

Business Process Management (BPM) at FDA: The Agency's Early Experience in Implementing BPM Software Tools

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EXECUTIVE SUMMARY

BPM is a business discipline to manage the business process lifecycle. It aims to achieve an organization's objectives through the improvement, management and control of essential business processes. BPM optimizes the performance of key business processes through use of process improvement methodologies and application of the tools used to aid those methods. The methodologies include the ways in which information about processes is gathered (i.e. Business Process Modeling), the process optimization methods (e.g. Lean, Six-Sigma, etc.), as well as the use of BPM for conducting business, performing analytics and measuring business performances. Some of the typical components of BPM tools are *Process Engine* (for modeling and executing process-based applications, including business rules), *Business Analytics* (for identifying issues, trends, and opportunities with reports and dashboards), *Business Intelligence Dashboards* (for reporting, workflow management and strategic planning) and *Knowledge Management* (including collaboration tools, discussion forums, e-mail system and message boards).

BPM has a long history that can be traced back to the work of the Father of Industrial Engineering, Frederick Taylor at the turn of last century. Taylor and his colleagues developed modern industrial engineering and process improvement, though the techniques were restricted to manual labor and production processes. Since then, BPM has undergone many reincarnations under various flavors and names, such as Juran Quality Management System, Toyota Production System, and Business Process Reengineering. Today BPM continues to evolve as a technology and methodology, promising productivity and financial benefits to the enterprises adopting it. FDA, as one of the leading U.S. agencies entrusted to protect public health, has been piloting BPM for the last few years. This presentation chronicled FDA's experience in piloting and implementing two BPM platforms (Appian 6.1 and Oracle BPMS) at a number of Centers at FDA. The Agency's experience and lessons learned in implementing BPM were captured for FDA Senior Management's considerations in deciding the future of further BPM implementations at FDA.



Figure 1. BPM deals with the management of business processes. Business processes support and contribute towards the fulfillment of strategic, tactical and operational objectives, with the assistance of technology and people

DETAILS OF SELECTED BPM PROJECTS AT THE CENTERS

CDER (Center for Drug Evaluation and Research)

Goal: Determine feasibility and effectiveness of using Appian BPM technology to support automating the NDA review process. iGrafx was used as the intermediate modeling tool.

Results: The pilot, completed in 6 months, was fully functional and had the desired graphical look-and-feel, as well as an executive dashboard feature. However, in late 2011 CDER Sr Mgmt decided not to pursue Appian development any further, due to lack of end-users buy-in.

