

ระบบการขึ้นทะเบียนยาแบบ **e-submission** สำหรับ ผู้เชี่ยวชาญ

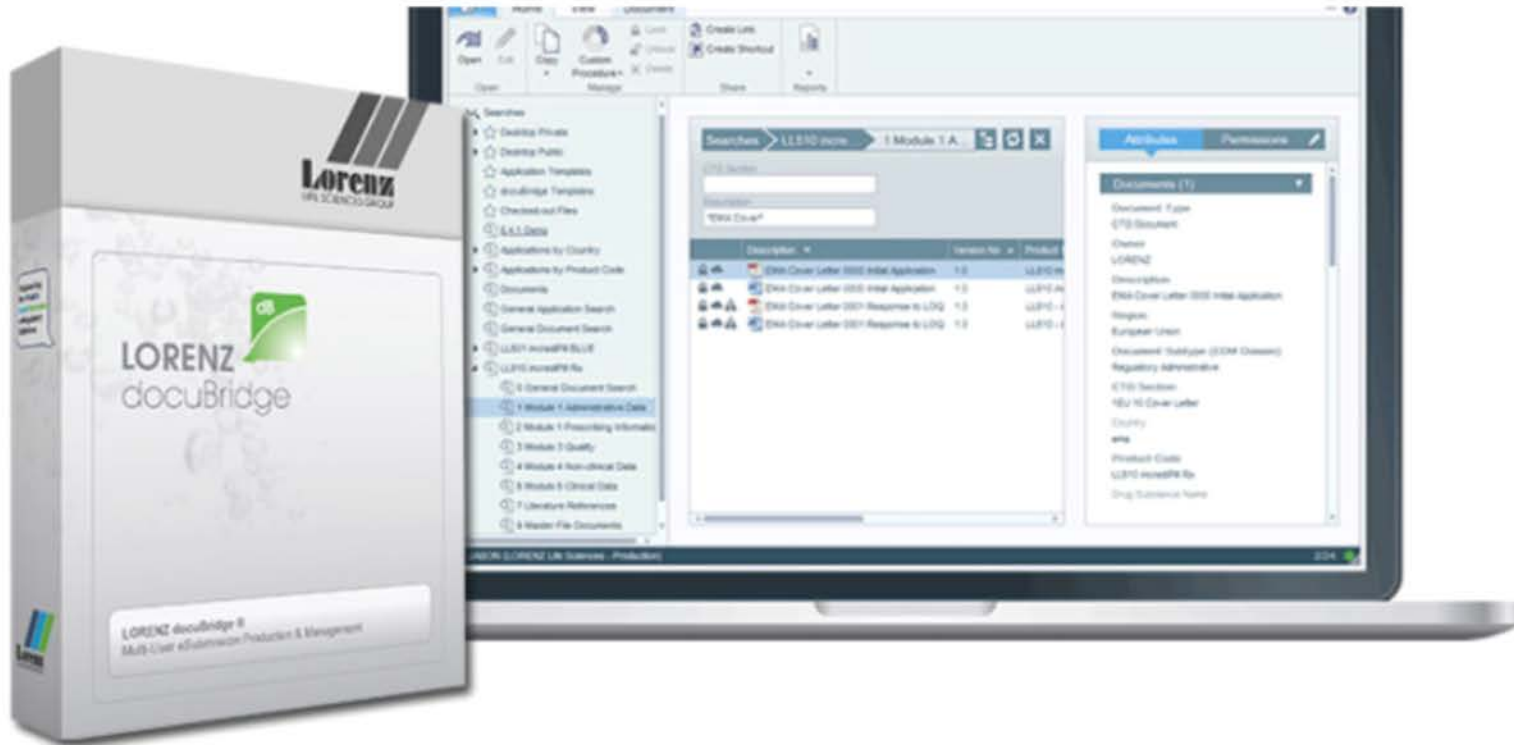
Agenda

- Review Process
- Introduction to docuBridge
- docuBridge Explorer
- The Submission Workbench
- The Navigation Bar
- Reviewing Submissions
- 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, there is a header bar with the logo and the text "docuBridge Explorer". Below the header is a menu bar with options: "+ New", "Open", "Copy", "Custom Procedure", "Edit Attributes", and "Check-Out".

