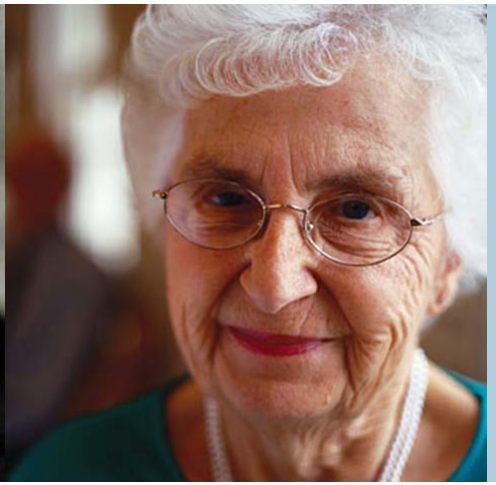
Common Electronic Submissions Gateway – Operational Considerations

Presentation to CAPRA

April 30th, 2014





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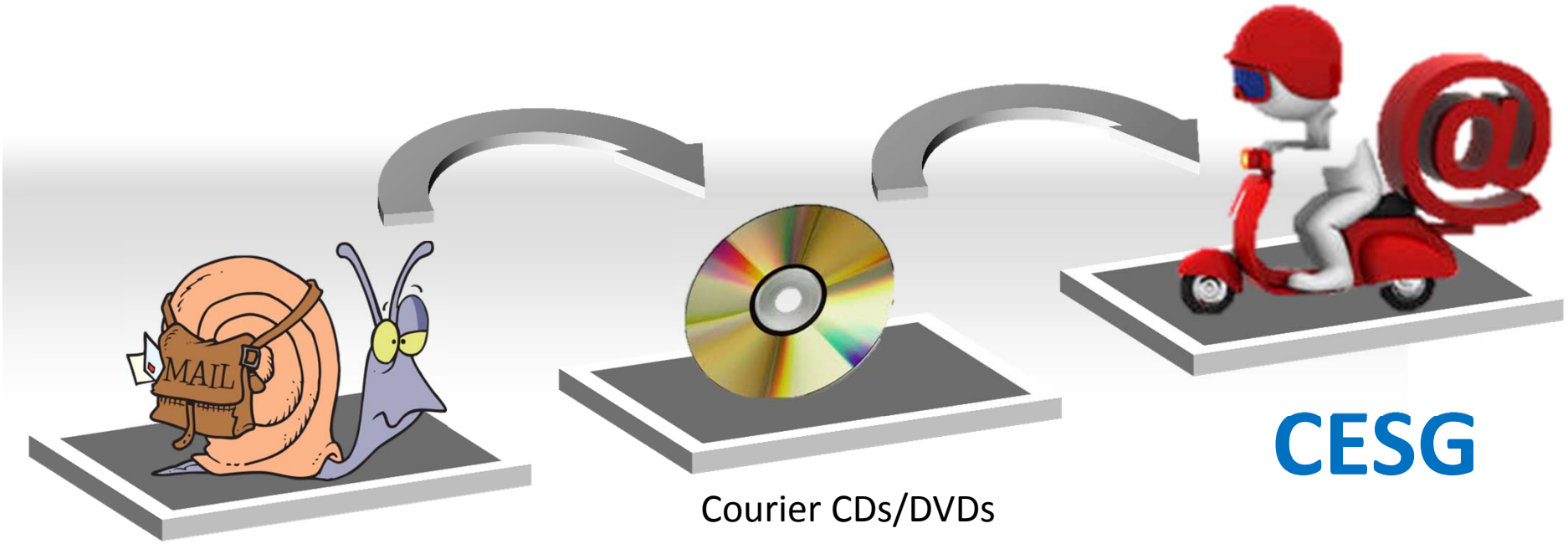
Agenda

- Evolution of Submission Methods
- CESG: Submission Options and Architecture
- E-Signatures
- How To: Register and Use
- Scope and Operational Considerations
- Lessons Learned
- RSS Feed and Who to Contact

