



**U.S. FOOD & DRUG  
ADMINISTRATION**

# DIGITAL TRANSFORMATION SYMPOSIUM

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# 2023

Hosted by FDA's Office of Digital Transformation





# CDRH Digital Transformation Moves to a Business Capability Driven Model

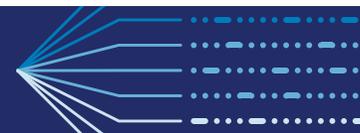
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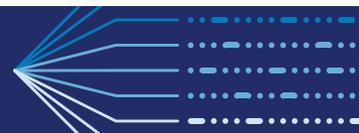
**Linda Peters, Program Manager**

**Office of Strategic Partnerships and Technology Innovation, CDRH**



# CDRH Digital Transformation

- Moving to Capability Business Model
- Customer Collaboration Metrics



# The Capability Driven Management Model

The capability driven management model is powered by business needs and then seeks to find the most effective way to meet those needs while also considering usage beyond a single use-case.



**Step 1: Identify the desired business need.**



**Step 2: Conduct discovery and technical assessment to study the current state, understand what works and what doesn't, and envision a future state.**



**Step 3: Crosswalk future state needs against the [Capability Catalogue](#).**

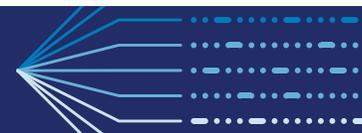
- *What existing capability features fully or closely align to the future state needs?*
- *Where may existing capability features need enhancements to satisfy needs?*
- *Where may entirely new capabilities be needed?*



**Step 4: Review findings and recommendations with key stakeholders for feedback, guidance, and ultimately prioritization – *Now, Next, Future***



**Step 5: Proceed with discovery, solutioning, and development.**



# Digital Transformation Capability Themes

## *Data Integration, Data Management*

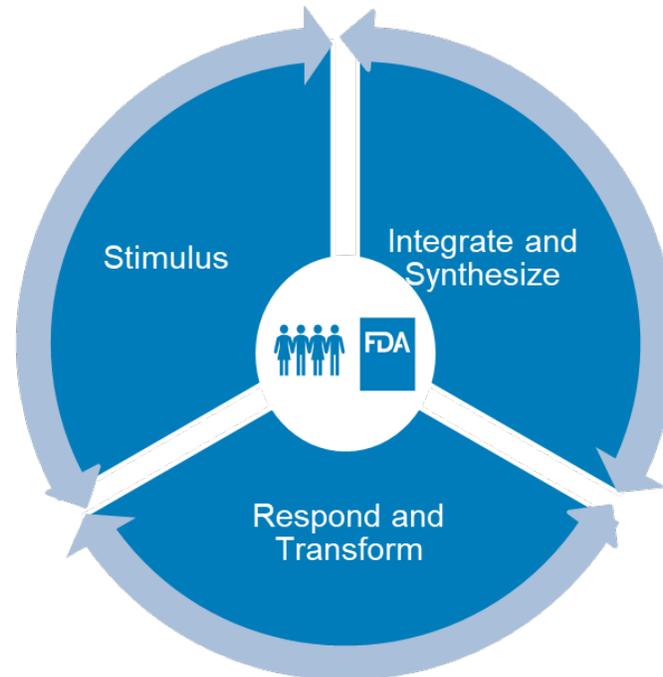
- *Data collation from multiple sources to support workflow*
- *Aggregate, cleanse, and curate data*
- *Identify relationships; Ensure common terminology*

## *Electronic Submissions, Progress Tracker*

- *Guide users through structured submission process to increase data quality and response efficiency*
- *Display of progress*

## *Data Delivery (e.g., Decision Support)*

- *Develop context specific models that seek to identify patterns*
- *Find data, expertise, decisions, and analysis across the Center to simplify re-use of institutional knowledge in various processes*



