

FDA USES EA TO STANDARDIZE AND SAVE WITH CONSOLIDATION EFFORT

The FDA Information Technology (IT) consolidation solution, driven by the Enterprise Architecture (EA) framework, benefits the Agency by: reducing costs; achieving better customer response; improving mission performance; and leading to a more engaged and qualified IT staff.

FDA PROFILE

Quick Facts

The Department of Health and Human Services (HHS) is responsible for providing health-related services to Americans. The Department includes over 300 programs with a variety of activities such as health and social science research, health information technology, services for older Americans and medical preparedness for emergencies.

FDA Mission Statement

The Food and Drug Administration (FDA), an operating division of HHS with 10,000 employees, distributed across eight centers and offices ensures:

- Foods, drugs, and cosmetics are safe and properly labeled;
- Drugs and medical devices are safe and effective;
- Blood is safe and in adequate supply; and
- Equipment that uses radiant energy, such as X-ray machines and microwave ovens, is safe.

THE SITUATION

In 2002, the President laid out his Management Agenda (PMA)¹ as a framework for a citizen-centered, results-oriented, and market-based Federal government accomplished through five executive branch-wide initiatives: improving use of human capital, financial management, electronic government, competitive sourcing, and budget and performance integration. In support of the PMA, HHS established its "One HHS" initiative to consolidate, streamline, and standardize administrative programs throughout the department. Additionally, the Prescription Drug User Fee Act (PDUFA)² required FDA to develop a plan for consolidation of its Information Technology (IT) infrastructure across eight division centers and identify standard software applications to be utilized for common business needs.

FDA faced several challenges including:

- The need to align information technology (IT) with the Agency business strategy;
- Limited funding and resources to support the effort;
- FDA's eight service centers and offices operated in a decentralized manner;
- Lack of standardized processes and systems to share and exchange information;
- Corporate culture resistant to change; and
- High expectations of FDA units being serviced.

"We needed to overcome cultural change by being flexible and inclusive. By providing leadership in this manner, our success could be shared by our dedicated FDA employees and managers. We learned to become customers as we learned to become providers," said Jim Rinaldi, the FDA Chief Information Officer (CIO).

¹ www.whitehouse.gov/omb/budget/fy2002/mgmt.pdf

² www.fda.gov/oc/pdufa/default.htm

THE SOLUTION

In response to the legislative and executive mandates, FDA turned to Enterprise Architecture (EA) to serve as the methodology to achieve its desired state of efficiency and effectiveness. FDA worked with each center and office to create a baseline architecture, approved and published agency-wide. This baseline was used to support the development of a consolidation blueprint for the IT infrastructure of FDA. Working closely with HHS at the department level, Rinaldi developed an IT consolidation plan by, essentially, "running a business within a business."

The Office of the Chief Information Officer (OCIO) was reorganized and common governance and reporting structures were established ensuring the department strongly supported FDA's mission, goals and objectives. FDA also established the Office of IT Shared Services which helps FDA focus on its core business; create satisfied customers and employees; leverage technology and information, and more effectively manage costs.

Business and IT could now align better under the critical mandates of EA and Capital Planning and Investment Control (CPIC). FDA's CIO added, "We chose to embrace change and install governance so that IT could meet the science-based mission of FDA and satisfy HHS and OMB. We could develop systems consistently across the Agency and reuse, leverage and consolidate applications where feasible."

Not only could FDA eliminate unnecessary duplication of resources and efforts, it could track all IT investments across the enterprise, adjust costs to meet reduced budgets, and enhance staff

skill levels while improving service delivery. Two key benefits of the consolidation were:

- ❖ Maximized infrastructure by replacing single-use environments with platforms shared across application system boundaries without respect to FDA center or office; and
- ❖ Leveraged IT operations staff from multiple buildings to two major locations by employing a homogenous platform architecture.

The FDA added the role of Chief Enterprise Architect (CEA), filled by Gary Washington, to its strategic IT management staff. The EA budget for FDA was approximately \$350K to \$500K (out of a \$200M total IT budget) per fiscal year, and the program utilized existing staff to manage the program. One of the CEA's first actions was to establish an EA Working Group (EAWG), with representatives from each center, to develop a standardized EA framework aligned to the Federal Enterprise Architecture (FEA) reference models. All FDA artifacts were placed in an EA repository, accessible for viewing FDA-wide. This framework provided the foundation for FDA to develop its baseline and target EAs including processes, systems, information, technology, performance, and security.

