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Life Sciences and Biotech

February 2017

Introduction

In the Bluegrass Region and Kentucky, Lexington is a hub for the life sciences industry. Lexington has leveraged its culture of innovation and commercialization, a superior business climate, top ranked research programs at the University of Kentucky, and an expansive network of medical centers to provide an environment where any market niche of the life sciences industry can grow. The life sciences industry has two components: direct patient care and biotechnology.

Direct patient care includes hospitals, nursing facilities, and medical centers, and is a prominent market in Lexington with a strong base of health care facilities, employers, and resources. There are several major medical centers including Baptist Health, Shriner's Hospitals for Children, St. Joseph Hospital (part of KentuckyOne Health), and the UK Medical Center. In fact, the UK HealthCare System is an extensive

network that includes four hospitals, over 80 specialized clinics, more than 140 outreach programs, and six health professional colleges. In 2015, the UK HealthCare network served over 581,000 outpatient visitors and performed 31,200 surgeries¹. The Lexington Clinic, a multi-specialty medical group with 25 locations throughout the Bluegrass Region, employs 200 physicians and provides services to more than 2,000 patients every day and 600,000 patients every year².



¹ UK HealthCare Annual Report 2015.

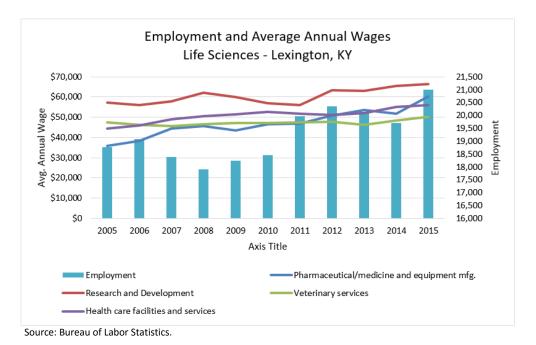
² https://www.lexingtonclinic.com/aboutusoverview2.html

Direct patient care is a major employment industry for Lexington, with a high-quality stock of human capital for medical professionals. According to the U.S. Bureau of Labor Statistics, over 19,000 people were employed as health care practitioners and technicians in 2015, including more than 5,100 physicians, 1,100 dentists, 184 optometrists, 560 specialty therapists, and 7,200 registered nurses.

Biotechnology includes institutions involved with animal and plant science research and designing and manufacturing medical/veterinary products. Biotechnology is one of the fastest growing industries in the United States, and Lexington is committed to fueling its growth in the Bluegrass. In fact, over 50 biotech companies have chosen to locate in Lexington.

Health care and biotechnology are supported by strong ties to academic programs at the University of Kentucky. UK's College of Pharmacy is one of the nation's top pharmacy programs, ranked the 6th Best Pharmacy Programs by U.S. News³ in 2016. The cutting-edge medical research on disease and drug development performed by the graduate students and faculty has benefited the area and the nation. Graduates enrich the workforce and faculty members have created 25 startup companies since 1989. Furthermore, UK allocates nearly \$328 million to research and development annually and the overwhelming majority of UK's R&D expenditures (over 70%) are devoted to the field of life sciences.⁴

Seven industries are part of the life sciences: pharmaceutical and medicine manufacturing; medical equipment and supplies manufacturing; scientific research and development services; veterinary services; ambulatory health care services; hospitals; and nursing and residential care facilities. In 2015, around 21,000 people were employed in the life sciences, with an average annual salary of \$55,800.



³ http://grad-schools.usnews.rankingsandreviews.com/best-graduate-schools/top-health-schools/pharmacy-rankings

⁴ http://www.locateinlexington.com/getattachment/SITE-SELECTION-SERVICES/Strategic-Targets/Life-Sciences/CLED-BioBrochure2016.pdf.aspx;;

Plant and Genetic Engineering

The Bluegrass Region has acquired a niche within the plant and genetic engineering segment of the life sciences industry, and many area companies are creating valuable pharmaceuticals. In 1980, scientist Dr. Pearse Lyons founded Alltech in Lexington, Kentucky. A top ten animal health company today, Alltech has bioscience centers in the U.S. and Ireland, offices and distributors in more than 120 countries, and nearly 100 production facilities globally, three of which are in Kentucky. In fact, Alltech's \$200 million algae production facility in Winchester is one of the largest algae production facilities in the world and was so successful that Alltech expanded to a second facility in Brazil. Algae are expected to become a crucial area of development as the United States pursues renewable sources of energy to power the country in the coming decades. Locally, the company is known for its beverage division. The Alltech Lexington Brewing and Distilling Co. produces an award-winning line of beers and spirits with a brewery and distillery in downtown Lexington and, soon, in Pikeville.

