LICHTENHELDT

The CMO-Expert in Liquids and Semi-Solids

COME TOGETHER

ENGLISH

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Quality, reliability and flexibility as success factors

Whether capacities are stretched, more efficient production is required, know-how is lacking or resources are too tight for regulatory tasks – there are plenty of reasons for outsourcing to a pharmaceutical contract development and manufacturing organisation. Sustainable reasons why you should decide for LICHTENHELDT are presented to you on the following pages. As an owner-operated specialist for liquid and semi-solid non-sterile drugs, we have developed over the past decades a sustainable business model that stands for both technology expertise and for top flexibility on the highes quality standard.

Our customers benefit from a made-to-measure full service portfolio – from development to delivery including administration. We are characterised by an specialised diversity of industrial production scale and by superior management of complex production processes. Regardless of whether you prefer full service or you wish to outsource only certain processes LICHTENHELDT always offers you a consistently high level of quality.
Please convince yourself.

Your

Andrea Schulze-Ayecke
Managing Partner
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Experts with a broad performance portfolio

Contract Manufacturing

LICHTENHELDT is your specialist when it comes to contract manufacturing and development of non-sterile liquid and semi-solid formulations. Eighty percent of our customer base is made up of medium-sized and large pharmaceutical companies. Besides over-the-counter (OTC) drugs, we are seeing high growth in prescription drugs (Rx) business. Our portfolio of medical devices includes disinfectants and products for hospital hygiene, as well as diagnostics to name but a few. Our extensive spectrum of services is supplemented with food supplements (nutraceuticals) and added-value cosmetics (cosmeceuticals). We support our customers both with innovative formulations and with high production capacities: around six million litres of bulkware leave our plant every year. LICHTENHELDT customers particularly appreciate our extraordinary flexibility: from hospital samples through to 20,000 litre batch sizes, we cover all relevant scales of production. In galenics, the portfolio extends over a dozen different pharmaceutical forms – from drops to suspensions and sprays through to gels and ointments.
One of LICHTENHELDT's special fields of expertise is the manufacture, filling, storage and transportation of products under explosion protected (Ex) requirements. Around one third of the products are produced in our plants in Wahlstedt, Schleswig-Holstein under Ex-protected conditions.

The LICHTENHELDT performance portfolio at a glance

- **Commercial batches**
- **Pilot, stability and feasibility batches**
- **Process and cleaning validation**
- **Packaging optimisation**
- **DMX-Coding, tamper-proof solutions**
- **Serialisation acc. to EU-FMD**
- **Monitoring of production and quality processes with barcode scanning**

Generalist in specialisations

Specialities

LICHTENHELDT also offers full service in its specialities portfolio: complete order processing, including distribution under Ex-protected conditions, filling and packaging under nitrogen gassing and individualised assignment of a data matrix code in the course of mandatory serialisation requirement. Implementation and assurance of preventive explosion protection is technically demanding and expensive. Many regulatory requirements also have to be considered.
As Ex-protected conditions play a role in 30 % of our orders, we possess long-standing experience. Our expertise extends over the entire process chain, covering all pharmaceutical forms and scales.

Serialisation and FMD compliance

LICHTENHELDT is excellently positioned for its customers in the serialisation of prescription drugs in the EU in accordance with the Delegated Regulation (EU) 2016/161, otherwise known as the Falsified Medicine Directive (FMD): we have over 10 years of experience in packing counterfeit-proof vignettes (foil stickers) and coding e.g. Bollini labels for Italy or DMX codes in France.
Controlling and monitoring serialisation, as well as track & trace processes, are undertaken by state-of-the-art software. The IT system generates and manages unique serial numbers and distributes the codes on 4 manufacturing lines ensuring process reliability. Since 2017 we implement aggregates on our packing lines to enable inline serialisation, control weighing, tamper-evident sealing and continuous serial number management.

Experience and technical know-how

Liquids

The development and production of non-sterile liquid forms is one of LICHTENHELDT's most important business fields.

With our longstanding expertise, we can fall back on a large number of existing format parts. Filling and packaging machines of a high technological standard, along with specialised and experienced staff, ensure efficiency and quality for every order. This enables us to offer a varied range of pharmaceutical forms galenics and innovative packaging systems to always meet our customers requirements for products tailored to market demands. Our spectrum of batch and packaging sizes is convincing too, from 5 ml to 1,000 ml for glass and plastic bottles and from 2 to 1,000 litre canisters and bulk containers – LICHTENHELDT can supply all relevant scales for the markets.

