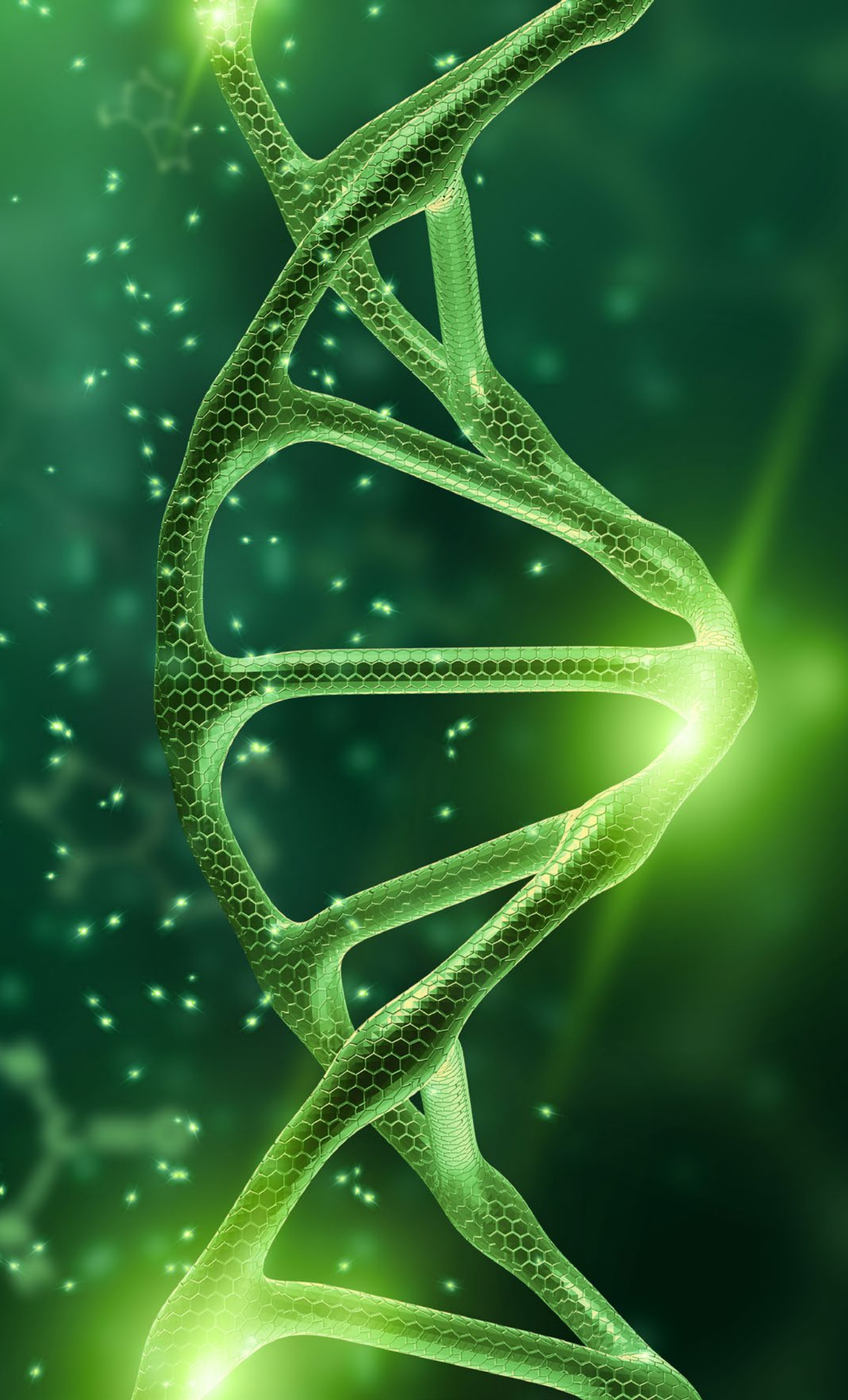
THAILAND BOARD OF INVESTMENT

BIOPHARMACEUTICAL INDUSTRY



Why Thailand for the Biopharmaceutical Industry?

Following North America and EU, Southeast and East Asia is ranked 3rd the highest projected pharmaceutical sales in 2024 with the value of USD 232 billion[1]. As part of the region, Thailand's pharmaceutical industry has grown and has been considered one of the top biopharma clusters regarding its public R&D spending, number of patents, initial public offerings, number of companies, and jobs[2].

Source: [1]Statista and [2]Genetic Engineering and Biotechnology News (2019)

Roadmap to Become a Pharmaceutical Hub

Recently, Thailand has already activated the policy for a sustainable recovery from Covid-19, the so-called Bio-Circular-Green Economy Model (BCG). This model is initially proposed by the Ministry of Higher Education, Science, Research, and Innovation (MHESI) as a new growth engine. The implementation under the BCG model is projected to span from 2021 to 2026, with an aim to generate THB 4.9 trillion at the end of the period. The total investment is forecasted to be THB 750 billion in 2026[1]. It focuses on 4 s-curve industries, including medical and wellness. BCG sets up the mission to reduce the import value of pharmaceuticals and vaccines worth approximately THB 100 billion per year.

Source: [1]Bangkok Post

Global and Local Demand

Thailand's healthcare sector is one of the fast-growing sectors driven by soaring domestic demand. Like many other countries in Asia, Thailand is heading towards an aging society. In 2020, the proportion of citizens aged over 65 was 13%, and it is expected to increase to 30% in 2050[1]. The rise of the aging population is associated with the demand for medical services in the decades ahead. As the number of elderly increases, they tend to develop certain conditions ranging from heart disease to blood clots, diabetes, and cancer. Biopharma products such as Tissue Plasminogen Activator, Insulin, and Therapeutic Antibodies are needed to treat diseases.

