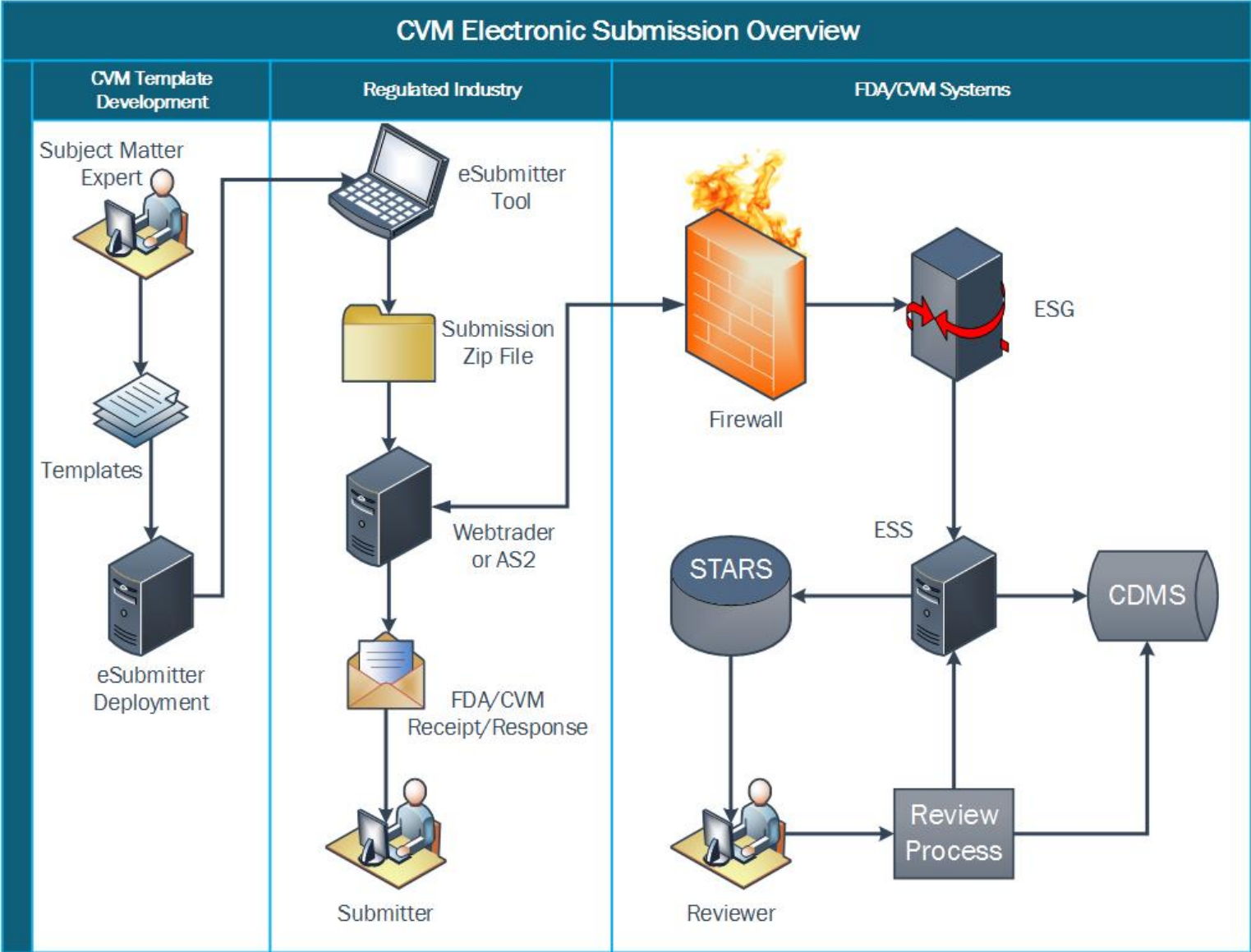


# **Webinar 1: FDA ESG and CVM ESS Registration Process**

May 23, 2018

# Agenda

- Introductions/Agenda: 9:00 – 9:05 am
- Overview of Electronic Submission Process: 9:05 – 9:20 am
- FDA ESG Registration: 9:20 – 9:50 am
- Question and Answer: 9:50 – 10:05 am
- CVM ESS Registration: 10:05 – 10:35 am
- Question and Answer: 10:35 – 10:50 am
- Closing Remarks: 10:50 – 10:55 am