Naprogenix is a startup biotech research company that derives compounds from native Kentucky plants to develop new technologies. Plants have a variety of uses in food and medicine and Naprogenix enhances specific bioactivity and qualities of native plants through genomics and molecular pharmacology to increase their usefulness to the pharmaceutical, health, and agrochemical industries. Naprogenix's products are natural, giving the company a competitive advantage as consumers increasingly pull away from synthetic ingredients in both chemicals and medicines.

Similarly, ParaTechs Corporation recently developed a bio-insecticide targeting corn earworm moths, the highest crop-damaging pest in North America and the second-highest worldwide. ParaTechs's bio-insecticide is a mutated nudivirus, a sexually transmitted disease that sterilizes 100% of corn earworm moths it infects, compared to a 30% effectiveness rate when the nudivirus occurs in nature. In addition to increased effectiveness, ParaTechs's bio-insecticide reduces the need for chemical pesticides and is unlikely to affect other species that do not mate with corn earworm moths. As a startup, ParaTechs was originally housed in UK's Advanced Science and Technology Commercialization Center (ASTeCC) before moving to its current location in 2010.



ParaTechs's lab space, courtesy of Angelika Fath-Goodin.

A third Lexington company developing enhanced organisms is MosquitoMate. Founded by University of Kentucky researchers in 2010, MosquitoMate has developed a biopesticide to reduce or eliminate Asian tiger and Aedes aegypti mosquitoes through sterilization. These pests carry several diseases that are harmful to people and animals, such as dengue, yellow fever, heartworm, West Nile virus, chikungunya fever, and the Zika virus. MosquitoMate infects male mosquitoes with a form of Walbachia bacteria and releases them to mate with females, who are permanently sterilized by the Walbachia. As a result, the next generation of mosquitoes is reduced and the spread of disease is prevented. MoquitoMate's biopesticide is not transmitted to humans, animals, or other insects, and does not include chemicals or genetic modification. MosquitoMate received two SBIR-STTR Matching Funds Phase I grants of \$150,000 and a \$497,894 Phase II grant. Currently, MosquitoMate is waiting for EPA approval to begin marketing its innovative method of pest control.



Evolva fermentation lab, courtesy of Evolva, photographer Beat Ernst.

Another Lexington-based biotech company has developed an effective and efficient means for producing valuable natural products. Evolva, formerly Allylix, Inc., can generate and isolate natural chemical compounds that are in high demand for pharmaceutical, agriculture, and flavor-andfragrance industries. Evolva uses reengineered version of the fermentation process to grow compounds in a way that is faster and more reliable that the traditional plant extraction process, and cheaper and less complicated than the chemical

synthetization process. Evolva is developing a library of compounds that will make many previously unstudied compound samples available for research screening by biotechnology and pharmaceutical companies. These compounds can be used in the manufacturing of products such as foods, medicines, cosmetics, insecticides, and industrial cleaners. Evolva is a global company with research facilities in Switzerland, Denmark, India, and the UK, specializing in molecules produced by yeast and discovering, producing, and supplying innovative, sustainable ingredients for health, wellness, and nutrition. Evolva USA was born out of the acquisition of Allylix and pursues its U.S.-based research facilities in Lexington.

Transposagen Biopharmaceuticals is a worldwide leader in genome engineering technologies and services with applications in therapeutics, research, drug discovery, bioproduction, clinical genetic testing, and agriculture. Transposagen specializes in genetic manipulation technologies, stem cell engineering services, and creating genetically modified laboratory rats. Altering the genetic code of rat models allows scientists and researchers to compare modified organisms with normal organisms to better understand gene functions and advance medical research on disease and drug discovery. In 2014, Transposagen entered into a multi-million dollar research collaboration and worldwide license agreement with Janssen Biotech, Inc. to develop allogenic cells that may one day be "on the shelf" cancer treatments that will not require a donor-recipient match. Transposagen's genome editing technologies will be used to create

allogenic Chimeric Antigen Receptor T-cells (CAR-T) therapies, and Janssen will pay up to \$292 million per CAR-T therapy. In 2015, Transposagen was honored with the Tibbetts Award, which is awarded to companies for exemplary technological innovation and SBIR achievement.

