



# MKS

ONE ARCHITECTURE  
ONE SOLUTION  
TOTAL VISIBILITY

## CUSTOMER SUCCESS STORY



**Puget Sound Blood Center**  
research | medicine | blood & tissue services

**“When we saw MKS Integrity Manager we realized it met the majority of our requirements for a ‘dream’ change control system.”**

**Peggy Dunn, Director of Information Technology at Puget Sound Blood Center**

**Puget Sound Blood Center**  
Internationally recognized for groundbreaking research in transfusion and transplantation medicine, Puget Sound Blood Center is a non-profit organization helping patients in Washington State who need blood, tissue and specialized laboratory services. Founded in 1944, the Blood Center has a long and unique tradition of blending community volunteerism, medical science and research to improve patients’ lives. The Blood Center serves patients in more than 70 hospitals and clinics in 14 counties with blood services, and provides tissue and transplantation support to 185 hospitals across the Northwest.

## CUSTOMER SUCCESS STORY

## IT AND REGULATORY COMPLIANCE

Puget Sound Blood Center's computer systems must be available 24 hours a day, 365 days a year - lives depend on it. Its critical Blood Banking system is considered a medical device and must comply with U.S. Food and Drug Administration (FDA) regulations. The FDA requires stringent application development and change control practices surrounding donor registration, phlebotomy, component processing, testing, and distribution of applications.

FDA Code of Federal Regulations (CFR) Part 11 concerning electronic records and electronic signatures, must always be considered in the design of software development processes and evaluation of supporting tools. The organization must also adhere to HIPAA regulations concerning the electronic exchange of confidential patient information. Other applications developed and maintained by the IT organization include medical, financial, and service bureau.

## MANAGING THE DEVELOPMENT PROCESS

Puget Sound Blood Center is a long time user of MKS's Implementer for System i (iSeries) software configuration management (SCM) and deployment. Implementer manages changes to software applications developed in RPG and controls movement of programs to the Quality Assurance department for validation. Once validation is complete, Implementer securely deploys each program to the production environment. Implementer also replicates the executable portions of the applications to a mirrored server while Lakeview Technology's Mimix handles real time data replication. Should a system failure occur in production, Mimix and Implementer have ensured the high availability of Puget Sound Blood Center's critical applications.

Besides RPG, the IT organization is also programming in Java and developing a lab information system in Visual Basic 6 and Visual Basic .NET.

## IT CHALLENGES

Puget Sound Blood Center has traditionally developed and maintained most of its applications on the System i (iSeries). The organization is now moving toward adoption of distributed development platforms such as Windows NT, driven by end user demand for more user friendly GUIs and Web-based front ends for applications. In the coming years the IT organization anticipates moving System i (iSeries) applications into the back office, with more and more applications having an attractive GUI front end.

In light of the need to comply with external regulations while adopting new technologies on distributed platforms, Puget Sound Blood Center was faced with the following challenges:

- Trouble auditing the software development and change process
- Weak security - unauthorized users were able to submit change requests.
- Manual approval cycle and paper audit trail - requests for changes to systems were in paper form and needed to be routed to the IT Director for assessment, approval, and assignment to the appropriate programming group before work could begin.
- Broken link between change requests and changes made - program design, code review, technical design review, and validation change requests as required by the FDA, were all stored on the network and sometimes attached to the hard copy and filed for future reference.

## AT A GLANCE:

### Primary Reason for Implementation:

- Regulatory compliance

### Business Benefits After Implementation:

- Enhanced assurance of compliance with FDA regulations
- Increased productivity
- Less administrative burden
- Annual cost savings of greater than \$40,000, quickly achieving a positive ROI on investment in MKS.

### The MKS Solution:

- Implementer
- MKS Integrity for Process and Workflow
- MKS Integrity for Software Configuration Management

## C U S T O M E R   S U C C E S S   S T O R Y

- Disparate change management control - Java and HTML developers were using a different change management system and method than developers on the iSeries, hindering visibility into the overall change process and reducing change-tracking capabilities.

Manual processes increased exposure to risk

- The lack of an automated system to move objects or programs to distributed servers increased the chance of application failure.
- The IT department attempted to manually notify requesters of task status and completion but status updates were sometimes missed.
- Incomplete and time-intensive reporting process
- Lack of real-time reporting - relied on Excel to track information and to report the status of tasks to various programming groups. Reports of open change requests were printed and distributed to department Directors on a bi-weekly basis.
- Unable to enforce mandatory data capture - it was sometimes difficult to run accurate reports because users had not filled out all of the required information.

