

# Electronic Submissions for CEP applications

EDQM Webinar

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# Agenda

- eSubmissions Roadmap for CEP applications with its major changes to current practices and key deadlines
- How to submit CEP applications in electronic format
- Baseline submissions
- New EU module 1 specifications version 3.0 for eCTD
- New version 2.0 of the Common European Submission Portal (CESP)

# EDQM eSubmissions Roadmap - Goals



- Efficient and secure electronic handling of data related to CEP applications (submission, reception, validation, processing)
- Fully electronic processing without paper or any physical media
- Automation of data transfer and storage
- Alignment with practice in place in regulatory agencies for eSubmission of marketing authorisation applications

# eSubmission Roadmap (1)

Topic	Objectives	Time-frames
Submission format and content	Single format for submission of data: eCTD (except for TSE only submissions and for submissions for substances for veterinary use only)	2020
Receipt and validation of data	Automation of data transfer and storage, reduction of manual handling and checks	2017/ 2018

# eSubmission Roadmap (2)

Topic	Objectives	Time-frames
Application form	Implement e-Application form/ upload of electronic information	2018
Submission Media	Single and secure entry point for eSubmission of data: CESP, or alternatively an EDQM dedicated portal	January 2017
Use by assessors	Full use of review tool	2017/ 2020

# Submission format and content

Timeframe	Actions
June 2016	No further acceptance of paper submissions for any kind of application (including TSE only submissions)
January 2017	Require eCTD submissions for new applications
January 2018	Stop accepting PDF submissions for revisions and renewals. Therefore, all such submissions need to be in NeeS or eCTD format
January 2020	Require eCTD submissions for all applications



# How to send a PDF submission

Annex 5 of the esubmission guidance:

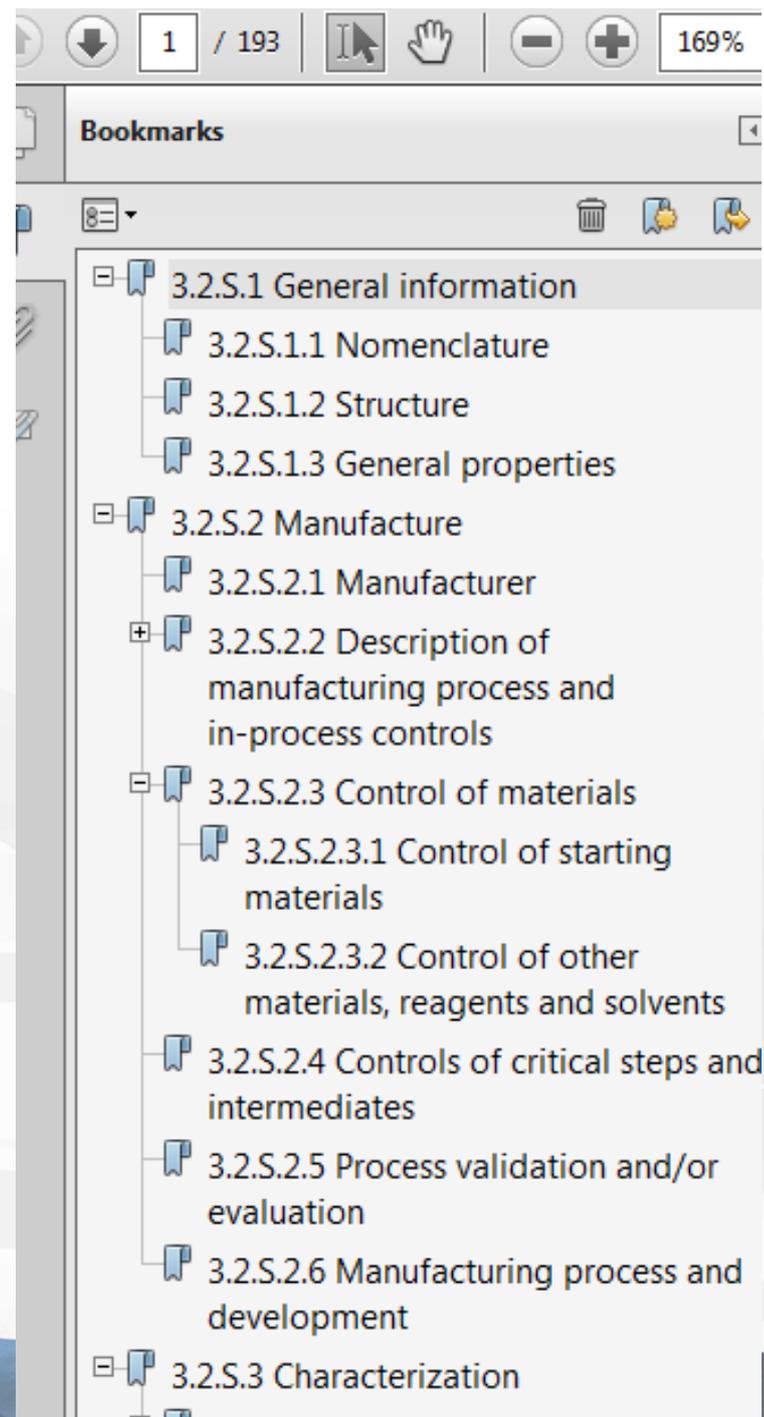
[https://www.edqm.eu/sites/default/files/guidance\\_for\\_esubmissions\\_for\\_cep\\_applications\\_june\\_2016.pdf](https://www.edqm.eu/sites/default/files/guidance_for_esubmissions_for_cep_applications_june_2016.pdf)

