AS2Gateway

AS2 Gateway for Regulatory Submissions

Product Overview

Version 2.3.14

Revision History

Date	Version	Description	Authors
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1. Overview

This document contains an overview of the AS2 Gateway application developed by Aayu Technologies (referred as "system") including customizations for regulatory submissions.

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2. Features

2.1 Send Profiles

Profiles allow you to group and easily select/manage the settings of a particular reporting destination or "submission profile" (e.g. "FDA eCTD"):

- *routing headers* to include (same as in the SaaS platform)
- *station* (sending identity) and *partner* (destination/receiver) for the transmission
- *type* of the submission (e.g. FDA, FDA HC, EMA), which governs how the submission files are selected and archived/composed

2.1.1 Profile types

Following profile types are currently supported:

1. `FDA1`: FDA standard (non-HC) submission format
    - path selection format (see "Making a submission"): `<application_id folder>/<sequence_number folder>`
    - compression: `tar.gz` with `sequence_number` folder at top level
    - automatically picks application ID and sequence number from path
    - final file (generated archive) name: `<application_id>-<profile_name>-<sequence_number>.tar.gz`
2. `FDA2`: FDA HC (Health Canada) submission format
    - path selection format: `<application_id folder>` (may contain multiple `sequence_number` subfolders)
    - compression: `tar.gz` with `application_id` folder at top level
    - automatically picks application ID and sequence number from path
    - final file name: `<application_id>-<profile_name>-<sequence_number>.tar.gz`
3. `EMA`: EMA submission format
    - compression: `zip`
    - path selection format: *any folder*
    - application ID, sequence number and final file name should be provided manually

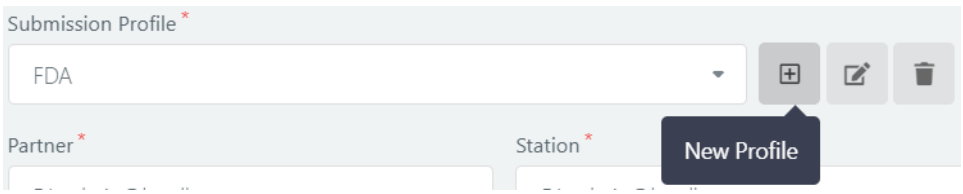
Additional submission mechanisms/formats can be facilitated in future, as appropriate.

2.1.2 Usage

Typically you would create in advance, a profile for each destination/center that you wish to submit, and select the appropriate profile when making a new submission.

Stations and partners have to be configured separately, before they can be assigned to a profile; this is outside of the current usage scope, but can be achieved easily by following the official guides for the SaaS platform.

You can create and manage profiles from the **Submission Profile** section of the **New Submission** page.



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2.2 Submissions

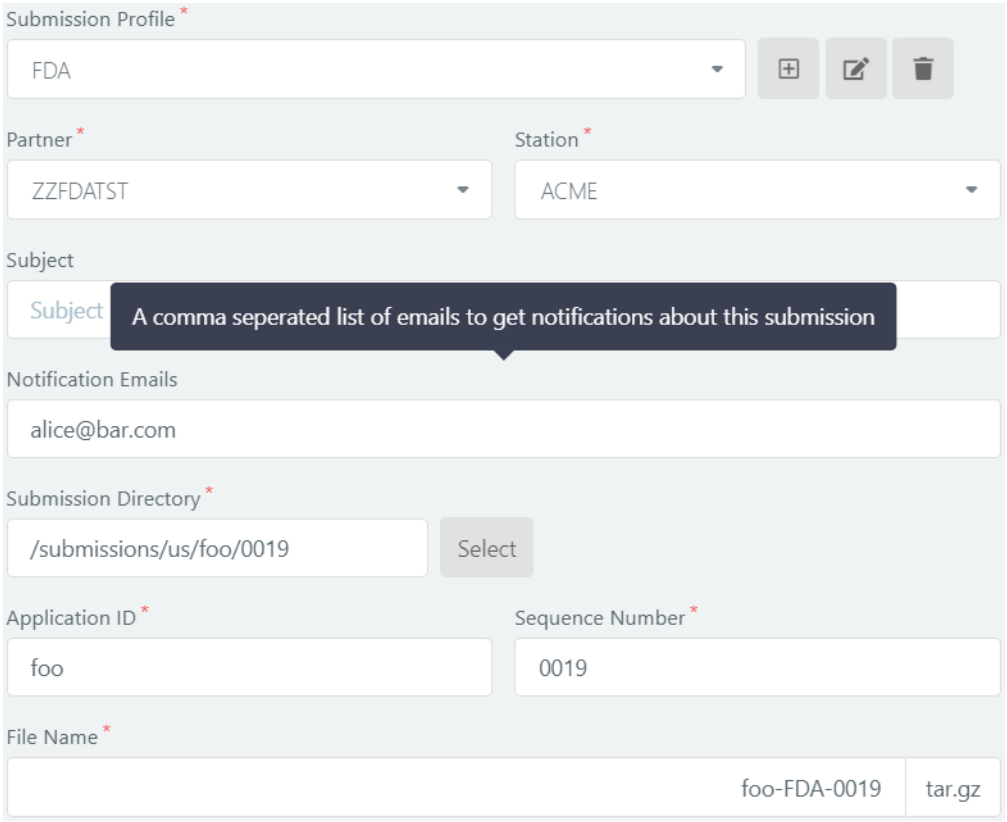
Submissions represent actual individual reports submitted through the system.

