



PegaWorldiNspire

# CDRH Promotes Digital Transformation

**Elizabeth McNamara**

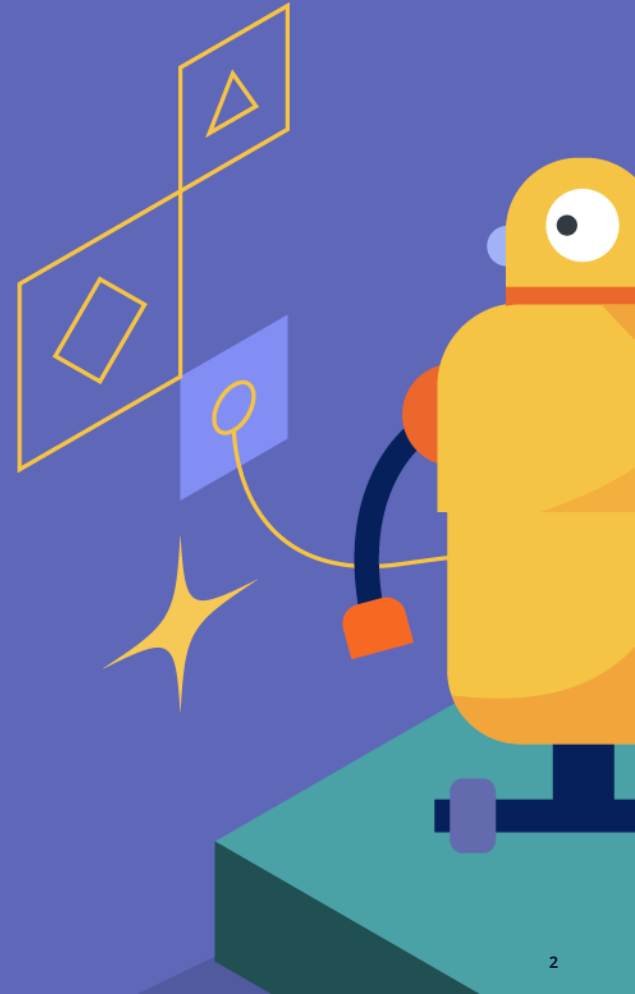
Program Director, Digital Transformation  
FDA, Center for Devices and Radiological Health (CDRH)

**Kenneth Sullivan**

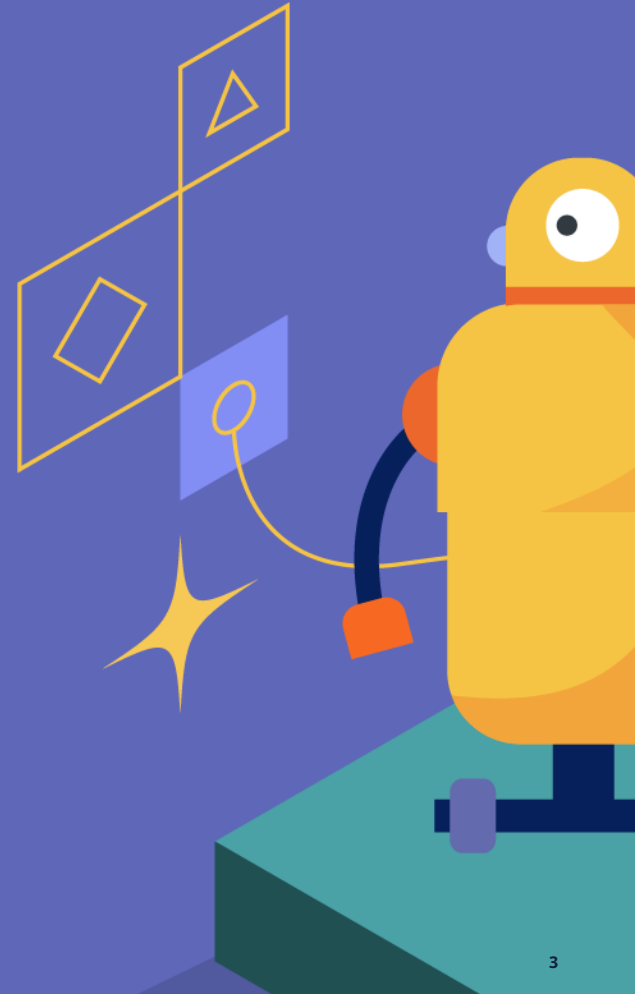
Principal  
Booz Allen Hamilton



# CDRH Promotes Digital Transformation



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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