Hera BioLabs Inc. is a Lexington-based Contract Research Organization (CRO) and a spinoff of Transposagen. Like Transposagen, Hera uses gene editing tools and services to manufacture genetically specialized products and services. In 2016, Hera announced an investment of \$1.8 million to move its operations from its current location on the University of Kentucky campus and establish a new headquarters, creating 23 new high-skill jobs in Lexington.

"We aim to help develop a safer, healthier world through the advancement of toxicology testing. Kentucky is an ideal location for a CRO like Hera to start and grow as it offers a competitive edge in manufacturing and an excellent place to recruit and attract the type of talent we are looking for."

- Jack Crawford, Hera CEO, 2016

Medical Application Technology

Application technology for the medical industry and pharmaceuticals is another segment of the life sciences industry being developed in Lexington. Several companies are headquartered in the UK Coldstream Research Campus, including Summit Biosciences and Intralink-Spine, Inc.

Summit Biosciences develops nasal delivery forms of pharmaceuticals traditionally manufactured as oral or injection products. Compared to tablets or capsules, nasal delivery uses a lower dose of the active ingredient and bypasses the digestive system, providing fast-acting aid. In many cases, nasal delivery can replace the hypodermic syringe and the biohazards associated with their use and disposal. In 2016, Summit Biosciences received FDA approval of the Abbreviated New Drug Application (ANDA) for Sumatriptan Nasal Spray, a generic version of GlaxoSmithKline's Imitrex Nasal Spray to treat migraines in adults. Summit Bioscience developed Sumatriptan for commercialization by Lannett Company Inc. and will continue manufacturing the product at their facility in UK's Coldstream Research Campus.

Intralink-Spine, Inc. develops and manufactures Rejuve, an injectable medical device to treat degenerative disc disease (DDD), lower back pain, and related spinal disease by stabilizing and reinforcing tissue, joints, and spinal discs. Intralink-Spine located in Lexington after receiving an SBIR match grant from the state in 2010. Currently, Intralink-Spine is in the process of expanding clinical trials into the European market.

Coldstream Laboratories Inc. is a specialty pharmaceutical contract manufacturer of sterile liquid and lyophilized parenterals and injectables. Founded by the University of Kentucky Research Foundation in 2007, Coldstream Laboratories has become increasingly successful. In 2015, Piramal Enterprises Limited purchased the company for \$35 million to enhance its products by acquiring Coldstream's expertise in developing and manufacturing sterile injectables. Piramal kept Coldstream's operations in Lexington, where the company continues to thrive.

In nearby Versailles, ECM Biosciences develops antibodies and other biological reagents for life science research in neuropathology, cancer, immune dysfunction, and cardiovascular disease. ECM Biosciences also offers custom antibody testing and production services and works in collaboration with other researchers around the world.

There are several national and international corporations in the medical device manufacturing industry currently located in Lexington. For example,



LexPlastics, formerly Interplex Plastics, Inc., manufactures plastic injection molding components that are used in a variety of medical, dental, automotive, and industrial applications including hospital beds, intravenous delivery systems, and oxygen concentrators. LexPlastics exports to Asia, Mexico, and India.

Neogen Corporation is a biotech company that produces food and animal safety products and technology. Founded in 1982, Neogen has grown to more than 1,000 employees in multiple U.S. and international locations. Utilizing many technologies spun out of University of Kentucky-based research, Neogen develops, manufactures, and markets a diverse line of products dedicated to food and animal safety. Neogen's Animal Safety Division is located in Lexington and develops, manufactures, and markets diagnostics, veterinary instruments, pharmaceuticals, rodenticides, disinfectants, vaccines, and ELISA testing kits.

A cutting-edge animal health products company, MEP Equine Solutions recently developed an innovative parasite diagnostics and management tool, the Parasight System, with support from the University of Kentucky's Maxwell H. Gluck Equine Research Center as a research facility partner. The Parasight System detects and diagnoses parasites through on-site sample collection, filtration, and analysis using a smartphone app. The existing method of analyzing intestinal parasites required special equipment, user expertise, manually counting fecal eggs on a microscope slide, and several days of processing, but the Parasight System is easy to use and produces immediate results on location.

Commercializing the Life Sciences Industry and Biotechnology in the Bluegrass

With an abundance of resources, the University of Kentucky is positioned to help companies with human capital and financing. Assisting companies with commercialization and technology transfer on the University of Kentucky campus are the ASTeCC/AgTeCC campus incubators, which provide lab space for startups and help connect researchers and entrepreneurs to economic development activities, such as commercialization and licensing. In addition, Lexington is home to the only research and development business park in the state of Kentucky – UK's Coldstream Research Campus. Coldstream, a 735-acre office park, was specifically designed for recruiting high-tech and biotech companies, university centers, and startups. Coldstream offers intellectual capital and resources from UK, as well as infrastructure for new and existing companies.

