plan, preparation	local team	15/09/2016												
	Risk Management Plan, preparation, Review & QC	Tram leader	30/09/2016												
Module 2	Module 2 (2.1~2.5) original	Head office RA	15/07/2016												
	2.1 Overall Common Technical Document Table of Contents, translation	CRO	31/07/2016												
	2.1 Overall Common Technical Document Table of Contents, translation, QC	Local RA	15/08/2016												
	2.2 Introduction, translation	CRO	15/08/2016												
	2.2 Introduction, translation, Review & QC	Local RA	31/08/2016												
	2.3 Quality Overall Summary, translation	CRO	31/08/2016												
	2.3 Quality Overall Summary, translation, Review & QC	Local RA	15/09/2016												
	2.4 Nonclinical Overview, translation	CRO	15/09/2016												
	2.4 Nonclinical Overview, translation, Review & QC	Local RA	30/09/2016												
	2.5 Clinical Summary, translation	CRO	30/09/2016												
	2.5 Clinical Summary, translation, Review & QC	Local RA	15/10/2016												
Module 3	Module 3 original	Head office RA	15/07/2016												
Module 4	Module 4 original	Head office RA	15/07/2016												
Module 5	Module 5 original	Head office RA	15/07/2016												
Publissing	Publissing	Local RA	30/11/2016												
	Pringing and Compiling	Local RA	15/12/2016												
	QC	Local RA	31/12/2016												
	Filing	Local RA	15/01/2017												
submission		Local RA	28/02/2017												

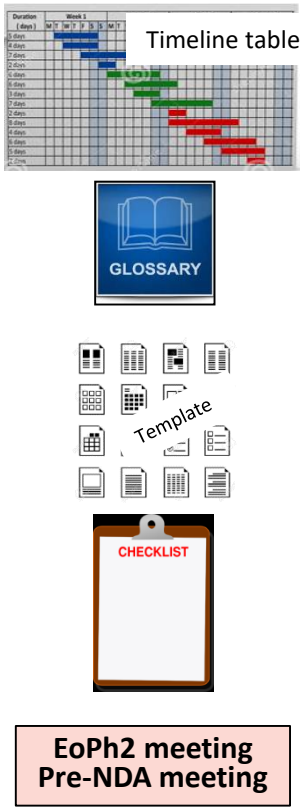
NDA Submission

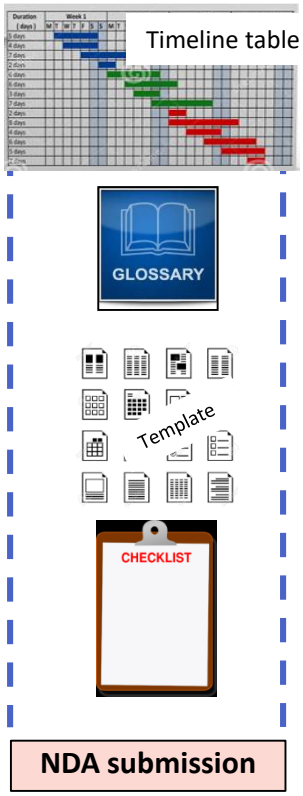
Examples of Timeline table (2)

- To create at planning session
- To keep the targeted submission date
- To put time for review and QC
- To have minimization of white space
- To share Timeline table in the submission team including multiple parties

Preparation timing of Support tools







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Day 2 Sessions A2

Preparation of Application Dossier

3-3. PRACTICE SESSION
HOW TO USE SUPPORT TOOLS

Agenda

Time	Item
120 mins	3. Dossier Preparation 3-2. Practice ・Orientation (10 min) ・Practice-1 (30 min) ・Practice-2 (30 min) ・Group discussion for presentation (10 min) ・Group presentation (5 Gr x 3 - 5 min)

