



Non-civil Service Vacancy

Senior Project Manager

Salary:

HK\$127,700 per month (plus end-of-contract gratuity)

Entry Requirements:

Candidates should –

- (a) be a Corporate Member of the Hong Kong Institution of Engineers (Electronics Discipline or Biomedical Discipline) elected after 5 December 1975, or equivalent;
- (b) have at least 10 years' post-qualification experience in the following areas of which at least 5 years should be in a supervisory position:
 - (i) regulation of medical devices, including pre-market control of development of Guidance Notes, Technical References, Codes of Practice and Operating Procedures, post-market surveillance of safety alert and adverse event; and
 - (ii) recognition of conformity assessment bodies; listing programmes of medical devices and local responsible persons, local manufacturers, and importers; and the planning and conduction of assessment and surveillance visits to the parties concerned;
- (c) preferably be familiarized with:
 - (i) other countries' medical devices regulatory systems;
 - (ii) international organizations' medical devices regulatory standards such as World Health Organization Global Benchmarking Tool plus Medical Devices ("WHO GBT + MD") and International Medical Device Regulators Forum's documents;
 - (iii) Quality Management System, Risk Management System and Occupational Safety and Health Management System; and
 - (iv) medical devices classification, principle of operation, clinical applications, safety, quality and efficacy; and
- (d) preferably have a good command of spoken and written Chinese and English.

(Note: Candidates should submit a copy of academic certificates/ transcripts and documentary proof of working experience.)

Duties:

A Senior Project Manager is mainly responsible for –

- (a) planning, developing, monitoring, evaluating and overseeing the daily operation of the Medical Device Administrative Control System ("MDACS") related to the control/regulation of medical devices including the development of Guidance Notes, Technical References, Codes of Practice, and Operating Procedures, etc. and listing of medical devices, conformity assessment bodies, LRPs, local manufacturers, and importers;
- (b) conducting gap analysis among MDACS, WHO GBT + MD, other countries' regulatory systems for development of a Regional Regulatory System for regulation of medical devices in Hong Kong in accordance with WHO GBT + MD;
- (c) assisting in the preparation of legislative proposal for the statutory regulation of medical devices;
- (d) planning, designing and developing the Medical Device Division ("MDD") and/or Centre for Medical Products Regulation ("CMPR") website, various database systems, computerized management and control system as required for MDD and/or CMPR daily operation of the medical devices regulation in accordance with WHO GBT + MD requirements;

- (e) assisting CMPR's accreditation of WHO GBT + MD maturity level 4 and WHO Listed Authority in medical devices regulatory system including development of Quality Management System and Risk Management System; and
- (f) overseeing the publicity and consultation programme and organization of workshops/seminars for liaising, cultivating and maintaining working relationship with traders, healthcare organizations, international forums, other stakeholders and the public in relation to regulation of medical devices.

(Remarks: Successful candidate will be required to perform outdoor duties/site visits. Working venues and hours may vary depending on operational needs of the Department. May be required to work on shifts.)

Terms of Appointment:

Successful candidates will be appointed on non-civil service terms. Renewal of contract will be subject to the service need of the Department and the performance of the candidate.

Fringe Benefits:

- (a) A gratuity may be granted upon satisfactory completion of the contract with consistently satisfactory standard of performance and conduct. The amount of gratuity payable will be the sum which, when added to the Government's contribution to a Mandatory Provident Fund (MPF) scheme as required by the MPF Schemes Ordinance (Cap. 485), equals to 15% of the total basic salary drawn during the contract period.
- (b) Candidates appointed are eligible for 14 days' paid annual leave. Other benefits such as rest days, statutory holidays (or substituted holidays), maternity leave/ paternity leave and sickness allowance, where appropriate, will be granted in line with the Employment Ordinance (Cap. 57).

