The Road to **DMF** Readiness

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compliance delivered

Make your plan well in advance!

The Solution

1. Identify Your Requirements & Next Steps

What DMF types do exist?	
Type I (no longer applicable)	
Type II Drug Substance, Drug Substance Intermediate, and Material Used in Their Preparation, or Drug Product	
Type III Packaging Material	
Type IV Excipient, Colorant, Flavor, Essence, or Material Used in Their Preparation	
Type V FDA Accepted Reference Information	
Check list	Description
What type of DMF filing is planned?	Type II to Type V
What is a document management system?	Document management is in place to maintain documents and versions
Software availability?	Do you have software or you are going to outsource
Validator availability?	Which validator to use for compiled output?
ESG* account is setup?	Do you have an ESG account or do you need to start a process for setting it up?

* ESG – European Submission Gateway

Many new requirements, concepts and terminology

2. Understand the eCTD & Submission Process

Check list	Description
Are your documents ready?	Are they available or pending? Paper needing to be scanned? Electronic already? Following CTD document granularity?
Which CTD sections apply to your type of DMF?	Different DMF Types utilize different sections of the eCTD
Electronic Submission Gateway requirements	The FDA's ESG has specific requirements
Electronic Submission Gateway set-up/registration	Give yourself enough time to get registered as it can sometimes take up to 30 days
Understanding compliance from Gateway	Know how to interpret responses from the FDA that are returned from the ESG

Follow FDA's suggestions & give yourself plenty of time

3. Prepare Your Sample ESG Submission & Submit via ESG

Check list	Description
Follow the recommendations from the FDA	Sample submission checklist outlines all possibilities but you need to adapt for your particular type of DMF
Ensure your submissions are accepted once FDA verifies you sample submission	Formal submissions cannot be sent until successful sample submission acceptance (can take up to 30 days)

Your successful transition to eCTD

4. Prepare and submit your DMF

Check list	Description
Organize your documents	Is your metadata complete? Are your documents in English? Are any documents scanned PDFs?
Build your submission & test output	Assign documents to proper folders Ensure bookmarks & hyperlinks are in place. Enter appropriate envelope information. Test output with agency validator. Correct errors
Build your final submission output	Generate final output and allocate sequence number
Transmit your final submission through ESG	Send your submission to the FDA
Understanding acknowledgements from Gateway	Receive response from ESG regarding acceptance

Understand your schedule

5. Manage eCTD Lifecycle

Check list	Description
Health authority correspondence	Ensure timely response or actions to divisions and/ or approval letters
Amendments	Only send new or updated information; do not resend previously submitted files
Letters of Authorization	Have a plan for how and when to submit
Annual Reporting	Know your schedule of annual reports

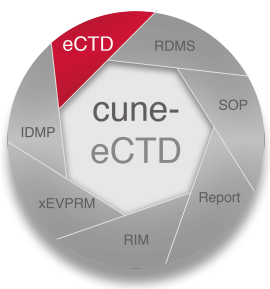
You need the right
People

- Extensive Regulatory Expertise
- Real Life Experience

You need the right
Process

- Speedy implementation
- Live training
- Compliance Guarantee

You need the right
Product



- Easy to use
- Built for eCTD
- Always up-to-date

Request a Demo

info@cunesoft.com

Additional Resources:

https://www.lorenz.cc/eSolutions/eValidator/
http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/
http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM514329.pdf