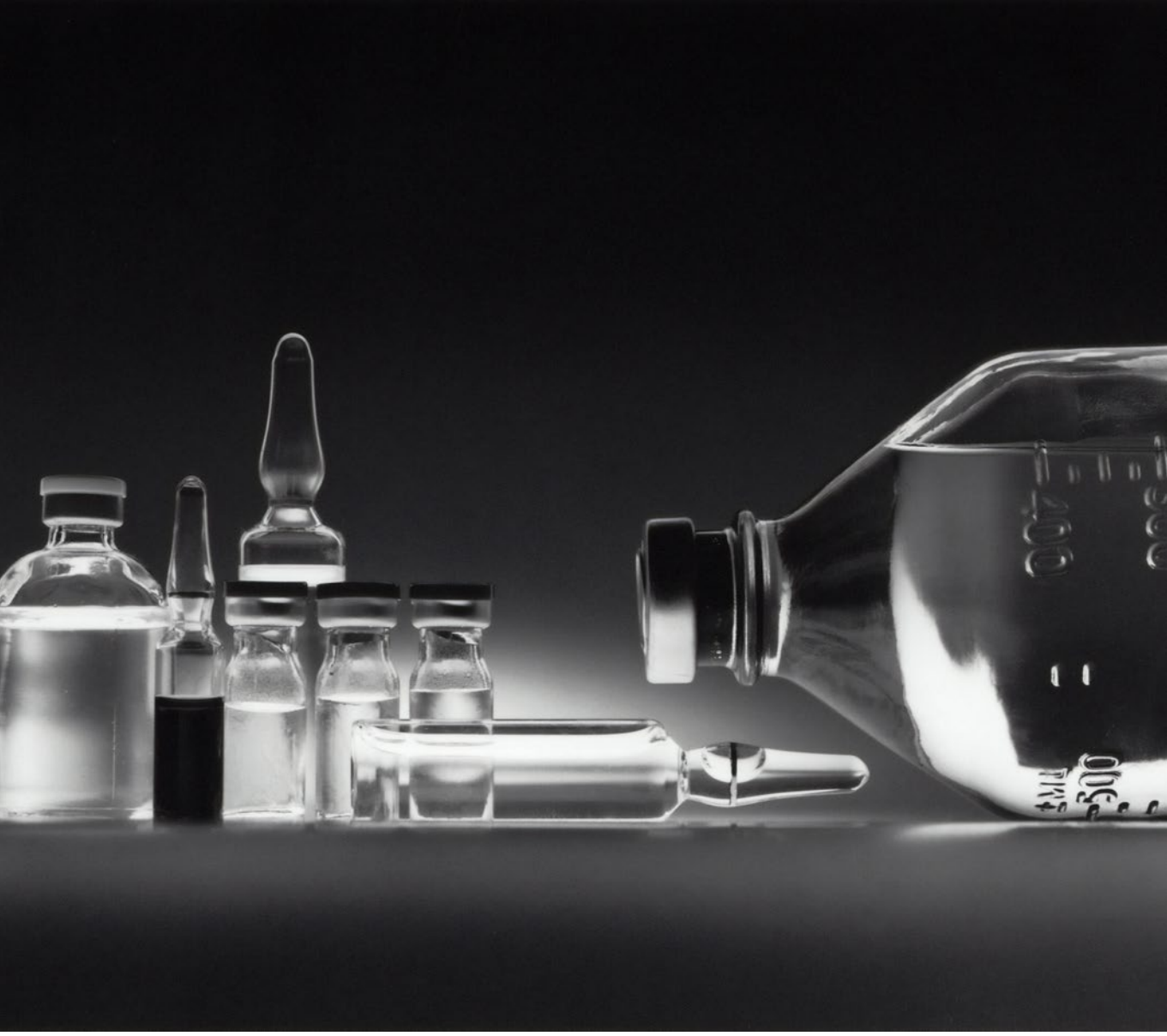
Apart from internal factors, the global pandemic has underlined the necessity of the biopharma industry. The demand for vaccines has risen sharply. Thailand embraces these opportunities and leverages the potential to become a production base for vaccines, rapid tests, and genomic products. It successfully attracted investors such as AstraZeneca, KinGen Biotech, and Apsalagen.

Source: [1]UN World Population Prospects

Healthcare Destination

Due to robust healthcare infrastructure, state-of-the-art medical facilities, highly skilled professionals, and affordable costs, Thailand is undoubtedly the destination for patients from abroad. Approximately 3.5 million tourists visited Thailand in 2019 and spent USD 726 million on healthcare services, accounting for 9% of the global total. It is the only country in Southeast Asia placed in the top 15[1]. As of July 2021, there are 61 Thai medical institutes across every region of the country that are Joint Commission International-Accredited, ensuring the world-class status of medical facilities. Thailand not only offers the opportunities of the market, but it also accommodates investors with a comprehensive supply chain from upstream to downstream industries. Manufacturers can access essential raw materials, clinical trial centers for testing drugs, and manufacturing facilities for production.

Source: [1]IMF



Fully Integrated R&D Hub

The existence of the following infrastructure and facilities has made Thailand a prime hub for biotechnology research and development.

