

# **eCTD Implementation: USA**

**Capra-Getting Ready for eCTD**

**April 2, 2003**



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# Agenda

- **eCTD Overview**
- **FDA Background**
- **FDA Regional/Additional Requirements**
- **Implementation Strategy**
- **Implementation Status**
- **eCTD Viewer System Overview**

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## **eCTD Overview-Lite**

- **Create and Transport eCTDs**
- **Accommodates CTD 2-5 ICH Modules and Regional Module 1**
- **XML Backbone – Table of Contents**
- **Maintained by ICH eCTD Implementation Working Group (IWG)**

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# FDA Background

- **FDA has experience in electronic submissions**
  - **Static table of contents**
  - **Single view of submission contents**
  - **Standard navigation is not conducive to user specific requirements**

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# **FDA Regional Requirements**

- **DRAFT Guidance for testing Posted- FDA Welcomes Comments**
- **Follows eCTD Specification - Headings**
  - **FDA Forms**
  - **Risk Management**
  - **Regional Components for IND**
- **Items in the XML Backbone Required by FDA eCTD Viewer System**

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# **FDA Additional Requirements**

- **Study Report-identified by FDA/PhRMA while putting together demo eCTD**
  - **Contained global and regional specific information, in effort to harmonize brought to ICH**

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# Implementation Strategy

- **Utilize eCTD with a Standard viewing system**
- **Develop an eCTD Viewer System(EVS) to integrate with our existing infrastructure and standards**
- **Integrate reviewer requirements into the system**
- **Test with Industry(PhRMA) test submissions**
- **Develop and implementation strategy**

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# Implementation Status

- **FDA Regional Module 1**
  - **Draft for testing Posted on FDA Internet**  
[www.fda.gov/cder/regulatory/ersr](http://www.fda.gov/cder/regulatory/ersr)
  - **Routed for internal Comment**
- **ICH Partner, PhRMA, piloting sample eCTD**
  - **July/August Timeframe for eCTD Workshop**
  - **Test Sample With FDA Processing Tool -Spring**



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# Implementation Status

- **eCTD Viewer System Project**
  - **Version 1 Scheduled for Spring 2003 for piloting**
  - **Guidance documents in process**

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# **eCTD Viewer System Overview**

- **Processing Tool**
  - **Verifies, Reports, and Parses XML**
  - **Generate overall structure for reviewer**
- **Viewer**
  - **Presents eCTD to Reviewer Logically**
    - View
    - Navigate
    - Download
    - Search
    - Profile

# eCTD Viewer System Overview

Address: C:\Program Files\eCTD\index.html

Internal Test Build, v1.00.00.12, 12/11/2002, 2:30 PM

Submit CCR

Online / Application # 99999

Information:

Application # 99999

Product: Cureall

App No.: 99999

App Type: NDA\_BLA

Applicant: Demonstrator

Original Application Submission Date: 2000-04-03

No. of Files: 101

No. of Submissions: 6

Viewer:

Modules	Original	Supplements	Submissions	Files	
	MODULE	# OF HEADINGS	# OF FILES	# NEW FILES	FILE SIZE
<a href="#">m1-regional</a>		5	0	0	0 k
<a href="#">m2-common-technical-docume</a>		3	0	0	0 k
<a href="#">m3-quality</a>		1	4	0	136 k
<a href="#">m4-nonclinical-study-reports</a>		1	0	0	0 k
<a href="#">m5-clinical-study-reports</a>		1	0	0	0 k
<a href="#">m1-2-reports-documents-summ</a>		6	0	0	0 k
<a href="#">m1-3-prescribing-certifications</a>		2	0	0	0 k
<a href="#">m1-4-forms</a>		1	0	0	0 k
<a href="#">m1-5-labeling</a>		1	2	0	4 k
<a href="#">m1-6-other</a>		0	1	0	2 k

First | Prev | 1 2 3 4 5 6 7 8 | Next | Last | All

# eCTD Viewer System Overview

Address: C:\Program Files\eCTD\index.html

Internal Test Build, v1.00.00.12, 12/11/2002, 2:30 PM

Submit CCR

Online / Application # 99999

**Information :**

Application: 99999      **Product :** Cureall  
**App No. :** 99999      **No. of Files :** 101  
**App Type :** NDA\_BLA      **No. of Submissions :** 6  
**Applicant :** Demonstrator  
**Original Application Submission Date :** 2000-04-03

