

# Investment Brochure Guangzhou Development District BIOMEDICINE

## Reference Guidebook

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广州开发区海德堡离岸创新中心

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## Biomedicine – REGULATIONS

More than **40% of healthcare related patents in China** are registered in Greater Bay Area. 22,600 patents in 2021 came from companies in China Singapore Guangzhou Knowledge City (CSGKC) alone.

CSGKC is the **national pilot zone for the reform of IP utilization and protection** introduced by the State Council and since then has been a driver of technological and industrial innovation in the area of IP protection and services. Today, CSGKC's IP institutions are in the unique position to having integrated the **management of all patent, trademark and copyright aspects and issues in one comprehensive system and service portfolio. More than 100 IP service providers and institutions** contribute to this setup.

Around its "IP-Core" at CSGKC, **Guangzhou City** has established an even more impressive **IP-Ecosystem**: 241 patent agencies, 3796 trademark agencies (9 national IP analysis & evaluation institutions, 11 patent navigation service base filing institutions, 11 national IP service brand cultivation institutions, 4 national IP information service centers for universities, 3 world IP organization (WIPO) technology and innovation support centers (TISCs), 4 national IP information public service outlet filing units.

### Main IP Institutions in Knowledge City & Huangpu District

#### Patent Examination Cooperation Guangdong Center of the Patent Office of the CNIPA

Established in Knowledge City (Huangpu District). Completed more than 1 Million patent examinations, which equals 1/5 of China's total.

#### South China Intellectual Property Court (Guangzhou, Huangpu)

Covering various IP areas such as patent inventions, designs, exclusive right to use trademark, unfair competition, etc. The court will give correspondent reply within 7 days.

#### Guangdong Province Intellectual Property Protection Center (Guangzhou, Huangpu)

Average pre-examination period of patents has been shortened to 4.7 days. The average examination period for trademark registration has been reduced to four months.

#### GBA Patent Registry, GBA IP Mediation Centre, GBA intellectual property innovation center

### Main NMPA & Regulatory Affairs Institutions in Huangpu District

#### Fully operational South China NMPA branch office – located in Science City of Huangpu District

#### Guangdong Institute for Drug Control

Port inspection of imported drugs, batch release of biological products and registration inspection, supervision inspection and arbitration inspection of drugs.

#### Public Service Platform for the Entry and Exit of Biomaterials in South China

Only Rapid Customs Clearance Platform after Beijing and in Shanghai. Seamless connectivity from biomaterials airport to platform ensures the shortest possible time for biomaterials to pass through customs.

## Biomedicine – REGULATIONS

### Huangpu NMPA Branch

Main responsibilities of Guangdong-Hong Kong-Macao Greater Bay Area Center for Drug Evaluation and Inspection of NMPA:

- (1) Assist the Center for Drug Evaluation of NMPA in pre- and in-process communication and guidance, as well as relevant inspections for drug review in the Guangdong-Hong Kong-Macao Greater Bay Area (GBA).
- (2) Assist in the acceptance and review of registration application of drugs in the GBA under the administration of the Center for Drug Evaluation of NMPA.
- (3) Assist in relevant inspections for drug registration application and for-cause inspections during the research and development process in the GBA under the administration of the Center for Food and Drug Inspection of NMPA (National Center for Vaccine Inspection).
- (4) Participate in the drafting of laws, regulations and normative documents related to the registration administration of drugs; participate in the formulation of relevant technical review norms, technical guidelines, inspection system specifications and technical documents for drugs and organize the implementation.
- (5) Carry out research on the theories, technologies, development trends, policies and legal issues related to drug review and inspection.
- (6) Carry out relevant consulting services, academic exchanges, and international (regional) exchanges and cooperation related to drug review and inspection.
- (7) Undertake other tasks assigned by NMPA, and other technical work assigned by the Center for Drug Evaluation of NMPA, and the Center for Food and Drug Inspection of NMPA (National Center for Vaccine Inspection).

