

วิธีการเข้าใช้งาน docuBridge ผ่าน webAccess

วิธีการเข้าใช้งาน docuBridge ผ่าน webAccess - สามารถเริ่มใช้งานได้ตั้งแต่ 18 มีนาคม 2567

1. เปิดเว็บเบราว์เซอร์ และไปที่ docuBridge webAccess URL

Production URL

<https://drugctd103.fda.moph.go.th/docubridge>

Test URL

<https://drugctd106.fda.moph.go.th/docubridge>


2. ทำการเข้าสู่ระบบด้วยบัญชีผู้ใช้งาน

Log in using – เลือก Username and Password

Username – ใส่ชื่อบัญชีของผู้ใช้งาน

Password – ใส่รหัสผ่านของผู้ใช้งาน

3. กด LOGIN



LORENZ Login

Log in using Username and password

Username

Password

LOGIN

docuBridge Explorer - หน้าต่างสำหรับการค้นหาตำรับ

docuBridge Explorer

+ New ▾ Reports ▾ Paste Refresh Layout ▾ Export to Excel

Navigation ▾

- Searches
 - Desktop Private
 - Desktop Public
 - Checked-out Files
 - Attachment Document
 - My Applications: 01 PTL
 - My Applications: 02 CO-PTL**
 - My Applications: 02 CO-PTL *e57*
 - My Applications: 02 CO-PTL *e58*
 - My Applications: 02 CO-PTL *e59*
 - My Applications: 02 CO-PTL *e60*
 - My Applications: 02 CO-PTL *e61*
 - My Applications: 02 CO-PTL *e62*
 - My Applications: 02 CO-PTL *e63*
 - My Applications: 02 CO-PTL *e64*
 - My Applications: 02 CO-PTL *e65*
 - My Applications: 02 CO-PTL *e66*
 - My Applications: 02 CO-PTL *e67*
 - My Applications: 02 CO-PTL *iSub*
 - My Applications: 02 CO-PTL by e-identifier
 - My Applications: 03 Internal Evaluator

Searches > My Applications: 02 CO-PTL

Status ▾ Object Locked ▾

Drag a column header and drop it here to group by that column

	eSubmission Ident...	Description	Version Number	Sequence Type	Sequence Descript...	Product Name	Contact Email
	e6604105	e6604105	0000	A: Pharmaceutics - New ...	Initial Submission	ARIPAZ-5	natkamon.tem@mail.gp...
	e6602475	e6602475	0000	A: Pharmaceutics - New ...	Initial Application	Suvezen 10/10 mg and S...	RA.Thai@sanofi.com
	e6602475	e6602475	0002	J: Supplementary Inform...	Response to Agency_20...	Suvezen 10/10 mg and S...	RA.Thai@sanofi.com
	e6602475	e6602475	0001	J: Supplementary Inform...	Response to Agency	Suvezen 10/10 mg and S...	RA.Thai@sanofi.com
	e6602628	e6602628	0000	A: Pharmaceutics - New ...	Initial Application	LAMIVIR	jinnarut.kit@mail.gpo.or...
	e6602628	e6602628	0001	A: Pharmaceutics - New ...	Comment clarification	LAMIVIR	jinnarut.kit@mail.gpo.or...
	e6604847	e6604847	0000	A: Pharmaceutics - New ...	Initial Application	ALVOXABAN 5 MG FILM-...	Pattadon.Hungraksa@al...
	e6604448	e6604448	0000	A: Pharmaceutics - New ...	Initial Application	Vildagliptin 50mg Tablets	ra1@camberglobal.com
🔒	e6604514	e6604514	0001	A: Pharmaceutics - New ...	Response to Questions	FARIC	rapharma@sriprasit.co.th
🔒	e6604514	e6604514	0000	A: Pharmaceutics - New ...	Initial Application	FARIC	rapharma@sriprasit.co.th
🔒	e6604514	e6604514	0002	J: Supplementary Inform...	Response to Request for...	FARIC	rapharma@sriprasit.co.th
🔒	e6604514	e6604514	0003	J: Supplementary Inform...	Response to Request for...	FARIC	rapharma@sriprasit.co.th
	i6602881	i6602881	0000	A: Pharmaceutics - New ...	0000	Cisatracurium Kalceks 2 ...	
	i6602881	i6602881	0001	A: Pharmaceutics - New ...	0000	Cisatracurium Kalceks 2 ...	
	e6603313	e6603313	0000	A: Pharmaceutics - New ...	Initial application	Ticagrelor 60mg, 90mg F...	ra1@camberglobal.com
	e6603313	e6603313	0002	A: Pharmaceutics - New ...	Response for screening ...	Ticagrelor 60mg, 90mg F...	ra1@camberglobal.com
	e6603313	e6603313	0001	A: Pharmaceutics - New ...	Response for screening ...	Ticagrelor 60mg, 90mg F...	ra1@camberglobal.com

