

CACLP



Entering the Chinese IVD Market

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China. A big market with a huge potential... If you are tempted to enter the Chinese IVD market but are not sure how to do so...

This guide gives you an overview of the first steps and considerations necessary before entering China with your products. You will find:

1. Overall market size and growth
2. Evaluate the market
3. Visit China
4. Choose the way you enter the market
5. Choose where you enter the market
6. Pricing
7. Regulatory
8. Intellectual Property Rights

This guide is the first in a series of articles and webinars produced by CACLP (Chinese Association of Clinical Lab Practice Expo), designed to give you straightforward, pragmatic information to assist you in step in the process.

1. Overall market size and growth

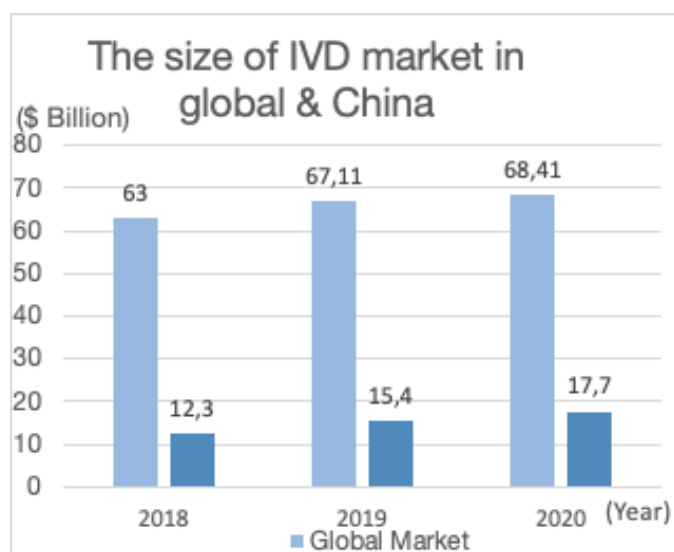
17.7 billion US dollars.

This was the size of the Chinese IVD market in 2020. 25% of the global IVD market and 2nd in size only to the United States. It's tempting to think this is a blip, an artificial high related to the global pandemic, but it's not. The Chinese IVD market has been growing steadily over the past years.

The same year, the North American IVD market was valued at \$21 billion and all of Asia-Pacific (excluding China), \$17 billion.

This is in line with overall growth in China.

Over the past 30 years, China's GDP grew an average of 8 – 10% each year, which means an overall growth of more than 10 times during that period. China's



GDP now exceeds \$14 trillion, and many analysts project that China will become the world's largest economy by 2050.[1]

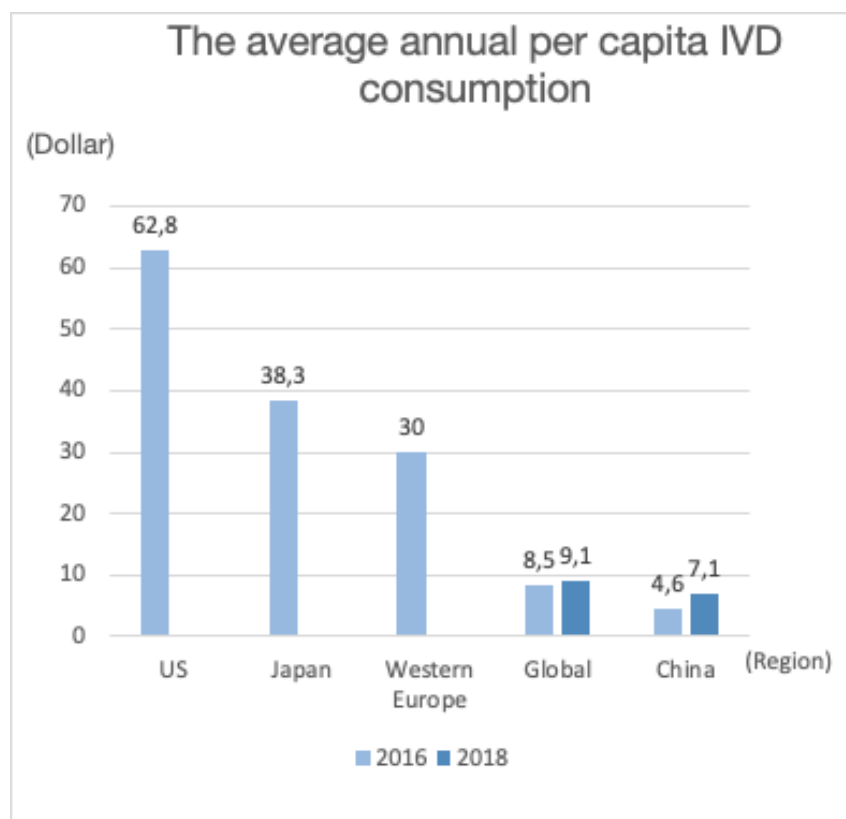
At the same time, the Chinese population is aging, which means an increase in chronic diseases. The general population is becoming more affluent, leading to more healthcare spending. Also, the government has created more healthcare clinics and hospitals.