For more information, please visit: [http://english.nmpa.gov.cn/2022-10/25/c\\_824449.htm](http://english.nmpa.gov.cn/2022-10/25/c_824449.htm)

### Other relevant biomedicine regulatory bodies in Huangpu:

- **Guangdong Institute for Drug Control**
- **Guangzhou Development District Pharmaceutical Regulatory Services Innovation Center**
- Huangpu is home to **TÜV, SGS, 3M** and other international standardized inspection companies.
- Huangpu offers easier **inbound and outbound biological materials inspection and quarantine**, such as the reduction of the approval process, simplification of approval materials, online approval.
- Huangpu has established a **green channel** for drugs, medical device licensing and inspection with Guangdong Food and Drug Administration

## Biomedicine – REGULATIONS

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### Hong Kong and Macao Medicine and Equipment Connect

The "Hong Kong and Macao Medicine and Equipment Connect" policy (known as “港澳药械通” in Chinese) was approved by the Chinese government in 2020 to allow hospitals in mainland cities in the Guangdong-Hong Kong-Macao Greater Bay Area to use drugs and medical devices already approved for clinical use in Hong Kong for appropriate clinical purposes in the Bay Area **without prior certification** from the National Medical Products Administration.

#### The policy is already in use:

- By the end of April 2023, a total of 23 such innovative drugs and 13 medical devices have been approved for use under the policy.

#### It is applicable in Guangzhou:

- Among 19 Greater Bay Area hospitals approved to partake in the fast track by the end of April 2023, there are 8 in Guangzhou.

#### How to enter this fast-track:

- Drugs/medical devices (already registered in HK/Macao) are approved subject to case by case scrutinization taking urgency/irreplaceability/bottleneck into consideration.

#### How we can help:

- Invest Huangpu & Guangzhou International Bioisland can help link experts/facilitator/resources accordingly if a company can specify a product which they would like to apply this fast-track to.

More info: <https://www.mdd.gov.hk/sc/whats-new/measure-of-using-hk-registered-drugs/index.html>

## Biomedicine - EDUCATION

Among 20+ prestigious universities in Guangzhou, there are 8 first-class pharmaceutical universities/comprehensive universities excelling in the relevant disciplines.

	University	Discipline
1	Southern Medical University	Discipline of Pharmacology and Toxicology ranks ESI Top 1‰.
2	Sun Yat-Sen University	
3	Guangzhou Medical University	Discipline of Pharmacology and Toxicology ranks ESI Top 1‰.
4	Guangzhou University of Chinese Medicine	
5	Guangdong Pharmaceutical University	
6	Jinan university	
7	South China University of Technology	
8	South China Normal University	Discipline of Materials Science ranks ESI Top 1‰.

- South China University of Technology and Sun Yat-Sen University are at the cutting edge of Materials Science and Engineering Science globally ranking ESI Top 1‰, followed by Guangdong University of Technology, Southern Medical University, South China Normal University and Jinan University ranking ESI Top 1‰.

### Student Numbers:

- Statistics show there are 1.55 million college students on campus in Guangzhou, among which **300,000 are studying bio-medicine/pharmacy.**

### Vocational / on-the-job training:

Huangpu is known for its biomedical talents training base with many such institutions/programs/platforms.

One of the most prolific is **Guangzhou Institute of Biological Manufacturing Technology** which has been operational since November 2020.

In the Institute, Huangpu District, GE Healthcare, Ireland's National Institute of Biotechnology Research and Training (NIBRT) work together to train more than 1,000 biomedical application talents every year by providing training services that meet the GMP standards.

### Guangzhou Medical Research Ecosystem:

- 6 National laboratory for biomedicine
- 3 Provincial key laboratories
- 6 Academician Workstations
- 615 healthcare service companies
- 52 Class A hospitals (among which 11 ranked in the top 100 nationally.)

## Biomedicine - KNOWLEDGE CITY POLICIES

### Specific benefits for biomedicine companies when they invest in Knowledge City (with KCI being a “province level project)

#### ▪ Focus on Major Projects

- Subsidize industrial projects playing a holistic driving or significant leading role in developing the biomedical industry in the district with 10%-30% of the total fixed asset investment, up to RMB 500 million.

