

# General Lithuania's Medical Device industry overview

#### **Key facts**

Lithuania is well estabilshed in international rankings and is listed together with the most developed countries:

Shares 1st position in Europe (7th globally) with Ireland in the Economic Freedom Ranking Source: Fraser Institute, 2021

■ The 2<sup>nd</sup> in the Manufacturing Risk Index in the CEE region (17<sup>th</sup> globally)

Source: Cushman & Wakefield, 2021

■ The 6<sup>th</sup> in International Tax Competitiveness Index Rankings among 36 OECD countries Source: International Tax Competitiveness Index Rankings, 2021

■ The **39**<sup>th</sup> in the **World Innovation Index** among 132 countries

Source: World Intellectual property Organization, 2021

■ The **4th** in **CEE** in **Innovation Scoreboard** 2021 with the highest strengths in Linkages, Digitalization, and Innovators

Source: European Commission, 2021

■ The 2<sup>nd</sup> globally for 'tertiary efficiency' which includes enrolment in higher education and the number of graduates in key innovation sectors

Source: Bloomberg Innovation Index, 2020

The 1st in CEE for university-business collaboration in R&D

Source: Global Competitiveness Report, 2019

■ The 1<sup>st</sup> in EU with 57% of scientists and engineers are women

Source: Eurostat, 2021

■ The **20**<sup>th</sup> position out of 193 countries in the **E-Government Development** Index

Source: UN Department of Economic and Social Affairs, 2020

■ The 4<sup>th</sup> in Global Cybersecurity Index in Europe (6<sup>th</sup> globally)

Source: Surfshark, 2021

■ In 2020, Lithuania's real GDP shrank only by 0.8% and it was the **2<sup>nd</sup> lowest GDP decline** across the EU due to **Covid-19 pandemics** 

Source: World Economic Forum, 2020

Lithuania demonstrated a certain level of FDI resilience to Covid-19 and jumped from 6<sup>th</sup> to 2<sup>nd</sup> place in the Greenfield Performance Index. 82 other countries were outperformed, including neighboring ones, Singapore, UAE and other both developing and developed states

Source: FDI Intelligence, 2021

#### Life Sciences - booming sector of Lithuania's economy

**Life Sciences – government priority.** In 2018, the government set Life Sciences as a priority sector, with an ambitious strategic goal to achieve 5% of GDP by 2030. Lithuania's life sciences sector grew by 22% during 2020, accounting for about 2% of GDP (Source: Statistics Lithuania, 2021).

**Life Sciences community.** Agile and tight-knit Lithuania's innovation ecosystem is a real community where solutions are quick, and networks are instant. A close and supportive community is often cited by life sciences companies as a draw to Lithuania.

**Life Sciences production export.** Lithuania's geographical position creates a convenient location for companies willing to manufacture their pharmaceutical products. For instance, 91 % of all Life Sciences manufactured products are exported. The main export markets are the USA (18,7%), Poland (8%), Germany (7,4%), China (7,4%), the UK (6,5%), and others (52,1%) (Source: Statistics Lithuania, 2020).

**Life Sciences sector profile.** The Life Sciences sector in Lithuania is divided into two main subsectors: biotechnology & pharma, and medical devices/ MedTech.

#### Life Sciences hub

**Life Sciences hub.** Two cities Vilnius and Kaunas are forming the Life Sciences hub, which is boosted by an integrated network of science valleys and educational institutions supplying businesses with an educated and motivated talent pool. The capital Vilnius was ranked 2nd after evaluation of the strategy to attract and retain smart businesses among the top smart cities of the future in 2019 by the Financial Times.

