PegaWorldiNspire

# CDRH Promotes Digital Transformation


**Elizabeth McNamara**
Program Director, Digital Transformation
FDA, Center for Devices and Radiological Health (CDRH)

**Kenneth Sullivan**
Principal
Booz Allen Hamilton


# CDRH Promotes Digital Transformation

**Disclaimer:**
**The view and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration**

# “CDRH Mission Statement”

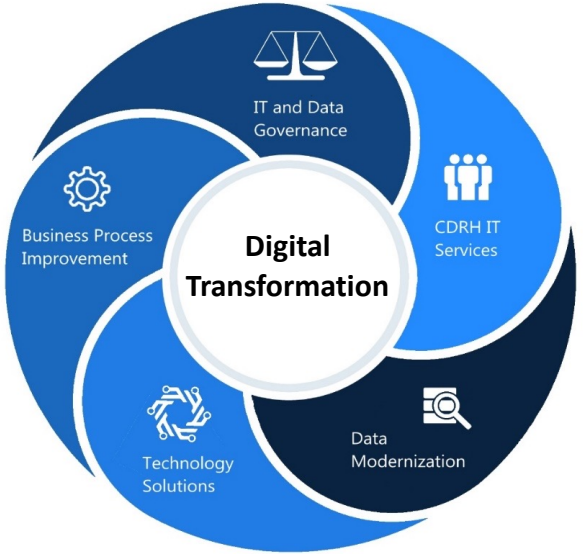
- The Center for Devices and Radiological Health (CDRH) is responsible for ***protecting and promoting public health*** by ensuring that patients and providers have timely and continued access to ***safe, effective, and high-quality medical devices.***
- To get ahead of stakeholder demands and expectations, CDRH is implementing a multiyear ***Digital Transformation (DT) initiative*** that includes
  - **Business Transformation** – harmonize and streamline processes to reduce the burden on staff and our stakeholders
  - **IT System Modernization** - address the growing scale and globalization of industry operations, evolving stakeholder demands, and growing complexity of medical devices
  - **IT and Program governance** - ensure we use IT resources efficiently and effectively

# Digital Transformation Goals

- Improve user experience for both customers inside FDA and with external stakeholders
- Improve ability to make system enhancements quickly
- Improve ability to accept and analyze data
- Improve governance of CDRH's IT Investments
- Improve IT service delivery while reducing IT costs

