

INTERNAL / EXTERNAL CALL

The Institute

The Fundació Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau (IR Sant Pau) is a scientific foundation whose mission is to improve the health and quality of life of the population through the production and dissemination of scientific knowledge, the training of researchers at an international level, and the promotion of innovation and health by integrating medical advances into clinical practice and health policies. Established in 1992, it has been a center of excellence affiliated with the Autonomous University of Barcelona (UAB) since 2009 and has been part of the CERCA (Research Centers of Catalonia) network since 2011.

For the Foundation, it is a priority to ensure that the recruitment of the most suitable candidate to fill a job is done through an open, transparent and merit-based (OTM-R) selection process. Following these guidelines will promote the mobility of staff, the exchange of knowledge and, ultimately, the increase in the quality of teaching and research. Faithful to the commitment to the human resources strategy of the European Union, our institution's personnel selection and recruitment procedures are governed by a set of basic principles that guarantee everyone equal access to employment. Therefore, the constitutional principles of equality, merit and capacity are followed, respecting in any case 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 for the recruitment of any staff of the institution, regardless of their professional category. For this reason, our Foundation has obtained the recognition of "Excellence in R&D in Research" awarded to the IIB Sant Pau, since 2015.



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

T4 CERT22 ISCIII

About the Unit / Group:

The Quality Assurance Unit manages the establishment of evaluation mechanisms for the Quality and Good Scientific Practices of the Institute, promoting continuous improvement and excellence in management. It also ensures the quality of Advanced Therapy Medicinal Products manufactured in the Clean Room.

Essential requirements

- Minimum required qualification: Graduates; Engineers; Architects; Graduates with a Degree ≥ 300 ECTS assigned to Level 3 (Master's); Graduates with a Master's (≥ 300 ECTS); Diplomates, Technical Engineers, and Architects with a Master's Level 3.
- Training and experience in the regulatory field of Good Manufacturing Practices for Advanced Therapy Medicinal Products (GMP-ATMP).
- Training and experience in Quality Management System audits.
- Oral and written knowledge of the two official languages of Catalonia. Catalan Level C or, if not, the selected candidate must demonstrate, or commit to acquiring, in no more than one year, correct knowledge of the two official languages in Catalonia.
- Intermediate level of English.
- Advanced knowledge of office tools (Excel, Word, PowerPoint, etc.).

Skills will be valued

- Minimum required qualification: Degree or Bachelor's in Biosciences, Chemistry, or Engineering.
- Training in the regulatory field of Good Manufacturing Practices for Medicinal Products (GMP).
- Training and experience in Risk Management analysis in the pharmaceutical/healthcare field.
- Training and experience in operations in clean rooms for medicinal product manufacturing.
- Training and experience in Quality Management System audits and R&D&i.
- Analytical ability, teamwork, initiative, organization, and task prioritization.

Functions

- Support in the following activities:
- Preparation of documentation applicable to Quality Assurance, according to the requirements of GMP-ATMP (procedures, records, change controls, risk management, Non-Conformities, deviations, etc.), ensuring compliance and updates, with the goal of expanding the Quality Management System to the new Advanced Therapies Unit.
- Monitoring and maintaining the Quality Management System, ensuring compliance with GMP-ATMP in the manufacturing processes of Medicinal Products in the Advanced Therapies Unit, as an independent Quality Unit.
- Creation, monitoring, and maintenance of incidents, Non-Conformities, OOS/OOT, change controls, and risk management. Establishment and follow-up of corrective/preventive actions.
- Validation of computerized systems and review of equipment qualification (IQ, OQ, PQ).
- Conducting audits of suppliers of the GMP Quality Management System.
- Participation in external inspections by the AEMPS.
- Implementation of the document management system in the context of GMP.
- Promoting a culture of quality.

Offered

- Temporary contract linked to the CERT22/00012 project
This contract is funded by the Instituto de Salud Carlos III with file code CERT22/00012, co-financed by Next Generation EU Funds and the Recovery, Transformation, and Resilience Plan.

Resolution of the Directorate of the Instituto de Salud Carlos III, O.A., M.P., granting subsidies for the selection and funding of members of the State Network Consortium for the Development of Advanced Therapy Medicinal Products (CERTERA), within the framework of the PERTE for Cutting-Edge Health and financed by the funds of the Recovery, Transformation, and Resilience Plan.

- Annual working hours: 1,627.50 hours (37.50 hours per week)
- Salary: According to ISCIII salary tables (€27,629.21 gross per year)
- Research Group: Quality Unit:

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 , indicating the reference **2025/049**:

**(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 April 16th, 2025, 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. 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, 02/04/2025



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 dpo@santpau.cat.

Consent

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

YES NO

Name & Surname:

Signature