



# eCTDGateKeeper™

## Safeguarding Your eCTD Submissions

Every sponsor organization would like to have a second verification of compliance before the submission is sent to the agency, either via media or through the gateway. It is every sponsor's goal to get it right the first time as any issues found at the agency, minor or major, could delay the review and approval process. This means a delay in patients' and physicians' access to new drugs as well as higher costs for the sponsor organization. Recognizing this need, Datafarm developed eCTDGateKeeper to validate all eCTD submissions created by any software application.

### CHECK AND DOUBLE CHECK

Validation of an eCTD is a very critical step within the regulatory submissions process. eCTDGateKeeper is a stand-alone, eCTD validation software solution ideal for providing Regulatory and Quality Assurance teams with an autonomous eCTD validation process completely separate from whichever eCTD assembly tool that is in use. Having two levels of validation provides added confidence and reduced risks for delivering electronic submissions.

### eCTDGateKeeper FEATURES

eCTDGateKeeper allows users to perform a complete or customized validation based on fully compliant validation rules. The following is just a sample of the features that eCTDGateKeeper provides:

- Validate directly from media
- Validate eCTD XML file(s) against the ICH DTD
- Validate regional XML files(s) against the corresponding regional DTD provided
- Validate files and folders provided against XML backbone references
- Validate that files provided in folder structure are referenced in the XML backbone files
- Verify PDF links and bookmarks

eCTDGateKeeper includes over 30 other validation rules that include ICH (Q36), and regional agency recommended validation rules.

Organizations cannot afford to take risks when the validity of a submission is critical to meeting compliance regulations – eCTDGateKeeper provides peace of mind at a cost-effective price.

### MULTI-REGION SUPPORT

In addition to compatibility with all eCTD assembly tools, eCTDGateKeeper offers a multi-region compliant validation capability and support. eCTD standard adoption is growing every day. Agencies around the world are accepting and, in some cases, requiring submissions in eCTD format. Regional agencies are issuing their own validation criteria in addition to the ICH validation requirements.

eCTDGateKeeper offers a multi-region compliant validation capability and supports the following:

ICH specifications:

- eCTD specifications
- ICH Study Tagging File (STF) specification

Regional Specifications:

- Canada (CA)
- Europe (EU)
- Japan (JP)
- USA (US)
- Swiss (CH)
- Taiwan (TW)

Datafarm is committed to supporting any new region as the specifications become available.



## ABOUT DATAFARM

Established in 1997, Datafarm is a world leader in high performance electronic submission solutions for the Life Sciences industry. Datafarm's open, modular technologies and professional services experts enable Life Sciences companies to meet the strict standards of regulatory authorities across the world, helping them achieve quality, accuracy, and compliance to efficiently deliver regulatory reports and submissions. Datafarm has helped hundreds of sponsor companies compress the regulatory submissions approval process, improving speed to market, cost control and productivity in order to achieve their ultimate goal of ensuring patients' and physicians' timely access to new drugs.

As a total solutions provider, Datafarm employs some of the industry's pioneers in document-based software development as well as world renowned life sciences regulatory specialists who proactively work with customers and business partners to drive new initiatives and maintain a market lead approach to development and services.