การค้นหาตำรับ

เลือกค้นหาตำรับที่ได้รับมอบหมาย ตามปีของหมายเลข e-identifier

- Attachment Document
- My Applications: 01 PTL
- My Applications: 02 CO-PTL
- My Applications: 02 CO-PTL *e57*
- My Applications: 02 CO-PTL *e58*
- My Applications: 02 CO-PTL *e59*
- My Applications: 02 CO-PTL *e60*
- My Applications: 02 CO-PTL *e61*
- My Applications: 02 CO-PTL *e62*
- My Applications: 02 CO-PTL *e63*
- My Applications: 02 CO-PTL *e64*
- My Applications: 02 CO-PTL *e65*
- My Applications: 02 CO-PTL *e66***
- My Applications: 02 CO-PTL *e67*
- My Applications: 02 CO-PTL *iSub*
- My Applications: 02 CO-PTL by e-identifier
- My Applications: 03 Internal Evaluator

Searches > My Applications: 02 CO-PTL *e66*

Status Object Locked

Drag a column header and drop it here to group by that column

	eSubmission Ident...	Description	Version Number	Sequence Type	Sequence Descript...	Product Name	Contact Email
	e6604105	e6604105	0000	A: Pharmaceuticals - New ...	Initial Submission	ARIPAZ-5	natkamon.tem@mail.gp...
	e6602475	e6602475	0000	A: Pharmaceuticals - New ...	Initial Application	Suvezen 10/10 mg and S...	RA.Thai@sanofi.com
	e6602475	e6602475	0002	J: Supplementary Inform...	Response to Agency_20...	Suvezen 10/10 mg and S...	RA.Thai@sanofi.com
	e6602475	e6602475	0001	J: Supplementary Inform...	Response to Agency	Suvezen 10/10 mg and S...	RA.Thai@sanofi.com
	e6602628	e6602628	0000	A: Pharmaceuticals - New ...	Initial Application	LAMIVIR	jinnarut.kit@mail.gpo.or...
	e6602628	e6602628	0001	A: Pharmaceuticals - New ...	Comment clarification	LAMIVIR	jinnarut.kit@mail.gpo.or...
	e6604847	e6604847	0000	A: Pharmaceuticals - New ...	Initial Application	ALVOXABAN 5 MG FILM-...	Pattadon.Hungraksa@al...
	e6604448	e6604448	0000	A: Pharmaceuticals - New ...	Initial Application	Vildagliptin 50mg Tablets	ra1@camberglobal.com
🔒	e6604514	e6604514	0001	A: Pharmaceuticals - New ...	Response to Questions	FARIC	rapharma@sriprasit.co.th
🔒	e6604514	e6604514	0000	A: Pharmaceuticals - New ...	Initial Application	FARIC	rapharma@sriprasit.co.th
🔒	e6604514	e6604514	0002	J: Supplementary Inform...	Response to Request for...	FARIC	rapharma@sriprasit.co.th
🔒	e6604514	e6604514	0003	J: Supplementary Inform...	Response to Request for...	FARIC	rapharma@sriprasit.co.th
	e6603313	e6603313	0000	A: Pharmaceuticals - New ...	Initial application	Ticagrelor 60mg, 90mg F...	ra1@camberglobal.com

