Creating Fluid Solutions

A MEMBER OF NIKKISO

LEWA pumps + systems

Pharma & Biotechnology

Metering pumps & High purity systems
for the pharma & biotech industries

- **Liquid handling systems**
- **Downstream processing**
- **Homogenization**
- **Mixing and metering**

This is LEWA:
Optimal configurations the first time

In pharma & biotech there are various applications that can be handled perfectly with LEWA metering pumps and systems, e.g. dosing in capsule and tablet production…

…in the purification of biotech products…

…or during the production of powdered active ingredients

The world population is increasing day by day. More than 7 billion people live on earth and they are advancing in years – consequently the demand for medication and healthcare products is growing continuously.

No doubt, that the pharma & biotech industries have a leading role as people put their trust in safe medical treatment for their continued health.

However, pharma & biotech must also face new challenges: Regulatory requirements to ensure safety are increasing, while research and development costs for innovative therapies are exploding.

This requires optimized processes. For the life science industries, it is more important than ever **to find intelligent ways to become more efficient. Integrated solutions are needed.**

The customers' challenge is LEWA's focus. **We are recognized worldwide as specialists in the handling of fluids.** LEWA has decades of experience and practical know-how in the pharma & biotech sector. **Our core competencies in building engineered process systems are precision, durability, low maintenance and cGMP compliance and make us the right partner for you.**

The requirements in pharma & biotech are considered the most challenging of all: The customer expects drainable, cleanable, high purity, documented systems built under their specific requirements and regulations.

A solution for your specific process demands can be provided by us. We deliver systems conforming to all regulatory requirements (cGMP, GAMP, 21 CFR, etc.), supported with a full documentation package, factory acceptance testing, installation, start-up services and validation.

LEWA integrates its specialists from the outset in the design concept and development of your production process and supports you to the end of the project. Careful planning in the design phase pays off in lower overall project costs. LEWA is your single source supplier for the project along the entire value chain and we ensure your success.

As a result **we promise efficient production systems with optimal configurations the first time.**

LEWA offers chromatography systems for the purification of biomolecules, e.g. vaccines, recombinant proteins, and hormones

LEWA supplies customer-specific solutions for extrusion processes where precise dosing is needed , e.g., for tablet formulation

Pharmaceutical production and products must be safe. In the pharma & biotech industries, metering accuracy, cleanability, sterilizability and precision are important process criteria. **LEWA sets the highest possible safety standards with reproducibility for validated production processes.**
LEWA manufactures hygienic diaphragm pumps which meet the highest requirements in hygienic and aseptic processes for the manufacture of sterile products. They are hermetically tight and offer zero leakage with absolutely no shaft connection to the product area, thus ensuring contamination-free metering over long periods of time.

The distinctive features of LEWA metering systems – in addition to being hermetically tight and easy to clean – are the precision, repeatability and fast flow control.

The pump characteristics of LEWA pumps are very linear. Many years of experience and the use of data from flow metering enable us to select the best possible process control concept. This assures metering accuracy and consequently high operational safety.

Cleaning of the system is essential for the process and is mandatory from the viewpoint of safety and risk analysis (HACCP). In order to ensure safety for your aseptic and sterile processes, LEWA tests hygienic pumps for their cleanability according to approved industrial standards (EHEDG cleanability test and QHD test system). They meet 3-A standards, are FDA conform as well as USP Class VI compliant. Moreover they correspond to the current international standards and guidelines.

Detailed documentation is a matter of course for LEWA. Pump data sheets with precise indication of pump specifications, materials and the surface quality are part of all documentation.

Manufacturers of pharmaceutical and biopharmaceutical products often require additional documents for qualification and validation. LEWA optionally supplies data for material traceability, additional drawings, hydrostatic tests, performance tests with specific measuring reports, surface quality data, material certificates, etc. We therefore supply the basic documents to qualify your process for safe production in line with pharma guidelines.

Pharma & Biotech Applications

Customer-specific LEWA systems for various pharma & biotech applications...

...such as homogenization processes with high-pressure pumps

When investing in new technologies, higher yield, higher throughput and utilization, lower consumption combined with higher system availability and flexibility are the top priorities. LEWA meets these requirements.