Despite these market drivers, there is still a gap between China's current spending on IVD and that of other countries.

[1] <https://kaloramainformation.com/blog/we-keep-saying-the-chinese-ivd-market-is-growing-thats-because-it-is/>

China's average annual per capita spend on IVD is still 16% lower than the global average, 76% lower than Western Europe, and 88% lower than the United States. As the Chinese economy continues to grow, this gap is likely to become smaller.

The proportion of personal health expenditure to total health expenditure is expected to reach about 25% by 2030. The market size of the health service industry is expected to reach CNY 16 trillion by 2030.

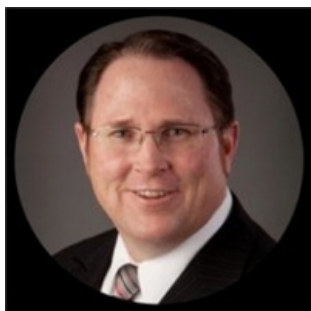


Until recently, government spending has tended to favor urban populations. WHO figures show that only 25% of public-health money was devoted to rural areas, although roughly 40% of the population lives there[CE1] [TW2] .[2]

With the Healthy China initiative, begun in 2007 and revised every ten years, the government is enlarging its focus. The goal of the initiative is to give basic healthcare to everyone, with more medical and health resources being allocated to the more remote areas. This also translates to more investments going to 2A hospitals, and a certain competition between 2A and 3A hospitals.

While improving overall access to healthcare, the government has also instituted certain reforms to reduce healthcare costs. In 2019, the government launched its “Reform Plan for Governance of High-Value Medical Consumables,” instituting a centralized volume-based procurement (VBP) system for high value medical consumables.[3]

To date, only Anhui Province has piloted the VBP of in vitro diagnostic reagents, mainly chemiluminescence reagents, including swelling marks, infectious hepatitis B, hormone thyroid function, myocardial, and inflammation PCT.



Randy Kirschman
Seasoned IVD professional

“We went from zero to 1/3 of our turnover in ten years. People keep saying the Chinese IVD market is going to slow down—but it’s slowing down to small double-digit growth. Other markets we are doing business in—US, Japan, Europe—you’re looking at no growth to 1 or 2%. In China, it used to be 20% and they say it’s slowing to 10%. That’s still ten times bigger than anywhere else.”

[3] <https://www2.deloitte.com/content/dam/Deloitte/cn/Documents/life-sciences-health-care/deloitte-cn-lshc-medical-device-white-paper-en-210301.pdf>

2. Evaluate the market

1The overall IVD market in China is large—and growing—but that doesn't necessarily mean that there is a market for your products. Before deciding to the Chinese IVD market, spend some time researching whether there is a potential for your products.

First, you will need to know more about your product category's size in China.

There is a lot of English-language information published about China on the internet, so you can start your research there. Then, to dive deeper into a specific product category, consult the IVD Blue Book whose chief editor is Mr. Haibo Song, associate dean of the Shanghai Academy of Experimental Medicine, and chairman of the China Association of In Vitro Diagnostics (CAIVD). Published in Chinese since 2016, the IVD Blue book was published for the first time in English in 2021, making it easier for international companies to have quality, detailed market information.



Detailed, trustworthy information about the China IVD market available from Springer.

How is your category evolving? What forces are driving this sector?

