

CASE STUDY NO.2

Process Development – system closure

PROJECT SPONSOR

Clinical phase company for orphan drugs

OBJECTIVES

To identify risks and non-compliance to GMP, reduce process time and labor

TIME FRAME

6 months

PROCESS IMPROVEMENT

- ✓ Combining multiple manipulation to one
- ✓ Moving to closer systems
- ✓ Replacing raw materials to GMP approved
- ✓ Simplifying steps
- ✓ Implementing jigs to minimize influence of employee techniques