Liquids production portfolio

Primary packaging

- Glass bottles: 5 ml to 1,000 ml
- Plastic bottles: 5 ml to 1,000 ml
- Canisters and IBCs: 2 l to 1,000 l
- Dosing aids and closure systems
- Tamper-proof closures & seals

Secondary packaging

- Labels, folding boxes, leaflets
- Sleeving
- Shrinking and bundling
- Cartoning
- FMD-Serialisation, DMX Coding, Bollini
- Palletising

On the pulse of the market

Semi-solids

In the manufacture of semi-solid products such as creams, ointments and lotions, we offer our customers the modern pharmaceutical forms demanded by the markets.

In the production and development of products for the OTC market, e.g. alcoholic gels, we can count on our experience and performance in Ex-protection. Here the percentage share of alcohol-containing products is growing in double-digit range.

LICHTENHELDT rounds off its range for semi-solid forms with a broad selection of applicators, adaptors and dosing aids for safe and hygienic administration of the products.

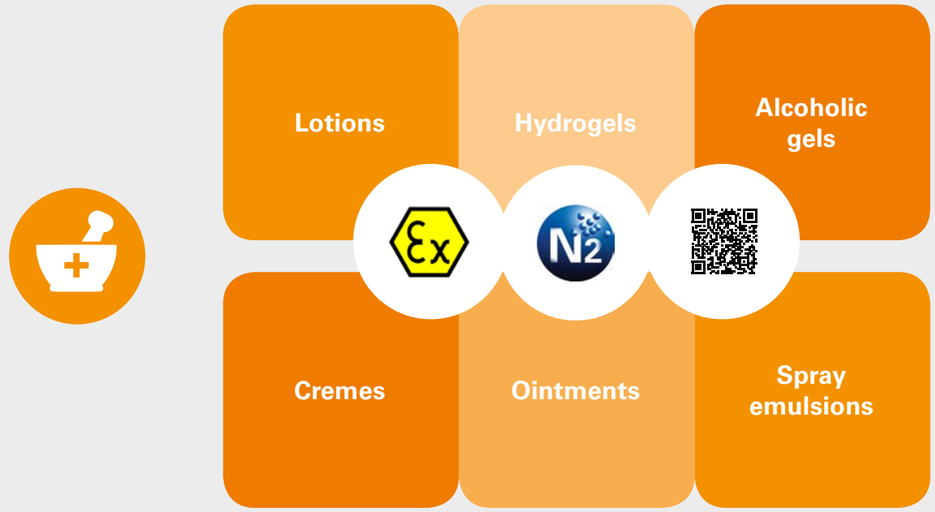
Semi-solids production portfolio

Primary packaging

- Tubes (aluminium and plastic): 5 ml to 250 ml
- Glass bottles: 5 ml to 1,000 ml
- Plastic bottles: 5 ml to 1,000 ml
- Canisters and IBCs: 2 l to 1,000 l
- Closures, applicators & dosing aids
- Tamper-proof closures & seals

Secondary packaging

- Labels, folding boxes, leaflets
- Sleeving
- Shrinking and bundling
- Cartoning
- FMD-Serialisation, DMX Coding, Bollini
- Palletising



Comprehensive testing – maximum safety

Quality control

Quality control in compliance with GMP is an integral part of our highly complex batch-based production. Testing of 1,600 production batches per year is carried out almost exclusively in internal labs. In our quality area exceeding 500 m², highly qualified LICHTENHELDT employees have an extensive range of modern lab methods at their disposal.

Sustainable quality control starts with supplier selection and extends to incoming goods inspection of raw materials and packaging, in-process controls, through to approval of finished goods for dispatch. The stringent control system pays dividends: our quality level is rewarded with a high level of customer satisfaction.

- **Analysis for batch releases**
- **Pharmacopoeia & raw material testing**
- **Batch documentation**
- **Microbiology**
- **Complaint and regulatory issues**
- **Stability studies: ICH, On-going, In Use**
- **Risk assessments**
- **PQRs**

Processes reliable on all levels

Quality management

LICHTENHELDT operates highly professional quality management throughout the organisation. We rely on cutting-edge technologies, for example a new and validated ERP- and MES-system.
Certification has been extremely important to LICHTENHELDT for decades: besides EU-GMP and the pharmaceutical manufacturing license, our company is certified according to DIN ISO 9001 and undergoes rigorous periodic inspection specifically for medical devices according to EN ISO 13485. Every year over 25 internal and external audits and certification runs are mastered with high success rates.
Once you visit us, our experts would be very happy to explain the decentralised „house of quality“ QM-system to you.

