

# Model **Application form** as part of module 1

## Options for alignment: proposal

Advanced Training Workshop: Building a CTD for registration  
of vaccines globally  
27th–28th March 2019, Singapore

Wednesday, 27 March 2019, Singapore  
CTD Training Season



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# ICH CTD

No.	Organization of the Dossier	
1	Module 1	Administrative Information and Prescribing Information
2	Module 2	Common Technical Document Summaries
3	Module 3	Quality
4	Module 4	Nonclinical Study Reports
5	Module 5	Clinical Study Reports

# ICH CTD : Module 1

No.	Organization of Module 1	
1	Sub Module 1.1	<p>Table of Contents of the Submission Including Module 1</p> <p>Note: Contains the overall Table of Contents of the whole CTD (module 1 - 5)</p>
2	Sub Module 1.2	<p>Documents Specific to Each Region (for example, <b>application forms</b>, prescribing information)</p> <p>Note: Contains documents <b>specific to each region/country</b>; for example, application forms or the proposed label for use in the region. The content and format of this module can be specified by the relevant regulatory authorities.</p>

# Example of Application Form from Different Countries

# Indonesia – Laos (ASEAN)



# Bhutan – Srilanka – India (South Asia)



# Ghana – Egypt (Africa)



# GCC – Iraq (Middle East)

**GULF COOPERATION COUNCIL (GCC) COUNTRIES**



## **G. C. C. STATES**

(U.A.E, BAHRAIN, SAUDI ARABIA, OMAN, QATAR, KUWAIT, YEMEN)



# Example of Application Form from Different Countries



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# Variation in Application Form

- **Product Scope**

Most countries (Indonesia, GCC, Srilanka, Bhutan, Laos, Irak) are having general **pharmaceutical application Form**.

Whereas some other countries are having different application form as follows:

**India** : some part of its application form are applied form general pharmaceutical products; whereas some other part is specifically for vaccine.

**Ghana** : having specific application form for Vaccine (for both human and veterinary)

**Egypt** : having specific application form for biological product for human use (but not specifically vaccine)

- **Type/Group/Classification of Information**

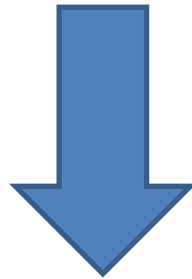
Basically, type of information needed consist of product information, manufacturer information, applicant information, registration information, declaration, and supporting document as attachment. However, there is also [country](#) which only focus on product information.

- **Detail Information (the deepness)**

The level of detail is different between countries. For example, there is [country](#) which put so many detail in manufacturer information compare to any other countries.

# Application Form

Specific to each country/region



Is there any option for harmonization (?)

# Harmonized Application Form

What type of information should be included(?)

Product, Applicant, Manufacturer, Registration, Attachment

How detail it should be (?)

Who should be expected to be able to answer the question (?)

## The Proposed Model



Thank You

