

# PRODUCTION CHANGE EFFICIENCY CASE STUDY: SLASHING TIMELINES WITH ONE-CLICK AUTOMATION

## Time to manage design spec changes and testing cut by more than half

Managing change documentation and test generation and approvals was sucking up valuable personnel time and extending project timelines for a leading biopharmaceutical company. The automation team was spending weeks manually updating design specs and creating test plans. The process was resource intensive, tedious, and involved peer scrutiny to avoid human error. They knew there had to be a better way.

With the help of Apperture Solutions and Informetric Systems, the company now uses AgileDoc® System Lifecycle Management (SLC) functionality to structure design specs and automatically generate consistent change markups, design specs, and test plans. The estimated benefit for a major project is from a dozen person-weeks of work to less than six, with smaller everyday changes consuming mere minutes of time vs a prior estimate of two hours. According to the company senior automation engineer: “We use it for everything, all the time, always...our ability to decrease project execution time has been more than worth the effort of implementation.”

“Any time we had a shutdown or some type of large global project, there could be hundreds of software objects being impacted...”

Senior Automation Engineer



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## An ever-evolving Manufacturing Landscape: Managing change at scale

The customer, a global biopharmaceutical company producing treatments across neurology, immunology, and rare disease, employs seven active facilities and is building a dedicated gene therapy site. Even with state-of-the-art manufacturing automation, managing production changes was consuming valuable time and energy for automation personnel facing ever-tightening timelines.

Very large events like shutdowns and global projects meant that hundreds of test protocols needed to be written, reviewed, and mapped to design spec updates, and much of this was being done manually. The team realized that “throwing bodies at the problem” was not the most effective solution.

### TIME SAVINGS

#### BEFORE

MANUAL COMPARISON AND  
REDLINING OF DESIGN SPEC AND  
WRITING OF CUSTOM TEST PROTOCOL  
- 2 HOURS

SMALLER DAY  
TO DAY CHANGES!  
HUNDREDS  
PER YEAR

#### AFTER

USE AGILEDDOC SLC TO GENERATE  
REDLINES, TEST TEMPLATES, AND SCOPE OF  
TESTING. STRUCTURED DATA AND VALIDATED  
PROCESSES TO GENERATE DESIGN SPEC  
CHANGES AND TEST PLANS AT THE PUSH OF  
A BUTTON - IN MINUTES

#### BEFORE

ANALYZING AND UPDATING DESIGN SPECS  
AND CREATING TEST PLANS ACROSS  
DOZENS OF PHASES, RECIPES, UNIT  
CLASSES, AND CONTROL MODULES: TAKES  
5-6 PEOPLE 2 OR MORE WEEKS

LARGE  
PROJECTS -  
ONE OR MORE  
PER YEAR

#### AFTER

TAKES A HANDFUL OF PEOPLE A FEW  
DAYS - MORE THAN 50% PROJECT  
TIMELINE SAVINGS AND UP TO 75% IN  
PROJECT PERSONNEL TIME SAVINGS

#### BEFORE

QUALITY TEST PROTOCOL  
PRE-APPROVAL REVIEW REQUIRED;  
PEER REVIEW TO CATCH HUMAN  
ERROR

QUALITY AND  
PEER REVIEW

#### AFTER

TRUST IN AUTOMATION SPEEDS  
PEER REVIEW; QUALITY  
PRE-APPROVAL OF TEST PLAN NO  
LONGER REQUIRED

With the implementation of AgileDoc® SLC and the accompanying redlining solution, fewer people were able to produce a consistently structured and automatable design change specification and test documentation process in far less time.

## Solution and Benefits

The company's legacy in-house design specification document generation toolset was not capable of automatically identifying design changes and their impact between dev and production, so redlining changes and test plan generation were both manual activities. For large production changes this meant the whole team working across dozens of specifications and thousands of modules to create corresponding updates and test plans.

With the help of solution architects and configuration engineers at Apperture and Informetric, AgileDoc functionality was leveraged to:

- Create a consistent, configurable, and repeatable approach for mapping software component information into auto-generated design documents
- Provide a user-friendly and easy-to-navigate way of generating redline markups to highlight design spec changes between production and development
- Create standardized test templates based on the newly standardized design spec elements
- Define repeatable, validated procedures using the new capabilities to generate design spec redlines and update design specs, create test plans, and route them for approval in less than half the time for large projects, and with even greater savings for smaller everyday changes

## PROCESS IMPROVEMENTS MADE POSSIBLE WITH AGILEDOC SOLUTION

### BEFORE

GENERATED USING CUSTOM IN-HOUSE TOOL - INCLUSIVE OF ALL SPECS WHETHER RELEVANT OR NOT

DESIGN SPEC CREATION

### AFTER

AUTO-GENERATED IN A STRUCTURED, CONSISTENT MANNER WITH THE ABILITY TO CUSTOMIZE WHAT IS INCLUDED

### BEFORE

MANUAL AND CUSTOM FOR EACH PROJECT - HIGHER CREATION AND REVIEW BURDEN AND INTRODUCES STRUCTURAL INCONSISTENCIES AS DOCUMENTS OVER TIME, INCREASING THE BURDEN

DESIGN SPEC CHANGE

### AFTER

EASY-TO-USE INTERFACE GENERATES CONSISTENT, STRUCTURED, REDLINE MARKUP FOR EASY REVIEW

### BEFORE

MANUAL AND CUSTOM FOR EACH PROJECT, MAY INCLUDE UNNECESSARY TESTS, AND NEEDS TO BE PRE-APPROVED BY QUALITY

TEST PROTOCOL CREATION

### AFTER

TRUST IN AUTOMATION SPEEDS PEER REVIEW; QUALITY PRE-APPROVAL OF TEST PLAN NO LONGER REQUIRED

Informetric Systems, Inc.'s AgileDoc® SLC automates the generation of lifecycle documentation by extracting data from automation and information systems, organizing it into a structured change control database using configurable object models. It ensures consistency and compliance through standardized templates, while its Elements module manages metadata and annotations to maintain traceability and data integrity across system modules.

The AgileDoc solution was implemented over time, with the original scope involving control elements and processes. Most recently the team worked with Informetric and Apperture to put the new processes in place for the team's ever-evolving manufacturing execution software components and processes. The MES implementation involved iteration between the customer automation team lead and the Informetric team to build out, test, and validate new configurations and templates in AgileDoc. The automation team lead reported a painless process and a high level of satisfaction with the support he received for the project, which took less than three months to complete.

"I would give them something and they would turn it around so fast...very impressive the way they were able to understand and implement based on customer input"

Ultimately, the real test of value is time savings, in an environment where time is money and speed to patient and market is critical. The AgileDoc solution saves hours per week and weeks per year, increasing confidence and freeing up time to focus on innovation, testing, and additional efficiency improvements.

**At Apperture Solutions,** we take a holistic view of operational procedures and critical equipment to achieve a competitive advantage for the long term. Working with solution partners like Informetric Systems, we leverage both existing and burgeoning technologies to help you turn your business goals into reality.

Does your manufacturing automation team struggle with change updates and test timelines, or other operational challenges?

Contact Us and Make A Change Today



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