Professional warehouse and transport concepts

Logistics

With 7,800 m² storage space for over 8,000 pallets LICHTENHELDT offers its customers extensive storage capacities. Our logistics know-how also encompasses Ex-protected products, toxic and hazardous substances. The professionally organised flow of products for incoming goods and dispatching finished goods is ensured by a modern ERP system, which also guarantees short response times in the event of extraordinary demands.

Storage & dispatch

Receipt of goods	
Storage of intermediate and finished goods	
Dispatch	
Barcoding at all stages	
Cool storage	
Storage space site 1	5,800 m²
Storage space site 2	2,000 m²
Pallet capacity (sites 1 & 2)	8,000
Paletts for inflammables	300

Business report

1,600 batches

40 million units

1,000 dispatched trucks

business volume 30 million €

50 product transfers/ developments

15,000 releases

400 finished products / 150 different formulations

200+ employees

Production portfolio

PHARMA
OTC
Rx / Gx
Veterinary

SMALL MOLECULES
e.g. CNS
Dermatologicals
Mucolytics
Laxants

NON PHARMA
Medical Devices
Cosmetics
Nutritionals

MATRIX PRODUCTS
Phytopharmacons
Homeopathics
Multi-Vitaminics

> 70 APIS

> 300 RAW MATERIALS

> 200 SUPPLIERS AT HAND

BULK PRODUCTION	FILLING – PRIMARY PACKAGING	SECONDARY PACKAGING	LOGISTICS
Drops Sirups Solutions Suspensions Sprays	Bottles Canisters Intermediate Containers	Labeling/Sleeving	Warehousing
		Leaflets/Booklets	
		Dosing Aids	Release
		Clinical Samples	Cold Storage
Creams Emulsions Gels Lotions Ointments	Tubes Bottles Intermediate Containers	Carton Packaging/ Sealing	Inflammables Storage
		Serialisation	
		Bundling/ Palletising	Dispatch

Q QUALITY ASSURANCE / QUALITY CONTROL

Equipment
Pilot and test units
600 l process unit
2,000 l process unit
2 x 5,000 l process tank
Up to 20,000 l tanks for solutions

Filling and packaging lines
Pilot and test units
6 lines for bottles
2 filling lines for canisters
2 lines for tubes

From product idea to registration

Pharmaceutical services

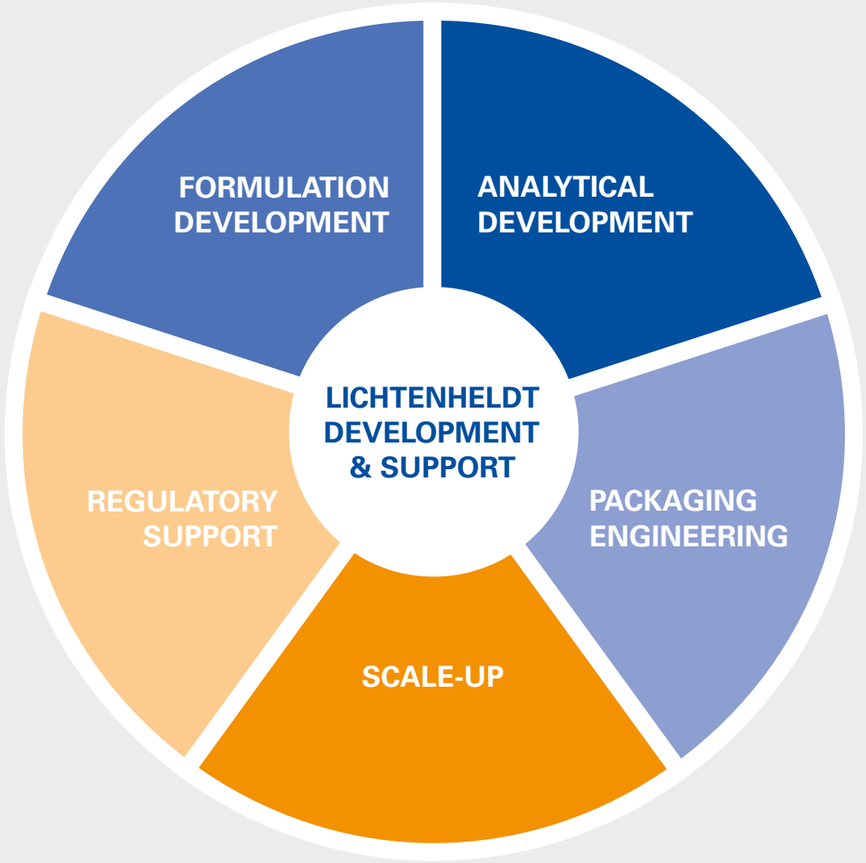
One of LICHTENHELDT's strategic focus areas is the galenic and analytical development and optimisation of liquid and semi-solid products. Whether a product idea, taste masking or stabilisation concepts for longer shelf life are concerned: our development team elaborates new methods and formulations and conducts baseline studies for formulations. Furthermore, LICHTENHELDT supports pharmaceutical customers in drafting their Common Technical Documents (CTD) during drug registration procedure and, if required, also in dossier management.