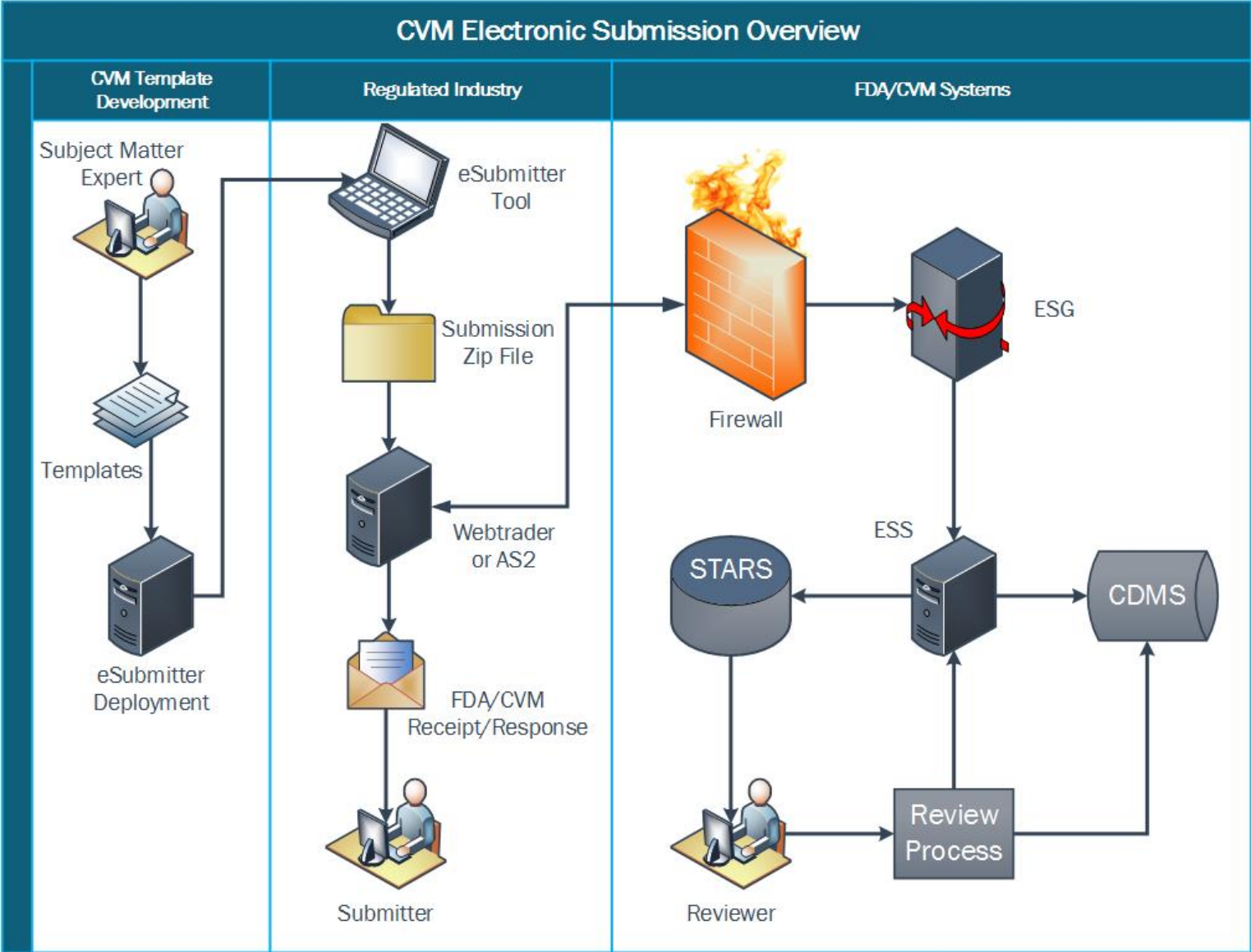


# Components of Electronic Submissions

- **eDesigner**
  - Tool used by FDA to create submission templates
    - Creates templates to be used in eSubmitter that provides for an XML structure with the ability to attach both XML and PDF document formats
- **eSubmitter**
  - Program used by sponsors to build and submit their correspondence
  - Uses data capturing forms (question and answer, file attachment capability, etc.) to walk users through the process of compiling a complete and structured submission to FDA.
  - Uses business rule logic (conditional statements) to require the submitter to complete sections based on previous responses
  - GOTS product that is easily downloadable for free by Industry directly from FDA website
  - Self-contained system install ensuring minimal configuration required by the Industry user
  - Auto-update feature enables FDA to easily promote system or template modifications
  - Stand-alone application allowing users to work on a submission offline, save, continue later
  - Submission is contained within a single ZIP file (> 1 GB)

# Components (cont'd)

- **ESG (Electronic Submission Gateway)**
  - FDA gateway for electronic communication with outside parties
    - Acts as a firewall and allows only those submitters who have an account and a valid VeriSign certificate to pass through to the destination Center
- **ESS (Electronic Submissions System)**
  - CVM system that authenticates the submitter with CVM's authentication program
    - Uses PDF digital certificates to validate the submitter
    - Performs rudimentary validation of submission (for example: document type and number exists, submitter is owner of document)
- **CDMS (Corporate Document Management System)**
  - CVM system used to store the sponsor submissions and CVM-created reviews/correspondence
- **STARS (Submission Tracking and Reporting System)**
  - The system used by CVM reviewers to track submissions



# Questions

