

**Invitation for Expression of Interest**  
**To Operate and Manage a Medical Device Testing Lab (“MDTL”)**  
**in Hong Kong**

The purpose of this invitation is to solicit companies to engage in preliminary but substantive dialogue, on a strictly confidential basis, with Hong Kong Science and Technology Parks Corporation. (“**HKSTP**”) on the topic of operating and managing its first Medical Device Testing Lab in Hong Kong.

Hong Kong aspires to be the leading biomedical hub in the Greater Bay Area and, to realize this vision, it is necessary to provide the essential infrastructure to support the processes for the translation of biomedical research into a marketable product. One such infrastructure is the provision of a Medical Device Testing Lab, the services of which will be openly available to all entities within the biomedical technology industry both within and outside of Hong Kong. Having such a facility would provide better IP protection, efficient turnaround time, and logistical convenience for medical device testing and development on a cost-effective basis.

**HKSTP now wishes to invite entities in the biomedical technology industry that possess the relevant qualification set out in the table further below and are interested in operating and managing the Medical Device Testing Lab, to engage in preliminary but substantive dialogue with HKSTP on a strictly confidential basis. Interested entities are reminded that, other than maintaining confidentiality of the identity of all interested entities and the content of their respective dialogue with HKSTP, such expression of interest and dialogue will not amount to or in itself constitute any legally-binding commitment on the part of HKSTP to any interested entities. All interested entities are further reminded that it shall be solely responsible for all costs (if any) associated with or arising out of any dialogue that it conducts with HKSTP in this regard.**

**Relevant qualification of Interested Entities**

	<b>Item</b>	<b>Compliance</b> <i>(Please indicate “Yes” or “No”)</i>	<b>#Supporting Document/ Proof</b>
1)	Possess a team of personnel with core member(s) having a minimum of 5 years’ relevant experience in operating a medical device testing lab		
2)	Possess experience of testing lab operation during the past 5 years in mechanical and material testing for medical devices		

3)	Project experience related to medical device testing in any of the following areas, such as: (a) Gap analysis (b) Protocol design (c) Fixture design & validation (d) Testing related regulatory submission (e) Testing standard development (f) Material analysis or characterization		
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#Company may provide the required additional information in separate sheets.

**Feedback from Interested Entities**


Based on the outcome of this invitation, HKSTP **may** proceed with issuing an official tender for the official selection and appointment of an entity to manage and operate its Medical Device Testing Lab in Hong Kong.

Background information regarding HKSTP, Hong Kong’s biomedical technology ecosystem and the project objectives are summarized in **Appendix 1**.

Evaluation by HKSTP of any expression of interest will take into consideration the following aspects of each interested entity:

- 1) Technical capacity and competence
- 2) Professional credibility and track record

HKSTP will evaluate proposals in strict confidentiality. HKSTP is NOT bound to invite any company to further submit any bids. It should be noted that HKSTP will not be responsible for the reimbursement of any cost incurred for the preparation of the submission.

For enquiries, please contact +852 2629 7019 or [medical.device@hkstp.org](mailto:medical.device@hkstp.org). You should not contact any other HKSTP personnel unless directed to do so by a HKSTP representative. HKSTP reserves the right to reject any proposals that do not follow the above guidelines.

**EOI Submission & closing Date**

If your company is interested in conducting preliminary discussions with HKSTP on this matter and possess the relevant qualification listed in the table above, please submit your expression of interest via our HKSTP tender website at <https://tender.hkstp.org> **by no later than 18 Jan 2021 12:00nn. No late submission will be accepted.**

*Remarks:*

- 1. First time users of the HKSTP TENDER Website are required to register as a supplier first before submission of your expression of interest can be made.*
- 2. As this process is still at an “expression of interest” stage, please input “0” under the “Total Contract Sum (HK\$)” section of the HKSTP TENDER Website.*

## **Appendix 1** **Background and Objectives of Project**

### **HKSTP – Company background**

Comprising the Science Park, InnoCentre and Industrial Estates, HKSTP is a Hong Kong statutory body dedicated to building a vibrant innovation and technology (I&T) ecosystem to connect companies in the I&T industry with technology and business partners, facilitate their collaborations, catalyse innovations and nurture technology talents to create economic and social benefits to Hong Kong and the region.

Established in May 2001, HKSTP has been driving Hong Kong's efforts to develop into a regional hub for innovation and growth in five technology areas, namely, Biomedical Technology, Information & Communications Technology, Electronics, Green Technology, and Materials and Precision Engineering.

More information about HKSTP is available at [www.hkstp.org](http://www.hkstp.org).