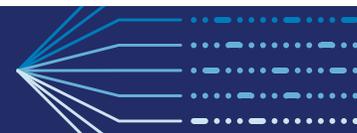
## *Workflows*

### *Guided Review, Enterprise Search, Content Mgmt.*

- *Define business rules*
- *Orchestrate actions across offices and across the FDA*
- *Create collaboration spaces to support collective review and actions*
- *Systematic analysis of the request to identify sensitivity and provide recommendations*

## *Omnichannel Communication, Content Collaboration*

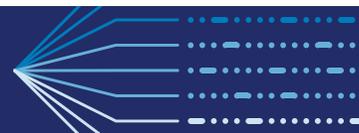
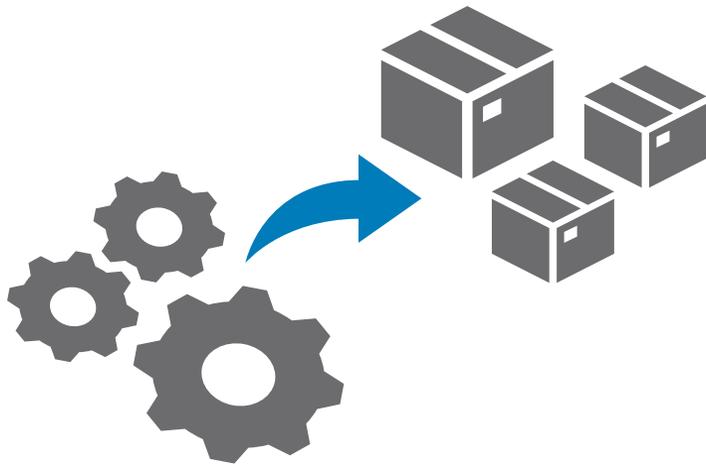
- *Create collaboration spaces with Industry users to create more effective and efficient dialog*



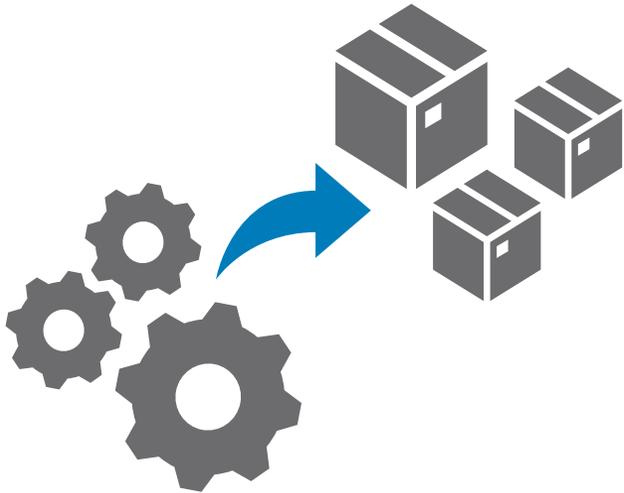
# What are Capabilities and Products

**Capability is an organized collection of technology that enables some functions and serves a specific business need.**

- Capabilities are expected to be **used by multiple products**
- Capabilities can be broken down to lower levels to **deliver specific functions**
  - For example, electronic submission using an online form (a.k.a. webform) capability that can be used across products such as TAP, Small Business Determination (SBD), and Accreditation Scheme for Conformity Assessment (ASCA)

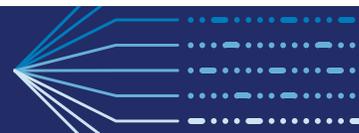


# What are Capabilities and Products (cont'd)



**Products consist of one or more capabilities and deliver value to the end customer and can be both external and internal.**

- **An external product is something that an end-user interacts with directly**
  - For example, a progress tracker for a 510(k) submission
- **An internal product is something that a business team relies on to do their work**
  - For example, the Policy Development workflow for requesting and developing a Guidance



# The Capability Catalogue – Capability Themes & Levels

## Electronic Submission & Progress Tracking

|   |  |
|---|--|
| <b>Electronic Submissions</b>   | <b>CCP Progress Tracker</b>  |
| <ul style="list-style-type: none"> <li>- File upload (e.g., eCopy, eSTAR) ●</li> <li>- Structured-data webform ●</li> </ul> | <ul style="list-style-type: none"> <li>- CTS-sourced progress tracking ●</li> <li>- DMP-sourced progress tracking ●</li> </ul> |