## "Evolve how we work today to stay ahead of tomorrow's challenges"

*DT Vision*

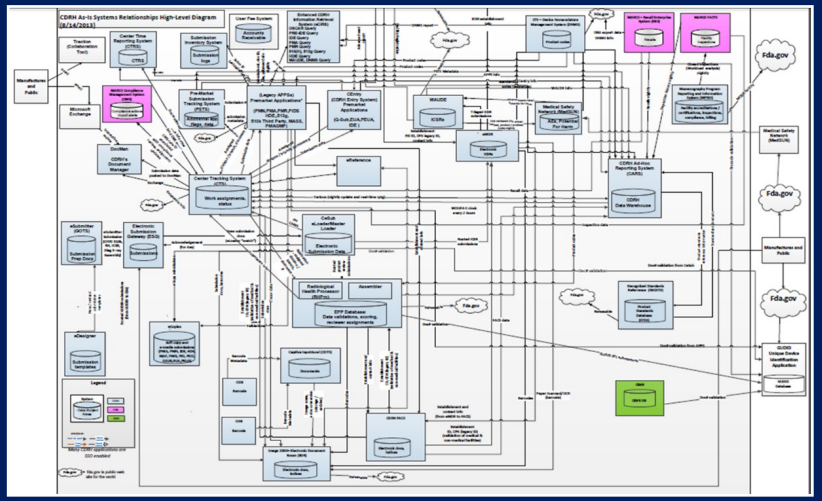



**+ Organizational Change**

# Previous State of Affairs

**Reliance on legacy systems:**

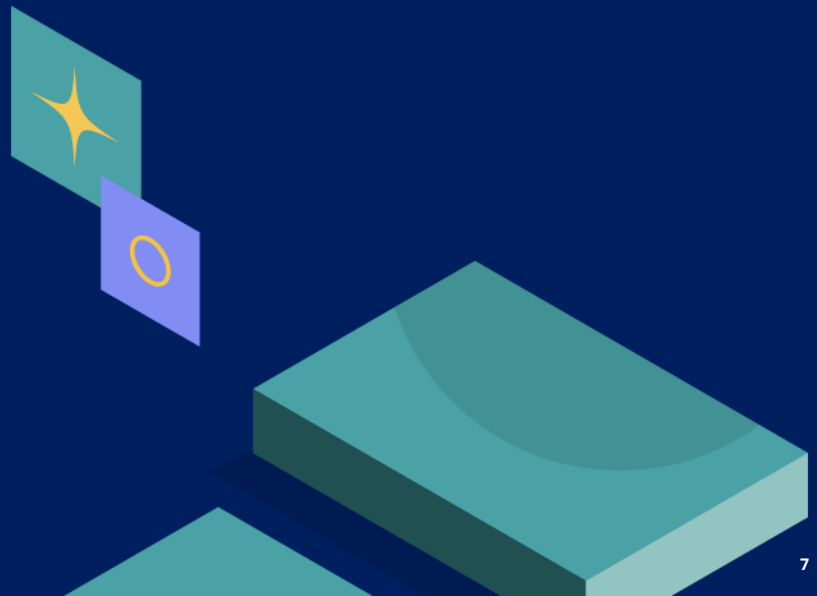
- Siloed capabilities
- Limited ability to make improvements due to high cost and long time to complete
- Compatibility issues with current systems and new applications
- Challenges in finding and linking information in our systems



# CDRH /Pega Partnership

Today, we're going to focus on ***three key elements*** of the digital transformation journey

1. **Establishing the foundation**
2. **Business process/workflows**
3. **Customer collaboration**



# Establishing The Foundation

# Business Process Development

- Establish a product driven mindset based on Agile principles to foster high quality, consistent delivery of capabilities, features and products
- Use Pega to facilitate discovery and prototype ideas with Product and Business Owners
- Develop and deploy MVP
- Incrementally release new features


# Technology Support

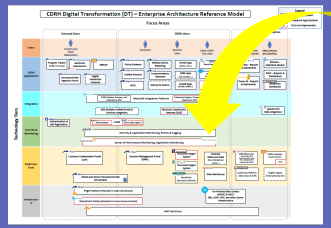
## General technology

- Utilize cloud architecture
- Modernize technology stack
- Optimize use of enterprise data

## Pega specific

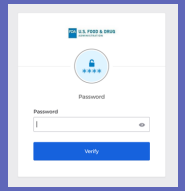
- Develop governance standards around:
  - User interfaces
  - Continuous improvement/continuous delivery (CI/CD) principles
  - Enterprise data models integration
- Develop common design components
  - Base workflow
  - Advanced workflow

# Foundational Road Map




PEGA

- Enterprise reference architecture
- Modernized tech stack

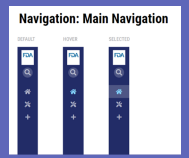



- CDRH portal (external)
- Decision mgt portal (internal)

You are here

Data product integration

- Pega layer cake
- UI design system v1.0


- Medical device review (MDR)
- 510(k) and pre-sub progress tracker
- Electronic submissions
- Policy guidance
- Communications clearance

