US DEPARTMENT OF HEALTH AND HUMAN SERVICES AND OPDIVS – WAY AHEAD

HIMSS
NATIONAL CAPITAL AREA Chapter
A Federally Focused Chapter

DEMONSTRATION: FDA Electronic Submissions Gateway (ESG)

THE CHALLENGE

2nd Generation, including the new Webtrader

- **The Challenge:** To ensure that the ESG is 100% available and can meet current demands and projected future increases in submission volume and size. Provide a user interface for web-based users that eases navigation, eliminates the Java applet dependency, and supports concurrent file upload.

- **The Need:** ESG is an Agency-wide solution for accepting electronic regulatory submissions with critical timelines. ESG enables the secure submission of pre-market and post-market regulatory information for review. ESG's availability and usability is critical to industry partners world-wide. Building a reliable, more robust system to significantly increase processing capabilities to process industry submissions and deliver acknowledgements faster.

- **The Intent**: To give industry partners a stable and more reliable method, that is also scalable for future growth, of sending their regulatory submissions to the FDA and to also provide a user interface that is user-friendly and intuitive.

THE IMPACT

Benefits:

ESG 2nd Generation provides a number of benefits to the FDA and Industry users to include:

- Increased system availability so users can always submit files and access historical submissions.
- The elimination of system downtime for planned outages by implementing server failover capabilities.
- An enhanced ESG User Interface for web-based users that eases navigation, eliminates Java dependency, and supports concurrent file upload.
- Support projected submission growth of 25-30 million submissions by 2020.
- Support large file submissions up to 100GB and growing.

Presenter Bio: Tina Nguyen & Srini Palle

Tina Nguyen is the Branch Chief of the Enterprise Applications Branch at the Food and Drug Administration with over 17 years' experience in Government. In her role, she is responsible for managing the teams that support multiple critical enterprise applications across the FDA. Her branch provides services to meet a multitude of system needs that include: Strategic Planning; Technical Analysis; New Software Development; Operations and Maintenance; and New Technologies Services Acquisition. Ms. Nguyen has a Bachelor's degree in Information Systems from University of Maryland and Masters Certificate in Project Management from George Washington University, including being PMP certified.

Srini Palle is Project Manager of Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG). He has over 11 years' experience supporting various IT projects at FDA, including managing FDA ESG for 7+ years. Mr. Palle leads day to day operations and new implementations for FDA ESG. Mr. Palle has a Bachelor's degree in Commerce and Master's degree in Information Systems from Eastern Michigan University.

About the Food and Drug Administration (FDA): The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.

FDA also plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

Additional information is available at www.fda.gov.

More Info on the Electronic Submissions Gateway: www.fda.gov/esg