### **Hong Kong's biomedical technology environment**

The life expectancy of the world population is on the rise and presents multiple challenges to humankind, including rising ageing-related and chronic diseases. The development of biomedical technology (BMT) provides promising solutions to these global challenges. The BMT industry has the potential to stimulate economic growth and elevate Hong Kong's profile as a knowledge-intensive economy. The development of health managing systems, advanced diagnostic and therapeutic systems, bio-medicine, and rehabilitation tools also complement the three overarching technology platforms available in Hong Kong, namely Healthy Ageing, Robotics, and Smart City.

As of mid-2018, Hong Kong has approximately 250-300 biotechnology-related companies. These comprise "mainly healthcare-related companies with business in pharmaceuticals, medicinal or healthcare products of traditional Chinese medicine (TCM) origin, medical devices, and diagnostics." The companies work on a wide range of activities, including product R&D, manufacturing, marketing, and sales.

Hong Kong's strengths, such as its strategic location in Asia, population with bilingual fluency in Chinese and English, judiciary independence, world number-one standing for economic openness, and the world's second-largest funding hub for biotechnology, has propelled the Government's active promotion of innovation and technology (I&T) development in Hong Kong. Biotechnology was identified in the 2018-19 Budget as one of the four priority areas. Various tax incentives and funding initiatives have been put in place to support the academia and I&T companies, especially those performing translational R&D for commercialisation of their research products. For example, by the end of January 2019, the Government's Innovation & Technology Fund (ITF) had approved total funding of about USD130 million for over 500 R&D BMT-related

projects, ranging from stem cell therapy and molecular diagnostics to the modernisation of TCM and biopharmaceutical manufacturing.

With the emergence of prompt and accurate disease testing, “omics” such as genomics, devices such as biosensors, bioinformatics, advanced therapies, and regenerative medicine in recent years, Hong Kong is seeing the establishment of more BMT companies focused on these areas. These technologies are anticipated to be in high demand in the future, not only locally but worldwide as well. The healthcare of tomorrow will be not only predictive and preventive, but also support care that is personalised and participatory.

In view of the burgeoning yet vibrant growth of the local BMT industry and the China Government’s recent announcement of the Greater Bay Area (GBA) initiative, Hong Kong has tremendous potential to become the biomedical hub for the GBA and the location of choice for BMT companies in Asia. Backed by the unwavering support from the Government and an enthusiastic BMT industry to develop a sustainable BMT ecosystem in Hong Kong, alongside the proposed enablers in place in the future, Hong Kong demonstrates significant promise to take on a leading role in BMT in Asia. The Medical Device Testing Lab is one of the proposed enablers.

### **Government support**

With vast opportunities opening up in the GBA, and building on strength, the Hong Kong SAR Government has identified the translation of biomedical research and development into marketable products as one of the priorities for the push to promote innovation and technology.

The Hong Kong Stock Exchange of Hong Kong Limited (“HKEX”) allows pre-revenue IPO listing of biotech companies which has drawn overwhelming interests from Chinese and international leading biotechnology companies. The relevant listing rules allow biotechnology R&D activities to leverage on Hong Kong’s well-established capital markets, and riding onto this new scheme, a large number of biotechnology companies are expected to come to Hong Kong for clinical trials and public listing. More information about HKEX’s listing rules on this aspect is available at [http://www.hkex.com.hk/News/News-Release/2018/180424news?sc\\_lang=en](http://www.hkex.com.hk/News/News-Release/2018/180424news?sc_lang=en).

In October 2017, the Chief Executive of Hong Kong announced her 2017 Policy Address. She has placed innovation and technology as the top priority, and identified biotechnology development as one of the key focus areas. Renewed impetus for developing innovation and technology in Hong Kong include: doubling R&D expenditures within five years, enhanced tax deduction for R&D expenses, and 8.25% profits tax for the first \$2m of profit. The Government has also allocated HK\$10 billion to create a healthcare technology platform to encourage overseas R&D institutions to conduct research in Hong Kong in collaboration with local universities. With such increased support from the Government, we anticipate to have a large increase of translational research and clinical application of biomedical innovation in Hong Kong.

Riding on the policy support, HKSTP has made substantial headway in discussions with authorities in the HKSAR Government on measures to facilitate biotechnology development in HK, including the provision of infrastructures to support biomedical translational research and a regulatory regime for medical devices.

## **Objectives of the project**

As a start, HKSTP wishes to invite industry players to manage and operate HKSTP's Medical Device Testing Lab at the Science Park that will offer accredited testing services as well as related consultancy services to the medical device companies in Hong Kong, Mainland China and overseas towards obtaining the necessary regulatory clearance as well as for other business demands. Such services are aimed at supporting the design verification and validation from the early R&D stage and throughout the device life cycle. The operator is expected to obtain at minimum the HOKLAS and CNAS accreditations for the Medical Device Testing Lab and manage the device testing and consulting services during the relevant contract period.