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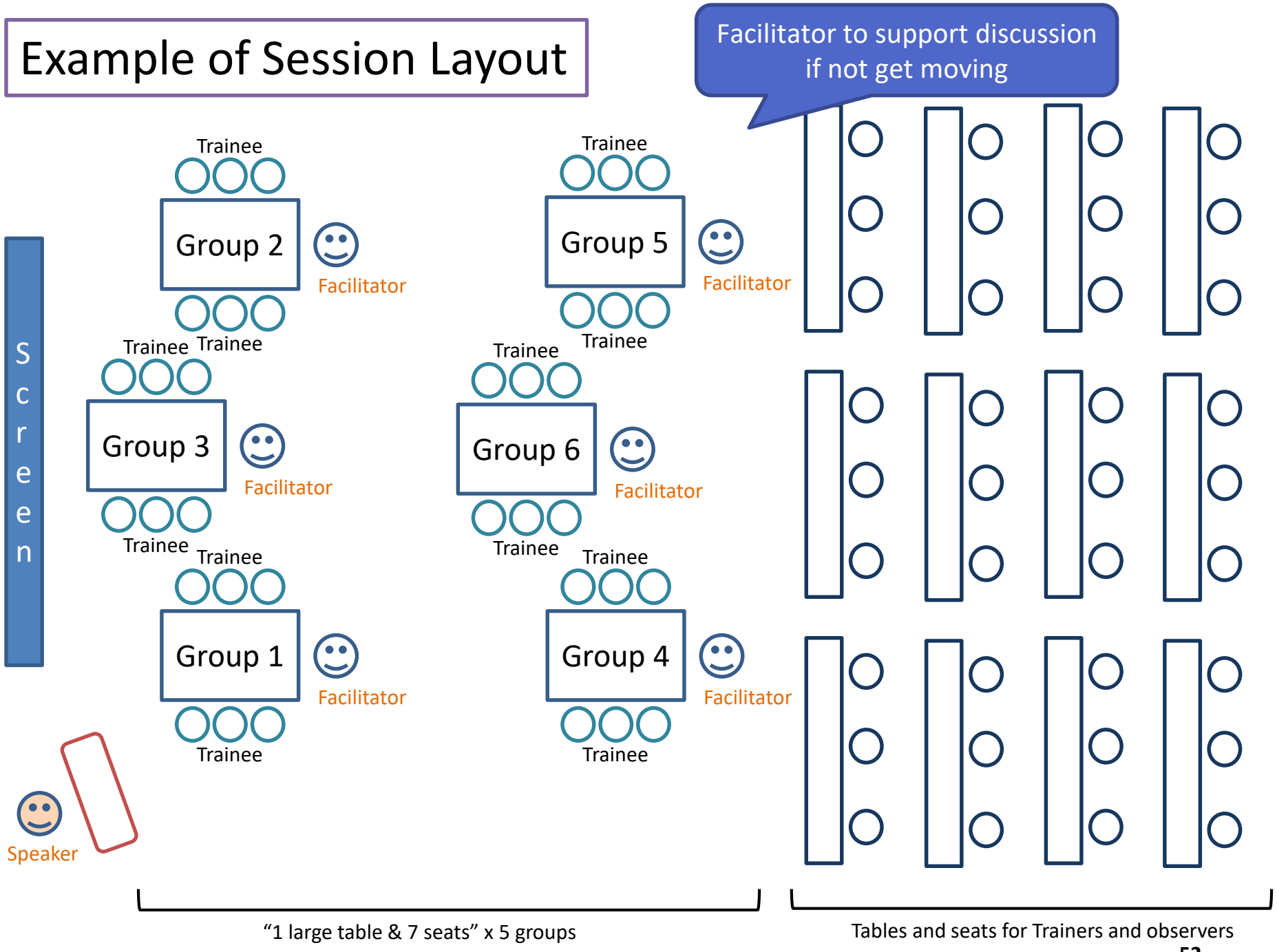
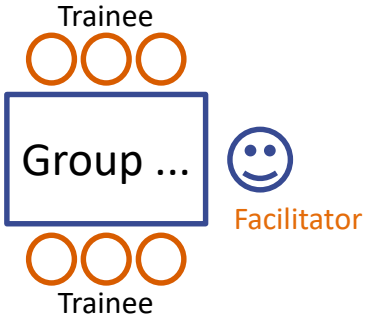
Example of Session Layout





