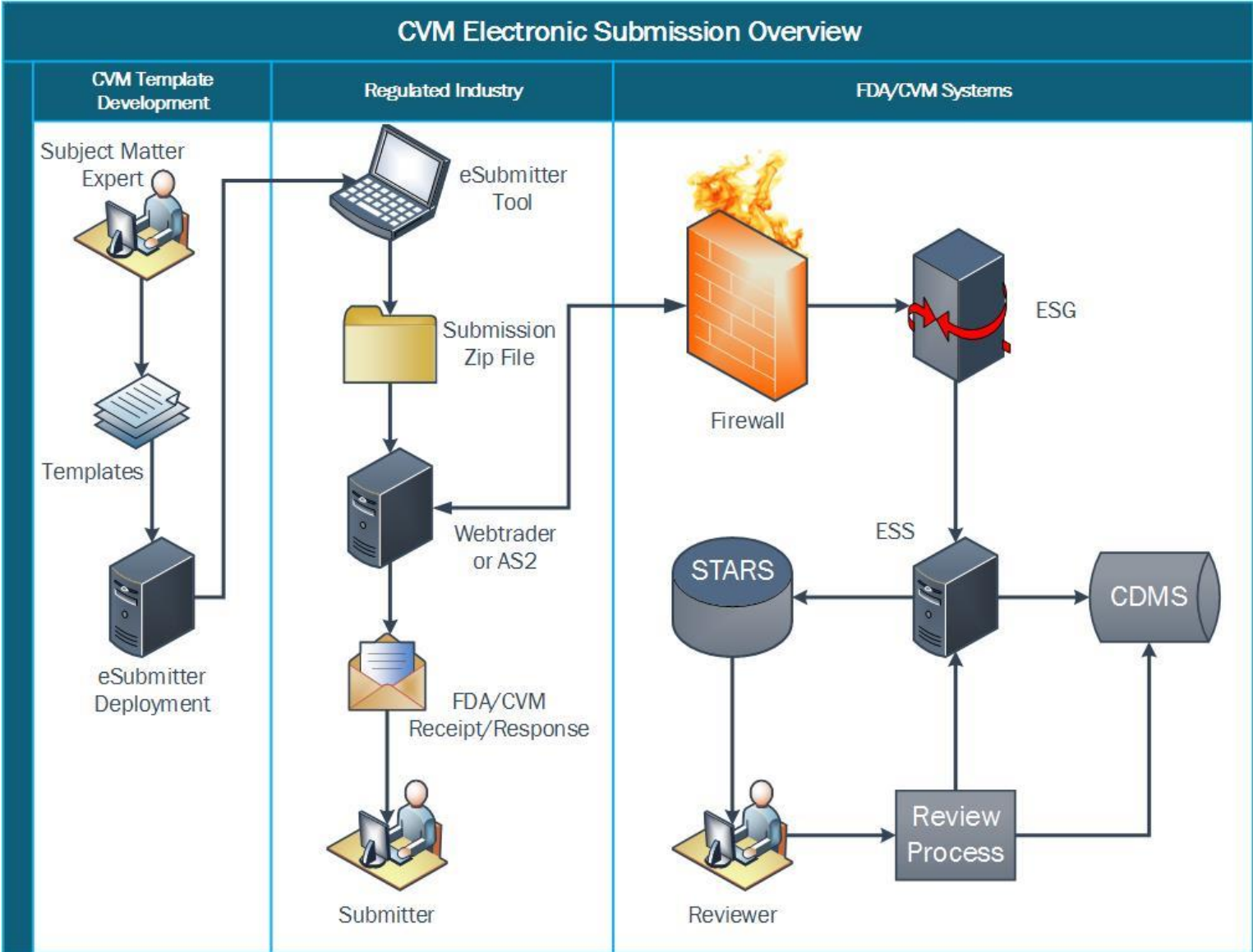


**Webinar 2: How to Use the CVM
eSubmitter Tool**
August 22, 2018

Agenda

- Introductions/Agenda: 9:00 – 9:05 am
- Overview of Electronic Submission Process: 9:05 – 9:15 am
- How to Use eSubmitter: 9:15 - 11:15 am
- Special Scenarios: 11:15 – 11:35 am
- Where to go for help: 11:35 – 11:50 am
- Question and Answer: 11:50 – 12:00 pm
- Break: 12:00 pm – 1:00 pm
- Afternoon Breakout Sessions: 1:00 pm – 4:00 pm