The organization needed a solution that could support multi-platform development, automate and enforce the change request and approval process, and provide a complete and automated audit trail to aid with FDA compliance.

## THE SOLUTION

Puget Sound Blood Center has relied on MKS's Implementer to manage software development and deployment on the System I (iSeries or AS/400) since 1992. Facing new IT challenges, the organization began gathering requirements for their ideal multi-platform SCCM solution. The most important requirements included:

- Ability to enforce multiple workflows;
- Ability to attach documents to a change request;
- Support for different types of change requests, capturing relevant data according to type;
- Automatic email notification for changes in the status of a request;
- Security enforcement that would ensure only authorized staff could submit change requests.

After an extensive evaluation, Puget Sound Blood Center turned to MKS Integrity for Process and Workflow, and MKS Source for enterprise SCM, a seamlessly integrated solution to manage change across their various platforms.

After successfully rolling out MKS Integrity for Process and Workflow to their 35-person IT staff, Puget Sound Blood Center took it to their 800 end users. With the web interface of MKS Integrity for Process and Workflow, authorized users can directly submit requests for changes and enhancements. Users receive automatic email notification regarding changes in the status of their requests throughout the development lifecycle.

Initially, Puget Sound Blood Center focused on automating the IT change request process. This process is enforced with six different workflows in MKS Integrity for Process and Workflow. Mandatory fields ensure that relevant data is captured in the initial change request, and then the request is routed through a strict approval process. The IT director receives an email when a new request is submitted, and can then assess and assign the task to the appropriate group. The approval process mandates that users, after being notified of task completion, must complete the workflow by signing off on the task. All related documentation can be attached to an issue (change request) and only authenticated users can view issues.

**“The possibilities are endless...**

**Initially, I worked with MKS Integrity to manage my priority issues, now everyone across the organization is using it. When there is a manual process that can be automated, MKS is the first thing we think of. It's great to see that others at PSBC reap the benefits of MKS and that they use it to make their jobs easier.”**

**– Peggy Dunn, Director of Information Technology at Puget Sound Blood Center**

## C U S T O M E R   S U C C E S S   S T O R Y

Since this initial process automation, Puget Sound Blood Center has automated eight different issue types with at least two workflows associated with each.

## VALUE

Since adopting MKS's comprehensive ALM solution, Puget Sound Blood Center has realized the following improvements:

- Enhanced assurance of compliance with FDA regulations because of a fully automated approval cycle and audit trail for all software change. Management has visibility into the change process across all development environments.
- Improved security ensures only authorized users can submit change requests.
- Permissions can be defined at the project, role, and user levels.
- Increased productivity and repeatability by automating and enforcing multiple processes and routine tasks.
- Better decision making as a result of real-time reporting capabilities. Queries and reports are easy to create and can now be managed by the user.
- Improved communication with end users because of their ability to submit requests and get real-time updates on their status.
- Faster development cycles since the bottleneck of task assignment has been eliminated.
- Reduction in training costs as a result of MKS Integrity's ease of use.

Due to the automation of IT change requests, Peggy Dunn estimates that she has personally saved 5 hours per week since moving from a manual to an automated approval process for change requests, translating to an approximate savings of \$13,000 per year. With the additional automation of eight issue types, others in the company have also gained more productive use of their time. The administrative burden associated with filing paper documents and manually creating reports for various user groups has been drastically reduced, and project lifecycles have shortened. Puget Sound Blood Center has benefited from an annual cost savings of greater than \$40,000 and quickly achieved a positive ROI on its investment in MKS.

## WDS*c*, SYSTEM i & WINDOWS - ONE INTERFACE, ONE REPOSITORY

Using integrations between the MKS Integrity solution and IBM WebSphere Development Studio Client (WDS*c*) for the iSeries, the entire development staff will work from a common (WDS*c*) interface. All projects can be associated with an issue in MKS Integrity for Process and Workflow and objects and programs can be checked out and promoted to all platforms utilizing the integrations between MKS Source, Implementer, and WDS*c*. These changes can then be deployed in unison to distributed servers. The System i (iSeries) will be used as a data repository with more visual programming (Java and Visual Basic .NET), and additional workflows will be supported by MKS Integrity for Process and Workflow. WDS*c* is integrated with Implementer so that for any development, whether for System I or Windows, there is a single interface and all projects are in MKS Integrity.

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