#### ▪ Accelerating Innovation Breakthroughs

- Subsidize each enterprise with innovative drugs or improved new drugs approved for clinical trials by the National Medical Products Administration and put into commercialization with 40% of their R&D expenses, up to RMB 100 million per year, and each enterprise with up to RMB 10 million for each new drug certificate or registration approval.

#### ▪ Driving Model Leadership

Accelerate the cultivation and introduction of leading contract research organizations (CRO):

- Subsidize each enterprise with 90% of the rent, up to RMB 1 million per year;
- Subsidize each enterprise with a fixed asset investment of over RMB 500 million and an annual operating revenue of over 200 million with 20% of its R&D investment during the construction period at one time, up to RMB 50 million;
- Encourage leading CDMO/CMOs to engage in drug production and subsidize each of them with 20% of the actual investment, up to RMB 15 million per variety and RMB 30 million per year in total.

#### ▪ Fostering a Sound Environment

- Set up new drug application service platforms and special teams for approval services to provide one-stop professional services for biopharmaceutical enterprises or institutions in the registration and application of drugs and medical devices;
- Carry out trial innovations in collaborative biomedicine R&D in Guangdong, Hong Kong and Macao, explore a customs clearance mechanism for biological products, biological materials and laboratory animals in Guangdong, Hong Kong and Macao, and support the cross-border use of medical data and biological samples such as blood by qualified research agencies.

#### ▪ Intensifying Financial Support

- Bring into play the guiding role of sci-tech innovation venture capital fund of funds (FOF) and raise a total of RMB 10 billion targeting seed-stage and start-up tech firms;
- Provide funding of up to RMB 20 million for well-known PE and VC agencies in the field of biomedicine.

**For more information, please read:**

[China-Singapore Guangzhou Knowledge City \(CSGKC\) Ten Measures for Promoting High-quality Development of the Biomedical Industry](#)

## Biomedicine: KEY PLAYERS PHARMA SECTOR

No.	Company Name (CN)	Company Name (EN)	Website
<b>In Vitro Diagnostics</b>			
1	广州万孚生物技术股份有限公司 	<b>Wondfo</b>  <b>POCT products, rapid diagnosis and chronic disease management solutions</b>	www.wondfo.com
2	广州达安基因股份有限公司 	<b>DAAN GENE</b>  <b>molecular diagnosis, molecular diagnostic test kits, automatic extractors and real-time PCR systems</b>	www.daangene.com
3	广州市康立明生物科技有限责任公司 	<b>Creative Biosciences</b>  <b>DNA test for early detection of colorectal cancer</b>	www.creativebio.cn
4	广州安必平医药科技股份有限公司 	<b>LBP</b>  <b>tumor screening and accurate diagnosis; product lines of LBP, PCR, IHC and FISH</b>	www.gzlbp.com
5	广州金域医学检验集团股份有限公司 	<b>KingMed</b>  <b>providing medical testing services for more than 23,000 medical institutions, with an annual specimen amount of over 150 million</b>	www.kingmed.com.cn
6	广州燃石医学检验所有限公司 	<b>Burning Rock Dx</b>  <b>next generation sequencing (NGS) technology in the field of precision oncology</b>	www.brbiotech.com
7	赛默飞全球精准医疗客户体验中心 	<b>Thermo Fisher Precision Medicine Science Center</b>  <b>Thermo Fisher's First Precision Medicine Science Center in China</b>	www.thermofisher.cn