Enquiry Address and Tel. No.:

Appointments Section, Department of Health, Room 1807, 18/F, Wu Chung House, 213 Queen's Road East, Wan Chai, Hong Kong (Tel: 2961 8444)

Closing Date for Application:

21 November 2024 (Thursday)

Newspaper(s) Advertised:

Recruit (8 November 2024) and Ming Pao Daily News (8 November 2024 and 15 November 2024)

General Notes:

- (a) Candidates must be permanent residents of the Hong Kong Special Administrative Region at the time of appointment unless specified otherwise.
- (b) As an Equal Opportunities Employer, the Government is committed to eliminating discrimination in employment. The vacancy advertised is open to all candidates meeting the basic entry requirement irrespective of their disability, sex, marital status, pregnancy, age, family status, sexual orientation and race.
- (c) Non-civil service vacancies are **not** posts on the civil service establishment. Candidates appointed are **not** on civil service terms of appointment and conditions of service. Candidates appointed are **not** civil servants and will **not** be eligible for posting, promotion or transfer to any posts in the Civil Service.
- (d) The entry pay, terms of appointment and conditions of service to be offered are subject to the provisions prevailing at the time the offer of appointment is made.
- (e) Where a large number of candidates meet the specified entry requirements, the recruiting department may devise shortlisting criteria to select the better qualified candidates for further processing. In these circumstances, only shortlisted candidates will be invited to attend recruitment examination and/or interview.

- (f) It is Government policy to place people with a disability in appropriate jobs wherever possible. If a disabled candidate meets the entry requirements, he/she will be invited to attend the selection interview/written examination without being subject to further shortlisting. Applicants who have declared disabilities found suitable for appointment may be given an appropriate degree of preference over other applicants whose suitability for appointment is considered comparable to that of the former. The Government policy and other related measures on employment of persons with disabilities are set out in the booklet “Employ People Based on Their Abilities – Application for Government Jobs by Persons with Disabilities” which is available for reference on the Civil Service Bureau's website at <http://www.csb.gov.hk> under “Administration of the Civil Service – Appointments”.
- (g) Holders of academic qualifications other than those obtained from Hong Kong institutions/Hong Kong Examinations and Assessment Authority may also apply but their qualifications will be subject to assessments on equivalence with the required entry qualifications. They should submit copies of their official transcripts and certificates by mail to the above contact address.
- (h) Non-civil service vacancies information contained in this column is also available on the “GovHK” on the Internet at <http://www.gov.hk>.
- (i) Towards the application deadline, the online system would likely be overloaded due to large volume of applications. To ensure timely completion of your online application, it is advisable to submit the application as early as possible.

How to Apply:

The application period for the position of Senior Project Manager is **from 8 November 2024 (Friday) to 21 November 2024 (Thursday)**.

Application Forms (G.F. 340 (Rev. 7/2023)) are obtainable from any Home Affairs Enquiry Centres of District Offices, Home Affairs Department or any Job Centres of the Employment Services Division, Labour Department. The said form can also be downloaded from the Civil Service Bureau's website (<http://www.csb.gov.hk>).

The new version of application form for Government jobs G.F. 340 (Rev. 7/2023) has been in use with effect from 26 July 2023. Candidates who make applications on or after 26 July 2023 should use the new G.F. 340 (Rev. 7/2023). If candidates submit the old version form (G.F. 340 (Rev. 3/2013)), they will be required to fill in the new G.F. 340 (Rev. 7/2023) afresh and submit it within seven days upon request. If candidates fail to submit the new G.F. 340 (Rev. 7/2023) within the stipulated deadline, their applications will not be processed further.

Completed application forms submitted in person or by post should reach the above contact address on or before the closing date for application together with copies of supporting documents listed in the entry requirements. Please specify “Application for the position of Senior Project Manager” on the envelope. To avoid delayed or unsuccessful delivery of applications by post, please ensure that the correct address is clearly printed or written on the envelope and sufficient postage has been affixed before posting. Mail items bearing insufficient postage will not be delivered to this Department and will be returned to the sender or disposed of by the Hongkong Post, where appropriate. Applicants will bear any consequences arising from paying insufficient postage. Applicants may also apply online through the Civil Service Bureau’s website (<http://www.csb.gov.hk>). Applications submitted by fax or e-mail will not be accepted.

For applicants who apply on-line, they should submit copies of the required supporting documents by post to the above contact address on or before 28 November 2024 (Thursday). The on-line application number should be quoted on the envelope and copies of the supporting documents. **Please do not send originals of transcripts/ certificates.**

If candidates fail to provide the supporting documents as required, their applications will not be considered. Applicants are encouraged to provide their email addresses on the application forms. Candidates who are selected for interview will normally receive an invitation (by email or by post) in about six to eight weeks from the closing date for application. Those who are not invited for interview may assume that their applications are unsuccessful.