Lichtenheldt GmbH – Pharmaceutical Contract Manufacturer and Developer for High Quality Liquid and Semi-Solid Non-Sterile Products

Visit the modern pharmaceutical production facility at Lichtenheldt GmbH in Wahlstedt in the German state of Schleswig-Holstein and it is hard to imagine that this specialist pharmaceutical contract manufacturer traces its origins back to a pharmacy store in the state of Thuringia founded in 1745 by the pharmacist and seller of essential oils, Johann Nikolai Lichtenheldt.

The Thuringian pharmacist who lend his name and the North German pharmaceutical company still have something in common after no less than 272 years. Fragrant oils, essences and ointments were the core competence of the one – the development and manufacture of liquid and semi-solid non-sterile finished products the business model of the other. But the company founder and the Lichtenheldt GmbH share more than just galenics: A productive wealth of ideas, high quality standards and the proverbial sense of integrity and solidity of an owner-operated company.

The Scientific and Technical Expertise to Become a Pharmaceutical Partner

Back in the 1920 s, the Lichtenheldt product range covered almost 300 products exported within Europe and overseas. After the Second World War, a new era opened up for Lichtenheldt in Wahlstedt, Schleswig-Holstein with a variety of its own brands approved for traditional drugs like tinctures and distillates.

The real breakthrough for the Lichtenheldt organisation came when Hans-Joachim Eisele purchased the company in 1984. Within a short period, the visionary entrepreneur had transformed Lichtenheldt into a pharmaceutical contract manufacturer and esteemed partner for the pharmaceutical industry. From the very outset, Eisele focused on top quality and continuous development of the production facilities and the portfolio. Just one year after Mr. Eisele took over the helm at Lichtenheldt, the company was GMP certified. DIN ISO 9001 and

■ Figure 1

Performance portfolio of Lichtenheldt GmbH.

DIN ISO 13485 certifications for medical devices also made Lichtenheldt a frontrunner among the contract manufacturers. Over the past 20 years, Eisele has continuously invested in expanding the laboratory, warehouse, administration and production to meet EU-GMP requirements for manufacturers of drugs and medical devices.

High Process Reliability with Frequently Changing Active Substances

Based on these capacities and state-of-the-art technologies, today the family business with its 200 employees at two locations in Wahlstedt produces 35 million individual packs for almost 400 finished products and a total of 6 million litres of bulkware. The company's core competence focuses on manufacturing and developing non-sterile liquid and semi-solid forms, particularly for the OTC sector (Fig. 1). Ranging from alcohol-based solutions to syrups, through to creams and spray emulsions, Lichtenheldt's production is characterised by an exclusive diversity of scales: preparations and batches vary from hospital samples to industrial production starting from 300 litres up to 20,000 litre process units and tanks.

At Lichtenheldt, complexity is managed with confidence: 11 flexible production and filling lines provide the efficiency necessary for widely varying batch sizes (Fig. 2). Seamless cleaning validation of the process units prevents cross-contamination and therefore avoids impurities entering the products manufactured.

One of Lichtenheldt's specialities is to manufacture and fill alcohol-based liquid and semi-solid products under ex-protected conditions. With its extensive ex-protection capacities in production and 300 special pallet storage spaces in the ex-protected area, Lichtenheldt has made a name for itself as a specialist in the pharmaceutical and medical devices industry in this area, where 25 % of the company's turnover is created.

GMP Compliance Every Time

It comes as no surprise that working with frequently changing formulations and active substance contents is highly complex and demands consistent control and documentation. To ensure the validity of all processes and absolute adherence with deadlines, Lichtenheldt invested in a new ERP and MES system, including infrastructure, in 2015. At the same time, the system was extended to include the use and processing of electronic manufacturing specifications. Additionally, integrated production quality assurance monitors the packaging and filling volume control. So it is no wonder that Lichtenheldt's complaint rates are below one percent which is well under the average of the industry.

This is also acknowledged by the pharmaceutical and medical device industry: Over 50 customers throughout Europe rate Lichtenheldt as an efficient and reliable contract manufacturer at the highest level each year – 90 % of them are existing customers.

Keeping Ahead in Implementing Serialisation Requirements

80 % of Lichtenheldt's customer base is made up of medium-sized and major pharmaceutical companies, including a growing number of prescription drug (Rx) companies. The Wahlstedt family business will soon offer manufacturers of prescription drugs something that is set to become mandatory as of 09-02-2019: A track & trace system aimed at implementing the EU Counterfeit Directive 2011/62/EU to affix safety features on the packaging of prescription drugs in a technically flawless way.

