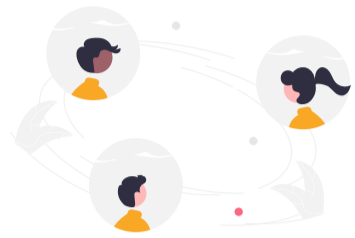


Current ESG vs. ESG NextGen

The following is a high-level comparison of the current ESG functionality and the expected functionality of ESG NextGen



User Account Management

Current ESG

- Test then Production Account
- Long turnaround time for account creation
- Lack of enterprise ICAM solution

ESG NextGen

- Comprehensive account provisioning workflow
- Direct production account creation
- Federated ICAM



Package Preparation

- Client-side software installation required
- LDownload & install may be blocked by company security policy
- No auto-update if FDA changes form(s)

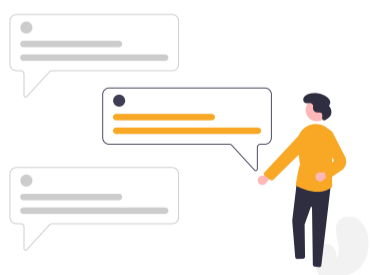
- Web-based step-by-step submission preparation
- In-page file upload
- File size-based submission workflow
- Incorporated Center submission wizards for a seamless user experience



File Submission

- Require digital certificate
- No large file submission capability
- Lack of transparent submission tracking
- No integration w/ other FDA Center portals

- eSignature to replace digital certificate
- Improved file upload performance
- Unified Submission Portal with status/tracking
- API service
- Large file submissions greater than 1 TB



Communication

- One-way user notification via acknowledgement

- Secure two-way user communication channel
- Broadcast capability
- Intelligent chatbot to improve user experience



Streamline your FDA ESG Submissions with secure AS2 channels