Facilitator to support discussion if not get moving

Facilitators

1. Atchara Montalta (**Wow**)
2. Supak Nimnualnwattana (**Tai**)
3. Thananant Hakkayananda (**Big**)
4. Jiraporn Jittangtong (**Ji**)
5. Pajaree Worawong (**Louknam**)
6. Monsamorn Choonharas (**Mon**)

Objectives of practice

To experience

- ✓ Preparation of each component
  - ➢ By utilizing Timeline table, Checklist
- ✓ Improvement of documents' quality
  - ➢ By utilizing Glossary and Template
- ✓ Compilation and assembling of submission dossier
  - ✓ By utilizing Checklist

Sakura

Nation

Green country

Company

Flower pharm co.

Work Experience

Sakura graduated from the university three years ago, She joined the company in order to fulfill her dream that patients access **essential** drugs early in her county.

She has worked hard and learned the role of regulatory affairs. Now she is appointed regulatory leader of the project(s).

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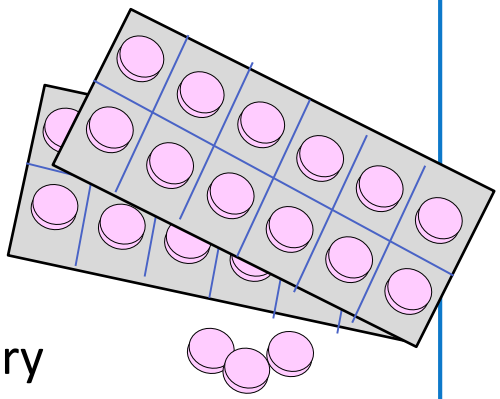
Sakuranitive tablets

- ✓ Sakuranitive tablets shows excellent efficacies in Phase 3 studies as life-saving medicine
- ✓ Approvals in Japan, US and EU, are expected in May, June and July, respectively
- ✓ Flower pharm co. are pursuing NDA submission of Sakuranitive tablets in Thailand by mid of **December**
- ✓ Intended commercial sites for Thailand
  - Bulk drug product
    - ➢ Newpower factory, Flower pharm co. in US
  - Commercial Packaging site
    - ➢ Spinach plant, Flower pharm co. in Green country



NDA requirements

Module 1	Application form*	
	1 CPP from reference country (JP, US or EU) with Notarization & Legalization	
	Proposed Package Insert in Green country	
Module 2	2.3.P.1 - 8	
Module 3	3.2.P.1	Description and Composition of the Drug Product
	3.2.P.2	Pharmaceutical Development
	3.2.P.3	Manufacture
	3.2.P.4	Control of Excipients
	3.2.P.5	Control of Drug Product
	3.2.P.6	Reference Standards or Materials
	3.2.P.7	Container Closure System
	3.2.P.8	Stability**

* Need consistency of proposed indications, manufacturers names/addresses among 'Application form', 'Proposed Package Insert' and 'CPP'

** Stability samples need to be manufactured at intended commercial sites including packaging site

SOP in Flower pharm co.

Head Quarter (HQ)

- ✓ Provide the latest NDA dossier in JP, EU, US
- ✓ Arrange CPP preparation
- ✓ Review and approve draft proposed Package Insert based on request by AS

Asia Region Head (ARH)

- ✓ Provide region specific item
  - Conduct additional stability studies and dossier update based on region specific requirements
  - Draft proposed Package Insert based on request by AS

Asia Subsidiary (AS)

- ✓ Manage NDA submission timeline based on corporate milestone
- ✓ Arrange Package Insert preparation
- ✓ Collect and compile NDA dossier
- ✓ Submit NDA dossier to the regulatory authority

Standard period

Application form (11 weeks)	Drafting by affiliate	2 weeks
	Legal review by HQ	8 weeks
	Return to affiliate & Signature	1 week
CPP with Notarization & Legalization (14 weeks)	Request HQ to arrange CPP	1 week
	HQ request authority to issue CPP	8 weeks (JP, US, EU)
	HQ received CPP from authority	1 week
	Notarization & Legalization	4 weeks
Proposed Package Insert (12 weeks)	Request ARH to draft	1 week
	Drafting	8 weeks
	PI Review process in HQ	2 weeks
	Approval	1 week
Compilation & Assembling in **November**		4 weeks
Final check before submission		1 week

