

## EXTERNAL CALL

### The Institute

The **Santa Creu i Sant Pau Hospital Research Institute Foundation** is a scientific foundation which mission is to improve health and quality of life of the population, through the production and dissemination of scientific knowledge, training of researchers to an international standard, and promoting health innovation and the incorporation of medical advances in clinical practice and healthcare policies. Created in 1992, the institute was attached to the Autonomous University of Barcelona (UAB) in 2003, and since 2011 it is part of the Government of Catalonia's CERCA Programme.

For the Foundation, it is a priority to ensure that the most suitable candidate is hired to fill a job through an open, transparent and merit-based selection process (OTM-R). Following these guidelines, staff mobility, knowledge exchange and, ultimately, the increase in the quality of teaching and research will be enhanced. Faithful to our commitment to the European Union's human resources strategy, our institution's personnel selection and recruitment procedures are governed by a set of basic principles that guarantee equal access to employability for all. Therefore, the constitutional principles of equality, merit and ability are followed, respecting in all cases the national and international regulations in force in this area, specifically the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers (C&C). The principles of C&C are applicable to the recruitment of any personnel of the institution, regardless of their professional category. For this reason, our Foundation has obtained the recognition of "Excellence in R+D in Research" granted since 2015.



HR EXCELLENCE IN RESEARCH

The **Santa Creu i Sant Pau Hospital Research Institute Foundation** needs to incorporate at the Quality Unit:

**A3B Senior Administrative Technician**

### **About the Unit / Group:**

The Quality Assurance Unit manages the establishment of mechanisms for evaluating the Institute's Quality and Good Scientific Practices, promoting continuous improvement and excellence in management. However, it ensures the quality of Advanced Therapy Medicines manufactured in the White Room.

### **Essential requirements**

- Minimum Qualification Required: Degree or Degree in the area of Biosciences, Chemistry or Engineering.
- Minimum of three years demonstrable experience in the regulatory field of Good Clinical Practices (GCP), Correct Medicine Manufacturing (NCF) or ISO 9001 standards.
- Oral and written knowledge of the two official languages of Catalonia. Level C of Catalan or, failing that, the selected candidate must demonstrate, or undertake to acquire, within a period not exceeding one year, a correct knowledge of the two official languages in Catalonia.
- Intermediate level of English.
- Advanced knowledge of office tools (Excel, Word, Power Point, etc.).

### **Skills will be valued**

- Master's/Postgraduate degree in the field of Good Clinical Practices, Good Manufacturing Practice (GMP), Good Manufacturing Practice (GMP) or ISO 9001.
- Training and experience in Risk Management analysis in the pharmaceutical/healthcare environment. \* Training and experience in Good Clinical Practice (GCP) regulatory environment.
- Training and experience in the regulatory environment of Good Manufacturing Practices for Advanced Therapy Medicinal Products (GMP).
- Training and experience in clean room operations in drug manufacturing.
- Training and experience in ISO 9001 Management.
- Training and experience in Management of Standard 166002.
- Training and experience in audits of Quality Management Systems and R&D&I.
- Analytical skills, teamwork, initiative, organization and prioritization of tasks.

## Functions

Support in the activities of:

- Elaboration of procedures, records, change controls, risk management, non-conformities, deviations and supplier management, among others, applicable to the Quality Assurance Unit, guaranteeing their compliance and updating based on the requirements of the applicable regulations.
- Follow-up of Good Clinical Practices at CIM Sant-Pau and collaboration in expanding the scope of certification at the Phase I/II Clinical Trials Unit of Medical Oncology.
- Internal audits of CIM Sant Pau Clinical Trials (BPC), as an independent Quality Unit.
- Monitoring of the Correct Manufacturing Standards for Advanced Therapy Medicines (NCF-MTA) in the White Room. Assurance that each batch of medicine has been manufactured and controlled in compliance with current legislation and the requirements required for the authorization of the AEMPS), as an independent Quality Unit.
- Advice on compliance with regulations.
- Follow-up of the ISO 9001 Standard at the PSCTs and extension of the scope of certification at the UICEC.
- Monitoring of the UNE 166002 Standard in the Transfer and Innovation Unit.
- Carrying out internal audits of compliance with regulations and audits of suppliers of management systems (ISO 9001, UNE 166002, BPC, NCF).
- Participation in external audits / inspections of compliance with regulations or requested by promoters, applicable to the different Management Systems certified / accredited by the IR-HSCSP.
- Implementation of the quality document manager.
- Promotion of the culture of quality

## Offered

- Indefinite contract,
- Annual workday of 1.627,50 hours (37,5 hours/week)
- Remuneration according collective agreement (31.916,36 annual gross)
- Research Group: Quality

## Documentation and deadline for submission

Interested parties should preferably deliver the documentation (1) in PDF, by e-mail to the Management of the Santa Creu i Sant Pau Hospital Research Institute Foundation, address [ir\\_seleccio@santpau.cat](mailto:ir_seleccio@santpau.cat) , indicating the reference **2024/120**:

### (1) Application letter and updated Curriculum Vitae and signed Data Processing Authorization\*\*

At the request of the Santa Creu i Sant Pau Hospital Research Institute Foundation, the candidates must present the documentation accrediting the merits mentioned in the curriculum vitae.