- For module 1: one or several PDF files
- For module 2: single PDF file
- For module 3: single PDF file, including bookmarks named according to CTD requirements and appropriate naming convention. The structure given in annex 2 has to be applied.

# Bookmarks

For your help, please see the following page, where bookmarks are described:

<https://helpx.adobe.com/acrobat/using/page-thumbnails-bookmarks-pdfs.html>





# How to send a NeeS submission

## Annex 4 of the esubmission guidance:

[https://www.edqm.eu/sites/default/files/guidance for esubmissions for cep applications june 2016.pdf](https://www.edqm.eu/sites/default/files/guidance%20for%20esubmissions%20for%20cep%20applications%20june%202016.pdf)

- A table of content with hyperlinks towards each file should be placed within the sequence

## TIGes/CMB harmonised NeeS guidance:

[http://esubmission.ema.europa.eu/tiges/docs/NeeS%20eGuidance%20Document%20v4%2002 final%20for%20publication%20Nov%202013.pdf](http://esubmission.ema.europa.eu/tiges/docs/NeeS%20eGuidance%20Document%20v4%2002%20final%20for%20publication%20Nov%202013.pdf)

# How to send an eCTD submission

## Annex 3 of the esubmission guidance:

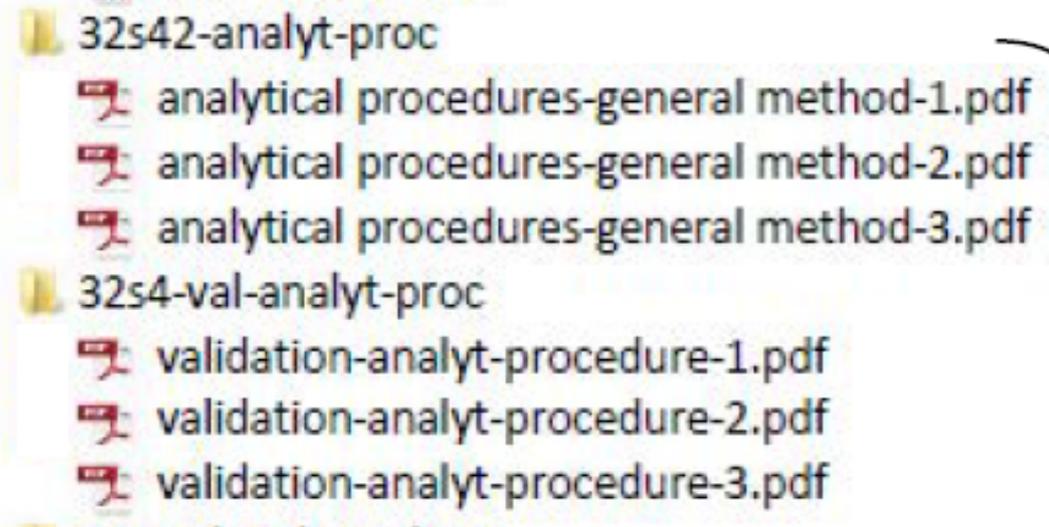
[https://www.edqm.eu/sites/default/files/guidance for esubmissions for cep applications june 2016.pdf](https://www.edqm.eu/sites/default/files/guidance%20for%20esubmissions%20for%20cep%20applications%20june%202016.pdf)

- Before submitting to EDQM, your submission should be technically validated with an appropriate validation tool
- The operation attributes chosen should be appropriate to allow the lifecycle of the submission

0001	 Replace	3.2.S.2.3 -Control of Materials Pages:165 Version:	
0000	 New	3.2.S.2.3 -Control of Materials Pages:164 Version:	

# How to send an eCTD submission

- Once eCTD – always eCTD: coming back to a previous submission format is not allowed
- For each update a new sequence 000(X+1) should be provided