การค้นหาตำรับ

เลือกค้นหาตำรับที่ได้รับมอบหมาย จากการระบุนหมายเลขตำรับที่ต้องการ

🔍 My Applications: 02 CO-PTL *e60*

🔍 My Applications: 02 CO-PTL *e61*

🔍 My Applications: 02 CO-PTL *e62*

🔍 My Applications: 02 CO-PTL *e63*

🔍 My Applications: 02 CO-PTL *e64*

🔍 My Applications: 02 CO-PTL *e65*

🔍 My Applications: 02 CO-PTL *e66*

🔍 My Applications: 02 CO-PTL *e67*

🔍 My Applications: 02 CO-PTL *iSub*

🔍 My Applications: 02 CO-PTL by e-identifier

🔍 My Applications: 03 Internal Evaluator

2

Searches > My Applications: 02 CO-PTL by e-identifier

eSubmission Identifier

1. เลือก My Applications: 02 CO-PTL by e-identifier
2. ระบุนหมายเลขตำรับที่ต้องการค้นหาในช่อง eSubmission Identifier

docuBridge eSubmission Workbench - หน้าต่างสำหรับการประเมินตำรับ

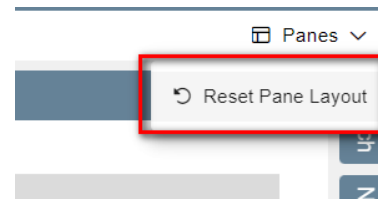
The screenshot displays the docuBridge Submission Workbench interface. The top navigation bar includes the logo, the title "docuBridge Submission Workbench", and user information "FT-TEST". Below the navigation bar, there are menu items: "View Content Catalog", "Review State", "Download File", "Annotations", and "Reports". On the right side of the navigation bar, there is a "Panels" dropdown menu.

The main content area is divided into several sections:

- Outline:** Located on the left, it shows a tree view of the submission structure. The root node is "0000", which is expanded to show three sub-nodes: "1 Administrative Information and Prescribing Information", "2 Common Technical Document Summaries", and "3 Quality".
- Administrative Information: Thailand v1.0:** This is the main content area, displaying a table of submission details.

eSubmission Identifier	e6792024
Sequence Type	A: Pharmaceuticals - New Chemical Entity
Regulatory Activity Lead	Pharmaceutical Product Review
Licensee Number	123/45
Licensee Name	FT Demo
Licensee Type	Manufacturer
INN or Generic Name	FT Drug
Product Name	FT Drug Demo
Sequence Number	0000
Related Sequence Number	0000
Sequence Description	Initial Application
Email	ft@factory-talk.com

On the right side of the interface, there is a vertical toolbar with icons for "Search", "Node Content", "Document Attributes", and "Hyperlink Editor".



เลือกคำสั่ง Panes > Reset Pane Layout เพื่อกลับสู่ค่า Layout เริ่มต้น

การเปิดอ่านเอกสาร

Outline

Node Filter
<none>

0000 1 - 1 1 1 1

- 0000
 - 1 Administrative Information and Prescribing Information
 - [0000] Thailand v1.0
 - 1.0 Cover
 - 1 1.0.1 Tracking Table**
 - [0000] Tracking Table
 - 1.0.2 Cover Letter
 - [0000] Cover Letter
 - 1.2 Application Forms
 - 1.2.1 Application Form
 - [0000] Application Form
 - 1.2.2 Annexes
 - [0000] Letter of Authorization
 - [0000] Manufacturing License
 - [0000] Production Permit

1. สามารถคลิกค้นหาเอกสารที่ต้องการอ่านได้ภายใต้ Outline Section
2. เอกสารจะแสดงในหน้าต่างด้านขวา

Tracking Table

119%

2

CONFIDENTIAL

THAILAND

MODULE 1.0.1 LIFECYCLE MANAGEMENT TRACKING TABLE

Sequence	Submission description	Date of submission
0000	Initial Application	Dec 10