Applications will be resolved within a maximum period of one month from the end of the deadline for submission of documentation. At the end of this period, without having been notified of an express resolution, the interested parties will be entitled to understand that their applications have been rejected.

Santa Creu i Sant Pau Hospital Research Institute Foundation may declare this call for applications closed if, according to its criteria, the candidates does not meet the conditions that the Institution considers necessary to fill the position.

The interpretation of the requirements and their enforceability to the candidates will be exclusive to the Santa Creu i Sant Pau Hospital Research Institute Foundation.

**\*\*It is essential to attach the duly signed data processing authorization  
(document attached at the end of the call) \*\***

**The deadline for submitting applications  
will end on July 30, 2024, at 3:00 p.m.**



*Fundació Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau, sited at C. Sant Quintí, 77-79, 08041, Barcelona, Tel: 93 291 90 50, NIF: G-60136934, as Data Controller and in compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) and the Organic Law 3/2018 of 5th of December, on the protection of personal data and the guarantee of digital rights, will treat your data with the sole purpose of developing this call. The legal basis for this treatment is the article 6.1 a, c and f from the GDPR, giving that we will ask for your consent, the treatment is necessary for the application of precontractual measures and its necessary to satisfy the legitimate interests pursued by the Data Controller.*

*The data will be kept during the necessary time to develop the call. Data will be treated solely by that areas and services that are allowed to in accordance with their assigned competences and functions. There will be no data cessions made unless there is a legal obligation to do so. You are entitled to exercise the rights of access, rectification, deletion, opposition, limitation and portability. In case you have any doubts, you can contact the data protection delegate at [dpo\\_ir@santpau.cat](mailto:dpo_ir@santpau.cat). You also have the right to file a complaint to the relevant control authority.*

**PERMANENCE COMMITMENT:** *Selected persons who will hold the summoned or vacant position, will not be able to apply for a new call until 1-year period has expired. In case of part-time job positions, this period will be of 6 months. In both cases, the period will compute from the date of publication of the resolution. The vacant summoned, and the ones that derive from it (intern movements), will be successively covered on the same proceeding among the submitted candidates to each particular call, regardless of whether this entails coverage of places in turns other than the call.*

Barcelona, 16/07/2024



**Human Resources Departament**

Santa Creu i Sant Pau Hospital Research Institute Foundation

**AUTHORISATION FOR PROCESSING PERSONAL DATA**

Dear candidate:

The Fundació Institut de Recerca del Hospital de la Santa Creu i Sant Pau, with CIF G-60136934 and registered office at C/ Sant Quintí, 77-79, (08024) Barcelona, as data controller, informs you that it will process your data for the following purposes:

- Receipt of applications.
- Analysis of applications in order to incorporate the worker into the team of the Fundació Institut de Recerca del Hospital de la Santa Creu i Sant Pau, for a current vacancy and for future selection processes that fit your profile.
- To carry out personnel selection processes, as well as to formalise the hiring of the employee, if applicable.
- Comply with the required legal obligations.

The legitimate basis for processing the data is based on the legitimate interest of processing this job offer, in accordance with the provisions of Article 6.1 b) of the General Data Protection Regulation, as your data are necessary for the performance of a contract, which the data subject is a party or for the implementation of pre-contractual measures at his or her request.

However, we inform you that your data (i) will only be processed by those departments or areas of the Institute which, according to their competencies and functions, have an interest in the selection of personnel, (ii) may be communicated to public authorities and organisations, in order to comply with a legal obligation, such as service providers and third parties necessary for the management and execution of the relations derived from the request made and (iii) that they will be kept for the periods foreseen for the prescription of legal responsibilities.

Finally, we inform you that you have the right to access your personal data, to rectify them, to request their deletion, to oppose their processing and to revoke your consent to this processing. In certain circumstances, you may request that we restrict the processing of your personal data, in which case we will only retain your personal data for the exercise or defence of claims. In addition, you have the right to make a complaint to the relevant data protection authority. If you have any questions about the processing of your data you can contact the Entity's Data Protection Officer by sending an email to [dpd@santpau.cat](mailto:dpd@santpau.cat).

**Consent**

I have been informed about the processing of my data and I consent to the processing:

YES                       NO

Name & Surname:

Signature