Evolution of submission methods

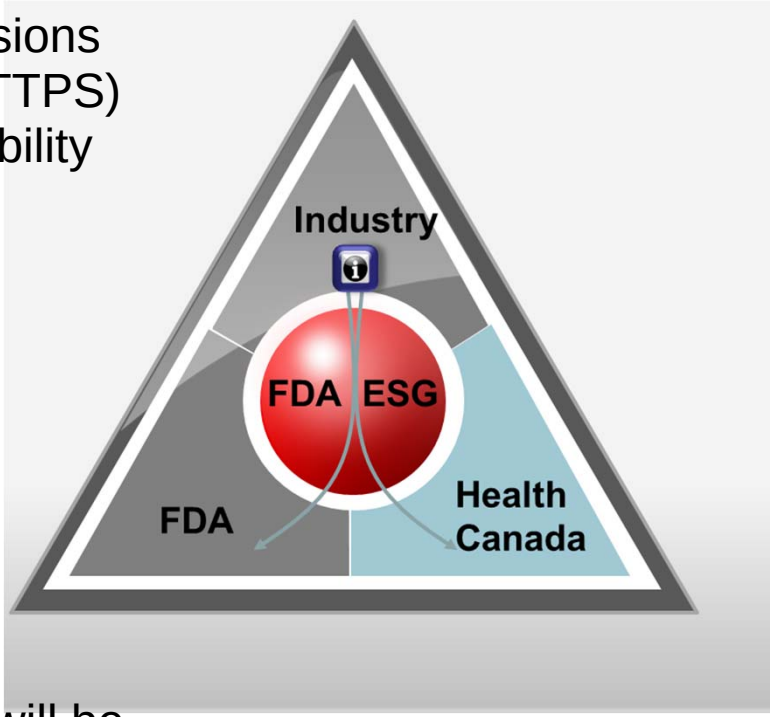


"Snail mail"
paper submissions

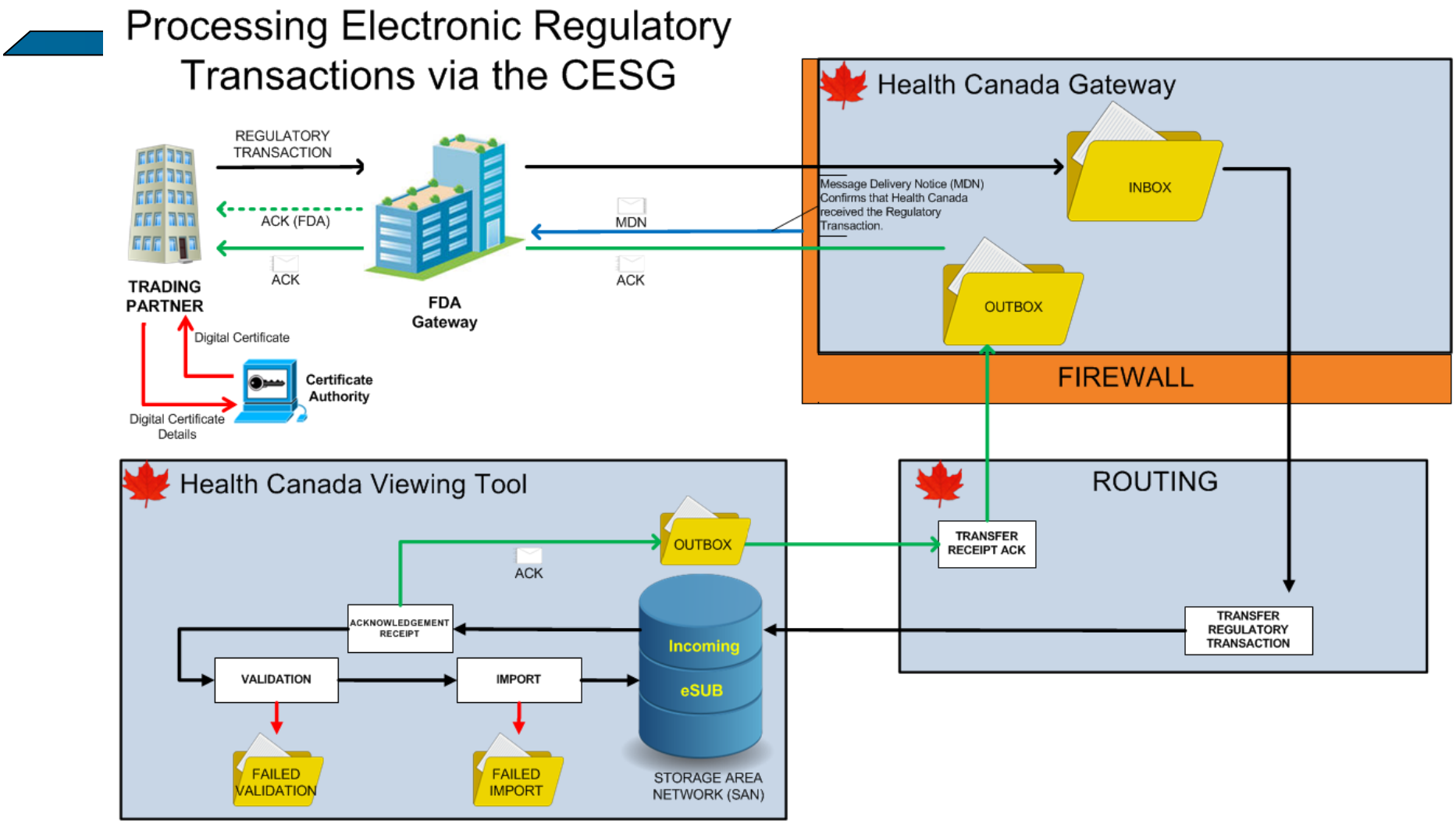
Courier CDs/DVDs

Common Electronic Submissions Gateway – Submission Options

- **FDA ESG Web Interface (WebTrader)**
  - The FDA ESG Web Interface sends submissions via Hyper Text Transfer Protocol Secure (HTTPS) through a web browser according to Applicability Statement 2 (AS2) standards.
  - Low cost option
- **Gateway to Gateway (AS2)**
  - Applicability Statement 2 (AS2) Gateway-to-Gateway
    - An electronic submission protocol that uses HTTP/HTTPS for communications.
  - Attribute/Header and routing ID information will be used to route submission
  - Requires an AS2 compliant gateway software