Our products have been used in particular for these applications – as stand-alone pumps or as an integral part of a system:

- Continuous, proportional blending of sensitive and/or expensive fluids
- Exact feeding of fluids in the chromatography process
- Purification of biomolecules and vaccines with chromatography systems
- Aseptic transfer of proteins and cells, e.g. micro-organisms or blood
- Micro- and ultra-filtration
- Dialysis systems with critical process control requirements
- Injection of fluids for extrusion in tablet production
- Injection of spray mechanisms for the production of powdered active ingredients
- High pressure and supercritical applications
- Dispersion processes (emulsions and dispersions) with high-pressure diaphragm pumps
- Creation of "fluid in one sphere" products or nanoparticles
- Purification of API and intermediates of pharmaceuticals with batch and continuous HPLC systems
- Support of crystallization processes for purification
- Inline dilution of buffer solutions
- Metering of sensitive fluids, such as enzymes, vitamins or flavors
- Addition of additives, such as colorants, toxic chemicals, etc.
- Creation of neutraceuticals and functional food ingredients

Dispersion processes with high-pressure pumps

LEWA triplex process pumps in hygienic design with M900 diaphragm pump heads are the proven solution to convert batch, continuous or semi-continuous homogenizing processes in pharmaceutical or biotechnology applications into aseptic solutions. Sterile products for food with high requirements (functional food, nutraceuticals), as well as pharma & biotech products, can be processed extremely reliably and with low wear using CIP/SIP-capable diaphragm process pumps from LEWA. As a user, you receive your customized system in compliance with EHEDG, FDA and cGMP.

High pressure homogenization pumps of a pressure range up to 1,200 bar are used in the clean room production of liposomes, intravenous emulsions, vaccines, etc. to realize a premixed solution down to the range of nanometers. To bring the process into a certain window of operation, we create a system that is custom-designed for your specific product: reliable, repeatable and under economical aspects following the cGMP specifications.

LEWA EcoPrime can be used e.g., for purification of monoclonal antibodies, vaccines, recombinant proteins, and hormones

Moreover, LEWA builds systems for micro- and ultra-filtration to purify biotech products

Chromatographic separation processes

LEWA diaphragm pumps are widely used by well-known suppliers of chromatography systems. We produced our first chromatography system using a LEWA pump for HPLC more than 30 years ago. Today LEWA supplies customer-specific chromatography systems to facilitate the purification of biotherapeutic active materials.

Spray drying

To bring the product from a fluid manufacturing step into a dry phase, spray drying is the method of choice in batch or continuous processes. The quality of the final product has to be constant and manufactured under controlled parameters. A certain amount of flexibility is needed during the development phase. Certain high pressures are needed to forward the fluid into the spray drying process. LEWA offers total solutions for this, from individual pumps to complete systems. In the past this application was performed almost solely with packed plunger designed pumps. However, customers are now increasingly requesting for a more hygienic, and hermetically tight pump. LEWA is uniquely qualified to provide such pumps at a high quality standard.

Extrusion processes for tablet formulation

In tablet production processes extruders normally form the final drug from powders and other ingredients. LEWA can supply customized solutions for these sophisticated processes.

In hygienic processes LEWA diaphragm metering pumps can be used as multiplex pumps and to facilitate aseptic processes e.g. for performance increase, for recipe metering or for the buffer dilution, inline mixing and dosing in biopharmaceutical sectors.

Optimized production of biopharmaceuticals with LEWA systems

LEWA ecodos hygienic pumps with LEWA intellidrive technology (patent pending)

LEWA EcoPrime performing the purification of a biomolecule in a cleanroom (patent pending)

LEWA intellidrive: Innovative mechatronic drive unit
LEWA has united what previously was separate: Pumps with standard frequency-controlled drives and separate stroke adjustment actuator can now be combined into one unit.

As an innovative mechatronic servo motor drive concept LEWA intellidrive uses PLC with flexible programming. This opens up innovative process application possibilities. It simplifies the installation and wiring effort, since preassembled plugs on the pump motor connect the supply and signal lines to the controller.

In chromatographic systems, LEWA intellidrive can play out all of its advantages simultaneously. For example, the combination 'speed variation' and 'partial stroke mode' yields an adjustment range of over 1:150. While conventional technology requires frequency converters and an electric stroke adjuster with separate power and data connections, LEWA intellidrive only requires just one connection. LEWA intellidrive can even choose the optimal adjustment mechanism. This enables the dilution of buffers over almost any value and with high precision in handling the eluent.

This can function both in low-pressure systems with the LEWA ecodos hygienic range and in HPLC with LEWA ecoflow hygienic series pumps. When this intelligent control of two pairs of pumps is implemented, reduction of pulsation reaches a new level.

This new, innovative approach may be upgradeable to your current chromatography system. Contact LEWA to see if your existing system falls short of your current needs.

LEWA EcoPrime: Full linear gradient for chromatography systems
Over the past few years, fermentation yields have increased significantly. Consequently monoclonal antibodies, or recombinant proteins occur in higher concentration in downstreaming during the purification of vaccines. This has caused the requirements for process chromatography to become significantly higher: Systems must not only be very reliable, but also capable of processing larger volumes significantly faster and repeatable in the same time period.