Who is your competition? There is likely to be local, well-established competition, and, as China moves so quickly, emerging players. Be sure to evaluate international players, as well. In 2020, six of the ten largest IVD companies in China were international companies. In fact, most major international IVD companies are established in China and represent potential competitive barriers.

Is there a gap in the market? Does your product or product lines offer something that is different, better, more economical, or more reliable than other products on the market? You have already determined your USP for your product in general, now you should evaluate whether that USP is relevant to the Chinese market.

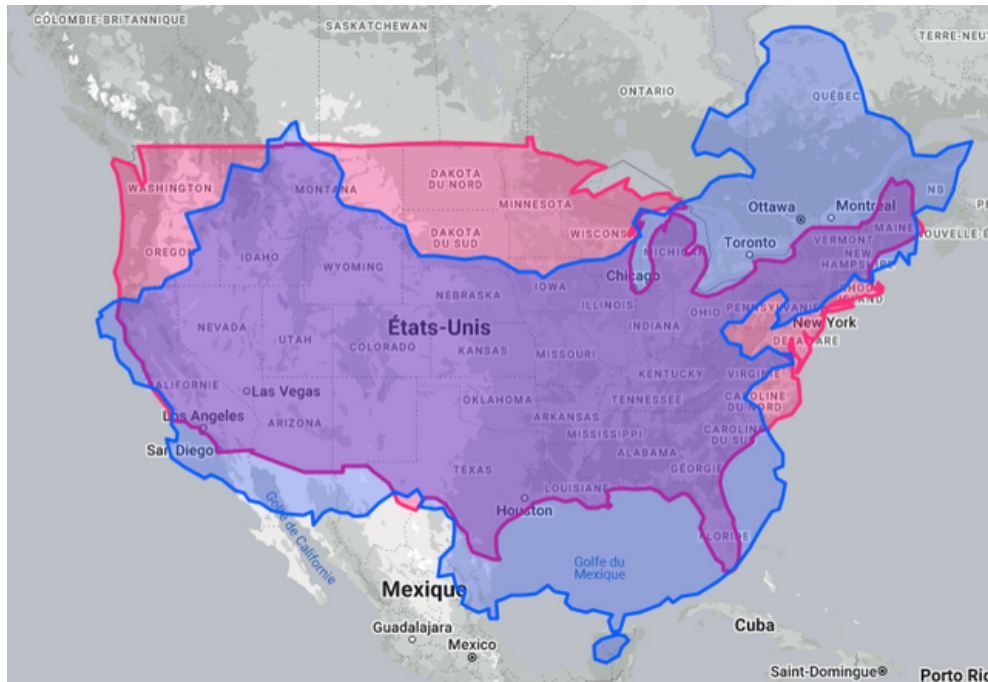


Shauna Parker-Clevenger
Senior Vice President, Rapid Screening & Precision Testing
CTK Biotech, Inc

“Entering the Chinese market is tough. There are already a lot of great products and it’s a mature market. So, if you’re bringing something in, it needs to be something really different, something that’s going to get the market excited.”

Next, consider hiring a market research firm to explore issues which you may have uncovered in your preliminary research. Entering the Chinese market can be a long process, you need to be sure that the potential benefits outweigh your investment.

3. Visit China



**A comparison
between China
and the United
States.
source:
TheTrueSize.com**

Nothing beats seeing things for yourself. Benoît Autem, Managing Director of D-tek S.A. in Belgium says:



**Benoît Autem,
Managing Director,
D-tek**

“I made my first trip in China in 2019. The most surprising discoveries of my trip were that you really have to go in China to understand and acknowledge the full meaning of ‘big’. Indeed, the Chinese market size from our European (or US) point of view is without any doubt underestimated.

This ‘big’ market is composed of multiple networks of personal relationships. In other words, if your Chinese partner does not have the right connections, you may lose a lot of time and even not be successful.

This is why a personal visit in China is compulsory to better understand the market and the efficiency of your Chinese partner.”