To further the progress of assisting life sciences entrepreneurs, Commerce Lexington Inc., the University of Kentucky, and the City of Lexington formed the Bluegrass Business Development Partnership (BBDP), which is funded by the City of Lexington. The BBDP's goal is to be a one-stop, super-service provider, linking entrepreneurs with the information they need to be successful, including assistance in financial planning, business plans, funding sources, real estate, and service providers.



Kentucky's Cabinet for Economic Development's Office of Entrepreneurship funds the Kentucky Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Matching Funds program to help create, recruit, and retain small businesses, including high-tech and biotech. The SBIR/STTR Matching Funds Program is an innovative initiative that provides matching funds up to \$150,000 for Phase I and up to \$500,000 for Phase II for Kentucky businesses. To date⁵, more than 250 Kentucky SBIR/STTR Matching Funds have been granted to small Kentucky businesses, totaling over \$61.3 million in state funding and \$112.5 million in federal funds. Small businesses and startups can also find help from the Bluegrass Angels, a local group of angel investors willing to provide seed capital and management guidance to local regional startups and new businesses. The BBDP has attracted over 28 new companies to Lexington because of the state match program, UK research assets, and great quality of life.

Local Attributes

Aside from an established life sciences industry in the local economy and a unique support system that emphasizes innovation, Lexington has numerous attributes to support the life sciences. Lexington's workforce, strategic geographic location, low cost of doing business, and high quality of life are among the city's strongest assets.

The 2015 Census data ranks Lexington the 11th most educated city in the nation among cities with populations of at least 300,000 people, with 41.6% of the population 25 years or older holding at least a bachelor's degree. Even more impressive, 18.9% have an advanced degree, ranking Lexington #9 for advanced degree attainment. These high levels of educational attainment are at least partially due to the 10 colleges and universities within 40 miles of Lexington. Nearly 70,000 students are enrolled in these institutions, graduating over 15,000 annually. Lexington has received numerous accolades for its educated population, including being ranked the World's 24th Smartest City by *National Geographic* in 2014 and #1 Best Midsized City for New College Grads Starting Careers by *Onlinedegrees.com* in 2016.

The Bluegrass Region's central location places Lexington within a 600-mile radius of the majority of the nation's employment, retail sales, and population. In addition, Kentucky's excellent transportation system of integrated state-maintained roads, interstates, and parkways the Bluegrass within overnight range of

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⁵ February, 2017.

more than half of the U.S. market. Central Kentucky boasts two major interstate highways, Interstate-75 and Interstate-64. I-75, a major north-south corridor, and I-64, a major east-west route, intersect north and east of downtown Lexington. Lexington is also home to the Blue Grass Airport and is within an hour's drive of the Cincinnati/Northern Kentucky International Airport and the Louisville International Airport.

Lexington and Kentucky have one of the lowest costs of doing business in the eastern United States. In 2016, *SmartAsset* ranked Lexington #8 City with the Lowest Startup Costs and KPMG ranked Lexington #7 Lowest International Business Location Costs in the U.S. Northwest/Canada Region in 2014. Kentucky enjoys a tremendous competitive advantage in the provision of energy, natural gas, and water supply. Kentucky's industrial sector energy costs are among the lowest in the nation, averaging almost 20% lower than the national average. In 2016, *Forbes* ranked Lexington #34 Best Place for Business and Careers and *Area Development* ranked Kentucky #10 Best State for Doing Business in 2015.

While Lexington is a first class place to locate a business, it is also one of the best places to live and raise a family. In addition to a low cost of living, affordable housing, and low commute times, the region enjoys a wealth of natural beauty and offers various outdoor activities. Lexington boasts many outstanding lifestyle and cultural amenities of a major metropolitan area including premiere horse-racing, numerous museums, and prestigious athletic teams. (Read more about living in Lexington in our <u>Quality of Life</u> and <u>Visitor Industries White Papers</u>.)