Comparison of One iGrafx Node to the Appian Equivalent

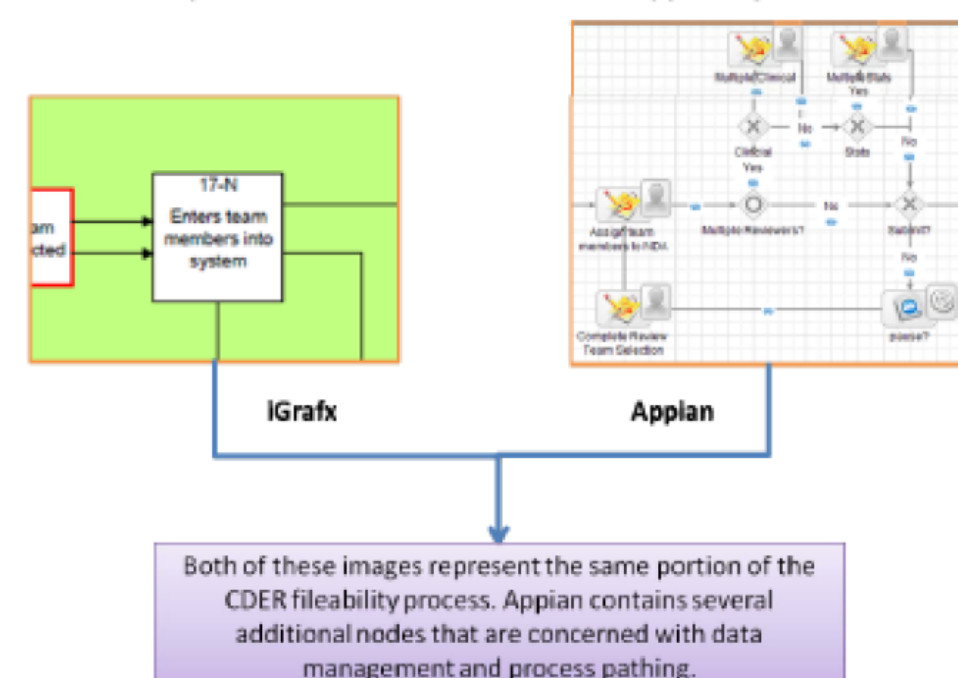


Figure 2. In order to accurately capture the NDA business processes from the end-users and business owners, iGrafx 2011, a Business Process Modeling graphical software tool, was used in conjunction with Appian. iGrafx allows for a quick and simple capture of process steps, and is used as an intermediate step

CDRH (Center for Devices and Radiological Health)

Goal: The goal of the iReview project was to automate parts of the review processes for 510(k) device marketing approval. Appian was used both for modeling and as the BPM tool

Results: Although iReview was completed on time and was fully functional, CDRH Sr Mgmt decided to cancel its planned launch of Sept 2010 due to lack of end-users buy-in. Furthermore, it would be unlikely for Appian in the future to be used in 'mission critical' applications at CDRH. Presently no other BPM system is being considered for use at CDRH.

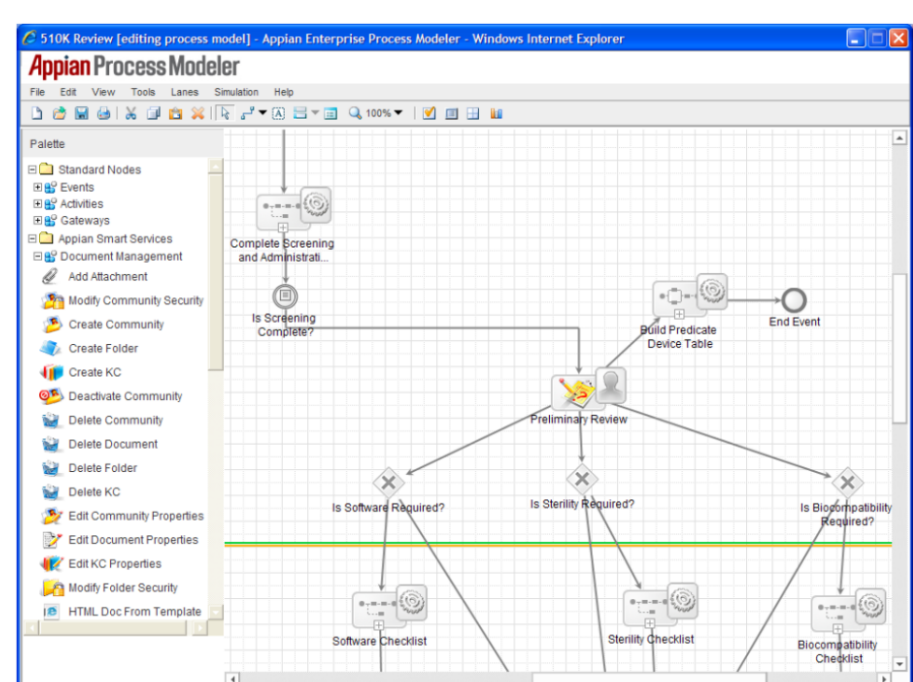


Figure 3. Appian Process Modeler with a portion of the iReview's 510(k) process model. Appian was used both for modeling the processes and as the BPM tool

CVM (Center for Veterinary Medicine)

Goal: Develop the Electronic Document Submissions & Review (EDSR) system for the Office of New Animal Drug Evaluations (ONADE). Elements of the newly developed Appian system were: draft correspondence mgmt; use of digital signature correspondence; storage of ONADE final correspondence; and send legal electronic correspondence to submitters

Results: CVM successfully implemented the Appian EDSR system. In Mar 2010, the system went to pre-production, with full product release completed in second half of 2011.