## Biomedicine: KEY PLAYERS PHARMA SECTOR

No.	Company Name (CN)	Company Name (EN)	Website
Pharmaceutical R&D and Manufacturing			
1	广州百济神州生物制药有限公司	BeiGene	www.beigene.com
2	广东恒瑞医药有限公司	Hengrui	www.hengrui.com
3	康方药业有限公司	Akeso Pharma	www.akesobio.com
4	广州诺诚健华医药科技有限公司	Innocare	innocarepharma.com
5	安济盛生物医药技术（广州）有限公司	angita	www.angitiabio.com
6	广州麓鹏制药有限公司	lupengbio	www.lupengbio.com
7	康融东方（广东）医药有限公司	AD Pharmaceuticals	www.krdf-pharma.com
8	广州市香雪制药股份有限公司	Xiangxue Pharmaceutical (XPH)	xphcn.com
9	扬子江药业集团广州海瑞药业有限公司	Hairui Pharmaceutical	hairuien.yangzijiang.com
10	拜耳医药广州公司	Bayer	www.bayer.com.cn
11	广州百特医疗用品有限公司	Baxter	www.baxter.com.cn
12	广州绿十字制药股份有限公司	Green Cross	www.m-pharma.com.cn
13	百奥泰生物制药股份有限公司	Bio-THERA	www.bio-thera.com
14	广州市锐博生物科技有限公司	RiboBIO	www.ribobio.com
15	广州康臣药业有限公司	CONSUN	www.chinaconsun.com
16	广州白云山中一药业有限公司	Baiyun Zhongyi Pharmaceutical	www.gz111.com
Vaccine R&D and Manufacturing			
1	绿叶生命科学（广州）有限公司	Luye Life Sciences	www.luye.com
2	威斯克生物医药（广州）有限公司	WestVac Biopharma	www.westvacpharma.com



## Biomedicine: KEY PLAYERS PHARMA SECTOR

No.	Company Name (CN)	Company Name (EN)	Website
<b>CRO/CMO/CDMO</b>			
1	龙沙生物技术有限公司	Lonza	www.lonza.com.cn
2	昭衍（广州）新药研究中心有限公司	JOINN Laboratories	www.joinnlabs.com
3	量子生物CRO/CDMO一站式平台	Quantum Hi-Tech	www.qhtcb.com
4	广州汉腾生物科技有限公司	Canton Biologics	www.cantonbio.com
5	广州博济医药生物技术有限公司	BojiMed	www.gzboji.com
<b>Medical Devices</b>			
1	赛默飞粤港澳大湾区基地	ThermoFisher GBA Base	www.thermofisher.cn
2	卡尔蔡司医疗技术（广州）有限公司	Zeiss	www.zeiss.com.cn
3	广州凯普生物科技有限公司	Hybriobio	https://www.hybriobio.cn/
4	广州创尔生物技术股份有限公司	Rauer	http://www.trauer.com.cn/
5	广州康盛生物科技股份有限公司	Koncen	https://www.koncen.com/
6	费森尤斯卡比（广州）医疗用品有限公司	Fresenius Kabi	https://www.fresenius.com/
7	广州科莱瑞迪医疗器材有限公司	Klarity	https://www.klarity-medical.com/
<b>Gene &amp; Cell Therapy</b>			
1	云舟生物科技（广州）股份有限公司	VectorBuilder	www.vectorbuilder.cn
2	广州派真生物技术有限公司	PackGene Biotech	www.packgene.cn
3	恒瑞源正（广州）生物科技有限公司	HRYZ BIO TECH CO.	www.shhryz.com

















## Biomedicine: KEY PLAYERS PHARMA SECTOR

No.	Company Name (CN)	Company Name (EN)	Website
<b>Headquarter &amp; R&amp;D</b>			
1	阿斯利康中国南部总部	AstraZeneca South China HQ	www.astrazeneca.com.cn
2	恒瑞医药南方总部及研发中心	Heng Rui Pharmaceuticals South China HQ & R&D Center	www.hengrui.com
3	丹纳赫粤港澳大湾区总部	Danaher Greater Bay Area HQ	www.danaher.com.cn
4	一品红药业股份有限公司	Yipinhong Pharmacy HQ	www.gdyph.com
<b>Medical Consumables</b>			
1	广东冠昊生物医用材料开发有限公司	Guanhao Biotech	www.guanhaobio.com
2	广州倍绣生物技术有限公司	Bioseal Biotech	www.bioseal.com.cn
3	广州迈普再生医学科技股份有限公司	Medprin	www.medprin.com
4	广州科方生物技术有限公司	Kofa	www.gzkofa.com

AstraZeneca 



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GUANHAO BIOTECH

  
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 倍绣生物  
BIOSEAL BIOTECH

 MEDPRIN  
迈普医学

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