#### Key R&D and manufacturing hubs

## Santaka Science Valley

- National Entrepreneurship and Innovation Centre
- Technology Transfer Centre
- 9 Research Institutes
- Advanced research in organic chemistry, medical technologies, nanotechnologies, robotics



### Santara Science Valley

- 5 research institutes and 4 private R&D facilities
- 3 GMP-compliant pharma plants
- Academic training centers and open labs
- Advanced research in medicine, physics, chemistry and biochemistry photonics, nanotechnologies





Continental, Hella, and others

Comparison of Vilnius & Kaunas						
	Vilnius	Kaunas				
Facts	<ul> <li>Capital city</li> <li>Population of 829 983 (2021)</li> <li>Unemployment rate 4,8% (2021)</li> <li>Average gross salary in all industries 1 567 EUR* (2021)</li> </ul>	<ul> <li>2<sup>nd</sup> biggest city in Lithuania</li> <li>Population of 565 628 (2021)</li> <li>Unemployment rate 6,7% (2021)</li> <li>Average gross salary in all industries</li> <li>1 465 EUR* (2021)</li> </ul>				
Exposure of talent	Vilnius is driven by STEM oriented young, multi-lingual talent pool	Kaunas population is comprised of a mix of blue-collar and white-collar employees				
LS profile	Digital Health Tech Present companies: Kilo Health, Oxipit, Ligence Pharmaceutical and biotech Present companies: Thermo Fisher Scientific Baltics, NorthwayBiotech, Teva, Froceth, Caszyme	Medical devices and hardware tech Present companies: Hollister, Esco Medical Technologies, Kitron, KB Components, Acconitum				
Other present	Global Business Services and Fintech Dexcom, AmerisourceBergen, McKesson,	Manufacturing and engineering				

Revolut, TransferGo and others

industries

#### Medical devices/MedTech in Lithuania

**MedTech industry potential.** Lithuania has all the attributes to support the dynamic MedTech industry worldwide. Lithuania puts high emphasis on fostering strong partnerships in the fields of scientific research between universities and businesses. Government makes its priority to ensure the development of Lithuania's talent pool. The STEM subjects is central of education in Lithuania from early schooling, right through to the postgraduate level. Lithuania provides a positive environment through the state-of-the-art facilities in science valleys, next to two university hospitals spread across the country's 2 main cities Kaunas and Vilnius.

**Key competences**. Among many developments in Lithuania key competencies in MedTech lies in Al and laser sectors. The country's artificial intelligence ecosystem expands rapidly, with more and more Al start-ups emerging. Kaunas Technical university host a remarkable team of experts in Al & ML at the Department of Multimedia Engineering. Recently, Prof. Maskeliūnas and one of his Ph.D. students announced having programmed an algorithm that predicts Alzheimer, by analyzing MRI scans, with nearly 100% accuracy.

Lithuania's laser industry occupies more than 50% of the global scientific market for ultra-short pulse lasers, and lasers created in Lithuania can be found in almost every continent In 2020, unique laser technology for measuring blood parameters was developed by researchers at the Lithuanian University of Health Sciences (LSMU), together with specialists from the company Brolis Semiconductors. The technology is expected to complement existing clinical methods, providing a non-invasive way to collect real-time information on changes in the blood – without the need for a needle.

#### **Digital Medicine**

Embarking on the evolution of the entire industry, Lithuania is offering centralized patient data and high-level tech talent to biopharma companies interested in piloting their Al-related projects locally.

**Data** has been collected within Lithuanian healthcare nationally for more than 20 years. In 2015, ESPBI IS, a centralized national health record system that serves as the foundation for the country's entire electronic healthcare ecosystem, was created. The data collected extends beyond the national patient registry to include a broad range of data points, from the birth registry, diagnosis of diseases and illness progressions through routine visit documentation. Using the latest data exchange standard, the system interconnects a wide variety of different stakeholders: from doctors to patients.

**Sharing and re-using health data for research purposes.** Lithuania, in line with the wider EU's legislation plan, passed the law allowing companies to access citizens' health data. A pilot version of the open data portal data.gov.lt, has been active for R&D-driven businesses since June 2020. Open data sets are constantly updated alongside maps of data and interfaces of the portal. Companies can also request specific data sets based on their research requirements.

**ICT Talent**. Lithuania has 52k ICT specialists employed and is a leading country in Europe for ICT specialists having tertiary education, 2nd in students choosing STEM studies and 4th by young specialists (age 15 – 34) joining ICT sector. Lithuania's IT talent pool primarily comes from 3 streams: universities (10,6k IT students enrolled in IT studies, ~2000 IT students graduate each year), private coding academies (~2500 people requalify as junior developers through private coding schools each year), positive migration trends (~4000 IT specialists moved to Lithuanian from non-EU countries in 2022 alone).

