

ระบบการขึ้นทะเบียนตำรับยาแบบ **e-submission** สำหรับ เจ้าหน้าที่สำนักงานคณะกรรมการอาหารและยา

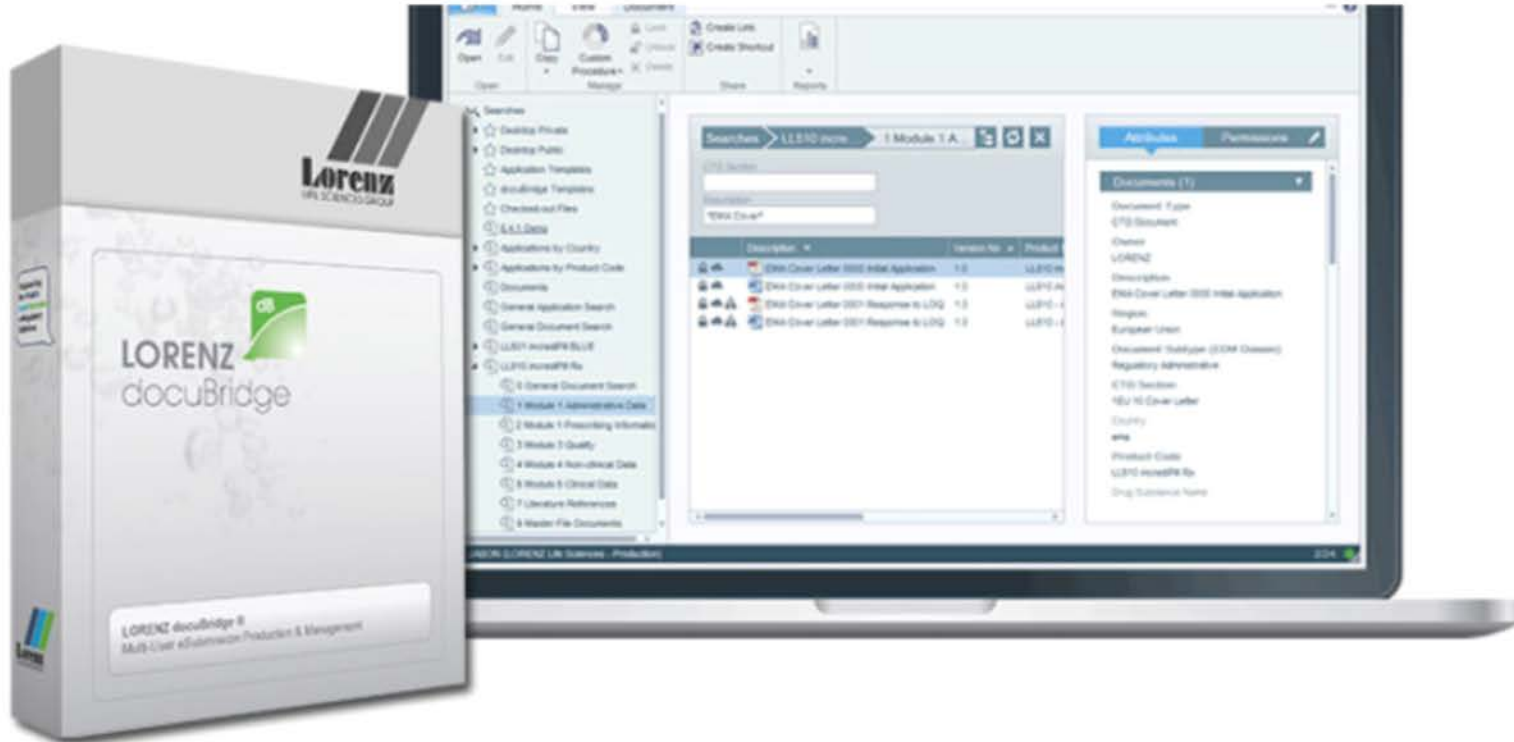
Agenda

- Review Process
- Introduction to docuBridge
- docuBridge Explorer
- The Submission Workbench
- The Navigation Bar
- Reviewing Submissions
- Custom Procedure (เปลี่ยนสถานะคำขอ)
- Custom Procedure (การกำหนดเจ้าหน้าที่ผู้เกี่ยวข้อง)
- Attached Document for Submission (แนบเอกสารเพิ่มเติม)
- Audit Trail Report

Review Process



Introduction



The world's most advanced multi-user eSubmission production and management system.

docuBridge Explorer

The screenshot displays the docuBridge Explorer application interface. At the top, the title bar reads "docuBridge Explorer". Below it is a toolbar with the following items: "+ New", "Open", "Copy", "Custom Procedure", "Edit Attributes", and "Check-Out". A large number "3" is placed over the "Edit Attributes" button.