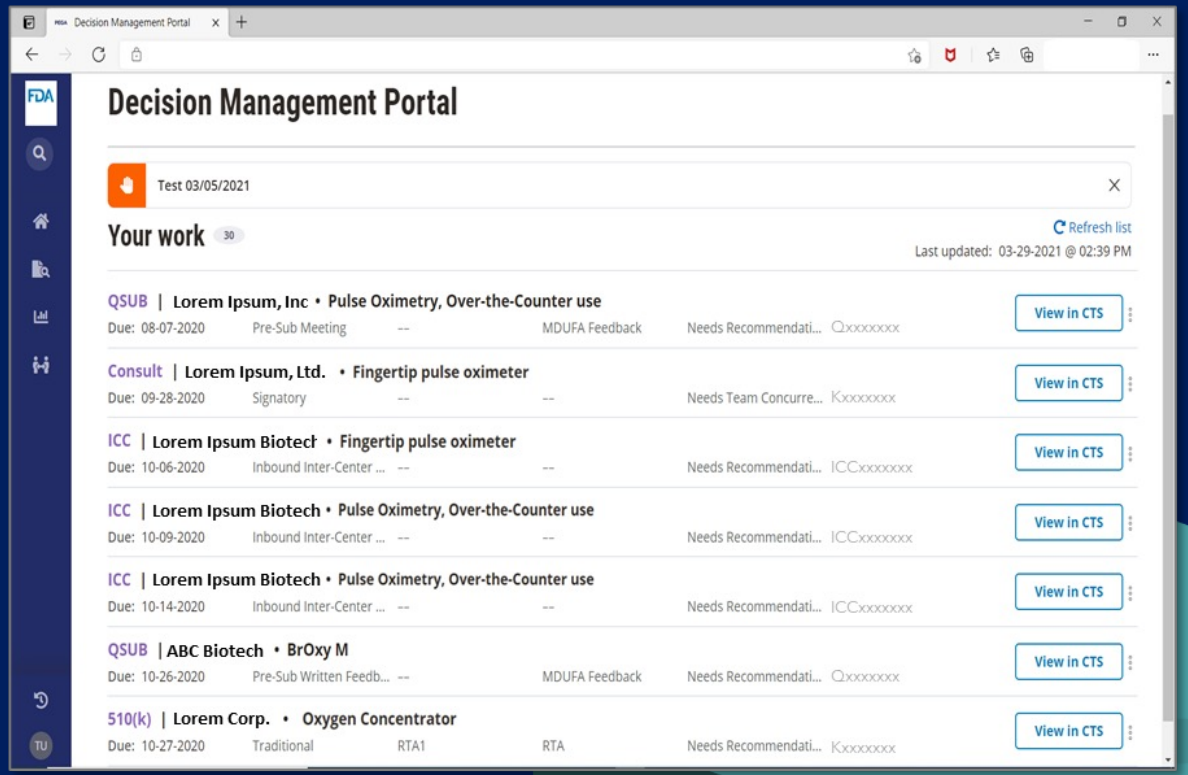
**In Production**

- Additional workflows (TPLC)
- Data science capabilities
- Enterprise search
- Guided review

**Future**

# Decision Management Portal

Provide centralize, uniform access to all CDRH Staff



# Customer Collaboration Portal

**Challenge:**

- External stakeholders demand information about the status of their device submission
- Submission processes are dependent upon manual creation of electronic submission packages that are then sent to CDRH via US Mail
- The submission packages consist primarily of unstructured data in the form of pdf and multimedia formats

**CDRH developed the CDRH portal –**

- ✔ View progress tracker
- ✔ Submit electronically
- ✔ Manage access

  **In Production**

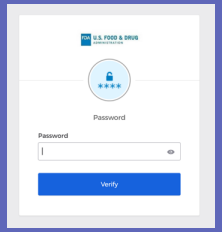
- – Collaboration
- – 360 view

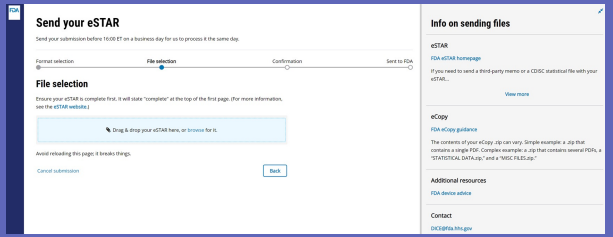
  **Discovery**

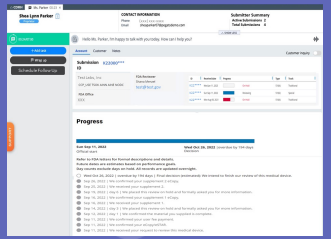
- – Structure and validate data
- – Improve efficiency of review process