**Enthusiasm for AI.** Lithuania is 4th in the EU for enterprises using at least two AI technologies. Lithuania has a strong AI community with an ever-evolving AI ecosystem. There are regular AI meetups gathering hundreds of participants. Some Lithuanian AI companies and startups have really shined and are helping to discover Lithuania as a country of AI developers. "Artificial Intelligence Association of Lithuania" - a community of professionals and enthusiasts dedicated to promoting and encouraging AI integration and development.

Key local enterprises: Baltic Amadeus, Neurotechnology, Magma solutions (Pixevia), Vilantis, Telesoftas, Easyflow, 1T2B, Agmis. Foreign: Satalia, InData Labs, Beyond Analysis, Jaydevs and others.

**Success cases.** Present ICT talent and favorable infrastructure provide a steady basis for successful Lithuanian Digital Healthcare companies. Lithuanian company Kilo Health, est. 2013, operating within digital health and wellness field, is the 2<sup>nd</sup> fastest growing company in Europe, with a strong global clientele base, mostly concentrated in the US.

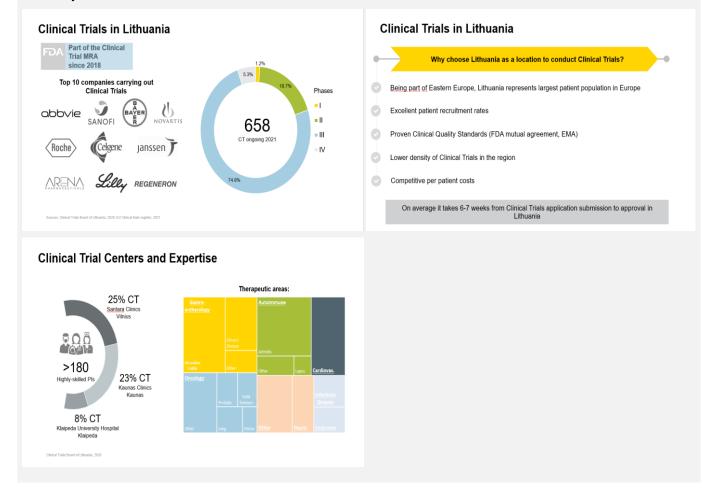
#### **Regulatory environment**

**Regulatory authorities.** Being a member of the European Union, Lithuania falls under European Medicine Agency regulations. Local authority State Medicines Control Agency (SMCA) is fully integrated within the EU regulatory system. Also, Lithuania has Mutual Recognition Agreement with FDA which provides foreign companies with an opportunity to apply for FDA approval with clinical trials data collected in Lithuania. Thus, making the drug approval process more efficient and convenient to cover both EU and USA markets at once.

**Exceptional regulatory environment.** Lithuania offers an exceptional regulatory environment for clinical trials, called hospital exemption, which allows hospitals and medical practitioners to provide ATMP classified products (including gene therapy medicinal products, somatic cell therapy medicinal products, and tissues engineered products) to patients, e.g., in case of high unmet medical need because there is no authorized ATMP alternative available. This exemption provides a mechanism for companies to apply products, and in parallel collect data for final approval which is an attractive and time-saving opportunity for companies allowing to start applying therapies before marketing authorization is granted.

#### Clinical trials in Lithuania

Lithuania offers a favorable business environment to conduct clinical trials. Over 90 international pharma and medical companies are already conducting clinical trials in the country, with Phase III being the most popular phase with the main research areas being gastroenterology, oncology, and endocrinology. It takes less than 60 days to receive approval to conduct the clinical trial in the country.



#### **Talent pool**

**Lithuanian population is among the most educated people in Europe,** with 94.9% of the workforce (ages 25-64) with upper secondary, post-secondary non-tertiary or tertiary educational attainment. The employment rate of tertiary-educated young adults in Lithuania is the highest across the EU at 93% (OECD Employment, 2020). Lithuania has an above-average number of graduates per 1,000 population in STEM (science, technology, engineering, and mathematics) subjects (Eurostat 1, 2020).

Lithuania offers a solid talent base for the manufacturing sector. In a survey, conducted by Invest Lithuania, the local workforce is highly valued for its adaptability, with 80% of companies rating the cultural fit and ability to learn of local talents as either "good" or "excellent". The local workforce was also rated highly for productivity and determination – 74% of companies rated work ethic and 60% of companies rated going the extra mile criteria as "good" or "excellent".

