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# VALIDATION OF APPLICATION LIFECYCLE MANAGEMENT SYSTEM (ALM)

## Client Profile:

A medical device company focused in diabetes who markets personal healthcare devices to measure glucose levels. The company was seeking to validate an Application Lifecycle Management System (ALM) in compliance with FDA guideines.

## Technologies Used:

Use Case Analysis, Requirements Engineering, knowledge of FDA regulated environments, FDA V & V Guidelines, experience in ALM processes and Quality Assurance projects and bug tracking.

## Project Summary:

The project consisted of reviewing Intended Use documentation from client (only test the features of the software that will be used by the client), creating Validation Test Plan (document and describe the software system, the environment it's installed in, assumptions and limitations, testing and acceptance criteria), creating Test Protocols (intended use of the software functionality, how it should work and how to prove that it works with scenarios to show conclusively that the software can generate the business process in a regulated environment), executing Validation Testing (validate the output of the software) and creating a Validation Report.