  **Backlog**

# Customer Collaboration Journey Map




You are here

Basic portal
- Security
- Access control
- Login

Electronic submissions
- Estar
- Ecopy

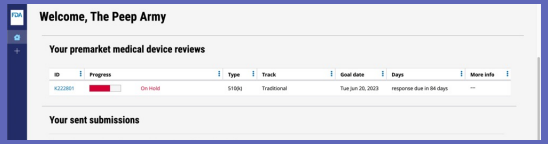
Structured ingest

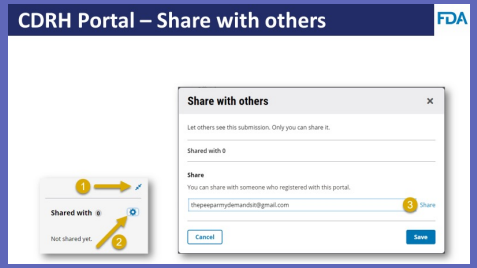
Progress tracker
- 510(k)
- Traditional
- Special
- Abbreviated

Progress tracker
- Pre-submission

User access mgt
- Delegation

Customer relationship mgt (CRM)
- Collaboration
- 360 view

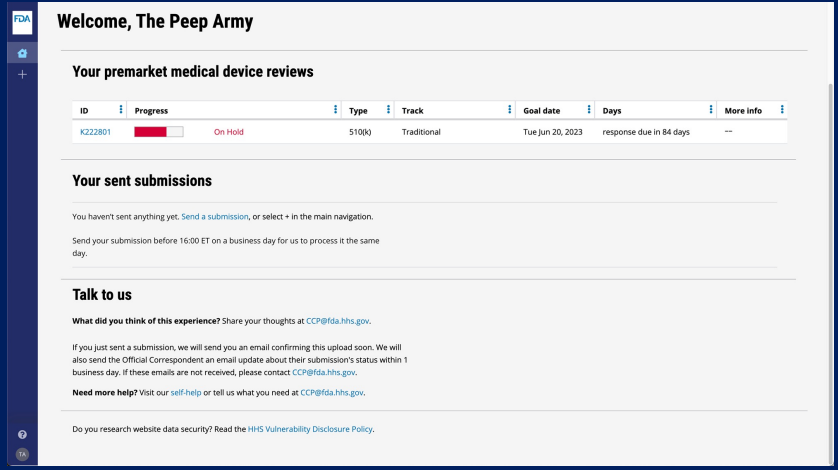


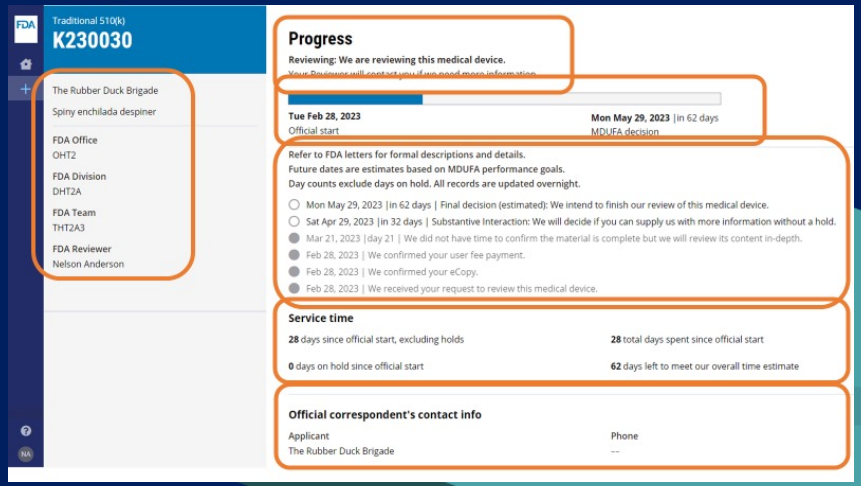




# Progress Tracker

View the status of your submission

