ASHVINSGROUP
TECHNOLOGY PROFESSIONALS

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CLINICAL LABORATORY QUALITY CONTROL SYSTEM SUPPORTING GLOBAL CUSTOMER BASE

Client Profile:

An industry leader in the field of clinical diagnostics who supplies clients with products and services that support laboratory Quality Control (QC) processes.

Technologies Used:

C/C++, Oracle, Oracle Forms and Reports, PERL, PL/SQL, Korn Shell, OCR for Forms, Rightfax, Adobe, Crystal Reports, WinRunner and AIX.

Project Summary:

Clinical laboratories are required by law to monitor and verify their data by using independent control samples to verify the validity of the patient results. The client requested the development of a web-based Quality Control/ Quality Assurance system consisting of a Windows based application, Web based interface and a central repository of data. The project was developed in phases beginning with the creation of the software requirements specifications for both the client and host applications. The client application standardizes the QC processes managed by the laboratory customers, and offers full CLIA documentation, comprehensive selection of QC Rules and immediately accessible data review reports. The system also included LIS/HIS interfaces to facilitate data submission, storage and management. Laboratory QC Systems are regulated by the FDA. These regulations require proper documentation and testing prior to release. Testing protocols, test cases and validation documentation were developed to ensure FDA regulation compliance. The entire system entails the acceptance of QC data via LIS/HIS interfaces, mail, fax, electronic data transfer and direct data submission via the Web based interface from the client application on a daily and/or monthly basis from labs around the world. Mailed and faxed data is processed using Optical Character Recognition (OCR) technology and imported to the Oracle relational database. Received data is stored in a central repository categorized by laboratory parameters. The data is analyzed for statistical validity and compared to other laboratories using similar test methodologies. Report pdf files are generated and are either printed for mailing or sent to users electronically.