

EXTERNAL CALL

The Fundació Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau needs to incorporate

T5 Technical Director of Sala Blanca (Qualified Person)

Essential requirements

- Minimum qualification required bachelor's degree or degree that accredits a minimum university training cycle in pharmacy, medicine, veterinary medicine, chemistry, chemistry and pharmaceutical technology or biology.
- Training and experience in Advanced Therapy Drugs (gene and cell therapy), especially detailed knowledge about CART Cell. Including cell and tissue biology, biotechnological techniques, cell processing, characterization, potency testing, and drug manufacturing stages.
- Experience of more than 2 years as Technical Director in clean rooms of drug manufacturing.
- Have exercised a minimum of two years, and in one or more companies that have obtained a manufacturing authorization, of activities of qualitative analysis of food, of quantitative analysis of active substances, as well as tests and verifications necessary to ensure the quality of the medicines.
- Training and experience in Good Manufacturing Practices of Advanced Therapy Drugs.
- Working knowledge of the NCF regulation specific to MTA (Eudralex. Volume 4. Part IV. MTA-specific NCF Guidelines).
- Biosafety Training.
- High level of oral and written English.
- Oral and written knowledge of the two official languages of Catalonia.
- Computer skills.

Skills will be valued

- Previous experience with processing with AEMPS and Department of Inspection and Control of Medicines.
- Experience in the maintenance of equipment and cleanroom installations.
- Analytical capacity, teamwork, initiative, organization and prioritization of tasks.

Functions

- Management and supervision of the activity of the Clean Room, ensuring compliance with current regulations applicable to the projects developed, including biosecurity regulations, preventive safety and Good Manufacturing Practices for Advanced Therapy Drugs.
- Ensure the proper functioning of the room, supervising the Maintenance Plan of the installation and equipment, cleaning and disinfection plan, product / process validations, material and personnel circuits and monitoring of environmental parameters, as well as leading the necessary actions for the correction of deviations.
- Responsible for each batch of medicines being manufactured and controlled according to the legislation that regulates the manufacture of medicines, including the NCF-MTA, as well as the applicable Quality Management System specifications/documentation.
- Responsible for the release of medicines.
- Replace the Quality Control Manager of the installation or the Production Manager, if necessary.
- Participation in the extension of the scope of certification of Good Manufacturing Practices of the Clean Room to new projects, as well as in the monitoring of the Quality Management System and in the improvement of processes.
- Participation in the design and commissioning of the new Clean Room..
- Conducting internal audits of compliance with NCF-MTA Regulations. Assist the inspection authorities in the exercise of their functions and be the interlocutor, per part of the IR-HSCSP, before the competent health authorities.
- Economic management of the Clean Room.
- Identification, analysis and development of new project opportunities.

Offered

- Indefinite Contract
- Annual workday of 1.627,50 hours (37,5 hours/week)
- Remuneration according to agreement and experience of the Candidate.
- Category T5, Head of Area.

Documentation and deadline for submission

Interested parties should preferably deliver the documentation (1) in PDF, by e-mail to the Management of the Fundació Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau, address ir_recursohumans@santpau.cat , indicating the reference **2022/064.**:

(1) Application letter and updated Curriculum Vitae

At the request of the Fundació Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau, 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.

The Fundació Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau 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 Fundació Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau.

**The deadline for submitting applications
will end on May 16, 2022, 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, 02/05/2022



Human Resources Departament

Fundació Institut de Recerca de l'Hospital de Sant Pau