FDA's EA is aligned to the directives and mission objectives set forth in the HHS/FDA Annual Strategic and Information Technology Plans and to HHS' department-level EA. The development and implementation of the center and FDA Enterprise baseline and target architectures was executed by key

stakeholders including the CIO, key IT and business staff, program executives, and center architects. The consolidation effort follows the target architecture as defined by the Technical Reference Model (TRM) under the FEA.

Using its baseline and target EAs, FDA performed a gap and redundancy analysis, followed by prioritizing the tasks needed to streamline the processes and systems of the organization. The gap and redundancy analysis identified overlaps across centers (e.g., FDA identified duplicate adverse event reporting systems) and areas where automation could be implemented to improve efficiency.

The EAWG has evolved into an EA Review Board (EARB); a council responsible for selecting and verifying IT investments against the division EA and ensuring policies and procedures are properly implemented. To be funded, investments must advance FDA's mission objectives and fulfill documented EA security and technology requirements. A change and configuration management committee works closely with the EARB and oversees the development, maintenance, and revision of the EA models and artifacts.

The EAWG developed a communications strategy to promote the use and value of EA to both IT and business stakeholders. Program officials now understand the value of EA in making better business decisions. The ability of center representatives to build EA artifacts and utilize an EA framework, processes, and terminology required technical training. Three center/office executives attended EA training and received the Federal Enterprise Architecture Certification (FEAC). FDA's EARB continues to provide EA training and communication across

centers to bridge the gap between program officials and IT.

The EA effort has resulted in FDA having a federated IT approach, meaning individual centers are expected to follow the same framework and approach as set forth at the Agency level. This approach allows FDA to implement its EA across all centers while providing the necessary detail related to center-specific processes and systems.

THE RESULTS

EA driven IT consolidation has allowed FDA, despite IT budget constraints, to use fewer resources while operating more efficiently and providing better services to citizens. FDA is moving forward with its plans for technology refresh, containment, and retirement. Systems and technology continue to be consolidated. The key results and outcomes of this effort include:

- ❖ *Increased cost savings.* Over the next five years, IT consolidation will help FDA avoid \$10 million redundant IT related costs.
- ❖ *Documented and standardized business processes.* Using the EA framework, over 85% of Agency-wide processes have been documented. Utilizing this information as a benchmark, FDA is evaluating processes such as the product review process across centers. Over the next several years, FDA has plans to standardize common IT processes such as requirements analysis and capacity planning. Finally, FDA's EA was used for the development of an electronic gateway; automating and standardizing the

process for industry to submit products to the FDA.

❖ *Consolidation of IT infrastructure.*

The EA effort was able to identify and drive consolidation activities and as a result, reduce the number of applications. For example, the number of correspondence tracking systems was reduced from 24 to 2. FDA has also established a draft target architecture to optimize web technologies. The FDA uses a web-based architecture for its e-submission and registration technologies. FDA plans to decrease its current server inventory of 778 by more than half in time for the move to its new facility in 2010.

❖ *Improved communication and efficiency.*

The EA initiative provided the forum to improve communications among stakeholders. To streamline the organizational structure, FDA reduced decision-making levels to no greater than four. Consolidation of administrative functions was aimed at improving the cost effectiveness of headquarters operations and to concentrate facilities into two locations by 2010.

❖ *Improved decision making.*

EA was integrated with other Agency processes including strategic planning, capital planning and investment control, and systems development life cycle (SDLC). Integration of EA with strategic and capital planning has allowed portfolio managers to focus where to spend IT dollars across 31

investment areas. As a result of the FDA EAWG working closely with the FDA CPIC team, FDA has reduced the number of OMB Exhibit 300's from 37 to 13 which allowed them to more accurately report its information technology expenditures.

FDA's CEA Gary Washington articulates: "We have an agency view of EA -- each center/office is now able to have a center/office view of their environments. It is a federated approach where we can analyze business processes and identify duplicate technologies. Our stakeholders are represented at all FDA locations."

EA continues to be part of FDA's strategic solution to standardize its business processes and consolidate its IT infrastructure. It helps IT align with the Agency business strategy and drives business decisions. The FDA IT consolidation solution, driven by the EA framework is reducing costs; improving mission performance; and leading to a more engaged and qualified IT staff.