

*Project
Management*



*Systems
Engineering*



ASSESSED AND HARMONIZED DESIGN HISTORY FILE OF A BLOOD SEPARATION DEVICE

APPROACH

- Reviewed product design history file (DHF), including requirements, verification, validation, regulatory compliance, and risk management file
- Identified gaps in system and software requirements, verification, documentation, and areas for testing and necessary remediation
- Addressed nonconformances identified by notified body
- Maintained consistent contact with client for maximum success

RESULTS

- Completed organization of entire DHF file,
- Harmonized traceability documentation, design verification testing, and supporting data records
- Closed all identified DHF remediation gaps
- Deliverables included the following:
 - > System traceability matrix
 - > System and software requirements
 - > DHF gap log analysis
 - > IEC 62304 compliance report
 - > DHF remediation verification effort
 - > Gap log memos
 - > Compiled DHF