The main interface is divided into two panes. The left pane, titled "Navigation", contains a list of search queries. The query "All Application Search *e6601*" is highlighted, and a large number "1" is placed next to it. The right pane, titled "Searches > All Application Search *e6601*", displays a table of search results. The table has a header "eSubmission Identifier ↑ (1)" and contains several rows of results, each with a document icon and the value "e6601000" or "e6601001". The second row from the bottom is highlighted, and a large number "2" is placed next to it. A large number "3" is placed above the "Edit Attributes" button in the menu bar.

Searches > All Application Search *e6601*	
Drag a column header and drop it here to group by that column	
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" on the left, and a user profile icon labeled "ADMIN" on the right. Below the header, a navigation bar contains links for "View Content Catalog", "Review State", "Download File", "Annotations", and "Reports". On the far right of this bar is a "Panels" icon.

The main workspace is divided into three vertical sections:

- Left Panel (Navigation):** Contains three stacked tabs: "Sequences", "Content Catalog", and "Bookmarks". The "Content Catalog" tab is active, showing a tree view of the document 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 displays "Nodes: 43 Documents: 19 Pages: 25".- Middle Panel (Tracking Table):** Titled "Tracking Table", it features a toolbar with icons for zooming (45%), panning, and other navigation functions. The main area shows a document page with the following content:

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THAILAND

MODULE 1.0.1 LIFECYCLE MANAGEMENT TRACKING TABLE

Item No.	Submission Description	Date of submission
0001	Initial Application	Dec 19

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


Tracking Table 1.0.1 Pg. 1
- Right Panel (Tools):** A vertical toolbar with icons for "Search", "Node Content", "Document Attributes", and "Hyperlink Editor".

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

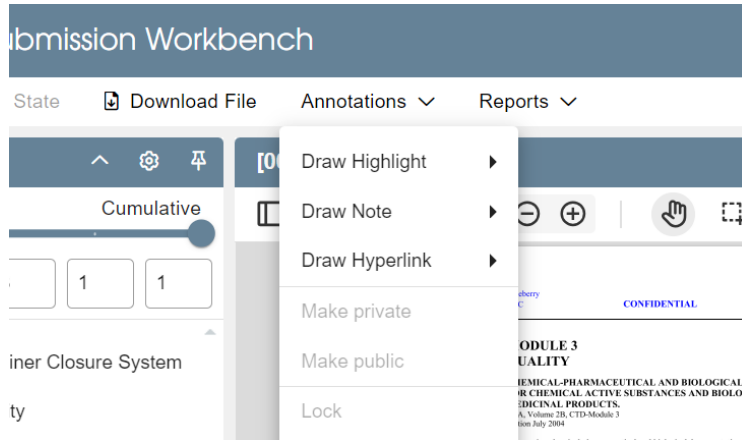
 แสดงหน้าต่อหน้า

 หมุนตามเข็มนาฬิกาหรือทวนเข็มนาฬิกา

 แสดงหน้าเดียว

 แสดงสองหน้าคู่กัน

Reviewing Submissions



MODULE 3 QUALITY

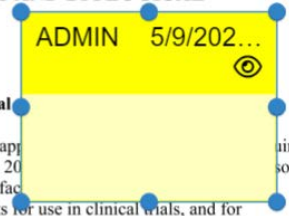
CHEMICAL-PHARMACEUTICAL AND BIOLOGICAL INFORMATION FOR CHEMICAL ACTIVE SUBSTANCES AND BIOLOGICAL MEDICINAL PRODUCTS.

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

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MODULE 3 QUALITY

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Color:



สีแดง สำหรับคำถามถึงผู้ประกอบการ

สีส้ม สำหรับคำถามภายในผู้เชี่ยวชาญ และเจ้าหน้าที่

สีเหลือง สำหรับใช้ส่วนตัว

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
- Edit Attributes
 - Content Assignment
- Share
 - Advanced Submission Content
- Reports
 - Deleted Documents Audit Trail

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