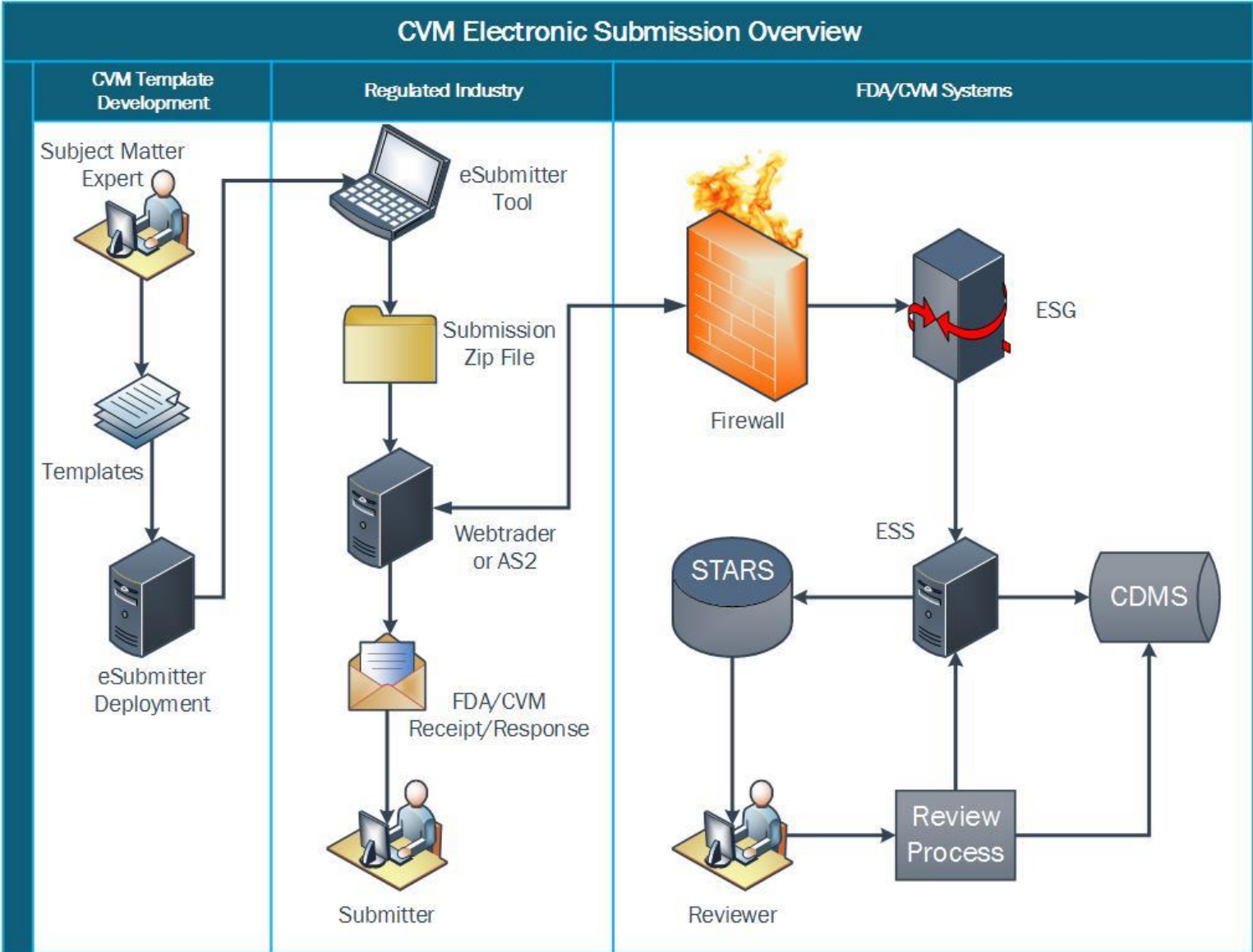


Components of Electronic Submissions

- **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



How to Use eSubmitter Topics

- Downloading and installing CVM eSubmitter
- Launching eSubmitter and basic navigation
- Creating a new submission
- Using the address book feature
- Understanding business rules (activating/deactivating questions based on responses)
- Attaching files
- Finalizing and packaging a submission
- Submitting to CVM and viewing CVM Responses
- Product description
- Amendment process
- G submission vs. GC document

Afternoon Breakout Sessions

- Animal Bioengineering and Cellular Therapies (ABCT) Team
- Chemistry, Manufacturing and Controls 1
- Chemistry, Manufacturing and Controls 2
- Target Animal Review Divisions 1
- Target Animal Review Divisions 2
- Target Animal Review Divisions 3
- Environmental
- Generic Review Division

Questions

