

# END-OF-LIFE DESIGN CHANGES & DESIGN HISTORY FILE REMEDIATION PLAN



## Medical

### OUR PRODUCT DEVELOPMENT SERVICES:



Brainstorming and  
Concept Generation



Feasibility Studies and  
System Architecture



Detailed Product Design



Prototyping



Design for Manufacturing (DFM)



Verification Testing



Manufacturing Assembly  
and Test Equipment



Sustaining Engineering

### CLIENT

Global leader in medical products

### OBJECTIVES

- Provide sustaining engineering for a blood separation device in production for roughly 20 years
- Harmonize the design history file (DHF)
- Determine end-of-life (EOL) components, and identify replacements
- Assess requirements and risk impacts of replacements and test for implementation
- Work directly with contract manufacturers (CM) to ensure smooth transition into production

### APPROACH

- Reviewed product DHF – requirements, verification, validation, regulatory compliance, risk management file, etc.
- Addressed non-conformances identified by notified body
- Identified, tested, and recommended EOL components

### RESULTS

- Allowed the client to sustain production of the device
- Completed organization of entire DHF, harmonization of traceability documentation, design verification testing, and supporting data records
- Assisted client through successful notified body audit (all non-conformances were closed)
- Lowered device production downtimes with EOL component management and the resulting decrease in supply chain risks and production delays

# NEW LIFE TO AN OLD PRODUCT

The client received this medical device as part of an acquisition. The device had previously been in production for roughly 20 years and the client was the fifth owner of the device. This made for a large convoluted mix of documentation to account for the Design History File (DHF). The client knew a solution was needed to sustain this device for production. They came to ALTEN Technology for our expertise in Sustaining Engineering with hopes of saving the device and creating some organization of its DHF.

## SUSTAINING ENGINEERING

This project required review of 20 years of DHF data which included product requirements, verification, validation, regulatory compliance, and risk management files. The client's recent registrar audit had exposed its need for DHF remediation. All DHF elements needed to be harmonized for design traceability and risk management, ensuring synchronization of all requirements and outputs to bring the product to standards with the client's Quality Management System (QMS).

The other piece of this project was the client's request for End of Life (EOL) component assessment. With a product as old as this one, the EOL component management would be critical for maintaining the life of this product. ALTEN Technology would be in charge of identifying EOL components and working with contract manufacturers to make recommendations. Managing the EOL from end-to-end would save resources on the client's side, while ensuring a faster line to production.

The complexity lay in the magnitude of data to review amidst the overarching concern of ensuring the product remained in production. The client recognized they did not have the bandwidth to manage these tasks. ALTEN Technology engineers would act as the client's own engineering department to accomplish the objectives.



## INSPIRED SOLUTIONS

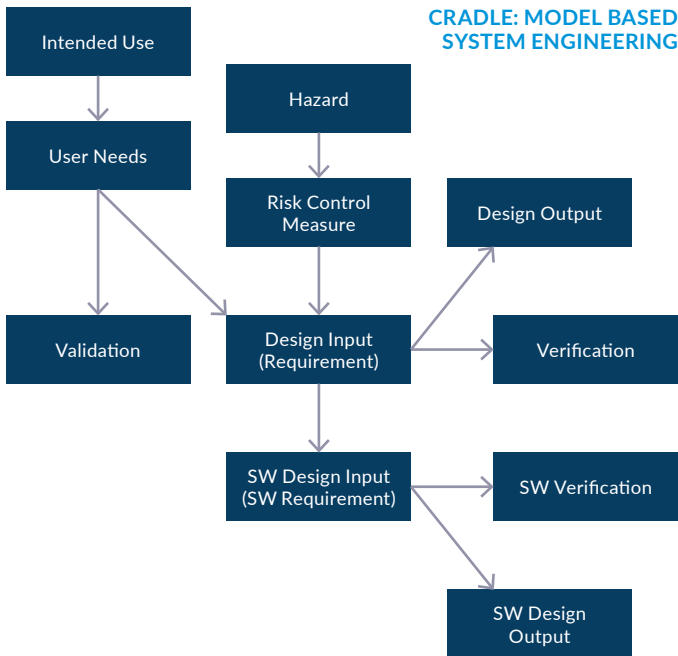
### DHF Remediation

ALTEN Technology Systems Engineers conducted a thorough analysis of the DHF for instances of non-compliance. We traced all requirements to design outputs and verification tests. With instances of non-conformity – where trace tests were non-existent or inadequate – ALTEN Technology engineers performed testing to meet conformity. ALTEN Technology created an accurate Traceability Matrix (TM) Report and Gap Log. In the process, ALTEN Technology made recommendations to address gaps, and helped to implement those recommendations later in the project. ALTEN Technology successfully closed all DHF Remediation gaps identified.

Ultimately, ALTEN Technology generated the below key deliverables to the client.

- DHF Gap Log Analysis
- IEC 62304 Compliance Report
- Compiled DHF
- System Traceability Matrix
- Updated System Requirements
- Updated Software Requirements
- DHF Remediation Verification Effort
- Gap Log Memos

Using Model Based System Engineering (MBSE) in Cradle, we were able to focus efforts efficiently in the DHF remediation process.



## OUTCOMES

Due to the successful completion of all objectives, the client was able to maintain the production of its blood separation device and decrease its risk of production downtimes. ALTEN Technology made sure the device met safety and compliance regulations by closing all assigned DHF gaps. ALTEN Technology helped the client to find and build in EOL component replacements, which in turn, lowered supply chain risks and production delays. The client now has a clear traceable DHF and a product ready for sell.

## END-OF-LIFE (EOL) DESIGN RECOMMENDATIONS

The EOL work followed the success of the DHF remediation and assistance for the client through its successful notified body audit. ALTEN Technology Engineers assessed the product for EOL components and recommended replacements. We performed requirement and risk impacts to determine the required testing for implementation (e.g., replacement of the device’s internal fan required recertification of EMC & Safety requirements – IEC 60601-1-2 and IEC 60601-1). Electrical Engineers assessed risk and safety requirements and tested potential component replacements for all pieces which had reached (or would be reaching) EOL. Further, ALTEN Technology produced the output documents for the recommended EOL components to be submitted for implementation.

## ABOUT ALTEN TECHNOLOGY

ALTEN Technology is an engineering consulting company that provides innovative solutions for engineering, technology, and product development projects across the product life cycle. For decades, ALTEN Technology has been helping clients develop products that are changing the world, whether by shaping the future of space exploration, saving lives with medical devices that set new standards of care, or creating the fully autonomous electric taxi of tomorrow. We provide support across industries including aerospace, defense, medtech and life sciences, unmanned systems and robotics, automotive OEM and tier 1 suppliers, commercial vehicles, electric vehicles, energy and environment, rail and more.