





## CASE STUDY: Facility Design

 <b>CLIENT SIZE</b>	Medium-sized US Company	 <b>GEOGRAPHY</b>	US
 <b>THERAPEUTIC AREA</b>	CMO to Biotech and Pharma	 <b>TIME-LINE</b>	Delivered intermittently over 12 months (ongoing)

### CLIENT NEED

- ▶ Client intended to build a new Aseptic Compounding and Fill-finish facility to handle highly potent compounds
- ▶ Following the initial engagement of an alternative consultancy company, the client ceased the contract due to inexperience in GMP and facility design and contacted PharmaLex Ireland
- ▶ PLx Ireland was requested to take over and perform a design of the proposed new facility within a compressed time-frame to ensure project delivery for the client

### OUR SOLUTION

- ▶ The team developed a tailored plan outlining the scope of the project to meet the client's requirements
- ▶ A gap assessment was performed by PLx Ireland on their client's current Control Strategy for the new facility against the requirements of the EU GMP Guide
- ▶ A number of risk assessments and technical documents were delivered to support individual elements of its design and operational strategies

### PHARMALEX VALUE TO CLIENT

- ▶ PLx Ireland developed a customized solution for the client
- ▶ Client successfully progressed to the final stage of the design process within a challenging time-frame
- ▶ Client has outlined, this would not have been possible without the help of PLx Ireland

DISCOVERY /  
NON-CLINICAL

CLINICAL  
DEVELOPMENT

MARKETING AUTHORIZATION  
/ APPROVAL

PRODUCT  
MAINTENANCE