2.2.1 Making a submission

You can initiate a new submission by clicking the **New Submission** button on the Submissions page (/submissions) or the bottom-right hovering button (paper plane icon) on any other page.

In the New Submission page, you can:

- select a desired *message-send profile* to use for the final composition
- select the *submission directory* containing files to send, from the shared network location connected to the deployment
- customize the *application ID* and *sequence number*, which the system would auto-extract based on the selected folder
- enter a *subject* for the AS2 message that would envelope the submission, if desired
- in case of EMA, provide the final file name to use for the submission
- provide a comma-separated list of *notification email* addresses ("interested parties") to receive notifications regarding future events (received ACKs, and any failures) for the submission



2.2.2 Submission process

1. Upon submission, system creates a new Submission entry in initial `PENDING` state. You will be able to see and track progress of each submission from the list page.
2. In the background, system compresses content of the selected folder, based on the selected profile (tar.gz for FDA, zip for EMA, etc.). Submission status changes to `COMPRESSION IN PROGRESS`, and then (after compression step is completed) to `PROCESSING`. (It may stop at `COMPRESSION FAILED` and notify interested parties via email, if an error occurs during compression.)

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3. System composes an AS2 *outbox* (queue) entry, associated with the submission, which will govern the rest of the AS2-level processing. The entry is visible in the **Outbox** (/messages/queued), and contains fine grained details of the AS2 transmission.
4. System composes an AS2 message using the compressed file, based on the AS2 configurations of the recipient (remote trading partner). Submission status changes to `PROCESSING`, and then to `SENDING`. (It may stop at `PROCESSING FAILED` and notify interested parties via email, if an error occurs.)
5. System transmits the AS2 message to recipient's endpoint. During this phase, submission status remains `SENDING`.
6. Depending on transmission result,
    - If successful, submission changes to `SENT` status; AS2 outbox entry gets moved to the **Sent** box (/messages/sent).
    - If transmission fails, submission status changes to `SENDING FAILED`. The next step depends on the nature of the failure:
        - If it is a non-recoverable error, such as a HTTP 3xx/4xx response (indicating a problem with the composed AS2 message itself), system will not retry the transmission;
            - submission status remains `SENDING FAILED`, and outbox entry is moved to **Stopped** list (/messages/stopped).
            - interested parties are notified regarding the failure.
        - If it is a recoverable/retryable error, such as a HTTP 5xx response (temporary error on remote server) or network-level issue (refused/broken connection etc.),
            - system keeps on retrying the transmission 10 times, with increasing delays (starting with 5 seconds, doubling it up to 10 minutes, and then at 10-minute intervals; the counts and intervals are globally configurable)
            - during retries, submission state may keep on cycling as `PROCESSING`, `SENDING`, `SENDING FAILED`; details of the last failure will also be visible in the submission's **detailed view** (accessible by clicking the **File Name** field on the list view)
            - when all retries are exhausted, system moves the outbox entry to **Stopped** list, and notifies interested parties regarding the failure (similar to the case with a non-recoverable error)
7. When partner sends back an **ACK1** (the *MDN receipt*, in AS2 jargon) for the sent message, system links it as the ACK1 of the submission.
8. When FDA sends back an **ACK2**, system parses its content and:
    - links it as the ACK2 of the original submission.
    - assigns the FDA-generated *CoreID* (correlation ID) found in the ACK2 response content, to the submission.
    - *tags* both the ACK2 and the original sent message with the CoreID, in the format `FDA:CoreID <CoreID value>`
9. When FDA sends back an **ACK3**, system identifies the CoreID from its filename and:
    - links it as the ACK3 of the original submission.
    - tags the ACK3 with the CoreID in the same `FDA:CoreID` format.