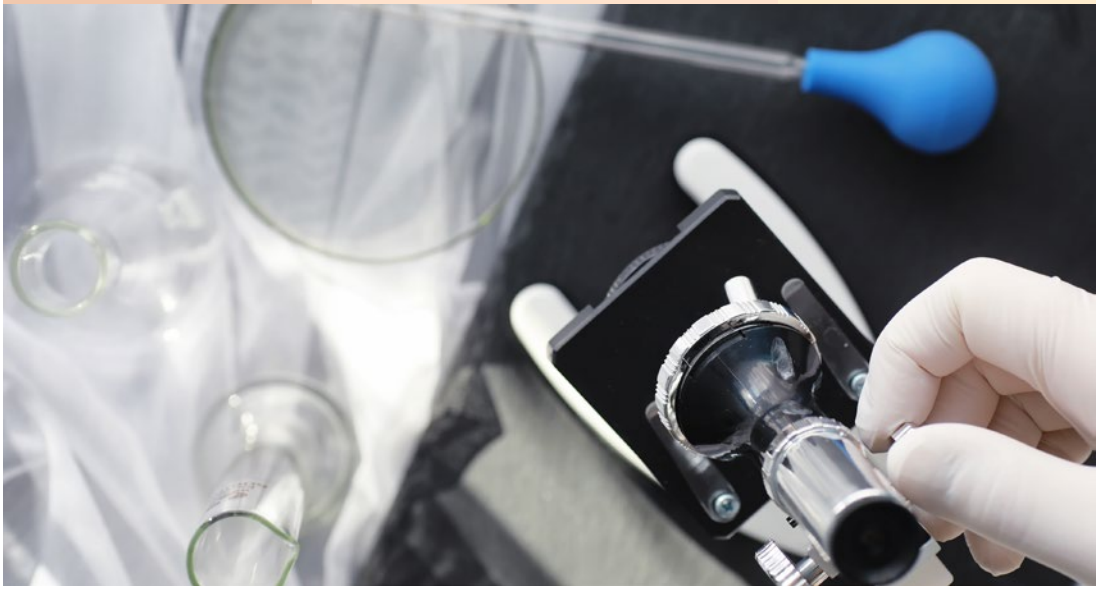
- **Thailand Science Park:** This country's first science and technology park offers facilities, business space, and a range of services to promote innovation development in the private sector. It is also a home for 110 firms and national research institutions and laboratories such as BIOTEC, TCELS CPU, and GMP Production Unit for Cell and Gene Therapy (CPU).
- **Biopolis:** The area established in the Eastern Economic Corridor of Innovation (EECi) exists as an innovation center and industrial cluster for life sciences and biotechnology. It provides long-term land leases, laboratory spaces, testbeds, and incentives for investors to scale up their research activities to mass commercialization.
- **Center for Medical Genomics (CMG):** The institution is under the control of the Faculty of Medicine Ramathibodi Hospital, Mahidol University. It positions itself as a platform to advance the region's genomic toolkit. Since 2014, CMG has joined forces with TCELS on pharmacogenomics research to increase Thailand's competitiveness in genomic medicine.

Notable Manufacturing Plants in Thailand

Biopharmaceutical manufacturers companies can be divided into 3 categories: international companies establishing manufacturing facilities in Thailand, a joint venture between government agencies and international companies, and Thai manufacturers. The example of them is as follows.

Table 1: Existing Biopharmaceutical Plants in Thailand

Plants	About	Main Products
Thai Red Cross Plasma Fractionation Centre	• Transferred technology from Korean Green Cross • Only plasma product manufacturing facility in Southeast Asia	• Albumin • IVIG • Factor VIII
Geo-Merieux Biological Products	• Joint venture between GPO, Sanofi and CPB Equity	• Flu vaccine • JE vaccine • Rabies vaccine • Hepatitis B vaccine
GPO Influenza Vaccine Plant	• Egg-based flu vaccine facility	• Seasonal flu vaccine
Bionet-Asia	• Thai-French privately held biotech company • Focusing on re-emerging diseases	• Pentavalent vaccine
Siam Bioscience	• The first Thai biopharmaceutical manufacturer • 2 subsidiaries: Abinis and Inno Biocosmed	• Erythropoietin • Filgrastim
Austrianova	• Biotech company based in Singapore • Expert in cell biology and encapsulation of living cells • Isolator-based manufacturing processes	• Full service for cell-based products



Source: TCELS, Bionet-Asia, Siam Bioscience

Overview of Pharmaceutical Industry

Driven by prominent factors including demographic shift, the prevalence of chronic diseases and the Covid-19 outbreak, the global pharmaceutical market is expected to grow from USD 405.52 billion in 2020 to USD 486.62 billion in 2021 at approximately 20% year-over-year growth[1].

Source: [1]Acumen Research and Consulting

Overall Pharmaceutical Market

In 2018, the sales value of pharmaceuticals in Thailand was USD 5.47 Billion. It is expected to reach USD 6.9 billion in 2024, which accounts for 1.1% of gross domestic product (GDP)[1]. The market size of Thailand has been the second largest in Southeast Asia, after Indonesia. The growing demand for medicines and treatment leads to the expansion of the domestic market by an annual average rate of 4.5%[2].

Source: [1]Fitch Solution and [2]Krungsri Research

Production

The manufacturers in Thailand usually import active ingredients such as aluminum hydroxide, aspirin, sodium bicarbonate, or deferiprone to mix and produce the finished generic drugs in-house. As of August 2021, 148 domestic pharmaceuticals producers were accredited with Good Manufacturing Practice (GMP) standard[1]. In 2020, investments in a pharmaceutical and chemical market were worth a value of THB 16.32 billion which the top contributors are from Thailand, Japan, India, Switzerland, and Cuba. The spending of newly established pharmaceutical and medical supply businesses was about THB 2.05 billion[2].

Pfizer is ranked 1st in terms of revenue, followed by GSK, MSD, Novartis, and Roche. The top 5 production values of modern pharmaceuticals are from Alimentary Tract and Metabolism, General Anti-infective-systemic, Cardiovascular system, Dermatological, and Hospital Solutions[3].