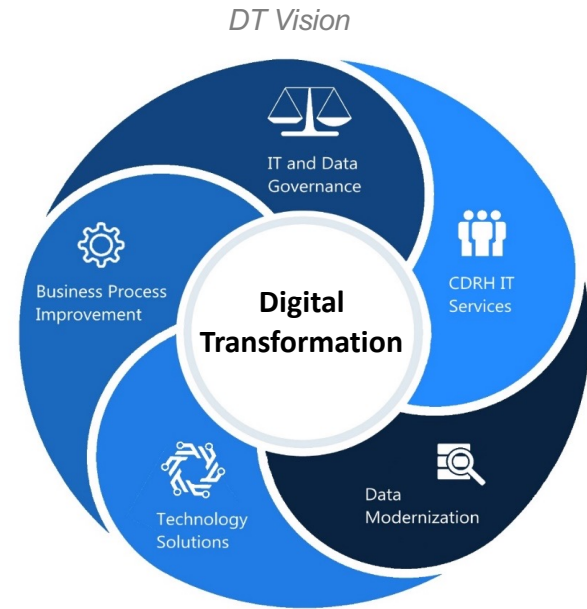
# “CDRH Mission Statement”

- 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”

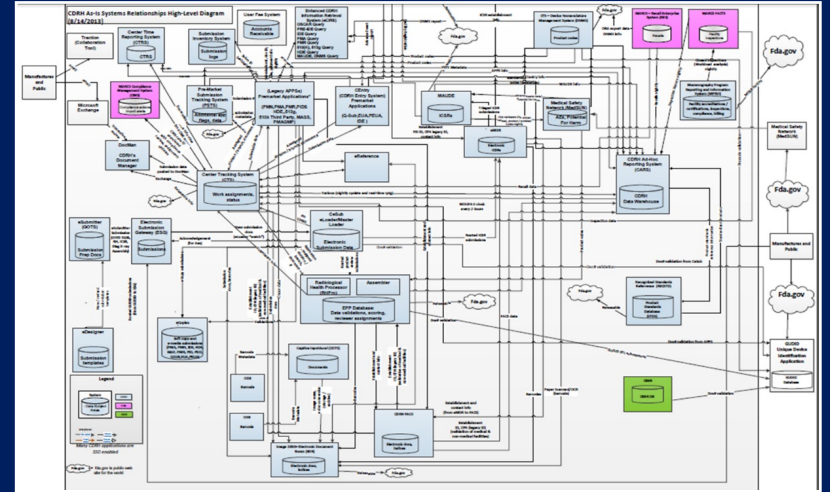


+ Organizational Change

# 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

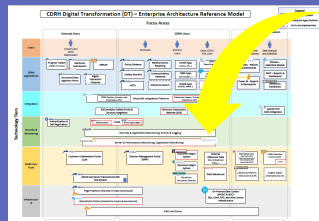
## General technology

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

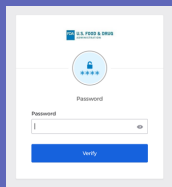
## Pega specific

- 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



- Enterprise reference architecture
- Modernized tech stack



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

You are here



Data product integration



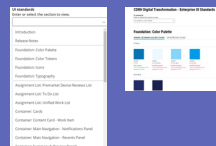
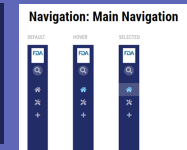
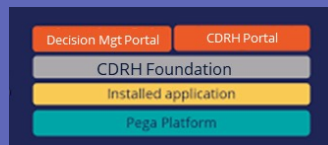
- Pega layer cake
- UI design system v1.0

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

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

Future

In Production



# Decision Management Portal

Provide centralized, uniform access to all CDRH Staff

The screenshot displays the Decision Management Portal interface. At the top, there is a search bar with a magnifying glass icon and a notification for 'Test 03/05/2021'. Below this is a 'Your work' section with a '30' badge and a 'Refresh list' button. The main content area lists several work items, each with a category, company name, product name, due date, meeting type, status, and a 'View in CTS' button.

