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QUARTERLY NEWSLETTER
Enterprise Information Technology
Project Management Office
(eIT PMO)

eIT Times

In this issue…

Overview of the eIT PMO

The USAMRMC Enterprise Information Technology (eIT) Project Management Office (PMO) is responsible for providing IT solutions to support medical research at USAMRMC in accordance with DoD/Army/MEDCOM policies and regulations.

The PMO facilitates full program coordination to ensure successful acquisition of required IT solutions to support Food and Drug Administration (FDA) compliance efforts.

The eIT PMO maintains a valid DoD Interim Authority to Operate (IATO).

EDMS "Hands On" Training Dates

Classes are held in Bldg 844 at Fort Detrick (DCO available by request).

Basic Functionality Training

Time: 0830-1000
06 August 2014
10 September 2014
08 October 2014

Manager Training

Time: 1000-1130
06 August 2014
10 September 2014
08 October 2014

Enterprise Connect Training

Time: 0900-1030
20 August 2014
03 September 2014
22 October July 2014

Advanced Training

Time: 0900-1030
27 August 2014
24 September 2014
29 October July 2014

Contact eIT PMO Mailbox to schedule: (usarmy.detrick.medcom-usamrmc.other.eit-pmo@mail.mil)

In the Spotlight…

Gain Efficiencies through Automation

Question: How many manual, repetitive business processes do you perform in your office on a regular basis—whether it's daily, weekly, semi-annually, etc.? The phrase 'repetitive process' makes it sound like it's a simple process that is used so often—you could do it with your eyes closed! *Easy*--Right? Unfortunately, even repetitive processes can prove to be inconsistent when you throw the human element into the equation. Process participants will tell you they never received a document; documents have gone missing in multiple local or shared drives; you can't recall if you're in the review or approval phase or even if you have the most recent version. *Is your head spinning yet?* You tell yourself there has to be an easier way--and there is. **Automation!**

The eIT PMO is providing customized **business process automation** to several organizations in the Command today, incorporating the efficiency, speed, accuracy, and manageability that come with using automated workflows and tools. While many organizations start process automation on a small scale, they soon begin to think in terms of how their organization is run; one process often flows to another process or event. Soon, they are thinking about broader and more complex process automation…and they want MORE!

Part of the eIT PMO team's job is to analyze these processes to determine if we can broaden the scope of impact provided by the workflows and tools we deliver. Can the solution to one customer's organizational requirements be easily adapted to fill another organization's needs? Many offices have similar repetitive processes; often, customized workflows and tools can be modified, reducing the amount of development time it takes to adapt the workflow or tool to another organization.

In our previous newsletters, we've included updates on the capabilities delivered during the quarter. For this issue, we thought we'd summarize what we feel, are the Top 5 capabilities we've delivered, or are on schedule to deliver soon (in no particular order).

DRAC Regulatory Workflow (WF): USAMMDA Division of Regulated Activities and Compliance (DRAC) needed an automated process to compile and route document packages thru a review, approval, and signature process, prior to submission to the FDA. The manual process previously used involved moving document packages between various shared network drives/directories and sending files around via email attachments. Tracking the routing progress, accountability, audit trail, and maintaining an authoritative source and storage for the packages was difficult. Use of the DRAC WF has provided measurable efficiencies in data integrity and process management:

- ***Provides single source for process deliverables***
- ***Provides consolidated dispositions in one location***
- ***Eliminates multiple local and shared drive document copies and sending of large email attachments***
- ***Allows for view-only capability***
- ***Allows electronic signatures on forms/documents***
- ***Automated upload of final submission package to EDMS***
- ***Provides document tracking, status, and version and audit control***
- ***Provides automated notification of pending tasks***

The WF also provides various reporting capabilities:

- ***Submissions Report displays submissions by date, type, and/or Regulatory Affairs Scientist***
- ***History by Submission Report displays milestone information for a specified Product/Serial number***
- ***In Progress Report displays all submissions and associated metadata and status currently running thru the WF process***
- ***Error Report provides error information and error description that occurred in the WF process***
- ***Product History All Report provides historical information on all events that occurred on a particular product number, including pre-WF information stored in EDMS as well as information gathered as the submission runs thru the WF***

Technology Solutions for Medical Research

In the Spotlight...Automation *continued.*

Sponsor's Electronic Regulatory Files (SERF):