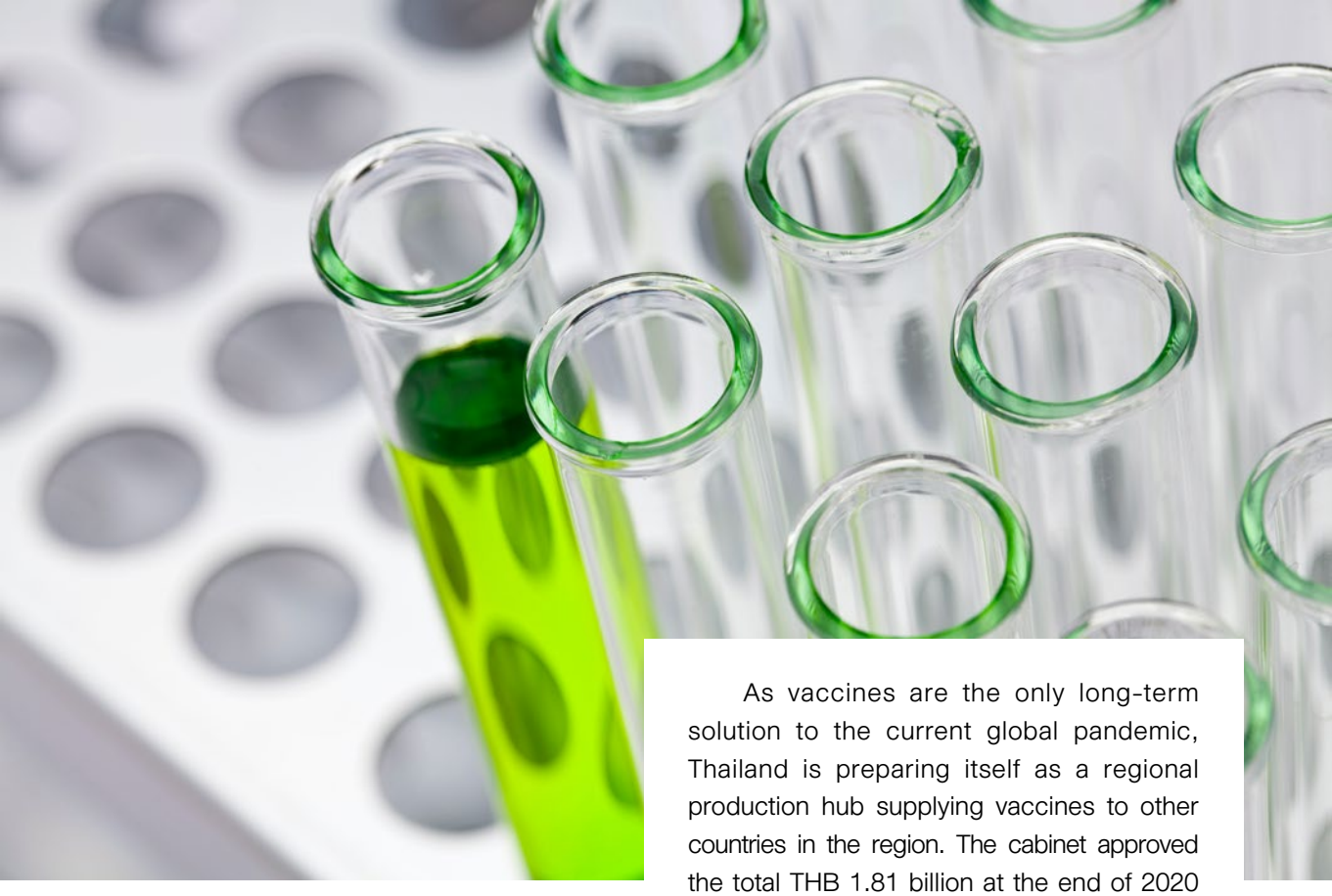
Source: [1]Thai FDA, [2]Statista (2020) and [3]Statista (2018)

Distribution

Due to the expansion of national universal healthcare coverage, there is a surge in demand for medicines from the domestic market. Approximately 90% of pharmaceutical output is distributed within the country, leaving 10% traded in an international market. In 2020, Thailand exported around THB 17.73 billion, with 3.34% CAGR growth over 5 years. The large share of export went to Asian countries. The top 5 destination took 58% of total value including Vietnam, Myanmar, Cambodia, Japan, and the Philippines. However, Thailand still needed to import some high-value products that were unable to produce domestically to satisfy the domestic demand. The value of imports was worth THB 77.83 billion in 2020, while the CAGR growth over 5 years was 2.16%. The main partners are Germany, the USA, France, India, and Japan[1]. This gap opens opportunities for investors to enter the market with strong potential for growth.

The main destination for the domestic market is hospitals, where government and private hospitals share 60% and 20% of total output. Most of the medicines distributed through this channel are prescription drugs. The rest becomes over-the-counter medicines sold by pharmacists, which have represented a stable share over years[2]. In 2019, there were 20,516 registered pharmacies nationwide while the number of pharmacists constantly rised from 7,690 in 2009 to 15,040 in 2019[3].

Source: [1]Ministry of Commerce, [2]Krungsri Research and [3]Statista



Investment Opportunities

Biotechnology is set as a priority sector to promote a post-Covid 19 recovery. In the first quarter of 2021, BOI approved new projects in this field worth around THB 2.4 million. This reflects investors' confidence in the sector's capabilities and opportunities from much broader and more diverse activities. Medical biotechnologies such as vaccines, genomics, and biopharmaceuticals are now under the spotlight and attract multiple manufacturers to launch and scale up their businesses.

Vaccines

Thailand has established itself as the leading developer of vaccines in ASEAN due to its high caliber of researchers and vaccine developers. Some of the remarkable vaccines developed by Thai manufacturers and laboratories are:

- Cocktail Vaccine (5-in-1), developed by NSTDA and BIO-NET Asia
- Haemophilus influenzae type b (Hib) Vaccine, developed by BIO-NET Asia
- Dengue Vaccine, developed by NSTDA
- HIV Vaccine, developed by the Vaccine Trial Centre from Mahidol University

As vaccines are the only long-term solution to the current global pandemic, Thailand is preparing itself as a regional production hub supplying vaccines to other countries in the region. The cabinet approved the total THB 1.81 billion at the end of 2020 to support Covid-19 R&D and vaccine production. The money was allocated to fund many projects from both private companies and public agencies. Several organizations and companies are in promising progress of Covid-19 vaccine development.

- **Siam Bioscience:** The company is selected by AstraZeneca to license its vaccine and currently supplies doses to Thailand and other countries in the region
- **GPO Saraburi:** The vaccine facility in Saraburi with the assistance from Texas University, is currently in Phase 1 of developing egg-based Covid-19 vaccine from its influenza technology
- **Baiya Phytopharm:** The Thai startup has developed its vaccine from plant leaves and has already passed a laboratory animal test.
- **BioNet-Asia:** Phase 1 of the vaccine, so-called COVIGEN, has been already approved by the University of Sydney
- **Chulalongkorn University:** The Chula Vaccine Research Center, in collaboration with Pennsylvania University, has developed an mRNA vaccine, ChulaCov19. The vaccine has already been tested on humans in June 2021.

