

CASE STUDY: Operational Excellence

**CLIENT SIZE**

Large US Pharma Company

**GEOGRAPHY**

US

**THERAPEUTIC AREA**

Biopharmaceuticals

**TIME-LINE**

1 month

CLIENT NEED

- ▶ A client engaged the services of PLx Ireland to help understand why competent, motivated people make errors in an attempt to reduce the number of human-error related deviations
- ▶ PLx Ireland was asked to develop the organizational competence to identify systemically and proactively the contributory causes of human error in pharmaceutical manufacture
- ▶ The approach in the pharmaceutical industry historically has tended to be more reactive than proactive

OUR SOLUTION

- ▶ Our team considered differences between automatic, skilled behavior and more conscious mistakes
- ▶ Although errors of skilled behavior are much more frequent than mistakes, they are often less well understood and dealt with less effectively
- ▶ PLx Ireland considered the natural vulnerability of human memory, vision and attention and considered what kinds of influences increase the likelihood that they will result in error
- ▶ A unique approach was developed to address human-error deviations

PHARMALEX VALUE TO CLIENT

- ▶ After the program, the client reached their goal to identify and mitigate 50 Risk Influencing Factors (RIF)
- ▶ The client has identified RIF hunters in each department that regularly reviews a process in their areas to find and mitigate RIFs
- ▶ RIF identification has been incorporated into the client's routine Risk Assessment process and as a result of the training, the client is actively engaged in gathering information which contributes to the reduction of the occurrence of human error

DISCOVERY /
NON-CLINICALCLINICAL
DEVELOPMENTMARKETING AUTHORIZATION
/ APPROVALPRODUCT
MAINTENANCE