Architecture of the CESG



E-Signature Policy

eSignature Policy Requirements

- To meet evidentiary requirements for submissions through the ESG,

  HC needs to be able to:

  - Capture the intention to authenticate a submission;
  - Identify the sender of a submission;
  - Ensure the integrity of the data;
  - Ensuring the sender is prevented from denying that he or she sent the document

- Based on requirements it is deemed that a digital signature is required for CESG.
- E-Signature guidance is included in new eForms Primer document that will be published soon

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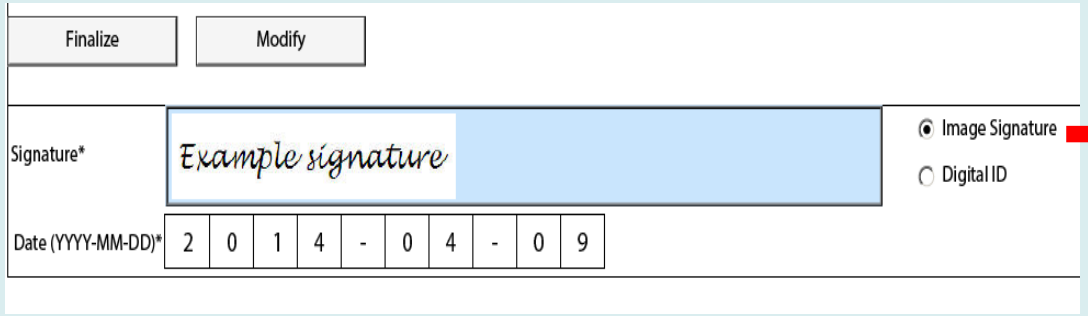
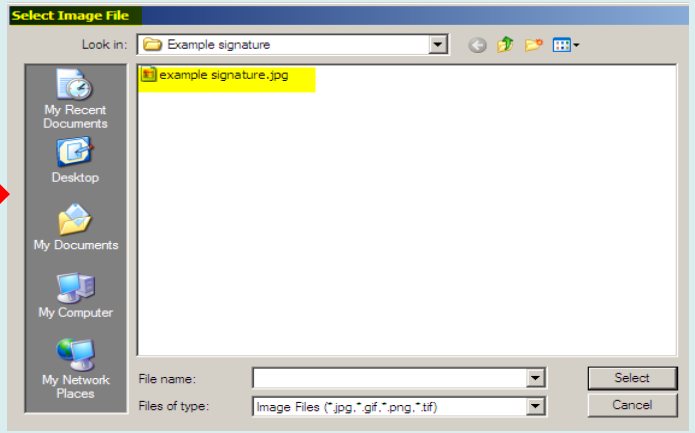
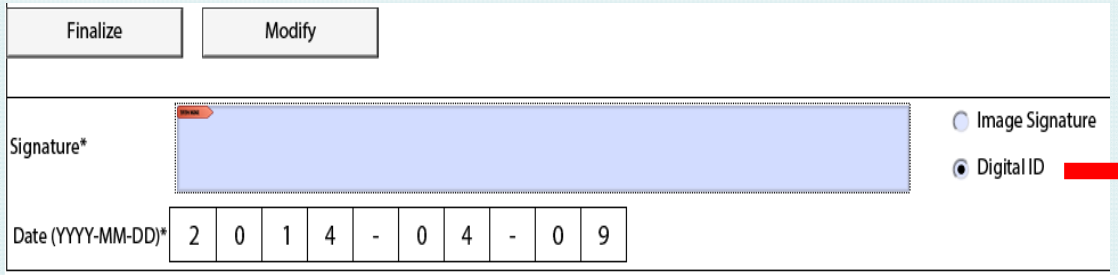
E-Signature - Examples