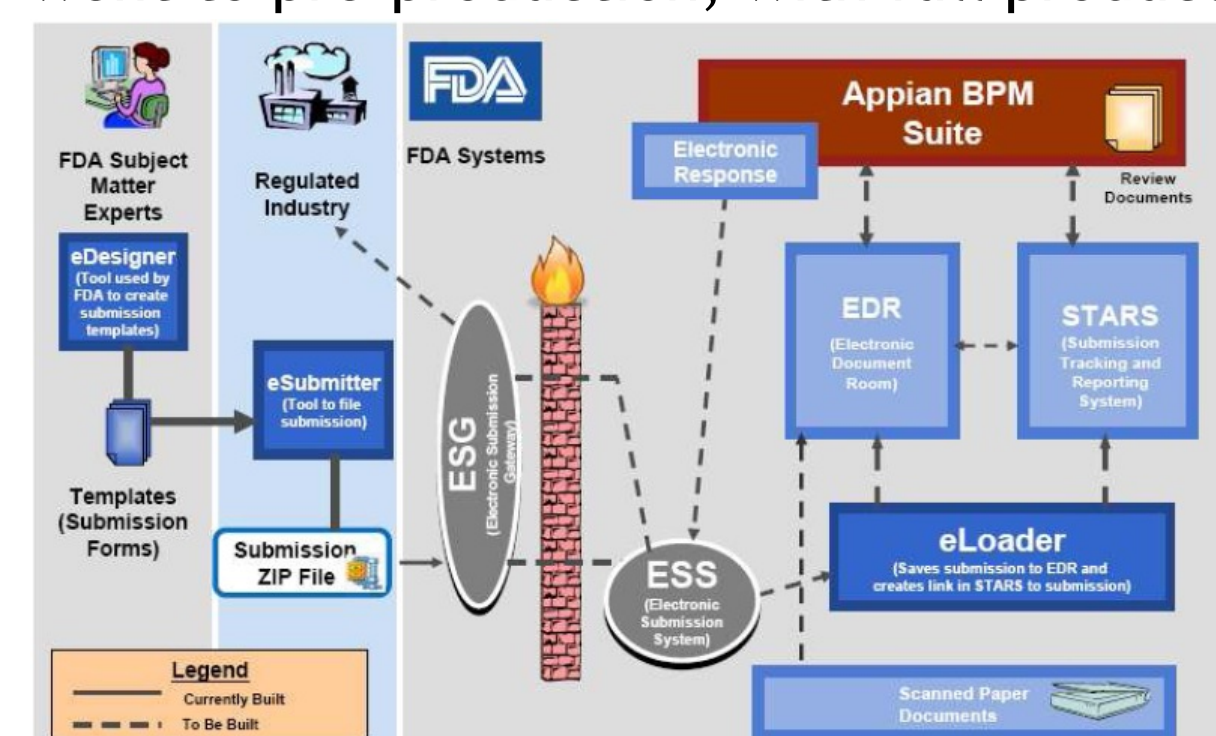


Figure 4. Appian BPM's Role in the EDSR (Electronic Document Submission and Review) system, supporting marketing application processes of ONADE (Office of New Animal Drug Evaluations)