**Universities.** There are 4 major Life Sciences universities. Two of them are located in the capital - <u>Vilnius University</u>, <u>Vilnius tech</u>, other two in the second-largest city Kaunas - <u>Lithuanian University of Sciences</u> and <u>Kaunas University of Technology</u>. The main programs at the universities are engineering, bioengineering, applied chemistry, chemical/bio/electronics engineering, pharmaceutical/medicinal chemistry, biochemistry, molecular biology, biology, biotechnology,

**Innovation oriented.** Lithuania is ranked 2<sup>nd</sup> globally by Bloomberg for 'tertiary efficiency' which includes enrolment in higher education and the number of graduates in key innovation sectors (Source: Bloomberg Innovation Index, 2020).

**Women in science.** According to Eurostat, women make up 58% of all researchers in Lithuania. In order to further promote women's leadership in both the biotechnology and life sciences sector, the Lithuanian Biotechnology Association organizes the platform Women in Biotech where world-renowned leaders in their field share inspiring thoughts on leading in the life sciences sector. In manufacturing companies

An example of women's leadership in science is highly represented by Vilnius University Life Science Centre scientists dr. leva Plikusiene and Joana Smirnoviene who were awarded the prestigious L'Oréal-UNESCO Baltic "For Women in Science" fellowship in June 2021. Lithuanian scientists were awarded for their contribution to scientific progress in a wide range of fields, from the development of smart materials for cancer treatment to tackling the COVID-19 pandemic.

#### Infrastructure

**Physical connectivity.** Lithuania's geographical position creates a convenient location for export. Developed road & rail, air and sea infrastructure guarantee fast production connection to the remaining parts of Europe, Asia and America.

**R&D** infrastructure. Understanding the importance of infrastructure for the sector to grow, the Lithuanian government has invested significantly in open R&D infrastructure – about 1 billion EUR (2006-2020) and 1 billion to be invested further for both the infrastructure and R&D activities.

Vilnius City Innovation Industrial Park (VCIIP) is an industrial park in the capital of Lithuania, dedicated exclusively to the development of innovative business. The park, which has been operating since August 2018, has already attracted more than 67 million investments. In the future, 30 companies are planning to establish themselves in the industrial park, most of them will develop projects in the field of life sciences. The importance of gathering strong life science companies and science centers of different profiles is evident – this park will serve as a science hub to develop products and innovations competing at the global level.

#### Sustainability

**Renewable energy.** Lithuania reportedly became the first country in the world to launch an online platform that enables consumers to buy electricity from a remote solar panel.

In 2020, Lithuania ranked 6th in Europe for the share of renewables used in district heating and cooling. Direct use of bioenergy has been the main source of TFEC and witnessed a further expansion in district heating (DH) with current coverage of half of the heat demand. Countries' domestic electricity generation is already low-carbon, with 37,6% of electricity produced from renewable sources (wind, bioenergy and waste, hydro, and solar).

**Energy independence.** In 2018 Lithuania adopted an Energy Independence Strategy which provides an outlook on countries' key energy targets for 2030 and guidelines for energy development until 2050. The first milestone towards energy independence was set in 2014 by building an LNG project which saves the country around 160-200 million euros every year. In response to continuing Russia's energy blackmail and aggression in Ukraine, in March 2022 Lithuania took final steps toward becoming fully energy independent by completely cutting out imports of Russian energy supplies.

#### Start-up ecosystem

Lithuania has created a supportive and open startup ecosystem, which is eager to support start-ups and future entrepreneurs. The country has active local investors and supportive governmental institutions environment. Start-ups have a number of co-working spaces and hubs, sandboxes, and plenty of other ecosystem players that could offer partnership and support. The start-up ecosystem in Lithuania has helped to emerge many Life Sciences companies, just to mention a few:

**Droplet Genomics** – designs microfluidic instruments, consumables, and data analysis tools, so biological samples can be analyzed at the granularity of single cells.