The main interface is divided into two panes. The left pane, titled "Navigation", contains a list of search queries. A large number "1" is placed to the right of this list. The right pane, titled "Searches > All Application Search *e6601*", displays a table of search results. A large number "2" is placed to the right of this table. The table has a header "eSubmission Identifier ↑ (1)" and contains several rows of data, each with a document icon and the value "e6601000" or "e6601001". A lock icon is visible on the left side of the table.

eSubmission Identifier ↑ (1)
e6601000
e6601000
e6601000
e6601000
e6601001
e6601001
e6601001
e6601001
e6601001
e6601001
e6601001

Submission Workbench

The screenshot displays the docuBridge Submission Workbench interface. At the top, the header includes the logo and title "docuBridge Submission Workbench", a user profile icon labeled "ADMIN", and a search icon. Below the header, a navigation bar contains "View Content Catalog", "Review State", "Download File", "Annotations", and "Reports". On the right side of this bar is a "Panels" icon.

The main workspace is divided into several panels:

- Left Panel:** Contains "Sequences", "Content Catalog", and "Bookmarks". The "Content Catalog" is expanded to show a tree structure:
 - 0000
 - 1 Administrative Information and Prescribing
 - [0000] Thailand v1.0
 - 1.0 Cover
 - 1.0.1 Tracking Table (highlighted)

At the bottom of this panel, it shows "Nodes: 43 Documents: 19 Pages: 25".- Top Panel:** Titled "Tracking Table", it features a toolbar with icons for zooming (45%), panning, and other navigation functions.
- Center Panel:** Displays a document page titled "THAILAND MODULE 1.0.1 LIFECYCLE MANAGEMENT TRACKING TABLE". It includes a table with the following data:


Sequence	Submission Description	Date of submission
0000	Initial Application	Dec 19
- Right Panel:** Contains "Search", "Node Content", "Document Attributes", and "Hyperlink Editor" tools.


Navigation Bar

 Fullscreen


 ย่อ ขยาย


 เปิดโหมด Interact


 โหมดเลือก

 สร้าง Notes


 สร้าง Highlights

 สร้าง Hyperlinks

 ตั้งค่า Hyperlinks

 ดูตัวอย่างหัวกระดาษและท้าย

กระดาษ

 แสดงหรือซ่อนบุ๊กมาร์ค

 ค้นหาข้อความใน PDF

 แสดงหรือซ่อนความคิดเห็น

 Download ไฟล์


 ไปที่หน้าเอกสารก่อนหน้าหรือเอกสารถัดไป


 ไปที่หน้าแรกหรือหน้าสุดท้าย


 ไปที่หน้าก่อนหน้าหรือถัดไป


 ซ่อนสัญลักษณ์ Notes, Highlights และ Hyperlink ด้านบน


 Panel

 แสดงหน้าต่อเนื่อง

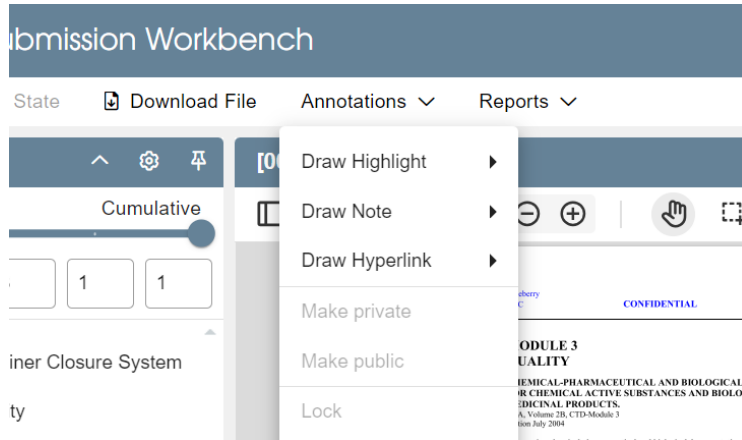
 แสดงหน้าต่อหน้า

 หมุนตามเข็มนาฬิกาหรือทวนเข็มนาฬิกา

 แสดงหน้าเดียว

 แสดงสองหน้าคู่กัน

Reviewing Submissions



MODULE 3 QUALITY

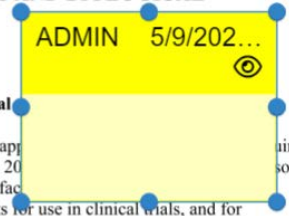
CHEMICAL-PHARMACEUTICAL AND BIOLOGICAL INFORMATION FOR CHEMICAL ACTIVE SUBSTANCES AND BIOLOGICAL MEDICINAL PRODUCTS.

NTA, Volume 2B, CTD-Module 3
Edition July 2004

Concerning chemical pharmaceutical and biological substance(s) and biological medicinal products

The principle of GMP and the detailed guidelines are applicable to all operations which require the authorization referred to in Article 40 of Directive 2001/83/EC as modified. They are also relevant for all other large scale pharmaceutical manufacturing processes, such as that undertaken in hospitals, for the preparation of products for use in clinical trials, and for resale, were applicable.

The analytical test procedures described in the various sections of the chemical, pharmaceutical and biological documentation must be described in sufficient detail to enable the procedures to be repeated if necessary (e.g. by an official laboratory). All procedures need to be validated and



Blueberry
ABC

CONFIDENTIAL

MODULE 3 QUALITY

CHEMICAL-PHARMACEUTICAL AND BIOLOGICAL INFORMATION FOR CHEMICAL ACTIVE SUBSTANCES AND BIOLOGICAL MEDICINAL PRODUCTS.