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Appendix A - Biotech Companies in the Bluegrass

Alkymos | alkymos.com

Alltech | alltech.com

AnnuLox | annulox.com

Biological Prospects | biological prospects.com

Biomedical Development Corporation | biodevcorp.com

Bluegrass Advanced Materials | bgamaterials.com

Catalent | catalent.com

Circadian Health Systems | tammyspurlin@hotmail.com

Coldstream Laboratories | coldstreamlabs.com

CoPlex Therapeutics | 502-767-1020

CytoInformatics LLC | karyn.esser@uky.edu

ECM biosciences | ecmbio.com

EmeraMed | emeramed.com

Enzymax | enzymax.com

Equine Diagnostic Solutions | edslabky.com

Equithrive | equithrive.com

Evolva | evolva.com

Exaatherm, LLC | mc3corp.com

F6 Pharma | bloftin@f6pharma.com

Gibson Laboratories | gibsonbioscience.com

GISMO Therapeutics, Inc. | gismotherapeutics.com

Hera Testing Laboratories | <u>icrawford@transposagenbio.com</u>

Hummingbird Nano | hummingbirdnano.com

Innovative Diagnostics Inc. | psiegelbdc@gmail.com

Intralink Spine | intralinkspine.com

Invenio Therapeutics Inc. | agarwamukesh@yahoo.com

LGC Group | Igcgroup.com

Mapigroup | mapigroup.com

Medmovie.com | medmovie.com

MiRx Pharmaceuticals | mirxpharma.com

MosquitoMate, Inc. | www.mosquitomate.com

Murty Pharmaceuticals | mpirx.com

Nano-Mite Technologies | nano-mite.com

Naprogenix Inc. | naprogenix.com

Neogen Corporation | neogen.com

Novobrace | novobrace.com

NX Development Corp. | nxdevcorp.com

Oraceuticals Inc. | 859-253-5357 Orthopeutics | orthopeutics.com

Parasight System | theparasightsystem.com

ParaTechs Corporation | www.paratechs.com

PDx Biotech | periodx.com

Quanteon | quanteon.cc

Seikowave | seikowave.com

Signal Solutions | sigsoln.com

Solidagex.Inc. | solidagex.com

Summit Biosciences Inc. | summitbiosciences.com

Topasol | topasol.com

TrackFive Diagnostics, Inc. | 859-335-8466

Transposagen Biopharmaceuticals | transposagenbio.com

Tribo Flow Separations LLC | triboflow.com

Twin Star TDS LLC | twinstarmedical.com

United State Equestrian Federation | usef.org

Venture Laboratories | ventlabs.com

Vindico Pharmaceuticals | vindicopharma.com

W-Z Biotech LLC | 859-494-4134

Appendix B – A List of Life Science Businesses in Lexington, KY

Abell Eyes Refractive Solutions

Allergy Partners of Central Kentucky

Assurance for Life, Inc.

Baptist Health

Bluegrass Community Hospital

Bluegrass Dermatology, PLLC

Bluegrass Internal Medicine Group, PLLC

Bluegrass Orthopaedics & Hand Care, P.S.C

Bluegrass Oxygen, Inc.

Breckinridge

Cardinal Hill Rehabilitation Hospital

Caretenders of Central Kentucky

Central Brace and Prosthetics, Inc.

Clark Regional Medical Center

Commonwealth Family Physicians, PSC

Cooley Medical Equipment

Dermatology Consultants, P.S.C.

Eckman/Freeman & Associates

Emergency Medical Training Professionals, LLC

Equine Diagnostic Solutions

Eye Consultants of Kentucky, PSC

Family Allergy & Asthma

Forcht Group of Kentucky

Fred A. Schroeder Cosmetic & Family Dentistry

Georgetown Community Hospital Auxiliary

Gibson Laboratories, LLC

Grace Place. The Health Club for Seniors

Health Management Associates, Inc.

Home Helpers / Direct Link

Hospice East Inc.

ITN Bluegrass

Jackie L. Banahan, DMD

Karim & Branch PSC

Kentucky Center for Oral & Maxillofacial Surgery, P.S.C

Kentucky Ear Nose & Throat - Head & Neck Surgeons

KenuckyOne Health

Kleinert, Kutz Hand Care Center

Lexington Clinic, P.S.C

Lexington Diagnostic Center and OPEN MRI

Lifeline Home Health, LLC

Medpro Safety Products, Inc.

Pediatric & Adolescent Associates, PSC

Premier Rehabilitation & Medical Services

Quality Assurance Specialists, Inc.

Redpoint Medical, PSC

ResCare HomeCare

Retina Associates of Kentucky

Shriners Hospitals for Children

Sorrell Home Medical Equipment LLC

Superior Van & Mobility, LLC

UK HealthCare