Image Signature





Digital ID



How to: Register as a Trading Partner

- Registration as Trading Partner occurs **with the FDA**

WebTrader

- Web-based Interface
- More straightforward setup and configuration
- Refer to sections 2 and 4 of FDA ESG User Guide

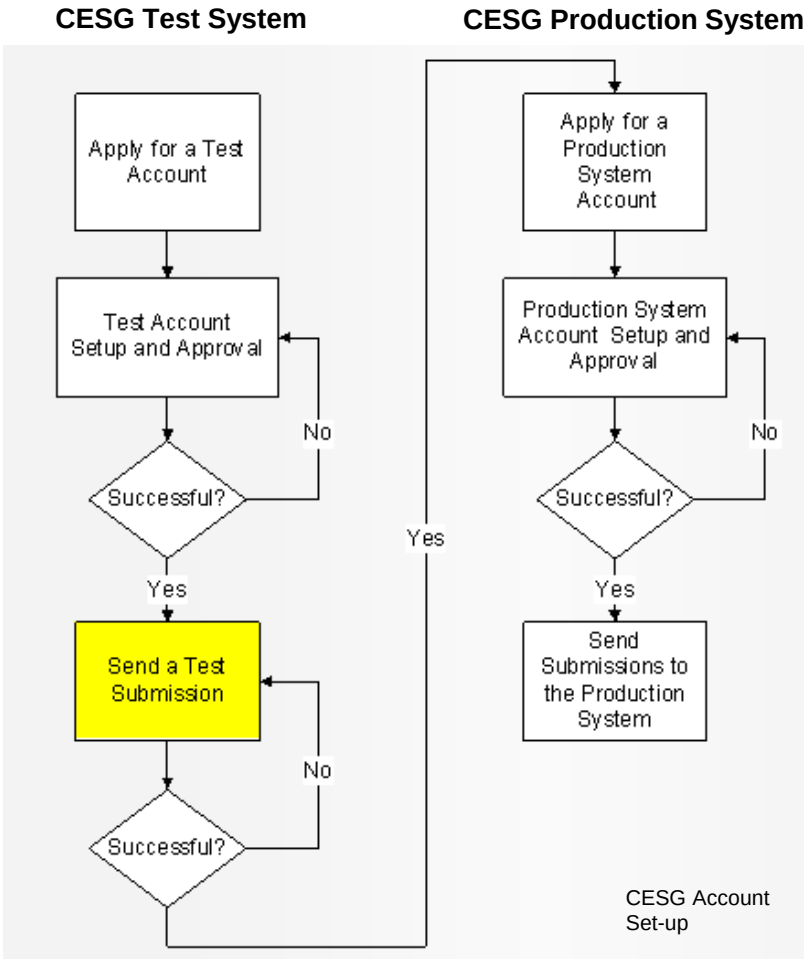
AS2

- Gateway-to-Gateway Interface
- Configuration and set-up more complex
- Refer to sections 2 and 5 of FDA ESG User Guide

Stay in touch with your IT team during set-up!!