## GLOBAL LOCATIONS:

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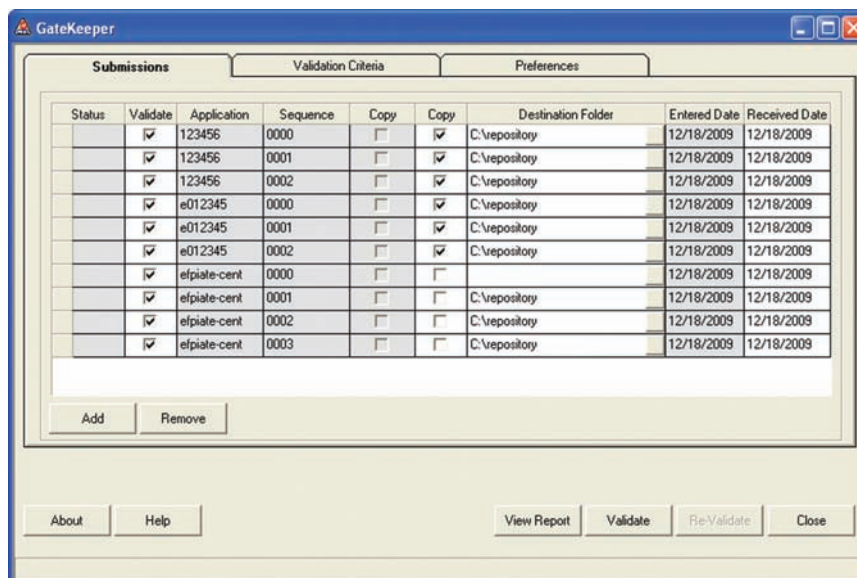
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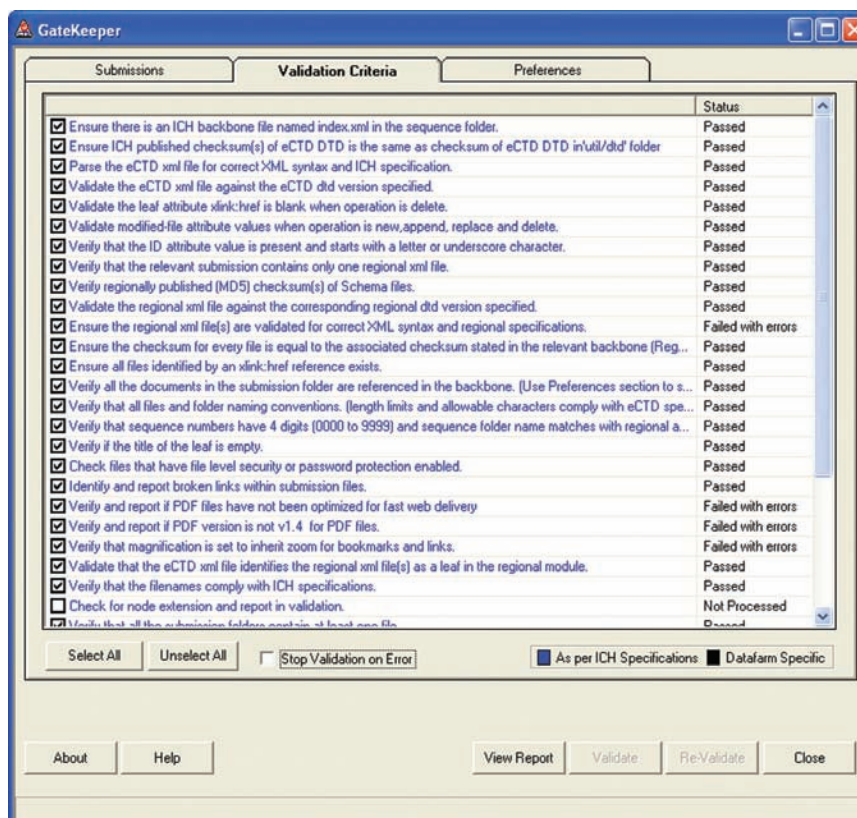
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Status	Validate	Application	Sequence	Copy	Copy	Destination Folder	Entered Date	Received Date
	<input checked="" type="checkbox"/>	123456	0000	<input type="checkbox"/>	<input checked="" type="checkbox"/>	C:\repository	12/18/2009	12/18/2009
	<input checked="" type="checkbox"/>	123456	0001	<input type="checkbox"/>	<input checked="" type="checkbox"/>	C:\repository	12/18/2009	12/18/2009
	<input checked="" type="checkbox"/>	123456	0002	<input type="checkbox"/>	<input checked="" type="checkbox"/>	C:\repository	12/18/2009	12/18/2009
	<input checked="" type="checkbox"/>	e012345	0000	<input type="checkbox"/>	<input checked="" type="checkbox"/>	C:\repository	12/18/2009	12/18/2009
	<input checked="" type="checkbox"/>	e012345	0001	<input type="checkbox"/>	<input checked="" type="checkbox"/>	C:\repository	12/18/2009	12/18/2009
	<input checked="" type="checkbox"/>	e012345	0002	<input type="checkbox"/>	<input checked="" type="checkbox"/>	C:\repository	12/18/2009	12/18/2009
	<input checked="" type="checkbox"/>	efpiate-cent	0000	<input type="checkbox"/>	<input type="checkbox"/>	C:\repository	12/18/2009	12/18/2009
	<input checked="" type="checkbox"/>	efpiate-cent	0001	<input type="checkbox"/>	<input type="checkbox"/>	C:\repository	12/18/2009	12/18/2009
	<input checked="" type="checkbox"/>	efpiate-cent	0002	<input type="checkbox"/>	<input type="checkbox"/>	C:\repository	12/18/2009	12/18/2009
	<input checked="" type="checkbox"/>	efpiate-cent	0003	<input type="checkbox"/>	<input type="checkbox"/>	C:\repository	12/18/2009	12/18/2009