Recently developed processes often require a linear gradient (linear concentration drop/increase) in order to elute the molecule from the chromatography column in a smoother and reproducible manner. With this technique the yield of the targeted product increases.

LEWA EcoPrime makes it possible to provide this linear gradient in a much broader range of mixtures. While traditional systems often work linearly only over a range between 20 and 70 percent – at an accuracy of 2 percent of the mixing range, EcoPrime offers a linear gradient between 1 and 99 percent – at an accuracy of about 0.5 percent.

Metering pumps in hygienic design: The core of LEWA systems

1

For medium to high pressures: LEWA ecoflow metering pumps in hygienic design

2

LEWA ecoflow offers the most advanced, safe, leak-free metering pumps for medium and high pressures

3

For lower pressures: LEWA ecodos metering pumps in hygienic design

4

For high pressures: LEWA triplex process diaphragm pumps in hygienic design

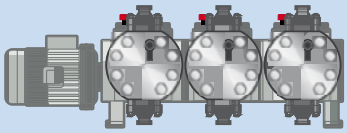
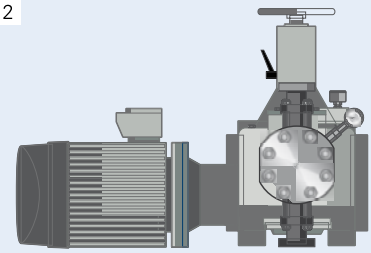
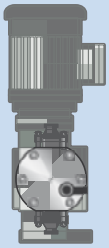
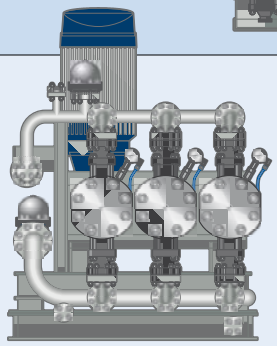
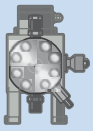
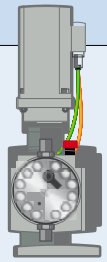
5

For laboratories and pilot plants: LEWA micro-metering pumps

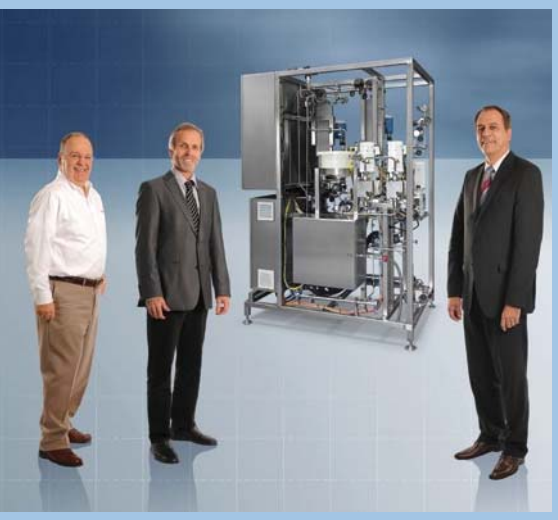
6

LEWA intellidrive: The innovative mechatronic drive unit for the proven

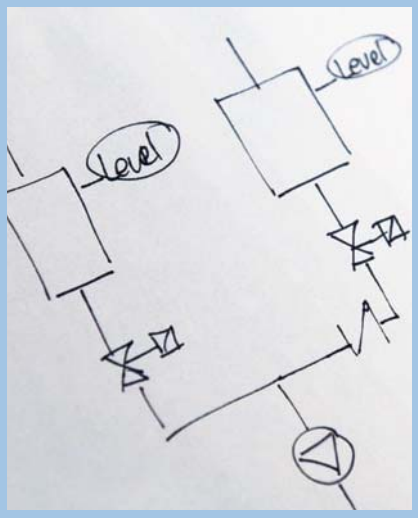
Overview of pumps for the pharmaceutical & biotech industries