**Viewer :**

Modules	Original	Supplements	Submissions	Files
MODULE			# OF HEADINGS	# OF FILES
				# NEW FILES
				FILE SIZE
<a href="#">m1-regional</a>			5	0
<a href="#">m2-common-technical-docume</a>			3	0
<a href="#">m3-quality</a>			1	4
<a href="#">m4-nonclinical-study-reports</a>			1	0
<a href="#">m5-clinical-study-reports</a>			1	0
<a href="#">m1-2-reports-documents-summ</a>			6	0
<a href="#">m1-3-prescribing-certifications</a>			2	0
<a href="#">m1-4-forms</a>			1	0
<a href="#">m1-5-labeling</a>			1	2
<a href="#">m1-6-other</a>			0	1

File Size: 0 k, 0 k, 136 k, 0 k, 0 k, 0 k, 0 k, 0 k, 0 k, 4 k, 2 k

First | Prev | 1 2 3 4 5 6 7 8 | Next | Last | All

Applet gov.fda.ectd.review.common.ErsMain started

My Computer

12:43 PM



# eCTD Viewer System Overview

Address: C:\Program Files\eCTD\index.html

Internal Test Build, v1.00.00.12, 12/11/2002, 2:30 PM

Submit CDR

Online / Application # 99999 / Modules / m1-regional / m1-2-reports-documents-summaries / m1-2-3-letters-of-authorization

Modules

- m1-regional
  - m1-2-reports-d
    - m1-2-2-financ
    - m1-2-3-letters-of-authorization**
    - m1-2-4-pate
    - m1-2-6-user
    - m1-2-7-cove
    - m1-2-8-waiv
  - m1-3-prescrib
    - m1-3-1-copy
    - m1-3-2-deba
  - m1-4-forms
    - m1-4-3-form
  - m1-5-labeling
    - m1-5-3-cont
  - m1-6-other
  - m2-common-techr
    - m2-2-introductio
  - m2-6-nonclinic
    - m2-6-4-phar
  - m2-7-clinical-s
  - m3-quality

**Information :**

Module

**Name :** m1-2-3-letters-of-authorization      **Product :** Cureall

**App No. :** 99999      **No. of Files (current) :** 1

**App Type :** NDA\_BLA      **No. of Modules (current) :** 0

**Applicant :** Demonstrator      **Original Application Submission Date :** 2000-04-03

**Viewer :**

**Files**

✓	TITLE	i	MODULE	SUBMISSION	STATUS	TYPE	SIZE
<input type="checkbox"/>	<a href="#">Authorization Letters</a>	i	m1-2-3-letters-of-auth...	0000	current		2 k

[Select All](#) | [Clear All](#)

First | Prev | 1 | Next | Last | All

Add to Queue | Cancel | Download Now

Applet gov.fda.ectd.review.common.ErsMain started

# eCTD Viewer System Overview

Request for Submission Processing - Microsoft Internet Explorer provided by Yahoo!

File Edit View Favorites Tools Help

Address <http://150.148.56.28/ectd/servlet/fda.cder.ectd.ui.SubmissionRequestServlet>

**eCTD Transformation Tool**

[Logout](#) [CDER](#) [FDA Home](#) [Links](#) [Help](#) [About](#)

**Server Status** [\[Submit\]](#) [\[Reset\]](#)

FDA Receive Date (MM/DD/YYYY)

**New Submissions** Selected EDR/Staging Server Directory:

Selected Application ID:

Selected Submission Serial Number(s):

Summary Information as Submitted:

Serial Number	eCTD File	FDA Regional File	Application ID	Applicant	Type	Product
[valid] 0001	<a href="#">ectd_0001.xml</a>	<a href="#">fda_regional_0001.xml</a>	771234	NovartisPharmaceuticalsCorporation	NDA	ReallyGoodI

[\[Submit\]](#) [\[Reset\]](#)

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# eCTD Future Directions

- **Future Versions**
  - FDA General Considerations for Viewing eCTD
- **Use of Backbone data to Populate FDA Databases**
- **Utilizes existing and future technologies to transport eCTD to agencies**
- **Leverage eCTD structure for other submission types where applicable**