**Oxipit** – a startup that developed ChestEye — the first AI chest X-Ray radiology suite for healthy patient reports.

**Rubedos** – developed unmanned missioning and computer vision solutions for industrial applications since 2009. The company provides hardware, software, and services to enable self-driving vehicle development, deployment and fleet operation. Rubedo can convert customer-selected vehicle platforms into robotic systems.

**Softneta** – specializes in medical imaging and communication solutions to improve the quality of healthcare. The company was founded in 2007 and possesses 14+ years of experience in the development of medical devices for processing, visualization and transmission of diagnostic medical data.

**Ligence** – develops machine learning algorithms that are capable of automatically detecting a person's heart functional and anatomical features from ultrasound images.

**Sentiance** – a data science company turning sensor data into rich insights about people's behavior. Their technology goal is to enable companies to understand how customers go through their everyday lives, discover and anticipate the moments that matter most, and adapt their engagement to real-world behavior and real-time context. Sentiance's technology is primarily used in insurance, health, and mobility applications.

#### Cost to quality ratio

**Excellent cost to quality ratio.** The quick ramp-up of the business in Lithuania is strongly influenced not only by the government support and complete ecosystem but also because of the cost to quality ratio. Considering the hypothetical scenario, that a company expands and opens a Biotech – Pharma Manufacturing facility in Lithuania and a team of 150 qualified people is hired, the total average annual labor costs for running a facility is approx. 2 to 4 times lower than in Spain, the UK, Ireland and Germany (Source: FDI Benchmark, 2021). This proves the competitiveness of establishing operations in Lithuania.

#### **Financial incentives**

**Free Economic Zones.** Lithuania has seven Free Economic Zones in various locations across the country. These provide unbeatable conditions to develop businesses by offering ready-to-build industrial sites with physical and/or legal infrastructure, support services, and tax incentives. Businesses that choose to locate themselves in these zones enjoy 0% tax on corporate profits during their first 10 years of operation, and only 7.5% tax over the following six years. In addition, these businesses are exempt from tax on dividends and real estate tax.

**FDI Invest LT+.** The Lithuanian government fosters sustainable investment by covering companies' expenditure on capital investment. Companies considering foreign direct investment in Lithuania may qualify for state funding, which is negotiated on a case-by-case basis in compliance with EU and national legislation.

**Triple deduction of R&D expenditure.** To promote research and development, Lithuania's government offers companies the opportunity to reduce their expenses incurred on R&D. R&D expenses are fully tax-deductible three times during the tax period in which they are incurred.

**Patent Box.** A reduced corporate tax rate of 5% applies to profits from copyrighted software created by Lithuanian subsidiaries, as well as inventions that meet the criteria for patentability.

#### Legislative package for large scale projects (LSPs)

Most notably – and unique to Lithuania – new support program for large scale investment projects that are valued at more than EUR 30M in capital expenditures and entail the creation of more than 200 jobs. The package offers significant tax incentives, including 0% of corporate tax for 20 years, and streamlines key processes in land acquisition, planning, and migration for large-scale projects.

Investments that o	nualify as a	large scale r	project will be	e eligible for t	he following incentives:
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0% corporate tax for 20 years	The unit in Lithuania will enjoy 0% of corporate income tax for 20 years since the day of agreement. This tax incentive combined with FDI Invest + the maximum intensity for the project can not exceed 25% on the CAPEX invested.
Recognition as a Project of State Importance	All LSPs will be given the status of Project of State Importance once the project has been added to an official list of LSPs.
Faster decision-making from public authorities	In general, public authorities will be required to decide on matters regarding LSPs within 3 working days.

Legislative package for larg	gislative package for large scale projects (LSPs)			
Access to land plots	Servitudes necessary for the LSP's operation, including private land plots, can be arranged under the administrative act. This will ensure faster planning for large territories.			
Leasing of state land	LSPs will be able lease state land without having to go through an auction.			
Streamlined migration process for employees	Employees of LSP will have the right to start working in Lithuania from the day they apply for the Temporary Residence Permit, and decision on whether an employee is necessary and suitably qualified will rest with the investor.			
Direct communication channel with the government	The Ministry of Economy will appoint an LSP coordinator responsible for overseeing LSP contracts and ensuring cooperation between investors and the relevant institutions. A consultative committee will be established to address key inter-institutional questions regarding LSPs.			