

Contract Development and Manufacturing By SEKISUI Diagnostics

Bring your next medical or
life science product to market faster!

DESIGN
&
PRODUCTION

LABELING
&
PACKAGING

LARGE
VOLUME
PRODUCTION

SHIPPING
&
RECEIVING

SEKISUI
DIAGNOSTICS
Because every result matters™

YOUR PARTNER OF CHOICE FROM DESIGN TO COMMERCIAL-SCALE MANUFACTURING

Over 10 years of contract manufacturing experience and 40 years of clinical chemistry reagent manufacturing.

End-to-end manufacturing for both liquid and lyophilized products, from small pilot runs to full commercial-scale batches. We provide the flexibility, quality, and scalability needed to bring your products to market with confidence.



Superior Supply Chain

Strategically positioned in Prince Edward Island, Canada we offer streamlined logistics globally.



Quality Assurance

A robust quality framework aligned with global standards and regulatory requirements. Our Quality Management System is compliant with US FDA QMSR, Canada MDR, EU IVDR, Australia, Brazil, and other international regulations.

- ISO 13485 (QMS)
- ISO 14001 (EMS)
- 21 CFR – Part 820
- Canada MDR SOR/98-282
- TG(MD)R Sch3
- IVDD 98/97/EEC
- IVDR EU 2017/746
- RDC 16/2013



Technical Support

Acting as a critical second line of support, our team bridges customer-reported issues with internal manufacturing, labeling, and production groups, facilitating clear communication, retaining reference kits for every lot, and providing targeted troubleshooting when first line support reaches its limits.

INDUSTRIAL LYOPILIZERS



AUTOMATED FILL LINES



MULTIPLE CLEAN ROOMS



LIQUID FORMULATION TANKS FROM 4,500 L TO 20,000 L

FLEXIBLE, HIGH-QUALITY MANUFACTURING FROM LIQUID TO LYOPHILIZED PRODUCTS

Ensuring product integrity with full traceability, comprehensive documentation, and rigorous validation.

Our analytical testing services are designed to safeguard product integrity through rigorous validation, complete traceability, and fully documented workflows.

- **Full traceability** throughout the testing process, ensuring every result is documented, auditable, and compliant.
- Comprehensive documentation packages available on request to **support regulatory submissions** and **customer quality requirements**.
- **Robust analytical testing capabilities**, including verification, validation, crossover studies, method comparisons, value assignment, and QC testing.

Reduce supply chain complexity by consolidating scale up and commercial filling with one CDMO.

Our comprehensive services consist of end-to-end manufacturing for liquid and lyophilized products, from design to full-scale commercialization. We handle formulation, design, development, filling, QC testing, packaging and labeling across a wide range of containers, vials, and custom kit assemblies.

- **Flexible liquid filling** capacity ranging from 0.3 mL vials to 1,000 L containers, giving you seamless scalability as demand grows.
- High-throughput lyophilization with multiple units capable of processing more than **26,000 vials per batch** for efficient commercial-scale production.
- Multiple ISO 8, spacious cleanrooms, providing controlled environments that support **consistent quality** and **reliable manufacturing performance**.



STREAMLINED LABELING, STORAGE AND GLOBAL DISTRIBUTION DESIGNED TO KEEP YOUR SUPPLY CHAIN MOVING WITHOUT INTERRUPTIONS

Automated labeling designed to enhance accuracy, traceability and production efficiency.

Our automated labeling capabilities ensure accuracy, consistency, and efficiency across every production run. With high-precision equipment and controlled workflows, we apply labels at scale while maintaining full traceability and compliance.

- High-precision automated systems deliver consistent, **accurate label placement** and **exceptional readability** across every batch.
- Flexible, configurable labeling supports vials, tubes, bottles, and custom kit components, adapting seamlessly to **diverse product formats**.
- Fully integrated labeling workflows connect smoothly with packaging and fulfillment operations, enabling **efficient, end-to-end processing**.

Flexible storage and fulfillment services engineered to reduce complexity and accelerate global distribution.

Ambient storage space designed for global distribution. We offer pallet storage and shipment, pick-and-pack services, and drop shipment capabilities to keep your supply chain moving smoothly.

- Pallet storage and shipment services that **streamline outbound** logistics and **reduce handling complexity**.
- **Pick-and-pack capabilities** to support customized orders, kit components, and multi-SKU fulfillment needs.
- Drop-shipment options that enable **direct-to-customer or distributor delivery**, shortening lead times and simplifying your supply chain.



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sekisuidiagnostics.com
questions@sekisui-dx.com