Sample Document modified from the TGA CTD Module 1 Administrative information and prescribing information for Australia version 2.2 from April 2014 for the eCTD version 0.90 from June 2014

Tracking Table 1.0.1 Pg. 1

Find - ค้นหาคำที่ต้องการในเอกสาร

1. เลือกคำสั่ง Find
2. พิมพ์คำที่ต้องการในช่อง Search document

Blueberry
ABC

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In the "Body of Data" reference is made to existing CPMP-ICH or CPMP guidelines which should be taken into account when compiling the chemical, pharmaceutical and biological part of the application. Further additional guidelines, which may be appropriate are listed in the Annex to Module 3. The following CPMP guidelines have a more general character and also, need to be considered, where relevant:

"Limitations to the use of Ethylene Oxide in the Manufacture of Medicinal Products" "The use of Ionising radiation in the manufacture of medicinal products"
"Dry Powder Inhalers"
"On Quality Of Modified Release Products: A: Oral Dosage Forms B: Transdermal Dosage Forms Section I (Quality)"
"Investigation of Chiral Active Substances"
"Radiopharmaceuticals"
"Production and Quality Control of Medicinal Products derived by Recombinant DNA Technology"
"Production and Quality Control of Cytokine Products derived by Biotechnological Processes"
"Production and Quality Control of Monoclonal Antibodies"
"Gene Therapy Product Quality Aspects in the Production of Vectors and Genetically Modified Somatic Cells"
"Use of Transgenic **Animals** in the Manufacture of Biological Medicinal Products for Human Use"
"Note for Guidance on medicinal gases - pharmaceutical documentation"
"Note for Guidance on requirements for pharmaceutical documentation for pressurized metered dose inhalation products" "Note for Guidance on quality of water for pharmaceutical use"
"use of Near Infrared Spectroscopy by the pharmaceutical industry and the data requirements for new submissions and variations"
"Note for Guidance on Allergen products"
"Note for Guidance on Harmonisation of Requirements for Influenza Vaccines" "Points to consider on the development of live attenuated influenza vaccines"
"Note for Guidance on production and quality control of **animal** immunoglobulins and immunosera for human use"
"Note for Guidance on Pharmaceutical and Biological Aspects of Combined Vaccines"
"Note for Guidance on Plasma-derived Medicinal Products"

References to guidelines are inserted to assist applicants. However, it remains the applicants' responsibility to ensure that all relevant legislation and guidelines, as revised or maintained, are taken into account in the preparation of each part of their dossier. The guidelines referenced in each section provide useful information on the content expected in that section. However this list should not be regarded as comprehensive.

Information extracted from the European Commission's
Presentation and Format of the Dossier CTD based on
NTA 2B , CTD-Module 3, edition July 2004

2

animal X

Case sensitive Whole word

2 results found < >

Page 2

Transgenic **Animals** in the Manufacture of Biological Medicinal Products for Human

of **animal** immunoglobulins and immunosera for human use "Note

1



Annotation - เครื่องมือรีวิวเอกสาร

1. เรียกดู Comments และ Reply ได้
2. ซ่อน / แสดง Annotation ทั้งหมด

The screenshot displays a document review tool interface. The main document is a package leaflet for 'FT-TEST' in Thai. The document content includes sections like 'PACKAGE LEAFLET: INFORMATION FOR THE USER', 'In this leaflet', and '1. WHAT X IS AND WHAT IT IS USED FOR'. A red annotation box is overlaid on the text, containing the text 'FT-TEST 3/13/2024, ... Need Revise' and 'ต้องการข้อมูลเพิ่มเติม'. A blue line connects this annotation to a comment in the sidebar. The sidebar on the right shows 'Page 2', 'FT-TEST 03/13/2024, 11:14:42 AM', and 'Need Revise ต้องการข้อมูลเพิ่มเติม'. Below this is a text input field 'Add reply...' and a search icon. On the far right, there is a vertical toolbar with icons for search, comment, and other functions. The numbers '1' and '2' are placed next to the comment and search icons respectively, corresponding to the numbered list on the left.

THANK YOU

Any questions?