| Category | Company             | Product                              | Due Date   | Meeting Type             | Status                             | Action      |
|----------|---------------------|--------------------------------------|------------|--------------------------|------------------------------------|-------------|
| QSUB     | Lorem Ipsum, Inc    | Pulse Oximetry, Over-the-Counter use | 08-07-2020 | Pre-Sub Meeting          | Needs Recommendation... Qxxxxxxx   | View in CTS |
| Consult  | Lorem Ipsum, Ltd.   | Fingertip pulse oximeter             | 09-28-2020 | Signatory                | Needs Team Concurr... Kxxxxxxx     | View in CTS |
| ICC      | Lorem Ipsum Biotech | Fingertip pulse oximeter             | 10-06-2020 | Inbound Inter-Center ... | Needs Recommendation... ICCxxxxxxx | View in CTS |
| ICC      | Lorem Ipsum Biotech | Pulse Oximetry, Over-the-Counter use | 10-09-2020 | Inbound Inter-Center ... | Needs Recommendation... ICCxxxxxxx | View in CTS |
| ICC      | Lorem Ipsum Biotech | Pulse Oximetry, Over-the-Counter use | 10-14-2020 | Inbound Inter-Center ... | Needs Recommendation... ICCxxxxxxx | View in CTS |
| QSUB     | ABC Biotech         | BrOxy M                              | 10-26-2020 | Pre-Sub Written Feedb... | Needs Recommendation... Qxxxxxxx   | View in CTS |
| 510(k)   | Lorem Corp.         | Oxygen Concentrator                  | 10-27-2020 | Traditional              | Needs Recommendation... Kxxxxxxx   | View in CTS |

# Customer Collaboration Portal



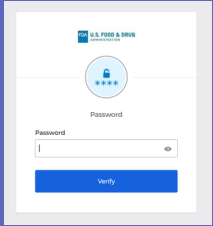
## Challenge:

- 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

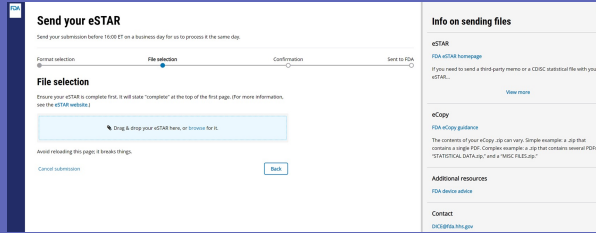
## CDRH developed the CDRH portal –

- ✓ View progress tracker
  - ✓ Submit electronically
  - ✓ Manage access
- } In Production
- Collaboration
  - 360 view
- } Discovery
- Structure and validate data
  - Improve efficiency of review process
- } Backlog

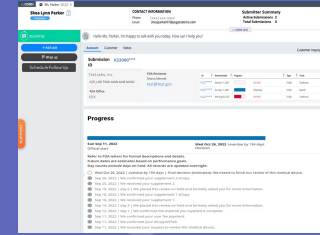
# Customer Collaboration Journey Map



- Basic portal
- Security
  - Access control
  - Login



- Electronic submissions
- Estar
  - Ecopy

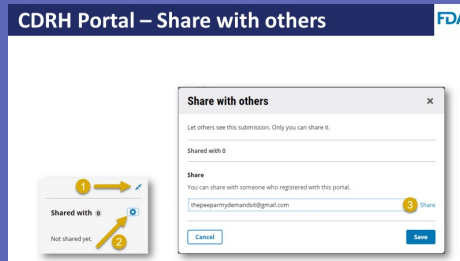
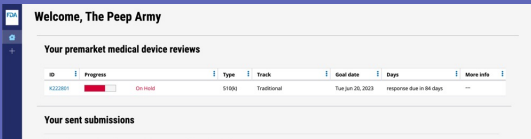