- Data pulled from external (legacy) system
- Plain language explanation
- Business rules drive display of timeline and detailed information
- Consistent user experience
- Ability to provide customer feedback

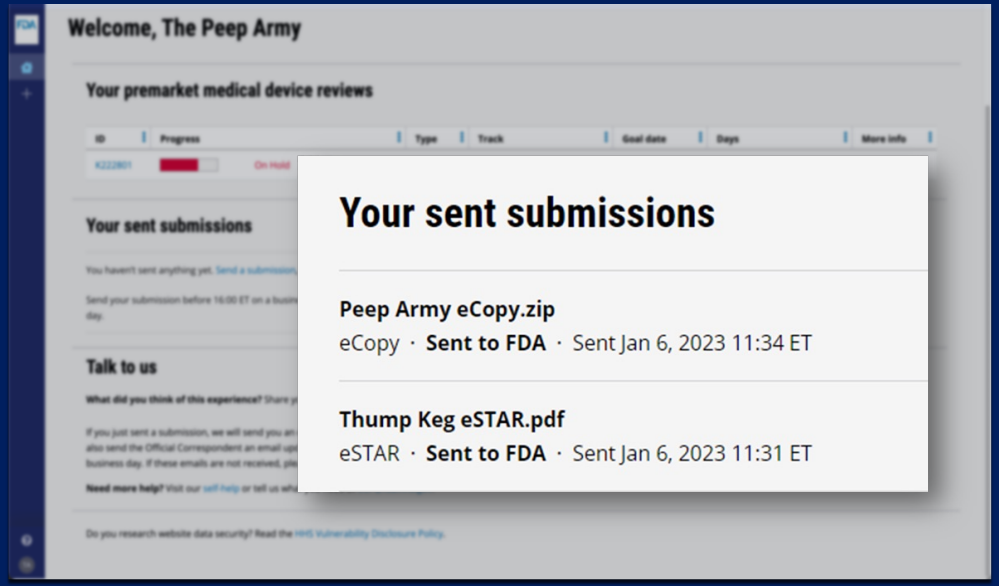


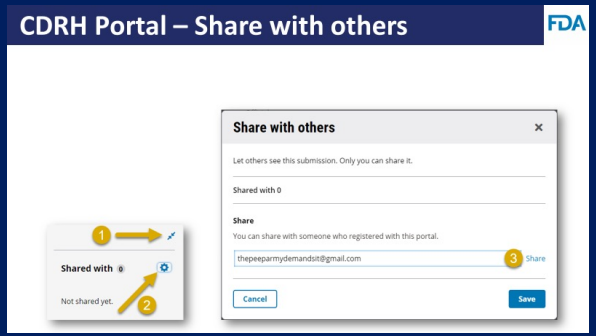



# Electronic Submissions

Simple file upload with background format checks and vulnerability scans

- Simple cloud integration with FDA GovCloud backend services
- Easy to use drag and drop interface
- Confirmation email
- Easy to share status with colleagues



