

# PharmaReady™



## Pharmaceutical, Clinical / Academic Research Industry Case Study

### PharmaReady™ Electronic Document Management System

#### PROFILE: Wake Forest University Baptist Medical Center

Wake Forest University Baptist Medical Center (WFUBMC), located in Winston-Salem, North Carolina, is the largest U.S. WFUBMC, one of the nation's preeminent academic medical centers, is an integrated health care system that operates 1,298 acute care, rehabilitation and long-term care beds, outpatient services, and community health and information centers.

The Medical Center has 20 subsidiary or affiliate hospitals and conducts 87 satellite clinics throughout the region. It provides a continuum of care that includes primary care centers, outpatient rehabilitation, dialysis centers, home health care, and long-term nursing centers.

Although its primary service area is North Carolina and southwest Virginia, the Medical Center in the past year has served patients from 91 North Carolina counties, 39 additional states and several foreign countries.

The Medical Center's component institutions carry out a joint mission of patient care, education, research and community service. The partnership includes three major members: Wake Forest University Health Sciences, North Carolina Baptist Hospital, and Wake Forest University Physicians.

#### BUSINESS PROBLEM

Custom-coded solutions for document management are often proprietary, resulting in high maintenance costs. TAKE Solutions, Inc's PharmaReady is based on Microsoft SharePoint and other state-of-the-art Microsoft products. By extending the existing products in a supported manner and predefining services using native product features, PharmaReady provides a low cost solution with minimal ongoing costs.

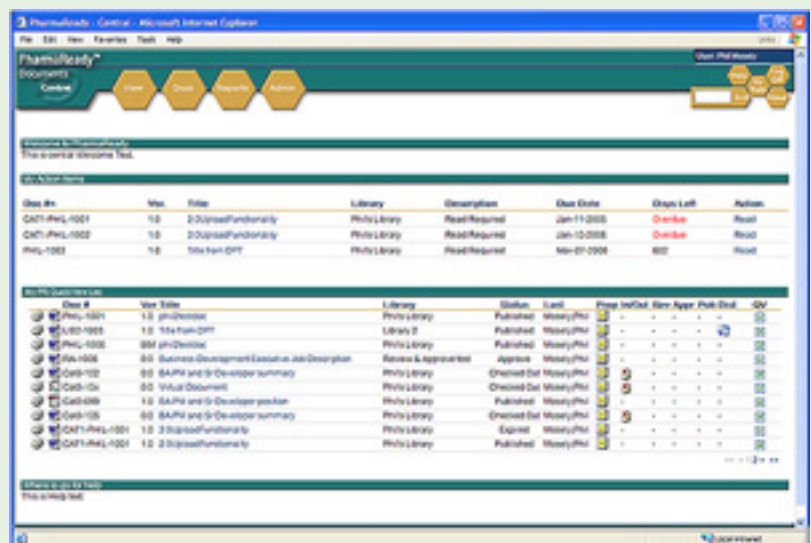
The PharmaReady FDA Compliant Document Management Solution allows drug makers to provide an effective enterprise-wide content, publishing and records management process to meet and facilitate

compliance within complex regulatory environments. Information provided enables managers, scientists and knowledge workers to have a unified view of the document workflow by integrating documented SOPs, work instructions, product / process specifications, manufacturing recipes, standards and legal documents such as New Drug Application (NDA) documents.

#### BUSINESS DRIVERS

Many business units within Pharmaceutical companies and Clinical Research Organizations such as WFUBMC must comply with Federal regulations concerning their processes and computerized systems. A key aspect of this is Title 21 of the Code of Federal Regulations, Part 11 containing numerous requirements for the management of SOPs and other documents within business areas regulated by the FDA and other agencies.

WFUBMC, impressed with TAKE Solutions' PharmaReady product, contracted with TAKE to implement the product to meet their regulated documentation management needs. Affordability, reliability, and the need to comply with FDA regulations were the biggest drivers in making the decision to select TAKE Solutions' PharmaReady product.



## SOLUTION

PharmaReady is a document management solution developed by TAKE Solutions designed specifically for organizations requiring insight into the full management of Standard Operating Procedures (SOPs) and other documents within business areas regulated by the FDA and other agencies. PharmaReady is a fully compliant FDA 21 CFR Part 11 document management solution based on Microsoft SharePoint™ Portal Server.

With PharmaReady solution, TAKE Solutions provided WFUBMC a document management solution utilizing proven Microsoft technologies implemented to be compliant with the regulations of FDA 21 CFR Part 11 and the predicate rules which govern the use of computerized systems for managing data related to clinical trials. PharmaReady is designed specifically for Pharmaceutical, Biotech, Healthcare, Life Sciences and Clinical Research Organizations requiring SOP and validation document management in validated computing environments.

With PharmaReady, extensions to SharePoint for Part 11 compliance and validation are provided by TAKE Solutions. And support for the underlying components, Microsoft's SharePoint Portal Server, SQL Server, and Windows Server, is provided by the world's largest software manufacturer. This synergy makes PharmaReady an ideal solution for your regulated document management needs with a total cost of ownership that customers afford.

## BUSINESS VALUE

Custom-coded solutions for document management are often proprietary, resulting in high maintenance costs. TAKE Solutions' PharmaReady product is based on Microsoft SharePoint™ and other state-of-the-art Microsoft products. By extending the existing products in a supported manner and predefining services using native product features, PharmaReady™ provides a low cost solution with minimal ongoing costs.

Scott Rushing, Deputy Director of Biostatistics for WFUBMC states, "TAKE Solutions' PharmaReady solution came at the perfect time for Wake Forest. With our confidence in the power of Microsoft's SharePoint™ Portal Server, TAKE Solutions successfully demonstrated how PharmaReady achieves

full management of SOPs, work instructions, and other documents regulated by the FDA - easily - and affordably. TAKE Solutions' knowledge and experience in both clinical research and information technology makes them an ideal business partner for Wake Forest. Any organization that's currently under-going a study to select an enterprise document management system should give PharmaReady careful consideration."

- FDA-Compliant Document Management
- Microsoft Technology Platform
- Full Implementation in under 1 month
- 100% Submission Success
- FDA-Audit Proven
- On-site or Remotely Hosted Deployments
- Easy to Implement / Easy to Use
- Strong ROI / Affordability

## Ready for more?

Visit [www.pharmaready.com](http://www.pharmaready.com) to take a look at PharmaReady. If you've looked at other regulatory information management products, we think you'll like what you see.

Learn how your organization can benefit from the most cost-effective, EDMS solution on the market today by calling: **877-320-3626** or visit: [www.pharmaready.com](http://www.pharmaready.com).



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