- Progress tracker
- 510(k)
  - Traditional
  - Special
  - Abbreviated

- Progress tracker
- Pre-submission
  - User access mgt
  - Delegation

- Customer relationship mgt (CRM)
- Collaboration
  - 360 view

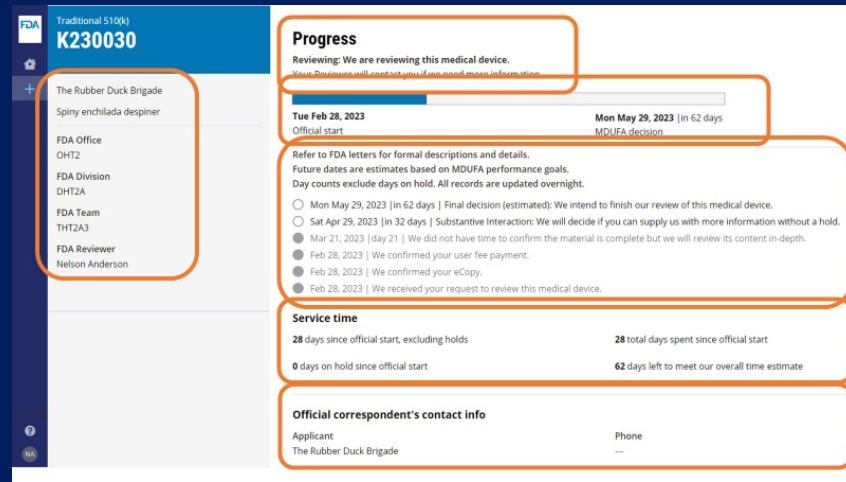
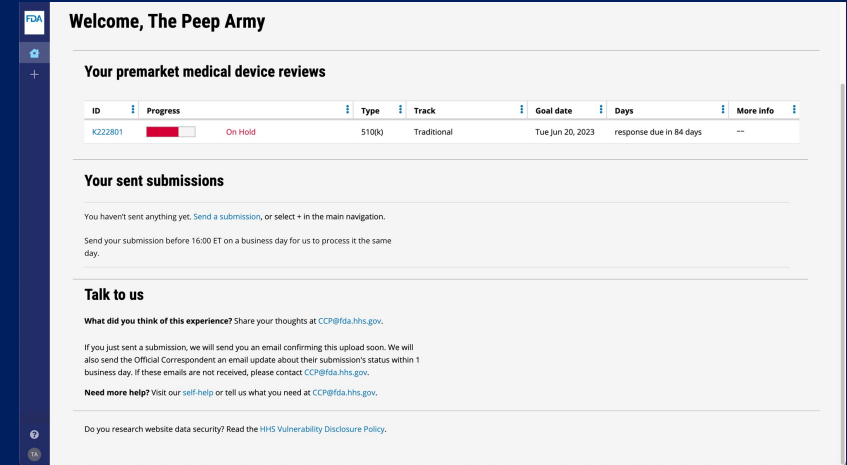
Structured ingest



# Progress Tracker

## View the status of your submission

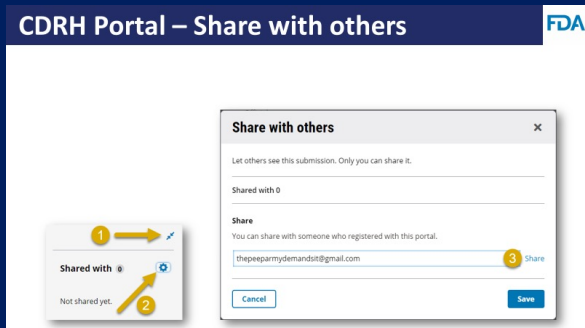
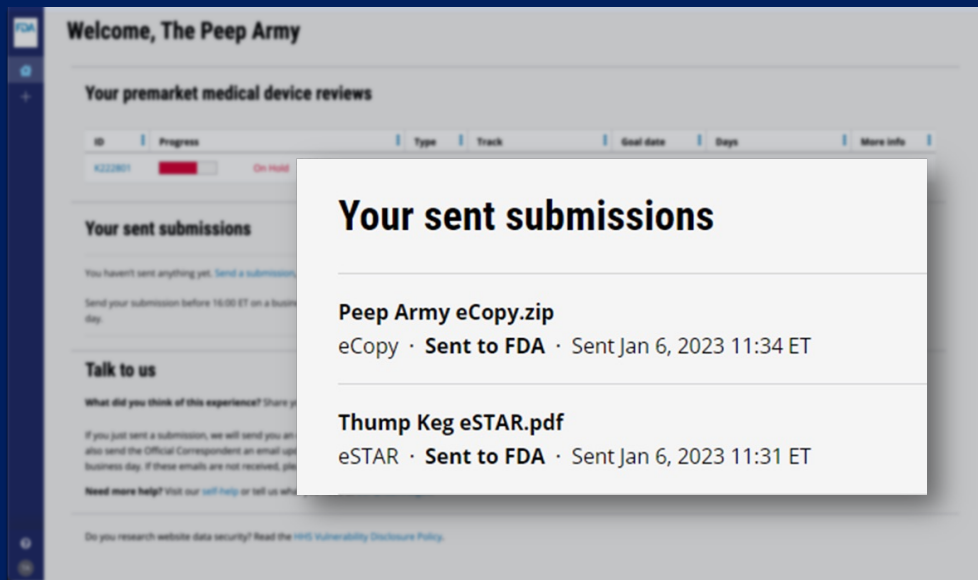
- Data pulled from external (legacy) system
- Plain language explanation
- Business rules drive display of timeline and detailed information
- Consistent user experience
- Ability to provide customer feedback



