

Dossier-Mgmt[®] - Pre-Quotation Form

Please fill the details in the table below as per your eCTD requirements.

Note: Pl. enable the active content for this document by clicking on the <options> button which appears on the word menu bar above (As a Security warning) when you open the document for the first time.

S.No	Details	Options
1.	Currently in which format do you send submissions or are planning to send?	
2.	Which countries do you plan to send eCTD submissions?	
2A.	Submission Publishing Tool (SPT) Note: This tool verifies and corrects most of the pdf document properties according to Regulatory PDF specifications; along with add-on features which aid during Hyperlink Process	
3.	Do you require the software to manage submissions for Rest of World (ROW) countries? If Yes, Please mention the countries in the text box.	<input checked="" type="radio"/> Yes <input type="radio"/> No <div style="border: 1px solid black; height: 40px; margin-top: 10px;"></div> <p>e.g. Egypt, Saudi Arabia etc..</p>
4.	Do you have submissions for APIs or Formulations or both?	<input type="checkbox"/> API <input type="checkbox"/> Formulations
5.	Do you have BA/BE data for your products?	<input type="radio"/> Yes <input type="radio"/> No
6.	How many eCTD submissions do you plan in a year?	Enter no of submissions in the text box below <div style="border: 1px solid black; height: 20px; width: 100px; margin-top: 5px;"></div>
7.	How many users plan to use the software?	Enter no of users in the text box below <div style="border: 1px solid black; height: 20px; width: 100px; margin-top: 5px;"></div>
8.	Do you already have eCTD submissions done by third party software which you need to migrate? If yes give number of submissions including amendments i.e. total number of higher sequences?	<input type="radio"/> Yes <input type="radio"/> No Number of eCTD Submissions to be migrated:

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S.No	Details	Options
		No. of Submissions : <input type="text"/> No. of higher Sequences : <input type="text"/>
9.	Are you planning to use the software from single or multiple locations? If you are planning for multiple locations then mention no of users who are going to use from different locations.	<input type="radio"/> Single <input type="radio"/> Multiple Enter No. of users from different Locations in the text box below <div style="border: 1px solid black; height: 70px; width: 100%;"></div> E.g. Mumbai – 2users UK – 5 users
10.	Do you plan to buy software for managing Package Inserts? (Send package insert data in xml format using SPL standard to USFDA)?	<input type="radio"/> Yes <input type="radio"/> No
11.	Name of the Company under whose name the submissions will be sent. If you have any sister concerns or subsidiaries in whose name you want to file the submission then Pl. mention them separately as Additional Applicant names. Please provide DUNS number for each Applicant name as it is required for US submissions.	Enter the name of the company below: <div style="border: 1px solid black; height: 20px; width: 100%;"></div> Enter Additional Applicant names needed in the text box below <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
12.	Are you planning to send the Veterinary submissions? If yes, in which countries?	