SUSTAINING ENGINEERING FOR
MEDICAL PRODUCT LINE

Medical & Life Sciences

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

ALTEN TECHNOLOGY