# 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

The screenshot displays a Pega CRM interface for a customer named Ms. Parker. The interface includes a header with the customer's name and role (Proprietor), contact information, and a submitter summary. A sidebar on the left contains a clock showing 00:24/07:00 and buttons for '+Add task', 'Wrap up', and 'Schedule Follow Up'. The main content area shows a submission ID 'K22000\*\*\*' for 'Test Labs, Inc.' with details for the FDA reviewer (Shana Menzel) and office (XXX). A table lists submission progress with columns for ID, Received date, Progress, Type, and Track. Below the table, a 'Progress' section shows a timeline from 'Sun Sep 11, 2022' to 'Wed Oct 26, 2022' (overdue by 194 days). A detailed progress log follows, listing dates and actions such as 'We confirmed your supplement 2 eCopy', 'We received your supplement 2', and 'We placed this review on hold and formally asked you for more information'.

CDRH Ms. Parker 00:23 x

**Shea Lynn Parker**  
Proprietor

**CONTACT INFORMATION**  
Phone (xxx) xxx-xxxx  
Email sheaparker07@pegatsdemo.com

**Submitter Summary**  
Active Submissions 2  
Total Submissions 4

00:24/07:00

+Add task

Wrap up

Schedule Follow Up

Support

Hello Ms. Parker, I'm happy to talk with you today. How can I help you?

Account Customer Notes Customer inquiry

**Submission ID** K22000\*\*\*

Test Labs, Inc  
CCP\_USE TSOX AINN AINE NODC

FDA Reviewer  
Shana Menzel  
test@test.gov

FDA Office  
XXX

| ID      | Received date    | Progress  | Type   | Track       |
|---------|------------------|-----------|--------|-------------|
| K22**** | Wed Jan 11, 2023 | On Hold   | \$100k | Traditional |
| K22**** | Sun Sep 11, 2022 | Reviewing | \$100k | Special     |
| K22**** | Mon Aug 09, 2021 | On Hold   | \$100k | Traditional |

**Progress**

Sun Sep 11, 2022 Official start Wed Oct 26, 2022 | overdue by 194 days Decision

Refer to FDA letters for formal descriptions and details.  
Future dates are estimates based on performance goals.  
Day counts exclude days on hold. All records are updated overnight.

- Wed Oct 26, 2022 | overdue by 194 days | Final decision (estimated): We intend to finish our review of this medical device.
- Sep 26, 2022 | We confirmed your supplement 2 eCopy.
- Sep 25, 2022 | We received your supplement 2.
- Sep 19, 2022 | day 6 | We placed this review on hold and formally asked you for more information.
- Sep 16, 2022 | We confirmed your supplement 1 eCopy.
- Sep 16, 2022 | We received your supplement 1.
- Sep 14, 2022 | day 3 | We placed this review on hold and formally asked you for more information.
- Sep 12, 2022 | day 1 | We confirmed the material you supplied is complete.
- Sep 11, 2022 | We confirmed your user fee payment.
- Sep 11, 2022 | We confirmed your eCopy/eSTAR.
- Sep 11, 2022 | We received your request to review this medical device.



# 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



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