Source: Thailand Board of Investment, The Chemical Engineer and Thai Publica

Genomics

In parallel to a fast-growing global market, Thailand is in a race to advance its medical services and R&D. Genomics is recognized as a significant technology to support the position of Thailand as a medical hub. In 2019, The government announced the national strategic initiative on precision medicine. The notable projects are as follows.

- Genomics Thailand Initiative: The program constitutes a collaborative research network running a flagship project to sequence the genomes of 50,000 Thai individuals and create a public genome database enabling precision medicine.
- National Biobank of Thailand (NBT): NBT is established with an aim to conserve bio-resources in Thailand ranging from plant to human genome and convert these specimens into a genetic database.

The areas of focus identified under the strategic plan are cancer precision medicine, rare and undiagnosed diseases, non-communicable diseases, non-invasive prenatal testing (NIPT), newborn screening, pharmacogenomics for rational drug use (RDU), and precision health[1]. In 2021, BOI already approved new incentives for the Genomics Thailand project to receive additional incentives in the EEC area equivalent to other targeted industries[2].

Source: [1]Genomics Thailand and [2]Bangkok Post

Biopharmaceuticals

Despite the high cost of products, biopharmaceuticals are a key partner in tackling non-communicable diseases that traditional medicine struggles to compete with. It is acceptable to use as a therapy for chronic diseases such as cancer, and genetic disorders such as Hemophilia and Anemia. The move to an aging society and incremental changes in health concerns have shone a bright light on biopharmaceuticals. Some of the products prevalently consumed are shown in the table.

Table 2 Example of Product, Application, and manufacturers/distributor in Thailand

Biopharma Product	Application	Manufacturers/Distributors
Insulin	Diabetes	Eli Lily, Novo Nordisk
Erythropoietin	Anemia	Amgen, Johnson & Johnson
Interferon α	Hepatitis	Roche
Factor VIII	Hemophilia	Bayer
Therapeutic Antibodies	Cancer	GSK, Amgen
GCSF	White Blood Cell	Amgen, Sankyo

Source: Advances in Industrial Biotechnology by Ram S. Singh and companies' website

Government and BOI Support

The following agencies are key stakeholders in Thailand's biopharmaceutical industry. They support industries both in terms of academic successes and promotion of business establishment.

BIOTEC

The National Center for Genetic Engineering and Biotechnology (BIOTEC) is operated under the National Science and Technology Development Agency (NSTDA) control. It is located in Thailand Science Park and functions as a research institute for agricultural, biomedical, and environmental science. The key research prioritization in the medical biotechnology sector is tropical and emerging diseases such as malaria, tuberculosis, dengue fever, and influenza. Apart from providing biotechnology infrastructure such as laboratories, it also acts as a policy accelerator that supports the linkage between academia and industries.

TCELS

The Thailand Center of Excellence for Life Sciences (TCELS) is established with the core intention to support, develop, and facilitate life sciences industries. In partnership with domestic and international institutions, it acts as a focal point for all life sciences stakeholders and creates the central link between innovation and investment. The current focus areas of TCELS include pharmaceutical and biotechnology, natural products, biomedical engineering, and medical services. TCELS has partnered with NSTDA, KMUTT, U Mahidol University, Thai Red Cross Society, and NVI to research 4 biopharma products: Erythropoietin, Growth Hormone, Trastuzumab, and Antibody against EV71.

National Biopharmaceutical Facility

National Biopharmaceutical Facility (NPF) is the first state-owned contract manufacturing facility under the collaboration between the King Mongkut's University of Technology Thonburi and BIOTEC. The facility can be divided into 2 units: Microbial Fermentation and Cell Culture. NBF provides a variety of services to biopharmaceutical manufacturers ranging from process development, GMP production for a clinical trial, technology transfer, and training and consultancy.

Chulabphorn Research Institute

Chulabphorn Research Institute is a biomedical and chemistry research institute operated by an independent fund from the Thai government. The institute's research activities consist of 9 areas, including natural products, medicinal chemistry, organic synthesis, biochemistry, chemical carcinogenesis, immunology, pharmacology, environmental toxicology, and biotechnology. In support of the progress towards the development of the biopharmaceutical industry, the institute aims to build up capabilities in producing high-quality but less expensive alternative drugs sold in Thailand.

BOI

The Board of Investment (BOI) offered tax and non-tax incentives for biopharmaceutical-related activities. The number of years for CIT exemption depends on activities, as shown in the tables.