You can contact your national trade mission to help you arrange appointments and visits (CACLP will publish a guide to resources for exporting mid July 2022). You can also visit tradeshows, to meet many industry players in one place. The two largest industry tradeshows are:

- ◆ CACLP, Chinese Association for Clinical Laboratory Practitioners Expo, focuses completely on the IVD industry. Over 1410 exhibitors and 40,000 visitors, it is the meeting place for the IVD industry in China. <https://en.caclp.com>
- ◆ CMEF, Chinese Medical Equipment Fair, is a general medical device exhibition, with IVD being just one of the product categories presented. <https://www.cmef.com.cn/en>

“CACLP has done very well for us. We try to get there every year.”

Randy Kirschman
Seasoned IVD professional

4. Choose how you enter the market

Should you work through a distributor? An agent? Should you set up your own company? A joint venture?

The form your market entry takes depends upon many factors within your company: the size of your firm, your products, your previous experience with exporting, business regulations in China, whether you need on-the-ground marketing and after-sales services, how the Chinese view your product, the future growth of demand for this product, intellectual property rights (IPR), the time and resources of your company, as well as the timeframe for entering the market.

Why should you open your own office in China?

"For my product line, from a bio-supply standpoint, the process is a little long because no bio product is the same with every lot that you manufacture. So, everything has to be checked out, has to meet a regulation, has to meet specifications, so that the process takes longer. Having inventory on hand that we could send ahead of time for the next year should improve our annual turnover enormously."

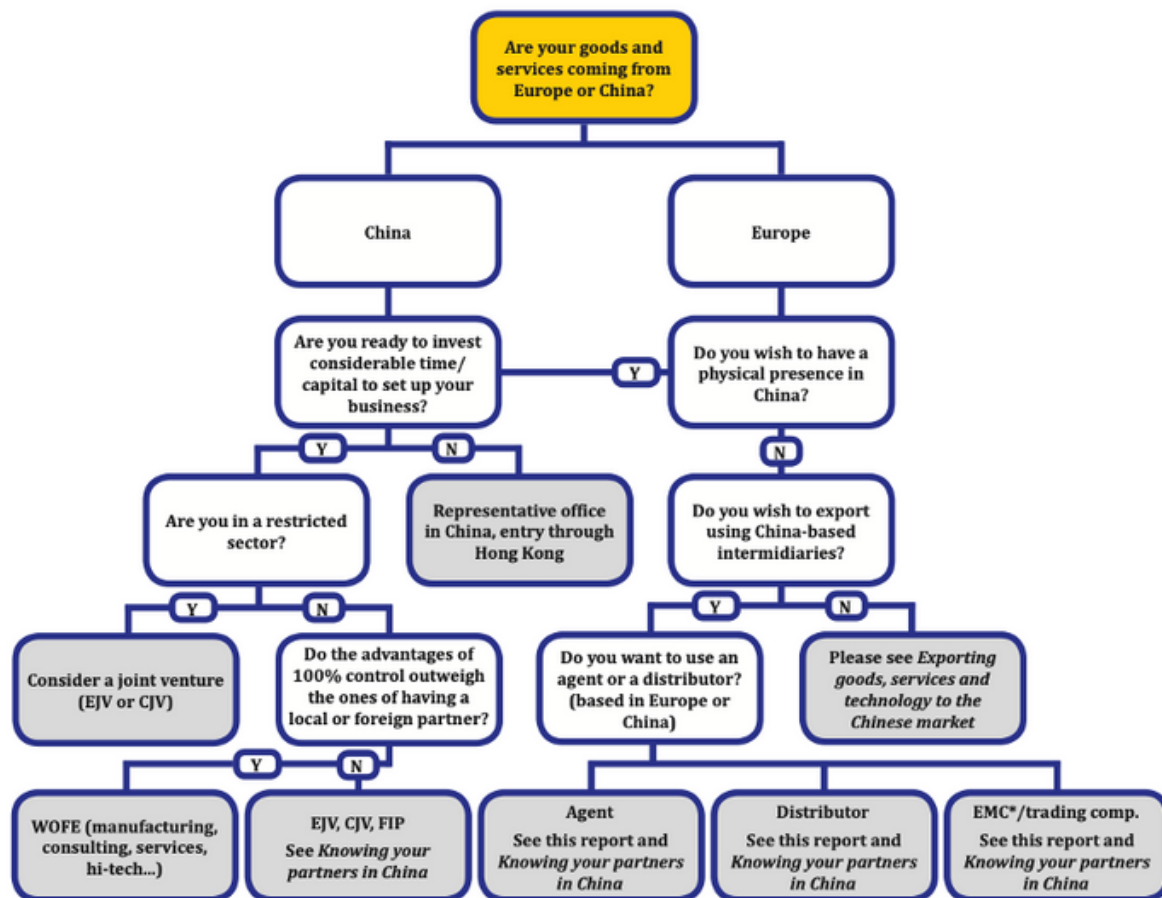
Randy Kirschman
Seasoned IVD professional

