



Nordic Life Science
Platform
FAST-TRACK CHINA ENTRY

NORDIC LIFE SCIENCE PLATFORM

- Fast-track China Entry

- Medtech, Healthtech, Drugs, and Rehabilitation Equipment

www.nlsp.dk

10 October 2024



Nordic Life Science Partners

- Fast-track Market Entry



Purpose

The **Nordic Life Science Platform** (NLSP) gives Nordic / European life science companies a **more safe, efficient, and easier access** to the rapidly expanding Chinese healthcare market by taking advantage of the preferential policies and opportunities at the **"Hainan Boao Lecheng International Medical Tourism Pilot Zone" (HBL)** and **"Guangdong-Hong Kong-Macao Great Bay Area (GBA)"**.

Mission

To **match the demand** for innovative medical devices, drugs, and rehabilitation equipment by the hospitals at HBL and GBA **with the supply** of Nordic / European companies to help access and develop **new sales/export opportunities** in China.

Partnership

To explore the market opportunities in China further, **NLSP** has established a partnership with the **Danish Life Science Cluster**.

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- Hainan Island & Great Bay Area



Guangdong - Hong Kong - Macao Great Bay Area (GBA)



Hainan Boao Lecheng International Medical Tourism Pilot Zone (HBL)





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- Stepping-stone to the Chinese Healthcare Market

Although China is the world's second largest market for both medical devices and drugs, many Nordic companies hold back from doing business in China due to lack of market knowledge and both perceived and real **entry barriers** and therefore consider it too difficult and risky.

This **uncertainty and doubt** includes geopolitical tensions, language barriers, poor IPR protection, forced technology transfer, hidden protectionism, unfair local competition, new laws & regulations, complex application & approval procedures, unclear procurement rules, and unknown distribution channels.

To **lower the entry barriers**, NLSP has gathered a team of experts with many years of know-how and experience from advising and assisting Nordic companies entering and operating in China.

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- Step-by-Step Market Entry Model

NLSP delivers a **Step-by-Step Market Entry Model** that supports companies all the way from exploring to entering the Chinese market with the option to pause after each step of the process.

NLSP offers **expert advice & supporting services** such as project management, legal assistance, IPR protection, hospital matchmaking, contract negotiations, fast-track approval, CRO selection, RWD Study implementation, NMPA filings, product registrations, market research, partner search, company set-up.





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- Hainan Boao Lecheng - Status

- On 10 September 2019, the State Council approved the “Implementation Plan for Supporting the Construction of Boao Lecheng International Medical Tourism Pilot Zone”.
- HBL granted preferential policies and incentives to create a world-class international medical destination and cluster for advanced medical treatment, rehabilitation, R&D, and technological innovation in China.
- Currently, 25 hospitals (Tier 3) are in operation with 3 new hospitals still to open in 2024, and 10 more planned. Total construction cost estimated at RMB 100 billion (USD 14 billion).
- When completed, it will provide 12,000 hospital beds, employ 28,500 medical personnel including 3,500 R&D staff, and by 2025 provide 1.5 million medical consultations per year.



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- Hainan Boao Lecheng – Preferential Policies

- Offers a **special fast-track approval procedure** that makes it easier and quicker to sell, register, and import “innovative” medtech, healthtech, drugs, and rehabilitation equipment at HBL without an NMPA registration.
- **Criteria:** 1) Product cannot have been approved in China but needs CE/FDA/PMDA approval, 2) Product shall be “innovative” and cannot be replaced by an already approved predicate in China, and 3) Product shall be used for a specific medical purpose at HBL hospital applying for its use.
- As of **September 2024**, **431 medical products** (270 medical devices + 161 drugs) have been approved by Hainan MPA for exclusive use at HBL.
- First place in China where it is possible to conduct **Real-World Data studies** of the use of medical devices and medicines imported under the fast-track approval procedure that can supplement the application for the **NMPA registration** and accelerate the approval process to sell in all of China.