Table 2: BOI Corporate Income Tax Incentives for Pharmaceuticals

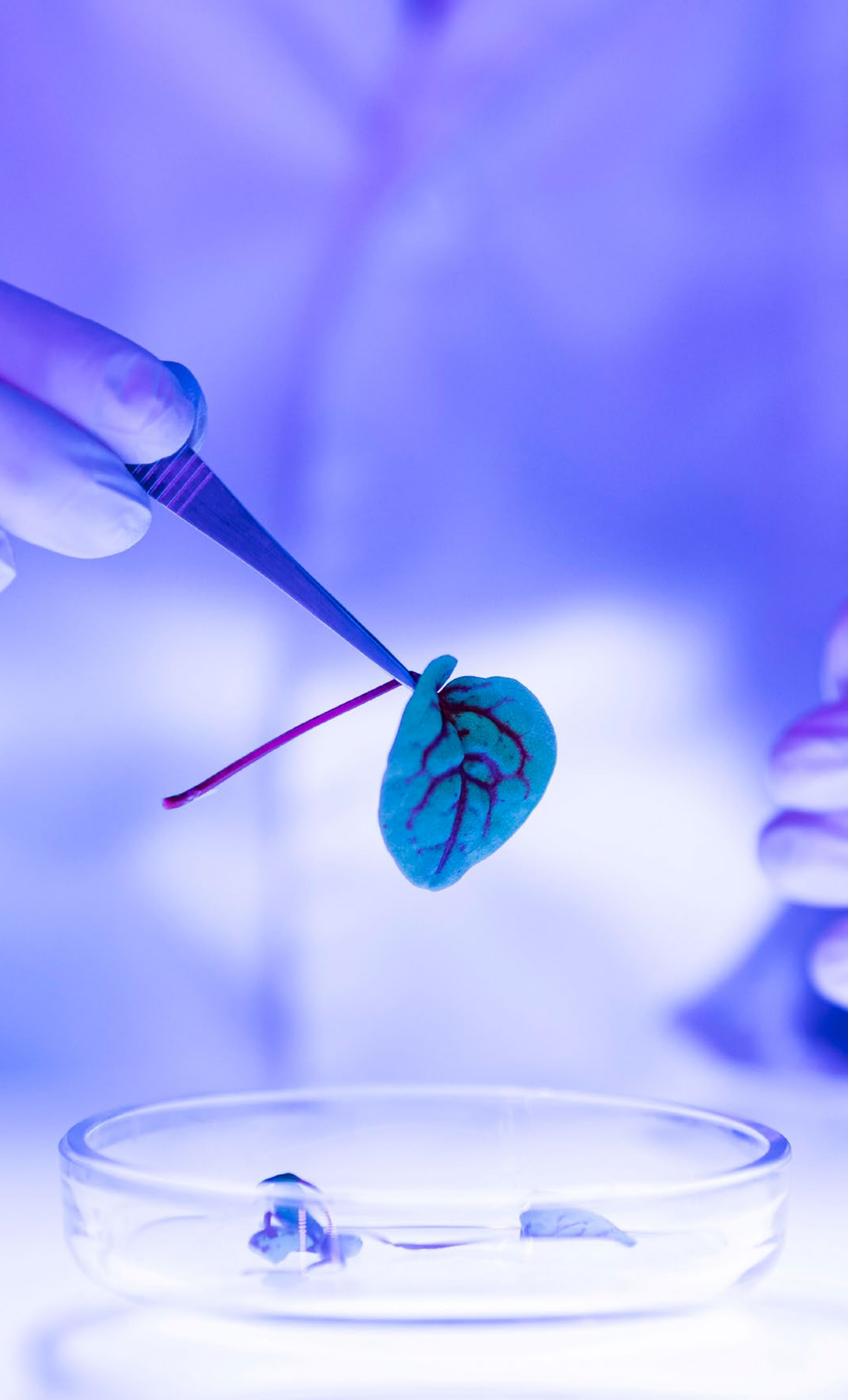
Type of Activities	Incentives
Active Pharmaceutical Ingredients	**8-year CIT exemption** * Must be for production of active or raw materials of active pharmaceutical ingredients (APIs)
Manufacturing of Targeted Medicines	**8-year CIT exemption** * Must engage in the manufacturing of targeted medicines as announced by the Ministry of Public Health * Must be GMP certified in accordance with PIC/S guidelines
Manufacturing of Conventional And Traditional Medicines	**5-year CIT exemption** *Must be GMP certified in accordance with PIC/S guidelines

Source: Thailand Board of Investment

Table 3: BOI Corporate Income Tax Incentives for Biotechnology Research and Development

Type of Activities	Incentives
Research and development (R&D) activity and/or manufacturing of biopharmaceutical agent using biotechnology	**8-year CIT exemption (no cap)** * Shall be granted import tax incentives on goods imported for research and development and all related experimentation for a period of one year on each occasion * Project located in a science and technology park will receive an additional 50 percent reduction of corporate income tax for 5 years after the end of its corporate tax exemption period

Source: Thailand Board of Investment



Regulatory Process

The following illustration describes your investment journey in Thailand. The BOI stands ready to provide investment facilitation services to ensure that you can fully comply with any regulatory requirement.

Apply for BOI incentives	Submit the application for investment promotion from Board of Investment
Register your entity	Register your business at the Department of Business Development, Ministry of Commerce
Get the certificate of investment promotion	Obtain the certificate of investment incentive from the BOI

Establishment of a Manufacturing Site

Dealing with Construction Permits	Building Permit and Occupancy Permit: apply at the Civil Works department of the area of your establishment Telephone: connect with the TOT Public Company Limited Water: apply at the Provincial or Metropolitan Waterworks Authority depending on your location
Getting Electricity	Connect with the Metropolitan Electricity Authority or the Provincial Electricity Authority depending on your location
Registering Property	Submit your documents at the Land Office, Department of Lands.
Recruitment	Understand Thai labor laws and business incentives for skill upgrading / training
Manufacturing License	• Authorization to Use Land • Authorization for New Factory Construction or Rental Factory Renovations • Authorization to begin factory
Import and Export License	e-Custom system
Foreign Business License	Obtain foreign business license if required

Approval of Drug Manufacturing

At the Thai Food and Drug Administration

Pre-marketing Control

License Application

- Review manufacturing plant layout before construction
- Apply for premise to manufacture, sell or import medicine

Drug Registration

Apply for drug registration certificates based on the ASEAN Harmonization guideline