Direct export or a rep office in China

The fastest way to enter the market. Exporting directly or having a rep office requires less capital investment and a low overhead. It is helpful for marketing, partner auditing and administrative tasks.

The EU SME Centre in Beijing created this decisional flow chart:

9. Recommendations on the best way to enter the Chinese market



Source: EU SME Centre, eusmecentre.org.cn

An agent or distributor

This is the model most often used by new entrants to China. It is relatively simple, especially for those who are unfamiliar with China. It is important to choose your agent or distributor wisely. Also, consider having multiple distributors or agents; it is rare for one company to be strong with all levels of clients and in all regions. CACLP will publish a guide to choosing a distributor in October 2022.

Wholly foreign-owned enterprise (WFOE)

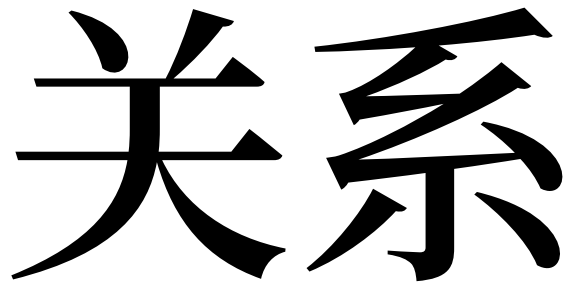
A WFOE requires a higher investment and longer time to enter the market. However, it offers a higher level of control, more IP protection, greater flexibility, is better for overcoming regulatory pressures and for sourcing price-competitive spare parts. Repatriation of profits can be a challenge.

Equity Joint Venture (EJV)

In an EJV, the Chinese partner gains full access to the foreign IPR, which means you need to choose your partner carefully. An EJV is helpful for meeting local production mandates and can reduce regulatory barriers to market entry. Also, you gain access to your partner's existing resources, in production and, perhaps more importantly, in their contacts.

In the report “Chinese Medical Device Industry, How to thrive in an increasingly competitive market?” Deloitte adds two reasons for investing in operations in China.

1. By investing in production in China for the purpose of selling to local markets, rather than exporting, manufacturers with domestic set ups can respond to customer demand more rapidly, and often more cheaply.
2. There are considerable financial incentives available via localization, including lower company income tax rates of 15% and reduced or eliminated VAT. These and other financial incentives are key financial factors in optimizing device makers' business models.^[4]



What is *guanxi*?

Guanxi refers to a person's contacts and connections—but it's more than that. It refers to having mutually beneficial personal and business relationships based on personal trust, moral obligations, and reciprocity. When you choose your Chinese partners, you will likely evaluate their local market knowledge and their deeper understanding of Chinese business, but don't forget their *guanxi*.

[4] <https://www2.deloitte.com/content/dam/Deloitte/cn/Documents/life-sciences-health-care/deloitte-cn-lshc-medical-device-white-paper-en-210301.pdf>

5. Choose where you enter the market

Westerners often think of China is a uniform and homogenous country. Culturally, this is not true, and it is not true economically, either.

“Uneven rates of economic growth in different parts of China over recent years have served to exacerbate many of the economic and social differences that already existed between different provinces. ...There are huge variations between different provinces in terms of population levels, per capita GDP, average income levels, consumer spending habits, education levels, literacy rates, lifestyles and so on. ... China is actually a collection of individual sub-markets defined by vastly differing demographic, economic and cultural characteristics.”[5]

Foreign companies often focus on tier 1 cities or the higher income coastal regions Zhejiang, Guangdong, Jiangsu and Shanghai.