Development portfolio

- Product and formulation optimisation
- Galenic developments of liquid and semi-solid forms
- Analytical method development and validation
- Scale-up to production batch size
- Process validation
- Dossier writing, e.g. CTD

Support portfolio

- Product transfer
- Stability tests / in-use tests
- Handling of registration issues
- PQRs



- **Own development team in own labs**
- **Preformulation studies**
- **Galenic development & optimisation**
- **Development & transfer of analytical methods**
- **Transfer & validation of production methods**
- **Dossier writing (eCTD, technical-pharmaceutical)**
- **Clinical samples**

Company milestones

2018
Ready for Serialisation

Upgrades of
ISO certifications

2015
New ERP- &
IT-Infrastructure

2008–2010
2nd Capacity
expansion

2004
EN ISO 13485

2000
1st Capacity
expansion

1994
DIN ISO 9001

1990
New site has
been built

GMP (1985)

1984
Takeover of business
by H.-J. Eisele

1948
Move to Wahlstedt,
Schleswig-Holstein

1745
Founded by
J.N. Lichtenheldt

From Wahlstedt into the world

LICHTENHELDT GmbH in Wahlstedt, Schleswig-Holstein, as a family-run, independent company, and looks back to a long tradition in the manufacture of drugs and health products for national and international customers. Our home market is Europe, but we also have specialised offers for overseas customers.

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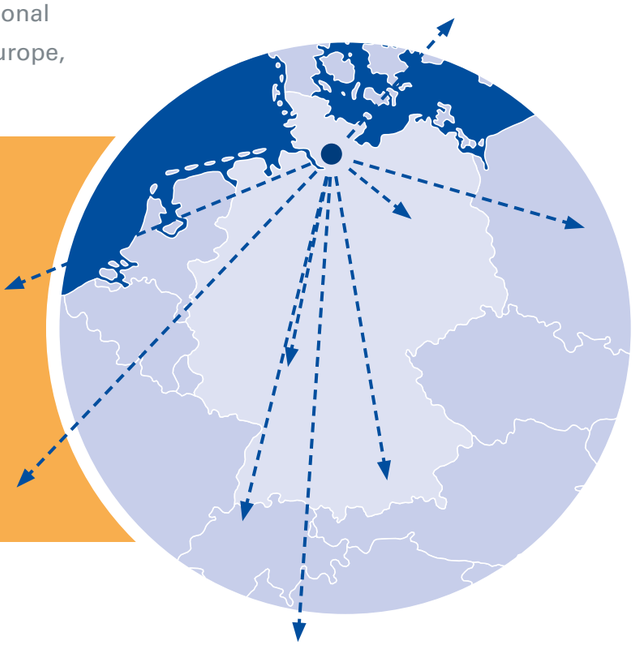
> Copenhague	300 km
> Warsaw	750 km
> Berlin	250 km
> Munich	600 km
> Milano	900 km
> Basel	700 km
> Frankfurt	400 km
> Paris	700 km
> London	700 km



Responsibility and sustainability

Code of Conduct

Ethical action and partnership-based cooperation with our customers, business partners and employees are at the core of our mission statement.
We oblige ourselves to adhere to current regulations and normative requirements and to accept our responsibility towards employees, society and the environment.
We foster respectful relations in leadership and in our teams, shape a safe and healthy working environment, promote continuous improvement and invest in personal and professional development of each individual for long-term employment.
Through the LICHTENHELDT ACADEMY, in technical presentations, seminars and courses we offer our employees diverse opportunities to expand their knowledge and skills.
With wide-ranging training and education for technical, chemical-pharmaceutical and commercial specialists, we actively support knowledge transfer and individual development of talented staff motivated to learn and perform.

LICHTENHELDT

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Wir fördern Wirtschaft
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Landesprogramm Wirtschaft: Gefördert durch die Europäische Union - Europäischer Fonds für regionale Entwicklung (EFRE), den Bund und das Land Schleswig-Holstein