STATUS OF BPM PROJECTS @ FDA

Center	Application	BPM	Status	Comments
CDER	NDA Fileability Pilot	Appian	Pilot completed March 2011. No further development planned	Scope limited to NDA fileability checklist process. CDER management decided that the application did not meet the end-users needs
CDRH	iReview 510(k)	Appian	Development completed Aug 2010. Implementation put on hold	iReview's was designed to automate parts of the CDRH 510(k) review process. CDRH management decided that the application did not meet the end-users needs
CFSAN	FARM (Food Applications Regulatory Management)	Appian	Pilot completed Jan 2011	Presently working on improving performance and modifying functionalities.
CVM	ONADE (Office of New Animal Drug Evaluation) electronic review system	Appian	Operational and in Production March 2011	Reviews and manages Investigational New Animal Drug (INAD) and New Animal Drug Applications (NADA) submissions
OC	FACTRS (FDA Advisory Committee Tracking Reporting System)	Appian	In Production starting Feb '11	FACTRS tracks list of AC members and manages potential conflict of interest.
ORA	MARCS (Mission Accomplishment and Regulatory Compliance Services)	Oracle BPMS	Project in progress Jan '11 onwards	Purchased Oracle software in Nov 2010 as part of a contract to update MARCS. In Apr 2011 ORA sought to leverage use of their Oracle license at other Centers

LESSONS LEARNED

The implementation of BPM systems (Appian and Oracle) at various Centers of FDA has been described in considerable detail. The results, so far, has been mixed at best. However, a couple key lessons could be extracted:

- Business needs for the BPM implementation should be strong and clear. The business users need to be clear on the types of business needs that are great fit (and those that are not) for BPM application, as the success (and failure) of the endeavor greatly depends on it
- Support from stakeholders and end users are critical. At CDER and CDRH the BPM pilots did not gained acceptance, even after completion of a finished prototype, due to failure in gaining support from end users
- Strong Project Management is essential in developing and deploying BPM. This will greatly impact the first impression of potential users (many were introduced to a BPM system for the first time) and the chances of gaining acceptance
- Selection of Appian or Oracle BPMS depends on business needs, IT sophistication of developers and O&M managers, budget availability and licensing structure
- At present, it is not entirely clear which (Appian or Oracle), if any, is the most suitable BPM for use at FDA
- Further studies are needed to determine the business process improvement needs of FDA and its Centers, and the suitability of current BPM systems offered in the market in addressing those needs

WHEN IT MAKES SENSE TO USE BPM

Drivers and triggers for the organization to consider a BPM - potentially leading to an automated solution - may include the following:

- A high volume of similar and repetitive transactions
- A clear flow of high-volume transactions that need to be passed from one person to another, with each adding some value along the way
- A need for real-time monitoring of transactions (a need to know a transaction status at all times)
- A critical issue with processing time - that is, time is of the essence
- A need to complete many calculations within the transaction
- Transactions of files need to be accessible by many parties at the same time

If one or more of the triggers apply, it is important to complete a root-cause analysis, as too often organizations take the easy way out and fight the symptoms rather than taking fundamental and structural steps to tackle the cause

It is imperative for an organization to avoid over-automating processes to the extent that the organization loses sight of the need for people involvement

WHEN SHOULD AN ORGANIZATION ADOPTS BPM

There are two process commonalities shared by organizations that are particularly suitable for adoption of BPM:

- Share common process challenges* (Does anyone know the current status of this request? What's the latest version of the form? Whose responsibility is it to complete this task? Etc.)
- Share a well-defined, routine process* (Automate manual, labor-intensive human tasks; Improve consistency via a repeatable and standardized process; Track and manage workload visually; Support business processes that span functional areas)

Specifically, BPM adoption is particularly suitable for organizations that are creating new operational processes on a regular basis, for the following reasons:

- BPM allows documenting business processes in the same system
- BPM allows for easily changing processes on-the-fly
- Continuous process improvement can be implemented when the system is operational
- Improvements and upgrades can be done incrementally; no need for major shutdowns
- Process automation can be implemented as standard functionality of BPM system

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