Economic growth and rising incomes in China's Tier 2 cities, as well as the investments made there under the Healthy China Initiative, as described above, make Tier 2 cities more attractive to foreign suppliers, especially since they have lower set-up and operating costs.

According to B2B International.com,
“Over the long term, including Tier 2 and even Tier 3 cities in their strategy can enable foreign companies to gain first-mover advantage in these cities and lead to greater long-term market success.”[6]

City tier system

It is quite common to see Chinese cities classified into tier 1, 2, 3, etc, ... but this is an unofficial classification only, created by the media as an easy point of reference, referring to differences in population size, income level, and consumer behavior.. Here are Chinese cities, tier by tier: [7]

Tier 1 cities

Beijing, Shanghai, Guangzhou, Shenzhen

New Tier 1 cities

Chengdu, Chongqing, Hangzhou, Wuhan, Nanjing, Tianjin, Suzhou, Xi'an, Changsha, Shenyang, Qingdao, Zhengzhou, Dalian, Dongguan, Ningbo

Tier 2 cities

Xiamen, Fuzhou, Wuxi, Hefei, Kunming, Harbin, Jinan, Foshan, Changchun, Wenzhou, Shijiazhuang, Nanning, Changzhou, Quanzhou, Nanchang, Guiyang, Taiyuan, Yantai, Jiaxing, Nantong, Jinhua, Zhuhai, Huizhou, Xuzhou, Haikou, Ürümqi, Shaoxing, Zhongshan, Taizhou, Jiujiang

Tier 3 cities

Weifang, Baoding, Zhenjiang, Yangzhou, Guilin, Tangshan, Sanya, Huzhou, Hohhot, Langfang, Luoyang, Weihai, Yancheng, Linyi, Jiangmen, Shantou, Taizhou, Quzhou, Handan, Jining, Wuhu, Zibo, Yinchuan, Liuzhou, Mianyang, Zhanjiang, Anshan, Quzhou, Daqing, Yichang, Baotou, Xianyang, Qinhuangdao, Zhuzhou, Putian, Jilin, Huai'an, Zhaoqing, Ningde, Hengyang, Nanping, Lianyungang, Dandong, Lijiang, Jieyang, Yanbian Korean Autonomous Prefecture, Zhoushan, Lanzhou, Longyan, Luzhou, Fushun, Xiangyang, Shangrao, Yingkou, Sanming, Lishui, Yueyang, Qingyuan, Jingzhou, Tai'an, Panjin, Dongying, Nanyang, Ma'anshan, Nanchong, Xining, Xiaogan, Qiqihar

[7] https://en.wikipedia.org/wiki/Chinese_city_tier_system

6. Pricing

Pricing has always been an issue for international companies marketing to China, and the medical industry is facing greater pressure since the government instituted a centralized volume-based procurement system.

If your products are impacted by the VBP system or if your products face stiff competition by local manufacturers, then you need to target volume rather than margins. Do you have the capacity to do so?