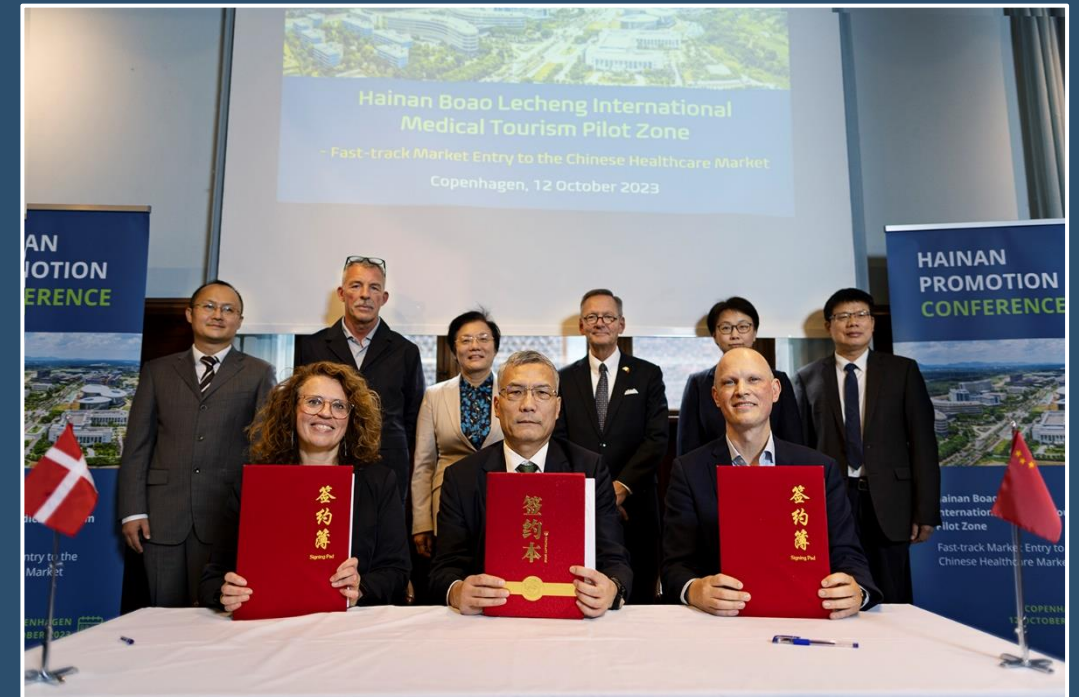
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- Strategic Cooperation Agreement

On **12 October 2023**, the Danish Life Science Cluster, Nordic Life Science Partners, and the Lecheng Administration (HBL), signed a **Strategic Cooperation Agreement** in Copenhagen, Denmark during a high-level medical delegation visit from Hainan headed by Ms. XIE Jing, Vice Governor of Hainan Province.



Ms. XIE Jing, Vice Governor of Hainan Province.



From left to right: Ms. Diana Arsovic Nielsen, CEO of DLSC, Mr. JIA Ning, Director of Lecheng Administration, and Mr. Noam David Stern, Co-founder & Owner of NLSP.

- The **Guangdong-Hong Kong-Macao Great Bay Area (GBA)** is a designated geographical area that includes Hong Kong, Macao, and the nine mainland cities of Dongguan, Foshan, Guangzhou, Jiangmen, Huizhou, Shenzhen, Zhaoqing, Zhongshan, and Zhuhai in Guangdong Province
- Offers a **special fast-track approval procedure** that makes it easier and quicker to sell, register, and import medical devices and drugs in “urgent” need by one of the currently 45 designated GBA hospitals.
- **Criteria:** 1) Product cannot be replaced by a similarly approved product in mainland China, 2) Product needs HK or Macao registration, 3) Product needs to have been procured and used by a public hospital in HK or Macao, and 4) Product shall be used for a specific medical purpose at designated hospital in the GBA.
- As of **June 2024**, **67 medical products** (33 medical devices + 34 drugs) have been approved by the Guangdong MPA for exclusive use at the designated GBA hospitals.
- Gives the opportunity to conduct **Real-World Data studies** that can supplement the application for the **NMPA registration** and accelerate the approval process to sell in all of China.

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- Expert Advise & Support



Noam David Stern
Co-founder & Director,
China



Daisy Du
Legal Advisor
China



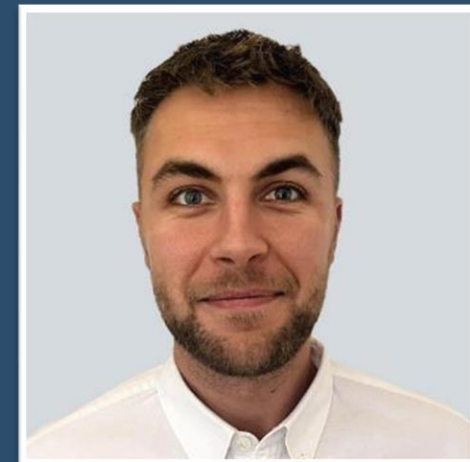
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China & Germany



Peter Ølbye
Co-founder & Advisor,
Denmark



Marcus Woldsen
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