## Data Delivery

|   |   |
|---|---|
| <b>Reporting</b>  |   |
| <ul style="list-style-type: none"> <li>- DMP-based reporting ●</li> <li>- Status reporting ●</li> </ul> | <ul style="list-style-type: none"> <li>- Performance reporting ●</li> <li>- Workload reporting ●</li> </ul> |

## Workflows, Guided Review, Enterprise Search, Content Management

|   |   |  |   |
|---|---|--|---|
| <b>DMP Unified Work List</b>  | <b>Base Workflow</b>  | <b>Advanced Workflow</b>   | <b>File Handling and Management</b>   |
| <ul style="list-style-type: none"> <li>- CTS-sourced task list ●</li> <li>- DMP-sourced task list ●</li> <li>- My Staff view ●</li> </ul> | <ul style="list-style-type: none"> <li>- Workflow ●</li> <li>- Request display and management ●</li> <li>- Internal communications ●</li> </ul> | <ul style="list-style-type: none"> <li>- Workflow ●</li> <li>- Request display and management ●</li> </ul> | <ul style="list-style-type: none"> <li>- Short-term file handling/repository ●</li> <li>- Long-term file handling/repository ●</li> </ul> |

## Communication & Collaboration

|  |   |
|--|---|
| <b>Omni-Channel Communications</b>   | <b>Collaboration</b>  |
| <ul style="list-style-type: none"> <li>- Portal communications ●</li> <li>- Official communications ●</li> <li>- Systematic notifications ●</li> </ul> | <ul style="list-style-type: none"> <li>- External-party tasking and monitoring ●</li> <li>- Interactive review ●</li> </ul> |

## Data Integration & Management

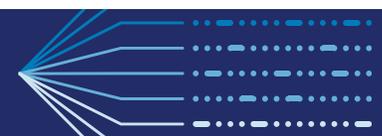
|   |   |
|---|---|
| <b>Data Model Integration</b>   | <b>Data visualization</b>   |
| <ul style="list-style-type: none"> <li>- Application of enterprise data models ●</li> </ul> | <ul style="list-style-type: none"> <li>- DMP Data visualizations ●</li> </ul> |

**Legend**

- In production
- Current Work

**Legend**

- Planned
- Future



# TPLC Advisory Program (TAP) Pilot

## Total Product Lifecycle Advisory Program (TAP) Use Case

TAP is intended to ... the benefits of process improvements to CDRH's early interactions with Industry users and other stakeholders



**Improves participants' user experience** by providing timelier premarket interactions with CDRH staff



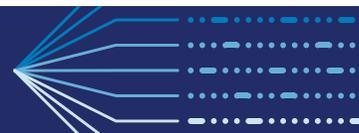
**Improves strategic decision-making** during device development



**Facilitates better engagement and collaboration** between FDA Review teams and Sponsors

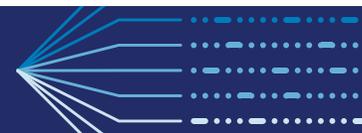


**Improves the efficiency** of premarket review process



# Digital Transformation Impact on Industry and the Public

- Greater and more **transparent** interactions between CDRH and its stakeholders, including providing industry with the ability to track their premarket submissions online and to engage with CDRH staff on their submissions in a virtual workspace.
- Business processes closer to the speed of industry to **streamline** workflows, reduce the cost of maintaining data and network security, and improve the timeliness of delivery of services.
- Fewer duplicative efforts and creation of one **integrated** environment for CDRH employees to find, integrate and analyze, using modern analytical/AI tools, complete information to more efficiently and effectively process applications and respond to regulatory questions.
- More **efficient** and informed review of device applications, postmarket surveillance, and decision making across the total product life cycle generally.
- Ultimately, help **advance** medical device innovation in the U.S. and more **timely** patient access to high-quality, safe and effective devices.



# Use of CDRH Customer Collaboration Portal has steadily increased and is now used for 85% of submissions

