

## **eCTD OUTSOURCE PUBLISHING PROJECT QUESTIONNAIRE**

*e-SubmissionsSolutions.com will not supply a cost estimate unless there is a fully-executed Mutual Non-Disclosure Agreement (MNDA). The e-SubmissionsSolutions.com agreement accompanies this form and must be completed and returned to: [AAzevedo@e-SubmissionsSolutions.com](mailto:AAzevedo@e-SubmissionsSolutions.com).*

*If your company requires the use of its own agreement, the information needed to prepare the agreement appears below.*

**Company name:** e-SubmissionsSolutions.com

**Company status:** California subchapter 's' corporation

**Place of business:** 3519 Eugene Place, San Diego, CA 92116

**Signer:** Antoinette Azevedo **Title:** President & CEO

Please send the MNDA with this questionnaire to  
[AAzevedo@e-SubmissionsSolutions.com](mailto:AAzevedo@e-SubmissionsSolutions.com):

**Does your company accept a digital electronic signature on the MNDA?**

Yes

No

I don't know

**PLEASE SEND THE COST ESTIMATE TO:**

**Name** \_\_\_\_\_

**Title** \_\_\_\_\_

**Company** \_\_\_\_\_

**Street Address** \_\_\_\_\_

**City/State/Zip Code** \_\_\_\_\_

**Direct Telephone #** \_\_\_\_\_ **Mobile Telephone #** \_\_\_\_\_

**eMail Address** \_\_\_\_\_

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## 1 PROJECT CODE NAME/DRUG PROJECT NUMBER

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## 2 MY COMPANY HAS COMPLETED AN eCTD READINESS ASSESSMENT

- Yes
- No
- I don't know

## 3 WHAT TYPE OF SUBMISSION DO YOU WANT PRODUCED?

- Presubmission meeting request
- Presubmission briefing booklet
- Annual report
- Initial CTA  CTA Supplement/Amendment - if so # of prior sequences \_\_\_\_\_
- Initial IND  IND Supplement/Amendment - if so # of prior sequences \_\_\_\_\_
- Initial MAA  MAA Supplement/Amendment - if so # of prior sequences \_\_\_\_\_
- Initial NDS  NDS Supplement/Amendment - if so # of prior sequences \_\_\_\_\_
- Initial NDA  NDA Supplement/Amendment - if so # of prior sequences \_\_\_\_\_
- Initial BLA  BLA Supplement/Amendment - if so # of prior sequences \_\_\_\_\_
- Initial ANDA  ANDA Supplement/Amendment - if so # of prior sequences \_\_\_\_\_
- Initial DMF  DMF Supplement/Amendment - if so # of prior sequences \_\_\_\_\_
- Initial ASMF  ASMF Supplement/Amendment - if so # of prior sequences \_\_\_\_\_
- Other \_\_\_\_\_
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#### 4 WHAT IS THE SIZE OF YOUR PROJECT?

Module #	# Pages			# Datasets	# CRF Pages
	Paper	PDF*	Other electronic format**		
1				N/A	N/A
2				N/A	N/A
3				N/A	N/A
4					N/A
5					

\*Fully-compliant with target health authority PDF specifications

\*\*Non-compliant PDF, MS Word, RTF, ASCII, HTM, Excel, PowerPoint, etc.

#### 5 MY PROJECT WILL NEED PAPER VOLUMES?

- Yes
- No
- I don't know

#### 6 MY PROJECT WILL NEED WORD PROCESSING SERVICES?

- Yes
- No
- I don't know

#### 7 MY PROJECT WILL NEED PDF CONVERSION & REMEDIATION SERVICES?

- Yes
- No
- I don't know

#### 8 WHAT IS THE TIMELINE FOR YOUR PROJECT?

Date *first complete* eCTD module is available \_\_\_\_\_

Date *last final document* is available \_\_\_\_\_

Target *date of submission* to health authority \_\_\_\_\_

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**9 WHICH OF THE FOLLOWING DOES YOUR COMPANY NEED IMPLEMENTED?**

- Company-specific email address (not allowed: gmail, yahoo, hotmail, etc.)
- Digital certificates
- Secure email with FDA
- Electronic signature policies & procedures
- FDA Electronic submission gateway (ESG) production account
- EMA Electronic submission gateway (ESG) production account
- Health Canada Electronic submission gateway (ESG) production account
- Agent to submit via Agent's own electronic submission gateway(s)

**10 DOES YOUR COMPANY HAVE AN ELECTRONIC DOCUMENT MANAGEMENT SYSTEM?**

- Yes
- No
- I don't know

**11 DOES YOUR COMPANY OBJECT TO USING E-SUBMISSIONSSOLUTIONS.COM'S SHAREPOINT SYSTEM?**

- Yes
- No
- I don't know

**12 DOES YOUR COMPANY HAVE eCTD TEMPLATES?**

- Yes
  - No
  - I don't know
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**13 DOES YOUR COMPANY HAVE eCTD VALIDATION+VIEW SOFTWARE?**

- Yes
- No
- I don't know

**14 DOES YOUR COMPANY HAVE PRIOR EXPERIENCE WITH eCTD FORMAT?**

- Yes
- No
- I don't know

**15 HAS YOUR COMPANY EXPERIENCED ANY OF THE FOLLOWING?**

- Refuse to receive (submission fails initial validation)
  - Refuse to accept (passes initial validation but health authority found other technical issues with electronic format)
  - Refuse to file (submission incomplete for review)
  - None of the above
  - Other \_\_\_\_\_
  - I don't know
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## 16 WHAT TRIGGERS YOUR COMPANY'S NEED FOR eCTD SERVICES?

- Health Authority requires eCTD format
  - Purchased/licensed-in drug project with prior sequences in eCTD format
  - My company wants to explore the cost of eCTD compared with current submission processes and formats
  - My company wants to gain eCTD experiences on small submissions first
  - My company has committed to the eCTD format
  - I don't know
  - Other \_\_\_\_\_
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## 17 MY ROLE IN INQUIRING ABOUT eCTD PUBLISHING SERVICES?

- I am a consultant working in behalf of a client
- I am a CRO needing outsource publishing services
- I am an administrative assistant
- I am collecting information for the decision-maker
- I am a decision-maker about my company's strategy for eCTD publishing
- I don't know

## 18 MY COMPANY HAS BUDGETED FOR eCTD PUBLISHING SERVICES?

- Yes
  - No
  - I don't know
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