

## Job Detail

Manager Level

Position Title	GCP Quality Compliance Lead at Global Healthcare Tech
Recruiter Company	Michael Page International Japan K.K./マイケル・ページ・インターナショナル・ジャパン株式会社
Company Name	Company name is private
Activated / Updated	2024-05-02 / 2024-05-02
Job Type	Medical/Pharmaceutical/Bio/Fabric/Food - QA/QC Medical/Pharmaceutical/Bio/Fabric/Food - Clinical R & D
Industry	Medical/Healthcare Services
Location	Asia Japan Tokyo
Job Description	<p>Reporting APAC in a stand alone position. Be a key member in clinical quality management to ensure effective compliance.</p> <p>Description</p> <ul style="list-style-type: none"><li>* Supporting clinical quality management including ICH GCP, clinical regulations/requirements, data management of clinical trials</li><li>* CSV</li><li>* Supporting clinical trial processes including eTMF, TMF, SMF</li><li>* Operate in quality incident management, internal quality system audits, customer audit/inspection</li></ul> <p>Profile</p> <ul style="list-style-type: none"><li>* University degree in scientific or related field</li><li>* High fluency in English and Japanese (non-native level speakers will not be selected)</li><li>* Clinical quality experience with strong understanding of ICH GCP ideally in the pharmaceutical industry</li><li>* CSV experience</li><li>* Exposure to quality systems processes including auditing, root cause analysis, and CAPA development</li><li>* PMDA inspection experience is preferred</li><li>* Ability to work independently</li></ul> <p>Job Offer</p> <ul style="list-style-type: none"><li>* Competitive salaries and benefits</li><li>* Great work life balance</li><li>* International working environment</li><li>* Hybrid working environment</li><li>* Work with industry leaders who are solving unmet needs</li><li>* Great career progression</li></ul> <p>Page Group Japan is acting as an Employment Agency in relation to this vacancy.</p>
Company Info	<ul style="list-style-type: none"><li>* Global healthcare technology company specialising in digitisation for clinical trials</li><li>* Supporting over 30,000 clinical trials around globe</li><li>* International working environment with extensive global collaboration</li><li>* Hybrid working style</li></ul>
English Level	Business Conversation Level (TOEIC 735-860)
Japanese Level	Native Level

Salary	JPY - Japanese Yen JPY 12000K - JPY 14000K
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