2.2.3 Notes

- For automatic ACK2/3 processing, the **FDA Integration** option should be enabled on the recipient partner's advanced settings.
- Each submission is associated with an outbox entry, which in turn has a unique *AS2 identifier* (AS2 `Message-ID`). This ensures that each transmission is identified uniquely at the receiver's end, without having to extract or inspect its actual content. It is recommended to include this identifier in any troubleshooting related communications/tickets.

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2.3 "Large" transfers

System is capable of handling large (gigabyte-sized) submissions efficiently, and has been internally tested with submission sizes up to 10GB.

2.3.1 Storage

- Source files/folders for submissions are directly displayed, selected and loaded from a shared file store, to save time and bandwidth; instead of uploading them directly to the system or web UI.
- Generated submission files (tar.gz/zip etc.) and composed AS2 payloads are stored in a similar shared file store. Only the entry metadata is stored in the main system database.

2.3.2 Transmission

- AS2 Restart profile is implemented for outgoing transfers. If a large submission gets interrupted during transmission, system will automatically negotiate with the remote server (receiver), and resume from the last successful position without requiring any manual intervention. This will save time and bandwidth, especially if the network link with the remote party is slow or unstable.
- As explained before, transmission failures will be automatically retried up to a (configurable) limit, with exponential back-off to cater for any short-term outages.
- Whenever a submission fails permanently, its interested parties will be notified via email. Additionally, standard AS2 send-failure notifications can also be enabled for system admins' convenience.

2.3.3 Notes

- AS2 restart capability is not enabled by default, and should be explicitly turned on under the recipient partner's advanced settings. Not all receivers may support this, as it is an optional AS2 profile; so it is recommended to check with the receiver/partner before enabling this option.
- It is recommended to also increase the *send timeout* advanced setting for partners that you wish to send large submissions.
- The system does not currently support *receiving* large messages (with sizes beyond several megabytes); if such a requirement also arises, please contact the support team.

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3. Troubleshooting

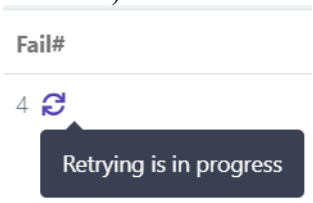
3.1 Standard AS2 aspects

Please refer the standard troubleshooting guide on SaaS documentation.

3.2 Platform specifics (SSO, submissions, large-file transfers, etc.)

NOTE: This section is a work in progress.

- **Q:** As soon as I log in to the web interface using the SSO facility, I get logged out again immediately (with an error message "Your authentication session was rejected").
    - The authentication token issued for you by the SSO platform, is either unacceptable or incompatible with the system. For security reasons the actual cause is not displayed in the web interface, but the details can be found on system logs of the *backend* component/deployment. Common causes include:
        - missing or unmatched groups on your SSO user, or the assigned groups not getting propagated to the SSO token properly (they are expected to appear in the token, under a `groups` claim)
        - rotation of the token signing keys (JWKS) on the SSO provider's side; system automatically reloads these keys every hour, but there could be brief periods where the tokens issued by fresh signing keys may be rejected by the system (right after the rotation). If this happens frequently, it is advised to re-check and properly configure the SSO provider's JWKS rotation schedule (`openid.provider.PROVIDER_NAME.jwksExpirationCron`) on the *backend* deployment.
- **Q:** Some of my submissions have been in `SENDING` status for an excessively long time.
    - If the submission is large-sized, the transmission may legitimately take several hours to complete, depending on the quality of the network link between your system and the receiver's endpoint.
    - However, if the system is known to have force-restarted or crashed, submissions which were being transferred (in-flight) at that time may remain in `SENDING` status, without getting resumed automatically. In such cases, you can force-retry such transmissions by **Shift+clicking** the *Retrying is in progress* icon against the outbox entry. (**Make sure** to confirm that the message is not already being transmitted, to avoid the possibility of duplicate transfers.)



- **Q:** I am getting an unexpected error (without a proper reason phrase) when performing an action on the web interface.
    - Please examine the system logs for the *backend* component, at the time of the occurrence of the issue, and share them with the support channels.

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