Post-marketing Control

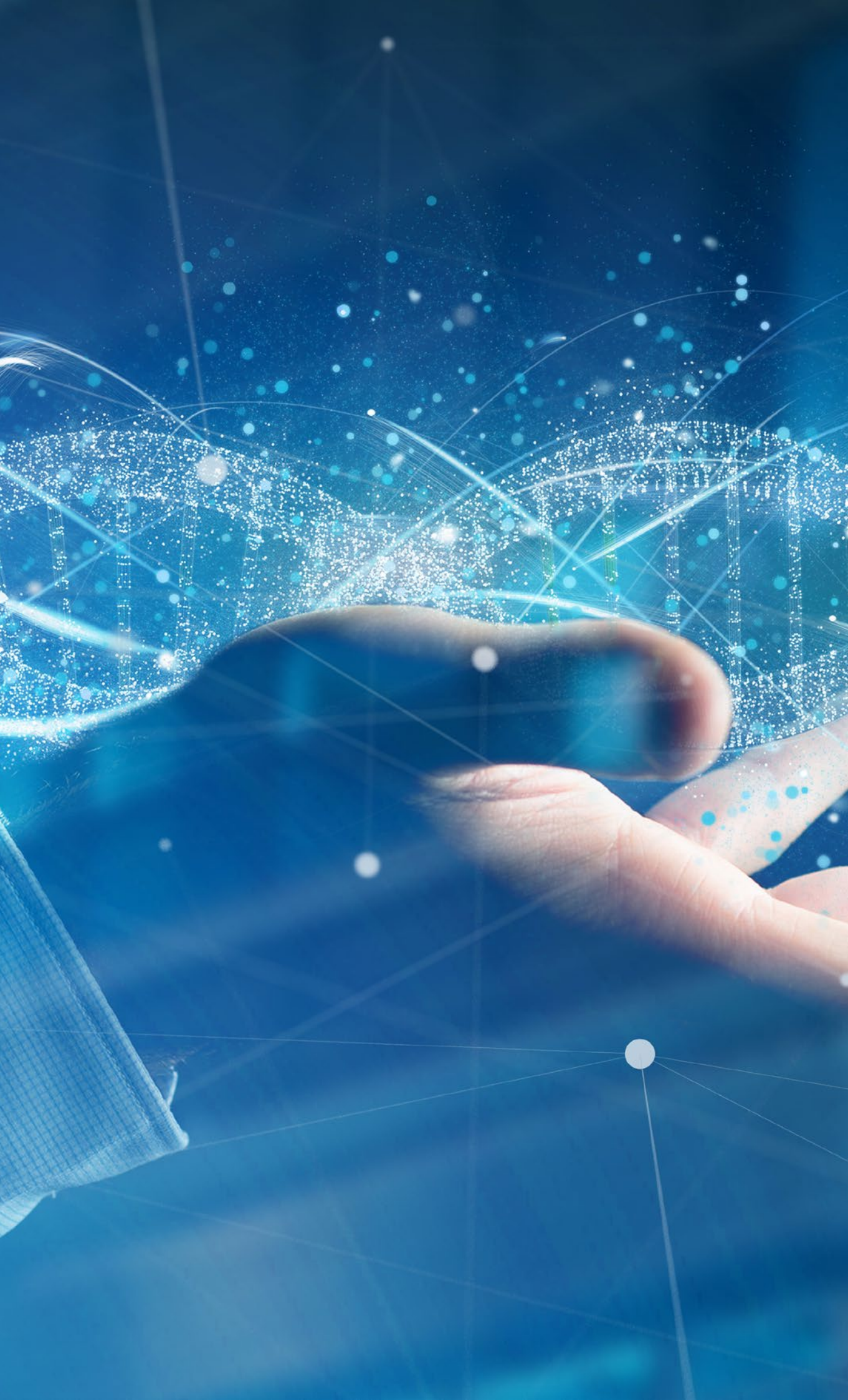
GMDP Inspection

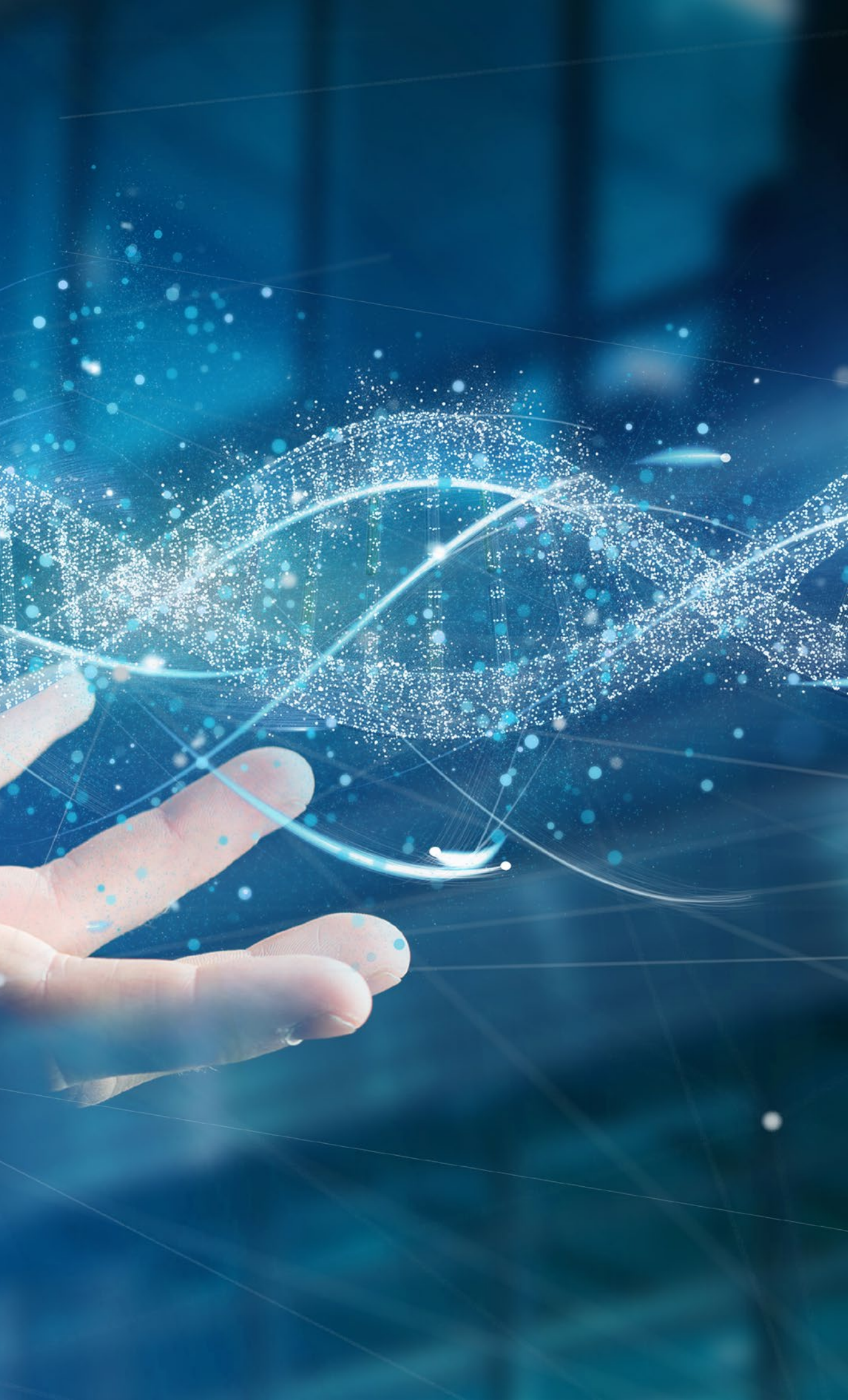
Inspect to verify compliance of IMPs, APIs, and finished products

