



## ILC Dover Biotherapeutic & Pharmaceutical Quality Assurance

### **Background:**

ILC Dover's quality assurance starts with a solid foundation of ISO 9001:2015. This groundwork supports our programs and practices specifically designed for our biotherapeutic & pharmaceutical customers. For 75 years, ILC Dover has provided critical-to-life solutions with the necessary critical-to-life quality including:

- Powder & liquid handling and containment solutions for biotherapeutic & pharmaceutical customers to protect people and processes for life-saving therapies
- Personal Protective Equipment (PPE) protecting healthcare workers, first responders, and biotherapeutic & pharmaceutical manufacturers
- A range of spacesuits for NASA, including the Extra-Vehicular Activity (EVA) and Launch, Entry and Abort (LEA), since the first moon landing and today on the International Space Station protecting astronauts from the hostile environment of space
- A large variety of military solutions protecting our fighting forces
- Flood protection products protecting lives and critical infrastructure from catastrophic flooding

### **ISO 9001:2015 Foundation:**

Our ISO 9001:2015 foundation assures that the basic structures and processes to assure quality are in place, optimized, and routinely audited. These include:

- Quality Leadership and Commitment to Quality
- Quality Planning for the Quality Management System (QMS)
- Quality Support and Resource Management
- Operational Planning and Control
- Performance Evaluation
- Continual Improvement

Additionally, ISO 9001:2015 ensures that basic quality processes are in place, such as document control, CAPA, supplier quality, complaint management, and management review. These processes are routinely audited against the standard by our independent third-party certifier.



## **Going Beyond ISO 9001:2015:**

Understanding that ISO 9001:2015 is only the foundation of providing world-class quality to our customers, we have built several additional layers specific to the biotherapeutic & pharmaceutical markets from design through sourcing, manufacturing, and delivery.

### **Quality by Design**

We utilize a New Product Development/Stage-gated process with its roots in Quality Deployment principles. Throughout the NPD cycle, we assess product requirements, ability of the products to meet those requirements, ability of the manufacturing process to repeatedly meet requirements, regulatory needs, and the ability to comply with these regulatory needs and supplier ability to meet both regulatory and product requirements.

### **Supply Chain**

We partner with our suppliers to ensure our starting materials meet our high quality and regulatory standards. ILC Dover routinely audits supply chain and periodically inspects incoming materials to ensure they meet requirements. We ensure that all suppliers have change control programs in place and notify ILC of any planned changes to product or process.

### **Manufacturing**

Biotherapeutic & pharmaceutical manufacturing takes place in certified ISO cleanrooms ranging from Class 8 to Class 7. Cleanroom design, testing, and maintenance are in accordance with ISO standards. Recertification of these cleanrooms occur annually, and environmental monitoring is completed monthly in accordance with ISO 14644.

Our manufacturing processes include proprietary heat-sealing technology which ensure seal integrity that is typically even stronger than the materials being sealed. Depending on customer and product requirements, many products undergo 100% final dwell testing in which each unit is pressurized to ensure proper containment of finished product.

### **Packaging and Delivery**

ILC Dover understands the unique packaging and delivery requirements for our biotherapeutic & pharmaceutical customers including dual-outer packaging for product use in cleanroom environments, stringent regulatory requirements for packaging relating to slip agents, as well as BSE/TSE and minimizing cardboard and particulate sources of contamination for our end customers.

We are committed to outstanding quality and reliability with assurance of product protection and employee safety.