Counterfeit protection of a drug focuses on assigning a unique serial number in conjunction with individual production data (product identification GTIN/NTIN/PPN, expiry data and lot number) in the form of a data matrix code. This distinctive mark, together with sealing labels affixed to the ends of the carton, protects against manipulation and ensures the authenticity and integrity of a drug unit. Traceability and testing is then undertaken directly at the POS as end-to-end verification by the pharmacist.

At the customer's request, Lichtenheldt can access new software for controlling and monitoring serialisation and track & trace processes.

Machine processes and software are currently undergoing selection and testing as part of a pilot project. The assemblies for the packaging lines intended for serialisation are now in the implementation phase,

Figure 2

Production and filling line.

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such that serialisation will soon be possible during control weighing and tamper evident sealing.

Experts in Pharmaceutical Filling and Packaging

Lichtenheldt is also very familiar with packaging beyond serialisation. The company processes over 30 million folding box units per year alone. Against the backdrop of over 30 years of experience, the company's inventory includes a large number of format parts for filling and packaging machines ensuring a rapid solution for every packaging task. Lichtenheldt offers almost all sizes, closures and dosing aids for primary packaging, including special formats. Apart from a 100 % inspection of each item of final packaging, the packaging specialists at Lichtenheldt deploy their expertise to make processes more efficient, faster and cost-effective through optimisation.

Quality Control and Development in In-house Labs

The Wahlstedt based company is particularly proud of its modern labs in which, among other things, release controls, microbiological testing and residue analyses, stability testing and ICH-compliant in-use tests are performed. As retained samples always remain on-site at Lichtenheldt, clients profit from rapid processing and quick results when it matters. In its choice of analytics, Lichtenheldt draws upon a broad spectrum of methods in its labs from automated titration to FTIR spectroscopy to High Pressure Liquid Chromatography (HPLC) with different detectors (Diode Array Detector (DAD), UV/VIS detectors (ultraviolet/visible), Evaporative Light Scattering Detector (ELSD)) as well as Headspace Gas Chromatography.

But the family business uses not only its labs for quality control. Its own team develops new methods and formulations and conducts baseline studies for formulations. Furthermore, Lichtenheldt supports other pharmaceutical companies in drafting their Common Technical Documents (CTD) in the drug licensing procedure and, if required, also in dose management.

Firmly Established Value Orientation

At Lichtenheldt, employees are the ones whose knowledge, experience and flexibility form the basis for success. Respectful cooperation is nurtured in management and in teams, and readiness to assume responsibility, adopt change and promote teamwork is encouraged as a means of meeting the growing demands of the market. Striving for permanent improvement is an integral part of Lichtenheldt's DNA.

The components to secure and develop the employees' qualifications and competences are constituted by an overarching training and qualification system, annual employee development interviews and needs-based training as offered by the Lichtenheldt Academy. What is more, with its wide-ranging training and education for commercial, technical and chemical-pharmaceutical specialists, Lichtenheldt actively supports knowledge transfer and individual development of junior staff motivated to learn and perform.

In its work design, Lichtenheldt relies on longstanding employment: This means that ergonomic workplaces with modern work equipment are standard, as is flexible work organisation that enables a healthy work-life balance.

As a sustainable enterprise, Lichtenheldt intelligently invests in the environment. With an energy management system launched in 2013, the management board committed itself to a long-term energy strategy in an environmentally and resource-friendly way. By implementing targeted measures, the trend of increasing consumption was not only to be stopped; it was possible to reduce energy consumption by 8 % on average. In addition, since May 2016 a combined heat and power plant supplies Plant 1's area of 11,300 m^2. Overall, this highly efficient system covers 55 % of the company's energy requirements.

Andrea Schulz-Ayecke (Fig. 3), daughter of the company owner Hans-Joachim Eisele, continues this mission as Managing Director with a passion for innovating the family enterprise since 2009. In 2016 Dr. Torsten Ziegler (Fig. 3) joined the management board, an expert for business development in the pharmaceutical and supply industry. Innovations "made by Lichtenheldt" are set to be on the agenda in the future.

Figure 3

Managing Directors of Lichtenheldt GmbH: Andrea Schulze-Ayecke and Dr. Torsten Ziegler.

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