- For some sections, a multiple file approach can be used, but there are limitations to the number of files included in one section





# How to avoid common format errors

- Use the CESP, do **not** send documentation via email
- Annexes/attachments are not allowed in module 3
- Coming back to previous submission format is not allowed
- All files should be in PDF



# Baseline Module 3

- Consolidated picture of all the CTD sections already assessed and approved
- Facilitates the management of the lifecycle for the applicant and EDQM
- highly recommended when switching from
  - paper to an e-submission
  - PDF/NeeS to an eCTD
- Baseline should be submitted at the start of a procedure
  - either as a separate sequence (preferred option)
  - or with revision/renewal included

# EU Module 1 eCTD specification

## Version 3.0 as of July 2016

- Country code (cc): **edqm**
- EU-envelope:
  - Country: **edqm**
  - Submission type: **cep**
  - Submission number: **cep application number if known**
  - Agency code: **EU-EDQM**
  - Procedure: **centralised**



# CESP version 2.0

- Connect to the CESP: <http://cespportal.hma.eu/>
- Step A – Preparation of Delivery file:

**Area:** EDQM

**Regulatory activity:**

- Request for new CEP
- Notification/revision/renewal
- Response to request for additional information
- EDQM inspection
- Other (e.g. submission of information not requested by EDQM)

**Comment:** CEP number, substance name

**Zip File Types**

## New Delivery File

Step 1 Step 2

Company \*

\_CESP TEST Company

Area \*

EDQM

Regulatory Activity \*

Request for new CEP

Sub Activity \*

H001 Not Applicable

Zip File Type \*

-- Select --

Comment

Place comments here concerning your dossier.

# Preparation of delivery file

- Please ensure that “**EDQM**” is selected. Once you have selected “EDQM”, click “**Submit**” which will present the “**Delivery Note Download**” page.

New Delivery File

Step 1 Step 2

Concerned Member State \*

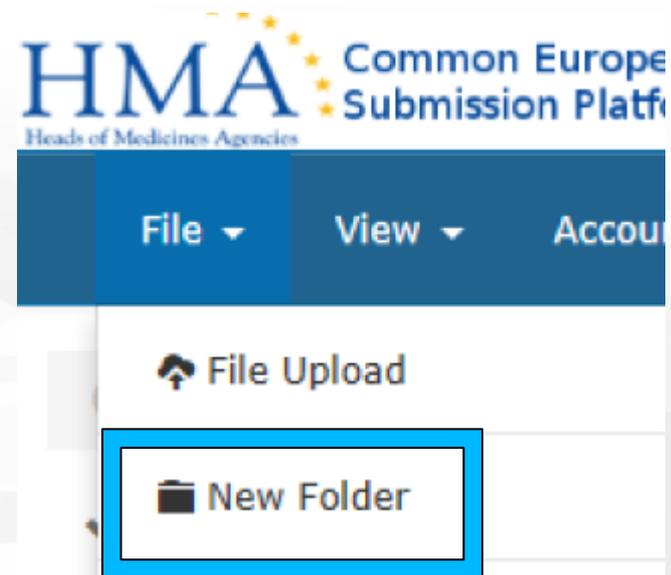
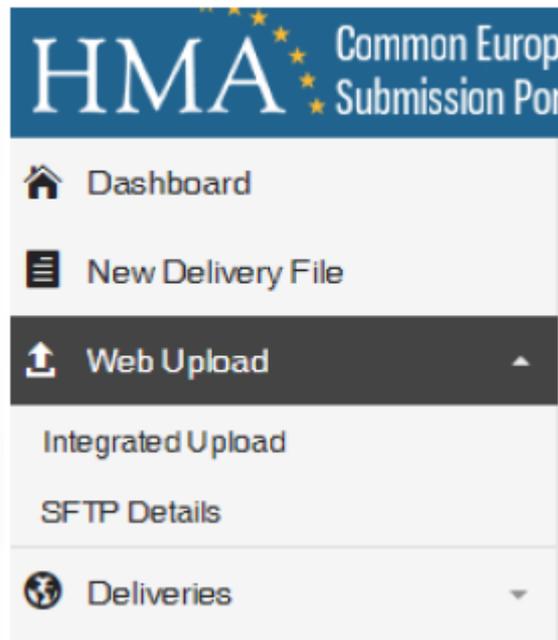
 EDQM

Additional Email Addresses

Email

# Step B– Transfer to CESP

Web based file transfer:



# Transfer to CESP

- Before progressing to the next step, ensure that ALL files have been completely uploaded, i.e. "completed".
- Then select the delivery file and drag it into the same folder. Moving the delivery file to the folder in the transfer pane on the right will trigger the sending of the submission to CESP.

My Folders / CESP test submission

My Folders

- My Folders
  - CESP test submission**

Name	Size	Date
<input type="checkbox"/> CESP_Submission_286015.xml	1.63 KB	2/2/2016
<input type="checkbox"/> test.zip	10.22 KB	2/2/2016

Transfers

- Completed - 2
- In Progress - 0
- No files in this activity zone
- Pending - 0
- No files in this activity zone

# Confirmation of CESP submission

After the submission has been sent, you will receive two emails:

- Firstly, you will receive an email to confirm that the submission has been uploaded to the CESP server
- Secondly, you will receive an email to confirm that the submission has been delivered to EDQM



**CESP support: [cesp@hma.eu](mailto:cesp@hma.eu)**



# Useful links

- **Guidance for electronic submissions for Certificates of Suitability (CEP) applications**

[https://www.edqm.eu/sites/default/files/guidance\\_for\\_esubmissions\\_for\\_cep\\_applications\\_june\\_2016.pdf](https://www.edqm.eu/sites/default/files/guidance_for_esubmissions_for_cep_applications_june_2016.pdf)

- **EDQM helpdesk**

<https://www.edqm.eu/en/faq-helpdesk-certification-and-ceps>

- **EU esubmission website**

<http://esubmission.ema.europa.eu>

- **ICH website**

<http://www.ich.org/home.html>

- **CESP**

<http://cesportal.hma.eu/>