Technical view	Product	Technology	Description
1 	LEWA ecoflow sanitary / hygienic (metering pumps)	Hydraulically actuated diaphragm metering pump Flow rate up to 6 m³/h per pump head, discharge pressure up to 100 bar	The innovative sanitary/hygienic metering pumps for hygienic applications in proven modular design
2 	LEWA ecoflow sanitary / hygienic (process pumps)	Hydraulically actuated process diaphragm pump Flow rate up to 19 m³/h per pump head, discharge pressure up to 1,200 bar	The robust and universal process pumps with DPS diaphragm protection system in proven modular design
3 	LEWA ecodos sanitary / hygienic	Mechanically actuated diaphragm metering pump Flow rate from 0.4 up to 1,500 l/h per pump head, discharge pressure up to 20 bar depending on model	The absolutely safe, hermetically tight and economical diaphragm metering pump, particularly if a hydraulically actuated diaphragm is not desired. In sanitary/hygienic design
4 	LEWA triplex sanitary / hygienic	Hydraulically actuated process diaphragm pump in monoblock design Flow rate up to 180 m³/h per pump, discharge pressure up to 1,200 bar	The robust and compact process pumps with DPS diaphragm protection system in sanitary/hygienic design
5 	LEWA microflow-metering pumps MAH, MBH, MLM	Hydraulically actuated solenoid metal diaphragm metering pumps Flow rate from 1.0 ml/h up to 57.5 l/h, discharge pressure up to 560 bar	Diaphragm metering pumps for smallest flow rates – the most economical solution when liquid components must be metered in proportion to a variable setpoint
6 	LEWA intellidrive	Mechatronic diaphragm metering pump with intelligent drive via servomotor Flow rate up to 4 m³/h per pump head, discharge pressure up to 1,000 bar	Design the suction and discharge stroke of the metering pump according to your wishes! LEWA intellidrive technology allows you to design the stroke characteristics individually

LEWA:
Your single-source provider



LEWA process experts help to solve your application requirements



Our specialists are involved from the outset in the design of the production process and offer support until the end of the project

We offer efficient production systems with optimal configurations the first time

Ultimately, your goal is finalizing the project – on time and on budget.
Time to market is becoming more and more important, in addition to all the requirements for meeting the demanding regulations in the pharmaceutical industry. Any delay affecting the launch of a new drug on the market can cost millions of dollars a day. Reliability and experience of the suppliers are more important than ever. And you can depend on LEWA to meet these requirements.

LEWA process experts can help to solve your application requirements. Our first step is to listen intently to your objectives, which may include converting a batch process to a continuous one, optimizing an existing system, or designing a new concept. Our team will generate recommendations using state of the art technology to ensure reaching your process goals.

Our process, mechanical, automation and design professionals simplify and optimize all aspects of the project, while creating a quality solution. The team will provide a quality plan, documentation schedule and delivery plan, P&IDs, functional specifications and test plan for you to sign off on.

Our services:
- Consultation in process design
- Selection of process components including high pressure pumps (>1,200 bar)
- Basic to final engineering design for the creation of your specific solution
- Complete fabrication of customized systems for development, pilot or production scale
- Use of process simulation software

Our field mechanical group specializes in field fabrication of new high purity systems, on-site retrofits, and suite upgrades.Whether it's planning a new facility or a critical plant shut down, our project managers schedule manpower and coordinate all activities for a successful project. We have design and fabrication experience with cGMP-conforming processes as well as high purity process utilities and CIP systems. Our team will implement prefabrication strategies that reduce project timelines for on-site projects. Factory Acceptance Tests (FAT) are standard and Site Acceptance Tests (SAT) can be carried out based on the scope of the individual project.

In short: LEWA is the right partner for your sophisticated visions in the pharmaceutical industry.

CE EHEDG ASME BPE-2012 FDA

Creating Fluid Solutions

A MEMBER OF NIKKISO

LEWA pumps + systems

LEWA proven services and technologies

Germany / Headquarters
LEWA GmbH
Ulmer Str. 10
71229 Leonberg
Phone +49 7152 14-0
Fax +49 7152 14-1303
lewa@lewa.de
www.lewa.de

Japan / Headquarters
NIKKISO CO. LTD.
Yebisu Garden Place Tower 22nd Floor
20-3, Ebisu 4-Chome, Shibuya-ku
Tokyo 150-6022
Phone +81 3 3443-3711
Fax +81 3 3473-4963
www.nikkiso.com

Contacts of LEWA's numerous affiliated companies and representatives can be found on **www.lewa.com**

Customized solutions for metering and process technology

For more than 50 years, LEWA has set the technical trends of metering pumps and systems. LEWA offers a single-source solution to handling complex metering and mixing tasks – ranging from individual pump configuration, basic and detailed system engineering and pretesting to onsite commissioning and maintenance services.

Good causes to rely on:

- A solution for your special application: from process analysis to global service
- Highest process safety: individual pump configuration and state-of-the-art design
- International engineering and project competencies
- Highest reliability: developed for continuous operation
- Low lifetime costs: reduced energy consumption and low-wear design
- Compliance with international standards, e.g. API, ASME, GOST-R, FDA, EHEDG, 3A, TÜV
- Comprehensive reference list

Areas of expertise:

Oil & Gas
Gas Odorization
Refinery
Petro-chemicals
Chemicals
Plastics
Cleaning & Detergents
Personal Care
Pharma & Biotechnology
Food & Beverages
Energy Utilities

Your local representative: