



Non-civil Service Vacancy

Contract Senior Regulatory Affairs Manager

Salary:

HK\$101,775 per month (plus end-of-contract gratuity)

Entry Requirements:

Candidates should –

- (a) (i) have a Bachelor's Degree in related subjects ^{Note} from a university in Hong Kong or equivalent with 15 years' relevant post-graduate experience; **or**
(ii) have a Master's Degree in related subjects ^{Note} from a university in Hong Kong or equivalent with 10 years' relevant post-graduate experience;

Note: includes (i) biomedical engineering, (ii) electronics engineering, (iii) biomedical sciences, (iv) biotechnology, (v) cell and molecular biology, (vi) biology, (vii) applied biology and (viii) applied physics.

- (b) have at least 10 years' post-qualification work experience in the following areas, of which at least 5 years should be in a supervisory position:
 - (i) regulatory affairs of medical devices, such as development of Guidance Notes, Technical References, Codes of Practice and Operating Procedures, pre-market listing application for devices and traders, post-market surveillance of safety alerts and adverse events; **or**
 - (ii) conformity assessment bodies for medical devices, assessment programmes of medical devices and local responsible persons, local manufacturers, and importers; planning and conduction of assessment and surveillance visits to the parties concerned;
- (c) preferably be familiar with:
 - (i) other jurisdictions' 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), International Medical Device Regulators Forum's (IMDRF's) documents;
 - (iii) Quality Management Systems, Risk Management Systems, Occupational Safety and Health Management Systems; 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, and good presentation and liaison skills.

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

Duties:

A Contract Senior Regulatory Affairs Manager is mainly responsible for –

- (a) assisting the 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, LRP, 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:

29 January 2026 (Thursday)

Newspaper(s) Advertised:

Recruit (16 January 2026) and Ming Pao Daily News (16 January 2026 and 23 January 2026)

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 must submit copies of their official transcripts and certificates by e-mail (appts_registry1@dh.gov.hk).
- (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 Contract Senior Regulatory Affairs Manager is **from 16 January 2026 to 29 January 2026**.

Applicants must apply online through the G.F. 340 Online Application System of the Civil Service Bureau (<https://www.csb.gov.hk>). Applications which are incomplete or submitted in person, by post, by fax or by e-mail will not be accepted.

All applicants should provide relevant documents in support of their (a) qualification; and (b) working experiences to the designated e-mail address (appts_registry1@dh.gov.hk) **on or before 5 February 2026 (Thursday)**. The title of the post being applied for and the on-line application number should be quoted in the e-mail and copies of the supporting documents.

If candidates fail to provide the supporting documents as required, their applications will not be considered. Applicants should provide their e-mail addresses on the application forms. Candidates who are selected for interview will normally receive an invitation by e-mail in about six to eight weeks after the application is received. Those who are not invited for interview may assume that their applications are unsuccessful.