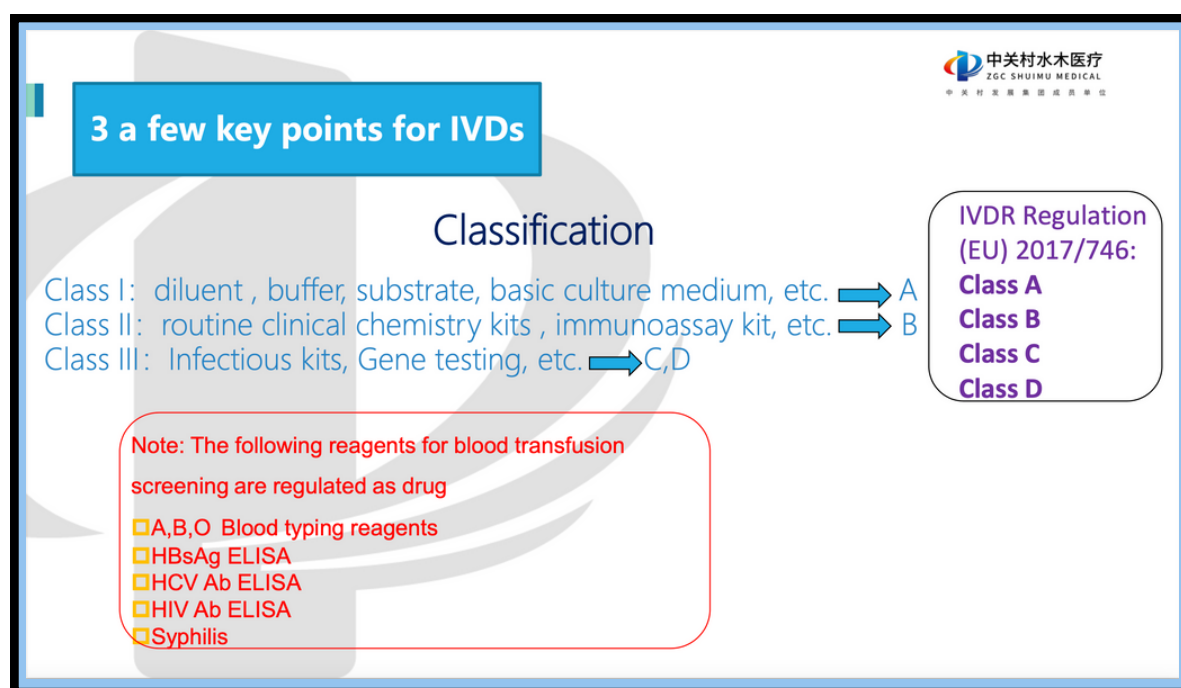
If not, you should focus on how you can develop higher value-added products which are not susceptible to commoditization. Think new technology, or new-to-China technology. Not only can new technology bring you higher prices, it can also help you expedite the regulatory process in China.

7. Regulatory

Navigating the product registration process can be daunting for international companies, especially since it changes so quickly. Depending on whether your product is Class I, Class II or Class III, you need to work with the National Medical Products Administration (NMPA) and/or provincial and municipal bureaus. Each has their own responsibilities and jurisdictions.

The first step in the process is to determine the classification of your product[CE1] [TW2] . For class I IVD products, the low-risk class, you need to submit applications to the NMPA[TW3] . Administrative review and MDRC issuance take about four weeks.

For Class II and Class III IVD devices, you must submit applications and supporting documentation to the NMPA, along with product testing certificates from a local NMPA certified laboratory and local clinical tests. The process lasts 12 – 24 months.



source: ZGC Shuimu Medical, Chinese regulatory consultants.

If your product is new technology or “new-to-China” technology, there is a fast-track process which can cut down registration times dramatically.

In September, we will organize a webinar on regulatory and product registration. [Click here to receive an alert.](#)

8. Intellectual Property Rights

Intellectual property rights (IPR) infringement is an issue in China. Having a patent on your technology in other countries, having trademarked your brand elsewhere, will not help you in China.

China has a “first-to-file” system for both patents and trademarks, which means that the first person or company to register in China is granted the patent or trademark whether or not they are the original inventor of the technology or the legitimate brand and logo owner elsewhere.

As a result, any company entering the Chinese market should register its trademarks, both in English and Chinese, with the China Trademark Office as soon as possible. Registering the trademark across several different categories may also be useful. Be sure to register internet domain names as well.

Filing a patent for the Chinese market is important but raises other concerns. Does the registration process risk disclosing key technical information? If so, could you be better served by employee and partner non-disclosure agreements?

There are no easy answers, no “one size fits all” solution to IPR in China other than making sure you formulate your IPR strategy with specialists *before* entering the Chinese market.

What's next?

China is fast-paced and ever-changing. New rules, policies, and regulations—it can be daunting. Depending on your product and its fit in the Chinese IVD market, it can be more than worth your while.

To help you in your research, CACLP will publish a series of articles, webinars, and infographics in the upcoming months. Here is what you can expect:

July	Clinical Chemistry
August	Country by country, what resources are available to help you export to China 10 Reasons you should enter the Chinese market Molecular Diagnostics POCT
September	Testimonials of previous exhibitors Regulatory and Product Registration Cytometry
October	Virtual visit of a laboratory Finding a distributor in China Coagulation analyzers Urine analyzers
November	Update of the China IVD market report Analyzers: sperm, vaginal secretion, cervical Immunoassay
December	Marketing in China Microbiology
January 2023	Preparing for the show

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