HQ: Head Quarter, ARH: Asia Region Head

Before beginning of practice

Please decide role of each member in your group

- Group leader
  - Lead discussion for practice and group/presentation
- Secretary
  - Wright group' thought on blank flip chart
- Speaker
  - Present group's thought at group presentation
- Dossier manager (SAKURA)
  - Manage all practice items
  - Compile submission dossier

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	Activity
Facilitator	Support group to decide member's role

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Sakura's Missions

planning for document preparation for submission

Practice 1 (30 min.)

- Decide CPP reference country
- Provide feasible Timeline table and Checklist
- Ask facilitator to review checklist and timeline table

Practice materials:

1. ***Checklist***
2. ***Timeline table***

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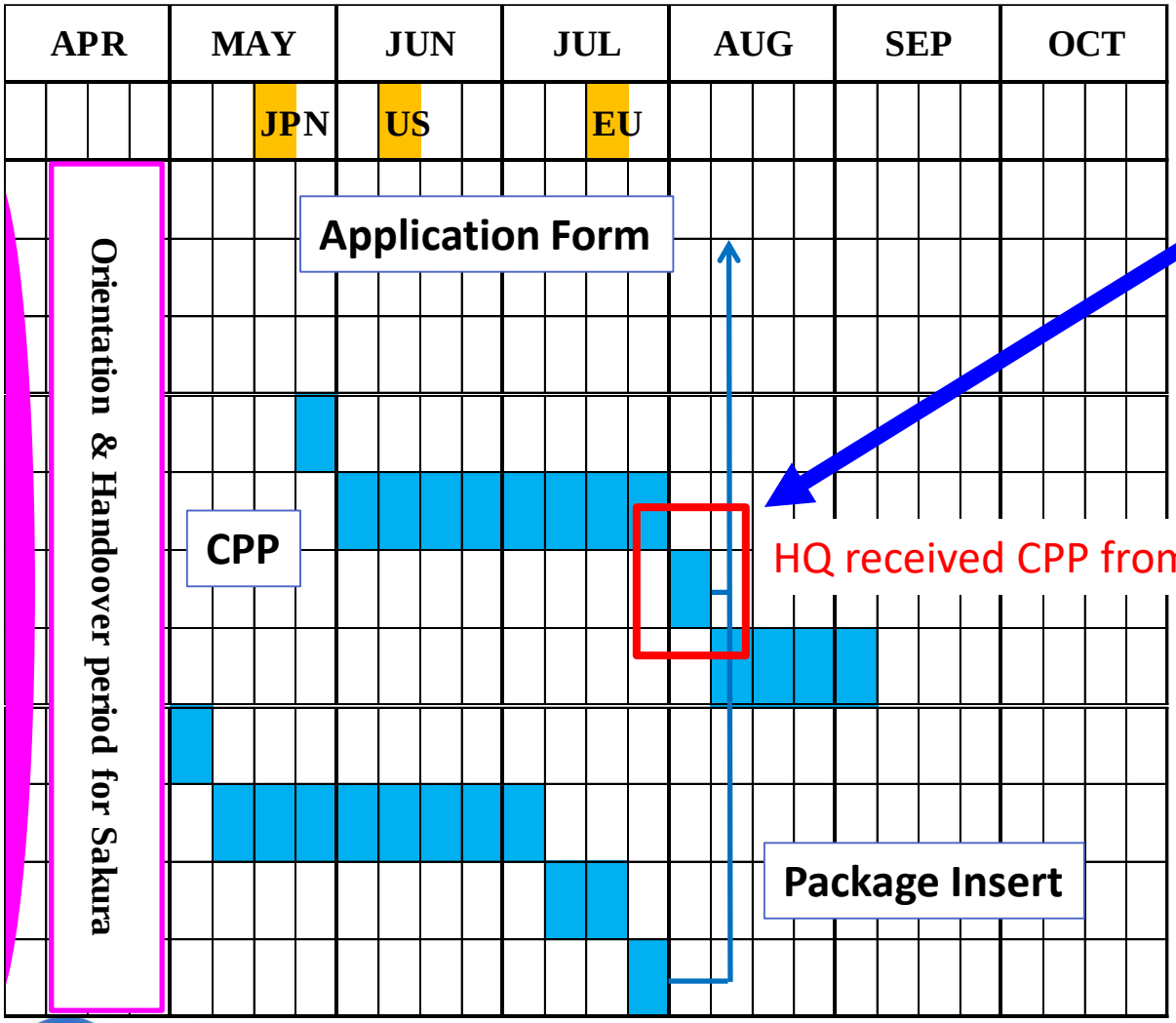
10 minutes