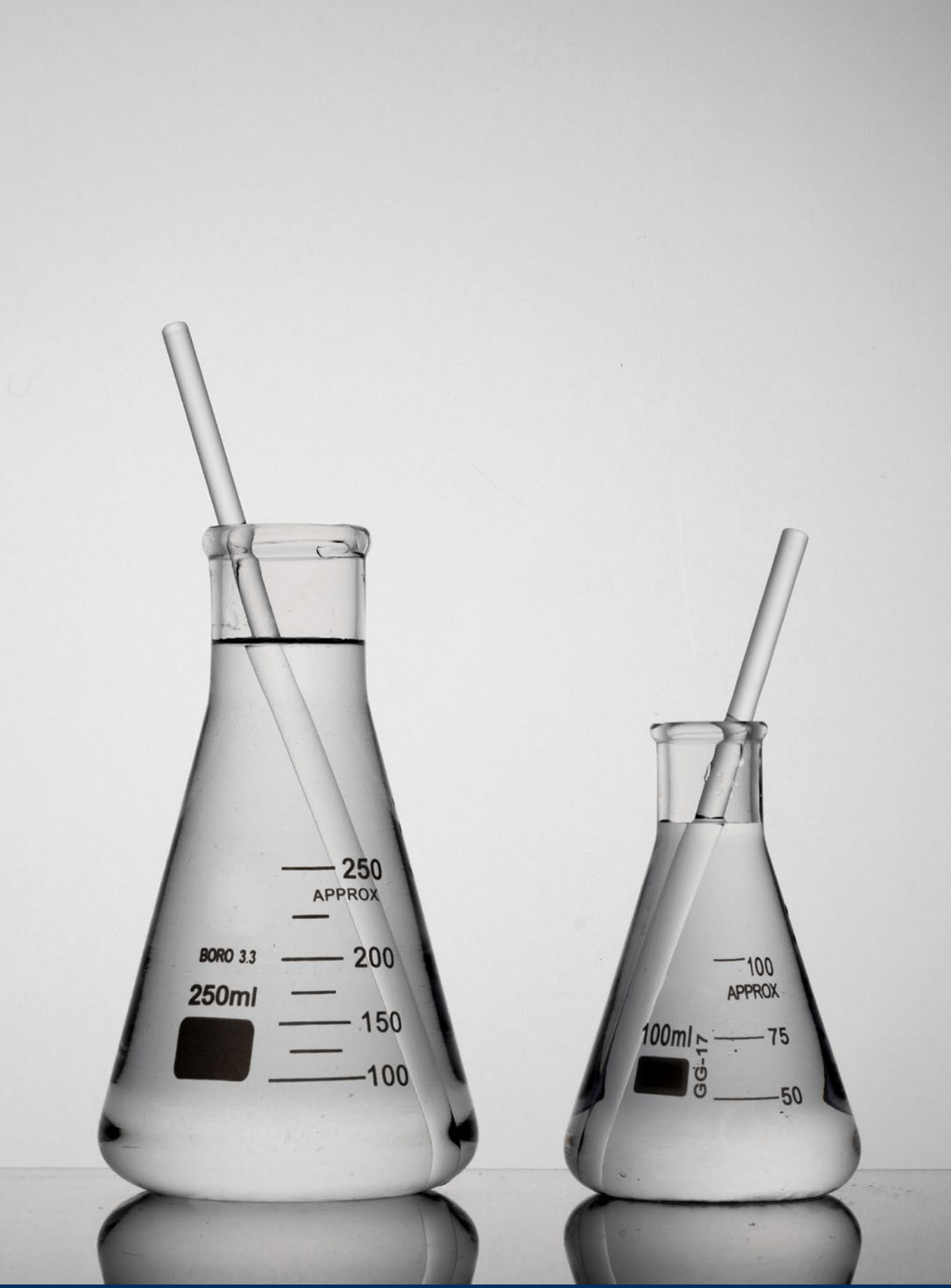
Per above illustration, apart from obtaining the BOI incentives and certificates, allow the BOI to assist you on the following processes.

Process	Details and Contact Point
Dealing With Construction Permits	• **Building Permit and Occupancy Permit:** submit building permit application at the Civil Works department of the area you are building your establishment. • **Telephone:** TOT Public Company Limited • **Water:** connect with Provincial or Metropolitan Waterworks Authority depending on your location
Getting Electricity	• Connect with the Metropolitan Electricity Authority or the Provincial Electricity Authority depending on your location
Registering Property	• Submit your documents at the Land Office, Department of Lands. • All corporate documents used in this process must be certified copies.
Recruitment	• Key takeaways in understanding labor laws in Thailand: protections, hours and holiday, compensation, social security, cessation of operation, termination, and minimum wage • Understand incentives for labor skill training
Manufacturing License	• Apply for Authorization to Use Land, Authorization for New Factory Construction or Rental Factory Renovations, and Authorization to begin factory • Connect with either the Industrial Estate Authority of Thailand (IEAT) or the Ministry of Industry (MOI) Provincial Offices (Dept. of Industrial Works) depending on the location of your establishment
Import And Export License	• Use of e-Custom system for importing and exporting
Foreign Business License/Certificate	• Obtain foreign business license if required per business type

Source: BOI OSOS Investment Center







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