USAMMDA DRAC is responsible for all official communications and submissions to the FDA and other regulatory agencies. This includes creation and maintenance of all regulatory files for OTSG sponsored products. Hence, DRAC required a robust and centralized document management capability. They needed a way to find documentation without having to wade through an exorbitant number of files/folders and standard search methods were proving frustrating to users. The eIT PMO developed a customized workspace in EDMS for DRAC, called SERF. The SERF workspace meets FDA compliance regulations and is used to store documentation that has been or will be submitted to the FDA. DRAC controls user access to content in this area. SERF customized tools have vastly improved efficiencies for DRAC by:

- ***Allowing users to automatically apply metadata to uploaded files; thereby, enhancing the search capability***
- ***Automatically storing uploaded documents in the appropriate area based on the applied metadata***
- ***Allowing users to quickly find information without having to navigate thru a file structure. The Custom Search Feature provides a screen with the metadata fields displayed to allow users to search files based on the applied metadata. A report displays the documents that match the specified search criteria***

PPA&E Workflows: The eIT PMO has developed several automated WFs for the USAMRMC Plans, Programs, Analysis and Execution (PPA&E) office in support of the Program Objective Memorandum (POM) process. Prior to automating these business processes, the participants relied on shared storage drives and email attachments to route the submission packages thru numerous review and approval steps. Using WFs as tools to prepare the various packages and briefings, the PPA&E office can now provide document control, efficient routing, and one authoritative source for all process updates. WF implementation has ensured continuity, suitability, quality, and efficiency in the POM process. In addition, enhancements made to these WFs have minimized the number of steps to complete the processes and provided for enhanced collaboration among participants. All of the WFs have a consistent look and feel, making them even more user friendly.

Each WF provides:

- ***A graphical representation to indicate to the users where they are in the process at each step within the WF***
- ***The ability to capture and maintain questions and/or comments throughout each review cycle***
- ***Previous review cycle comments that may be viewed and/or printed during subsequent review cycles***
- ***Final briefing packages and documents that are stored in a centralized location in EDMS for future use and collaboration.***

SOP Management Tool: This tool was developed to fill a need for the eIT PMO. However, it can be easily applied to any organization needing to track SOPs, Work Instructions (WIs), and other standard documentation requiring periodic review and update. The eIT PMO formerly used an Excel spreadsheet to manually track and maintain a list of all SOPs, WIs, document templates, and associated personnel training records for these items. The manual process was time consuming, prone to human error, and did not provide adequate reporting to track when updates were due. Use of this tool provides:

- ***Metadata to track titles, version numbers, owner's name, date for review/revision, type of document (SOP, WI, Template), product name, and more***
- ***Reports displaying documents needing revisions within a specified timeframe***
- ***Custom Search capability, allowing users to search on the metadata captured for each document.***

Enterprise Document Routing Workflow: The eIT PMO's first truly 'enterprise-wide' WF is planned for release in the next quarter, and will be available to **all** EDMS users. Typically, documents are routed thru the use of email, hardcopy, and/or posted on network drives. This practice often means that documents are lost and versions are difficult to track. EDMS users need an ad-hoc, generic WF to route documents for review, approval and/or signature in order to conduct business and collaborate more efficiently. This WF will provide numerous, measurable benefits:

- ***Allows user to initiate their own automated WF, anytime they want, for routing a document package for review, approval, and/or signature***
- ***Cycles can be performed multiple times***
- ***Provides tracking, status, version control and audit trail***
- ***Provides automated notification of pending tasks***
- ***Allows Initiator to view the progress of WFs in motion***
- ***Allows Initiator to specify where the documents will be stored in EDMS once the WF is completed.***

If the workflows and tools listed here could be used to make your organization run more smoothly, contact us to discuss! The efficiency, accuracy, and manageability you will gain will be worth it!!

Product Updates

Medical Dictionaries

WHO Drug Dictionary updates for June 2014 are now available within SAE and EDC.

Future Capabilities

EDMS Customized Tools in Development

❖**Folder Automation Tool**
This tool is being developed for USAMMDA DRAC users, who create and prepare protocol submissions to the FDA, to automate their folder structure creation process. The tool will automatically apply the appropriate permissions to the structure. Users will have the capability to change permissions on folders as needed. Other benefits include the ability to add new products, add new submissions to existing products, and submission archival.

❖**Tasker Tracker Tool**
This tool is being developed for the WRAIR Experimental Therapeutics team to track both internal and external taskers. The tool provides the ability to create new tasks and sub-tasks, search tasks within the application, print and/or export search results, and view all tasks. When a new task is submitted, the application automatically creates a corresponding folder area to store documents associated with the task. A historical audit event table is maintained for each task.

Want More?

If you and/or your organization are interested in learning more about the IT capabilities offered by the eIT PMO, we will be happy to meet with you!

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