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Color:



สีแดง สำหรับคำถามถึงผู้ประกอบการ

สีส้ม สำหรับคำถามภายในผู้เชี่ยวชาญ และเจ้าหน้าที่

สีเหลือง สำหรับใช้ส่วนตัว

Custom Procedure (เปลี่ยนสถานะคำขอ)

om Procedure ▾ Edit Attributes Check-Out

Searches > All Application Search *e67*

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

Description	eSubmission I...
e6700025	e6700025
e6788888	e6788888
e6788888	e6788888
e6700052	e6700052
e6700189	e6700189
e6700189	e6700189
e6700112	e6700112
e6781234	e6781234
e6700249	e6700249
e6700071	e6700071

- Open
- Open in SWB
- Copy ▶
- Custom Procedure ▶
 - Industry Response Procedures
 - Pharmaceutical Procedures
 - Pharmacovigilance Procedures
 - Distribute to Screening - Pharmacovigilance
 - Biologicals Procedures
 - Document Attribute Procedures
 - * Add INN or Generic Name
 - * Delete INN or Generic Name
 - * Add Product Name
 - * Delete Product Name
 - Version Attribute Procedures
 - ** Add myself to Evaluators
 - Assign Team - Screener
 - ** Add Product Team Leaders - Processing
 - ** Delete Product Team Leaders - Processing
 - ** Add Co-Product Team Leaders - Processing
 - ** Delete Co-Product Team Leaders - Processing
- Unlock
- Delete
- New ▶
- Edit Attributes
- Share ▶
- Reports ▶

Custom Procedure

(กำหนดเจ้าหน้าที่ผู้เกี่ยวข้อง)

~~~~~ Version Attribute Procedures

\*\* Add myself to Evaluators

Assign Team - Screener

\*\* Add Product Team Leaders - Processing

\*\* Delete Product Team Leaders - Processing

\*\* Add Co-Product Team Leaders - Processing

\*\* Delete Co-Product Team Leaders - Processing

\*\* Add Internal Evaluator(s) - Processing

\*\* Delete Internal Evaluator(s) - Processing

\*\* Add External Evaluator(s) - Processing

\*\* Delete External Evaluator(s) - Processing

Add Comment

Add Task for PTL

Add Task for Evaluator












# Share Application - WebAccess

The screenshot shows a list of applications in a table. A context menu is open over the 'Share' option of the application with ID 'e6700035'. The menu contains two options: 'Copy webAccess Link to Clipboard' and 'Copy native SWB Link to Clipboard'. The application list includes columns for an icon, ID, and other attributes.

| Icon | ID       | Action          | Attribute 1 | Attribute 2 |
|------|----------|-----------------|-------------|-------------|
|      | e6700249 | Delete          | 0249        | 0000        |
|      | e6700071 | New             | 0071        | 0000        |
|      | e6700110 | Edit Attributes | 0110        | 0000        |
|      | e6700035 | Share           |             |             |
|      |          | Reports         |             |             |

- Copy webAccess Link to Clipboard
- Copy native SWB Link to Clipboard

# Attached Document for Submission (แบบเอกสารเพิ่มเติม)

|                                                                                              |          |      |
|----------------------------------------------------------------------------------------------|----------|------|
|  e6788888   | e6788888 | 0000 |
|  e6788888   |          | 0001 |
|  e6700052   |          | 0000 |
|  e6700189   |          |      |
|  e6700189   |          |      |
|  e6700112   |          |      |
|  e6781234   |          |      |
|  e6700249   |          |      |
|  e6700071   |          |      |
|  e6700110 |          | 0000 |
|  e6700035 |          | nnnn |

- Open
- Open in SWB
- Copy ▶
- Custom Procedure ▶
- Unlock
- Delete
- New ▶
- Edit Attributes
- Share ▶
- Reports ▶

- Sequence
- Create...
- Related
- Upload File...
- From Template...
- Application...

# Audit Trail Report

|  | Description | eSubmission I... | Version Number |
|--|-------------|------------------|----------------|
|  | e6788888    | e6788888         | 0000           |
|  | e6788888    |                  | 0001           |
|  | e6700052    |                  | 0000           |
|  | e6700189    |                  | 0001           |
|  | e6700189    |                  | 0000           |
|  | e6700112    |                  | 0000           |
|  | e6781234    |                  | 0000           |
|  | e6700249    |                  |                |
|  | e6700071    |                  |                |
|  | e6700110    |                  |                |
|  | e6700035    |                  |                |

- Open
- Open in SWB
- Copy
- Custom Procedure
- Unlock
- Delete
- New
  - Audit Trail
  - Content Assignment
  - Advanced Submission Content
  - Deleted Documents Audit Trail
- Edit Attributes
- Share
- Reports

×

**Audit Trail**

**Options**

Include events of the entire DVO structure

Include children

**Filters**

Date filter: 5/3/24 – 5/9/24

User filter: ADMIN

Event category filter: Created

Create
Cancel