An example of eCTDGateKeeper Validation Sequences



Validation Criteria	Status
<input checked="" type="checkbox"/> Ensure there is an ICH backbone file named index.xml in the sequence folder.	Passed
<input checked="" type="checkbox"/> Ensure ICH published checksum(s) of eCTD DTD is the same as checksum of eCTD DTD in util/dtd folder	Passed
<input checked="" type="checkbox"/> Parse the eCTD xml file for correct XML syntax and ICH specification.	Passed
<input checked="" type="checkbox"/> Validate the eCTD xml file against the eCTD dtd version specified.	Passed
<input checked="" type="checkbox"/> Validate the leaf attribute xlink:href is blank when operation is delete.	Passed
<input checked="" type="checkbox"/> Validate modified-file attribute values when operation is new,append, replace and delete.	Passed
<input checked="" type="checkbox"/> Verify that the ID attribute value is present and starts with a letter or underscore character.	Passed
<input checked="" type="checkbox"/> Verify that the relevant submission contains only one regional xml file.	Passed
<input checked="" type="checkbox"/> Verify regionally published (MD5) checksum(s) of Schema files.	Passed
<input checked="" type="checkbox"/> Validate the regional xml file against the corresponding regional dtd version specified.	Passed
<input checked="" type="checkbox"/> Ensure the regional xml file(s) are validated for correct XML syntax and regional specifications.	Failed with errors
<input checked="" type="checkbox"/> Ensure the checksum for every file is equal to the associated checksum stated in the relevant backbone (Reg...	Passed
<input checked="" type="checkbox"/> Ensure all files identified by an xlink:href reference exists.	Passed
<input checked="" type="checkbox"/> Verify all the documents in the submission folder are referenced in the backbone. (Use Preferences section to s...	Passed
<input checked="" type="checkbox"/> Verify that all files and folder naming conventions. (length limits and allowable characters comply with eCTD spe...	Passed
<input checked="" type="checkbox"/> Verify that sequence numbers have 4 digits (0000 to 9999) and sequence folder name matches with regional a...	Passed
<input checked="" type="checkbox"/> Verify if the title of the leaf is empty.	Passed
<input checked="" type="checkbox"/> Check files that have file level security or password protection enabled.	Passed
<input checked="" type="checkbox"/> Identify and report broken links within submission files.	Passed
<input checked="" type="checkbox"/> Verify and report if PDF files have not been optimized for fast web delivery	Failed with errors
<input checked="" type="checkbox"/> Verify and report if PDF version is not v1.4 for PDF files.	Failed with errors
<input checked="" type="checkbox"/> Verify that magnification is set to inherit zoom for bookmarks and links.	Failed with errors
<input checked="" type="checkbox"/> Validate that the eCTD xml file identifies the regional xml file(s) as a leaf in the regional module.	Passed
<input checked="" type="checkbox"/> Verify that the filenames comply with ICH specifications.	Passed
<input type="checkbox"/> Check for node extension and report in validation.	Not Processed
<input checked="" type="checkbox"/> Verify that all the submission folders contain at least one file.	Passed

An example of eCTDGateKeeper Validation Criteria

## TRUST IN A PARTNER THAT DELIVERS – eSUBMISSIONS MADE EASY

Datafarm approaches each client as a partner to create the optimum solution for each specific business challenge. With more than a decade of experience in eSubmissions software and services, Datafarm has partnered with hundreds of life science companies to help ensure compliant eSubmissions. Whether the organization needs software, services or a combination of the two, Datafarm will help design a comprehensive, cost-effective solution.