Time management
by Session leader

Plan Prepare SUBMIT Communi cate



Group can get CPP information and start to draft Application Form from this time

10 minutes

Time management by Session leader

Plan Prepare SUBMIT Communi cate

Please start checklist after fixing timeline table

PROJECT Sakuranitive

Flower pharm co.,

Checklist-1

Please fill in!

Item		To Whom*	By When	*Check*
Module 1	Application form			
	CPP with Notarization & Legalization			
	Proposed Package Insert in GRN			
Module 2	2.3.P.		4th week, October	

*Regulatory window person for dossier preparation

Head Quarter (HQ): Jasmine Blue (jasmine-b@flower.com)

Asia Region Head (ARH): Margaret Sky (margaret-s@asia.flower.com)

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Sakura's Missions

QC and Compilation

Practice 2 (30 min.)

- Do QC of '3.2.P.3.1 Manufacturer(s)' based on glossary, and make annotations
- Review application form
- Compile submission dossiers based on checklist
- Ask facilitator to check submission package

Practice materials:

3. ***Glossary***
4. ***3.2.P.3.1 Manufacturer(s)***
5. ***CPP***
6. ***Proposed package insert***
7. ***Application form***
8. ***2.3.P and 3.2.P cover pages***
1. ***Checklist (again)***

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0-10 minutes

Time management by Session leader

Plan Prepare SUBMIT Communicate

Please make annotations freely based on glossary

The site address, contact information, and roles of each factory/plant involved in the manufacture, packaging, testing of Fukuramitin tablets for Green country, are provided in Table 3.2.P.3.1:1.

Table 3.2.P.3.1:1 Manufacturer

Manufacturer	Contact information	Role
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

10-20 minutes

Time management by Session leader

Indications (need to same as that in proposed package insert)
Manufacturer(s), (name and address in official certificate issued by reference country)
Applicant Signature: _____ Date: _____ **Name (Printed):**

Please refer to source documents, proposed Package Insert and CPP, correctly

Please select signer

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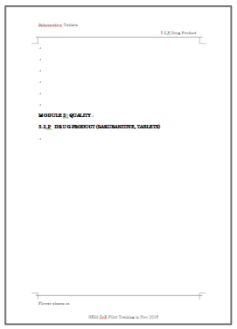
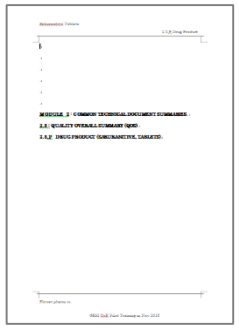
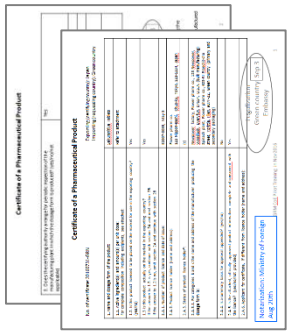
20-25 minutes

Time management by Session leader

Plan Prepare SUBMIT Communi cate







Please compile submission dossier based on checklist and NDA requirements

Submission dossier

GROUP PRESENTATION

Group presentation

Presentation topics

1. Can your group complete all missions?
   - ✓ Reference country, Checklist, Timeline table, QC, Application form, Compilation
2. Which item is most difficult or easy for your group?
3. If there are no supporting tool, what will be happened?
4. Please freely share your group's idea, how you can improve dossier preparation process.

- ***Group discussion for presentation (10 min)***
- ***Group presentation (6 Gr x 3 - 5 min)***