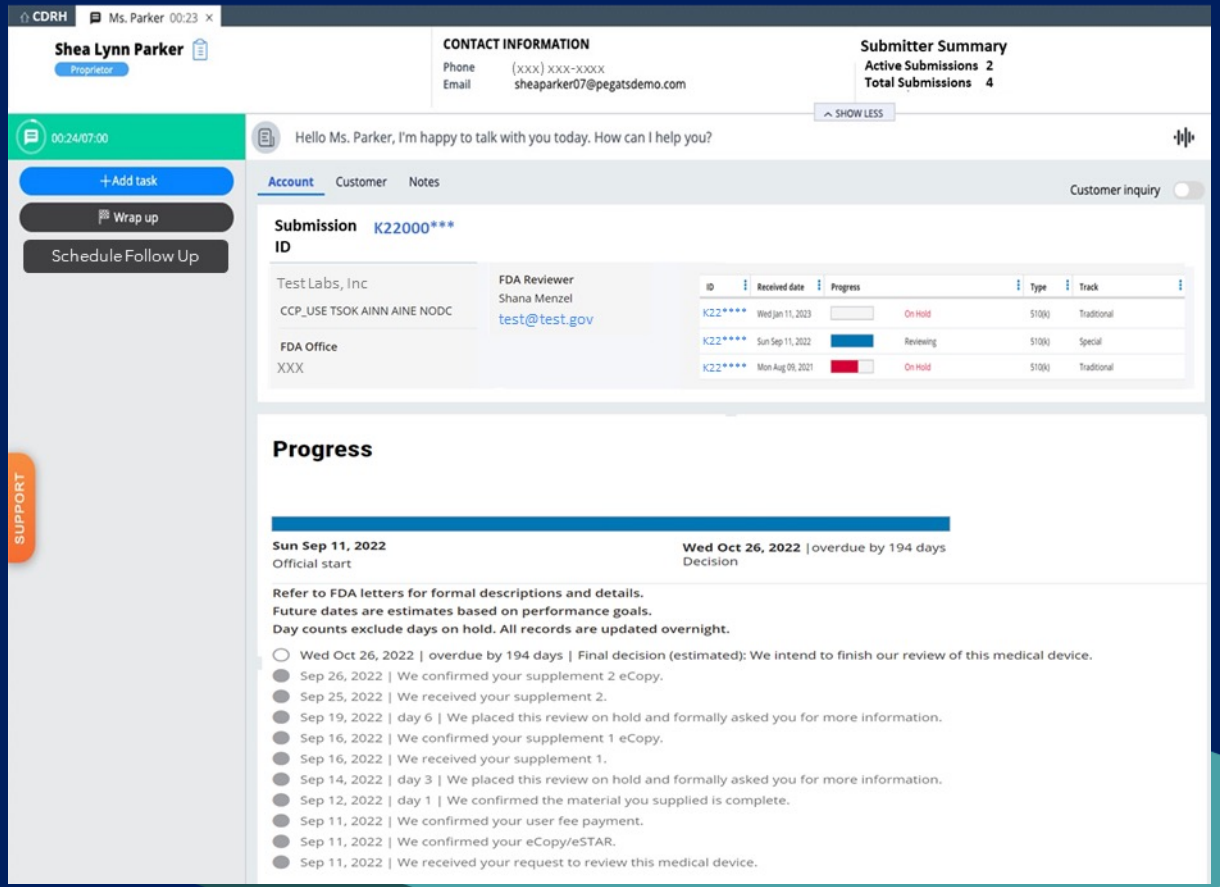



# Customer Collaboration Portal

## Configure Pega CRM

Potential features

- Knowledge management
- Next best action advisor
- Co-browse
- Unified reviewer/submitter desktop
- Web messaging
- Mailbox automation



# Quotes from Industry Users

I love the portal. Such a delight to use after 34yrs of fedexing in submissions

I am writing to express how absolutely impressed I am with this portal. It is easy and convenient

Good morning. I will start my email by saying fda's CCP is terrific! Thank you for all of the work that has gone into making this such a simple way to upload and check on the status of FDA submissions!

Incredibly helpful, informative and easy to use. So much better than the past methods of understanding where we were in the submission process

PEGA

# PegaWorldiNspire