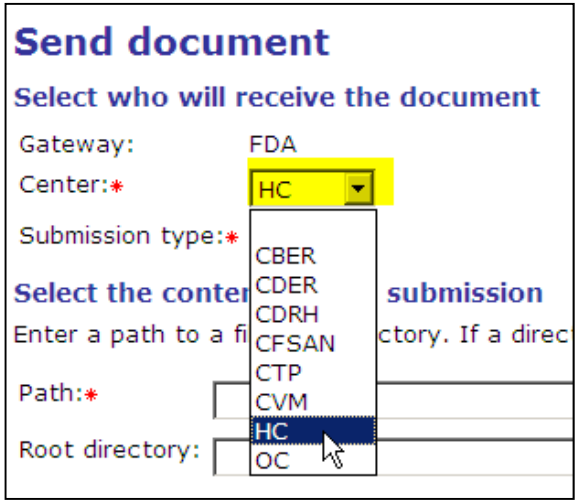
How to: Register as a Trading Partner

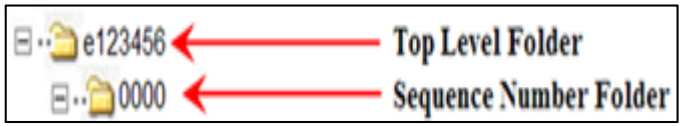
- Test Submissions for New Accounts
  - Minimum requirement: only need to send test submissions to a single center (e.g HC)
  - Recommendation: send a test submission to each centre you will be submitting to. This ensures your files are constructed correctly for each centre.
- Existing FDA ESG Trading Partners do not need a new account



How to: Use the CESG

- Same process as if you were sending to the FDA
- Health Canada (“HC”) selected as the “Centre” and your regulatory transaction will be automatically redirected
- Ensure that all regulatory transactions are in eCTD format and have the Top-Level Folder is included in the folder structure





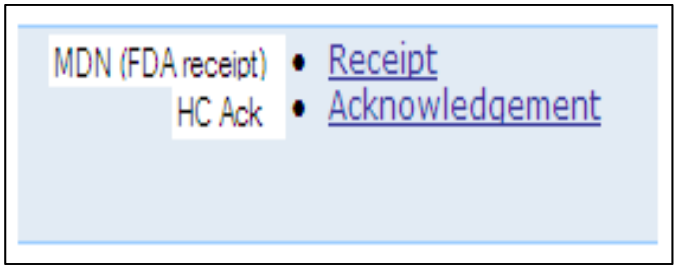
How to: Use the CESG

- Receive 2 notices when you submit to the “HC” Centre:
  1. FDA Message Delivery Notification (MDN)

     The FDA portion has successfully received your transaction
  2. Health Canada Acknowledgement Receipt

     The Health Canada portion has successfully received your transaction

- How the 2 messages appear in your inbox:



CESG: An Electronic Courier

- Documents sent to Health Canada via the CESG are not accessed nor opened by the FDA.
- The FDA ESG, also known as the Common Electronic Submissions Gateway (CESG), does not keep copies of submissions targeted for receipt by Health Canada for any duration of time.
- Essentially, the CESG is an **electronic courier**

Scope CESG: eCTD Regulatory Transactions

- Response to a Clarification Request;
- Periodic Safety Update Report (PSUR) requested during the pre-market review process by Therapeutic Products Directorate (TPD) and Biologics and Genetic Therapies Directorate (BGTD);
- Comments to the Summary Basis of Decision
- Pristine Product Monograph;
- Second Language Product Monograph;
- Drug Notification Form (DNF)
- Post-Notice of Compliance (NOC) Changes: Level III

Scope CESG: eCTD Regulatory Transactions

Proposed Updates

- Additional Information:
  - Solicited Information such as Response to a Clarification Request; Response to Telephone Request, Response to email Request, Response to Screening Acceptance Letter,
  - Unsolicited information such as safety information and changes in the name of the sponsor or product during review
  - Note: For more details about solicited and unsolicited information, see Section 5.5, “Evaluation of Submissions,” in Health Canada’s Guidance for Industry: Management of Drug Submissions
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- Comments to the Summary Basis of Decision
- Pristine Product Monograph
- Second Language Product Monograph
- Drug Notification Form (DNF)
- Post Clearance Data
- Minutes of Meeting (pre-submission meeting NON meeting NOD meeting etc.)
- Cancellation Letter

FEEDBACK?

Operational Considerations

- Internal operational process and policy changes required adjustment in order to accept eCTD transactions through the CESG.

Folder structure

- Consultation with On-boarding participants regarding folder structure options to minimize “exceptions” in HC Acknowledgement Receipts
- Based on feedback received a suggested folder structure has been published when submitting regulatory transactions in eCTD format via CESG

Operational Considerations

- Internal operational process and policy changes required adjustment in order to accept eCTD transactions through the CESG.

eForms – eCTD Module 1 Validation

- New eForms are encrypted, and will be accepted when electronically submitted in eCTD format for Module 1.
  - Will allow PDF forms to be accepted with warnings
- "eForms" Primer document will be published
- Adjustments allowed for roll-out of CESG with defined regulatory transactions (e.g. Clarifax responses, Pristine Product Monographs etc.)

Lessons Learned

- CESG project team has considered many valuable lessons from the Pilot and On-boarding experiences
  - A clear process for communication between CESG team and trading partners e.g. failed transmissions or outages, support model considerations
  - Implementation of HPFB eSignature policy for CESG business processes
  - **Continued industry participation** and a **phased approach** are important to effectively roll out the CESG across eCTD regulatory activities and transactions.

- Lessons learned inform FAQs posted on the CESG webpage. We continue to encourages industry input and feedback.

CESG RSS Feed

- The HC CESG team invites you to subscribe to the CESG RSS Feed to stay informed on:
  - Gateway Functionality
  - Scope changes
  - CESG Webpage updates

- Visit http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/cesg-pcde/index-eng.php or http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/cesg-pcde/index-fra.php to for more information

Who to Contact and When?

FDA Contacts

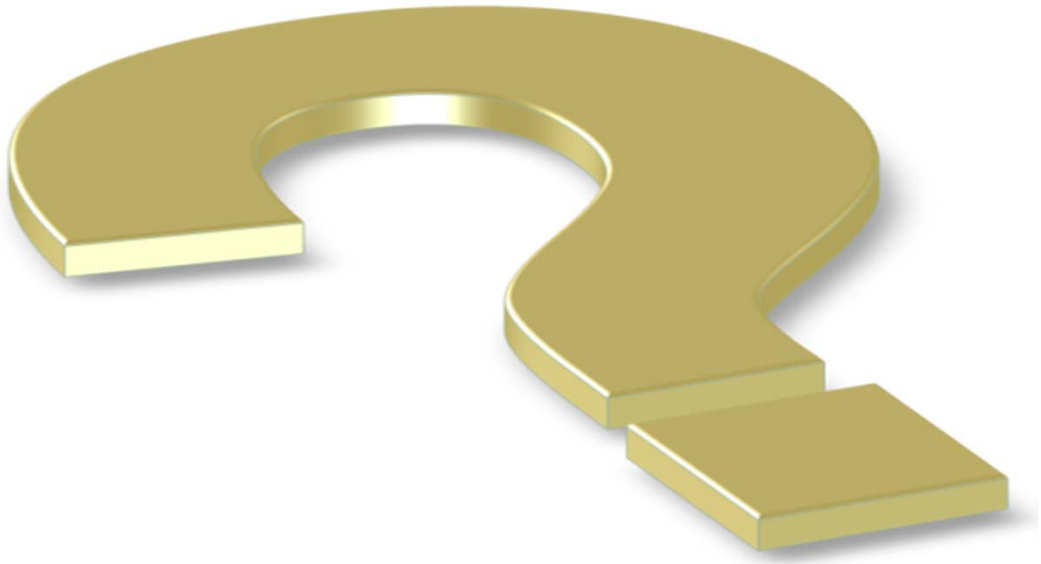
- For preparation/registration/policy questions:
  Email: esgprep@fda.hhs.gov
- For technical issues with regulatory transactions after becoming a Trading Partner and/or if you have not received the Message Disposition Notification (MDN): Email:ESGHelpDesk@fda.hhs.gov

Health Canada Contacts

- For technical issues with Regulatory Transactions after receiving the MDN, or for any Health Canada CESG related inquires: Email: hc_cesg_pcde_sc@hc-sc.gc.ca
- For submission content or procedural questions contact eReview@hc-sc.gc.ca

If in doubt, contact hc_cesg_pcde_sc@hc-sc.gc.ca and we will direct you to the right place!

Questions?



Contact the HC CESG Team at
hc_cesg_pcde_sc@hc-sc.gc.ca