

### The Situation

US based Fortune 500 healthcare corporation sought assistance from Protocol Link to provide validation support services for equipment qualification, computer validation, and cleaning validation at its FDA-regulated repackaging facility.

### The Solution

Protocol Link provided experienced Subject Matter Experts (SMEs) to maximize efforts and accomplish specified validation tasks within the project schedule of 16 months

**Equipment Qualification:** Completed preparation of required Standard Operating Procedures (SOPs), Work Instructions, and equipment qualification protocols. Provided oversight and assistance in field execution of the protocols. Prepared and delivered final reports summarizing the results of protocol field execution. Managed associated change control activities, and determined the need, as well as requirements, for revalidation.

- Installation, operation and performance qualification (IQ, OQ and PQ) of an automated blister packaging line.
- IQ and OQ of automated Checkweighers.
- IQ and OQ of automated Cartonners.
- IQ, OQ and PQ of automated Labelers.
- Computer Validation of Labeling Software.

**Recovery Study:** Completed preparation and execution of a Cleaning Validation recovery study associated with Client's FDA-regulated repackaging operations for the newly installed thermoforming equipment.

- Prepared a Cleaning Validation Recovery Test Plan, contacted laboratories for required services, and trained laboratory personnel on test plan execution.
- Provided on-site oversight for test plan field execution, coordinated field execution activities and supervision of the field execution process, and reviewed and analyzed the resultant data.
- Prepared and issued a final report summarizing the field execution data and data analyses.

**ERP System Implementation / MAPICS Validation:** Implemented the ERP System and validated the MAPICS Computer System (hardware and software) at the Client's repackaging facility.

- Identified the MAPICS Modules that required validation
- Completed preparation of the validation protocols in conjunction with Client's cross functional team.
- Field executed the validation protocols, and prepared final reports summarizing the work performed, review and analyses of data, discussions (including any discrepancies) and conclusions.

### The Result

Utilizing the expertise and guidance provided by Protocol Link SMEs, the automated blister packaging line, auxiliary equipment, applicable computer systems, and applicable cleaning methods at the Client's repackaging facility were qualified and validated assuring compliance with FDA requirements.