

Fact Sheet: LEWA Bioprocess Group

Capabilities, Clients and Capacity

LEWA Bioprocess Group - Single Source Capabilities

The Bioprocess Group of LEWA- Nikkiso has deep expertise in High Purity Process Systems, Process Engineering Services and Process System Automation. The LEWA Bioprocess Group provides single source capabilities employing full time Mechanical Trades, Process Engineers, Process Automation Engineers, Project Managers, QA/ QC SNT-TC-1A Level II Certified Inspectors, and full time CAD Designers. We have a 15 year history, beginning as Integrated Process Technologies, Inc. in 2000 and after being acquired by LEWA-Nikkiso in 2013 became the center of excellence for bioprocess system design and manufacture for LEWA-Nikkiso customer world-wide.

Broad Project Capacity – Across the Downstream Manufacturing Suite

LEWA Bioprocess Group alone executes up to 100 projects each year ranging from \$10K-\$6.0MM. The product mix includes EcoPrime LPLC, HPLC, multi-column chromatography skids, TFF, cell harvest / clarification (centrifugation), buffer in-line dilution systems, caustic dilution, formulation and blending systems as well as custom high purity process systems. We routinely design and fabricate process skids with particular expertise in Chromatography Systems, Buffer Dilution / In-Line Mixing Systems, Batch and Continuous Formulation and Membrane Separation Systems for the GMP environment.



Above: LEWA Devens Bioprocess Systems Manufacturing Complex, Devens, MA USA

Manufacturing Facility; From Concept Design Though FAT

LEWA's Devens, MA USA facility is a state of the art high purity process fabrication site. This group, in addition to our platform systems, executes design - build and OEM build systems including control systems / automation and simple to complex process skids commonly deployed in GMP facilities. Our operations service clients globally including CE work and welding standards certified by TUV for certification to: DIN EN ISO 14732, DIN EN ISO 15614, and DIN EN ISO9712. The manufacturing facility is a stainless steel only fabrication facility and is approximately 21,000 ft² (1,950 m²) with 37 foot (11.27 m) high ceilings and has full FAT capabilities.



Above: LEWA Bioprocess Systems Manufacturing Hall, Devens, MA USA

Full Service Shop and Field Capabilities

LEWA has on staff several QA/QC Level II visual weld inspectors certified to the SNT-TC-1A standards. The company owns more than 20 orbital weld machines, 35 tacking rigs, and the requisite amount of small tools, safety equipment, and cut off machines for shop projects. Our bioprocess fabrication group has polishing capabilities located at the Devens' facility that is completely segregated from the shop floor and segregated from all welding locations thereby minimizing the risk of cross contamination from particulates when polishing is occurring. The polishing area is capable of providing a mirror polish down to 5 Ra on any 316SS material. LEWA has its own CAD designers for complete isometrics and detailing work.



Above: LEWA Bioprocess Systems Skilled Staff Are Certified and Experienced

ASME Code R and U Stamp Certified; CE and DIN certificates

The LEWA Deven's facility holds National Board "R" and "U" Stamp Certificates for the alteration and repair of ASME code pressure retaining items and the manufacturing of pressure vessels in accordance with the ASME Boiler & Pressure Vessel Code Section VIII Div. 1. LEWA can provide CE work and welding standards certified by TUV for certification to: DIN EN ISO 14732, DIN EN ISO 15614, and DIN EN ISO9712.

Our Client Base – Serving the World's Leading Corporations - Confidentially

LEWA Bioprocess clients are recognized throughout the industry for implementing state-of-the-art downstream processes in their manufacturing facilities. These leading companies have looked to the LEWA Bioprocess Group as the leading source for precision purification equipment, custom skid design services and support. Our personnel have developed close working relationships with key contacts from our customers, supporting them through all phases of process implementation, from planning through turnover, as well as ongoing system support.

Our clients look to us for as a source of ingenious solutions; understanding and advancing their needs, our work results in array of technologies that provide a competitive edge. Therefore we treat each project in confidence and do not release our customer names.

The LEWA Bioprocess Group has delivered products and services of single project values up to \$6M in a variety of industries & applications. Examples include;

- ❑ Biotechnology: Chromatography – LPLC, Membrane Systems, Buffer-in-Line Dilution, Filling Stations
- ❑ Pharmaceutical: Chromatography – HPLC, Buffer-in-Line Dilution, High Purity Distribution Systems
- ❑ Nutraceutical / Personal Care / Cosmetic : Product Preparation, Fragrance Additions, Liquefied Ingredient Blending
- ❑ API / Fine Chemical: Preparation of API, Pigments and Coatings
- ❑ OEM: TFF (UF/MF) Systems, Centrifugation Systems

We Understand

With our project management capabilities and long industry experience, we understand what goes on upstream and downstream in your process, allowing us to avoid project snags and optimize systems for lifecycle costs and maximum efficiency. Our team completes hundreds of installations per year, and is backed by LEWA and Nikkiso global sales and service organizations, with field offices in 80 countries around the world.

We welcome the chance to help you to lower your Total Cost of Ownership (TCO), efficiently scale production, reduce your line's footprint, and improve product consistency and integrity. To start a profitable discussion, please let us know the best way to be in touch: sales@lewapt.com.



Above: A few of our staff representing the diverse and broad skill set of the bioprocess systems' team