Creatio | Production and validation center of advanced therapies UNIVERSITAT DE BARCELONA

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Open position for: **Advance Therapies production facility**

TITLE: Quality Control manager

Ref: CRE22-01 **Call closes on**: January 23th, 2022

ACCOUNTABLE TO: Dr. Josep M Canals

CONTRACT: Quality Control manager position at the University of Barcelona/Fundació Bosch i Gimpera

Job Summary

The Quality Control Manager position is available in the Area for Clinical Production of the Production and Validation Center of Advanced Therapies (Creatio). The position involves the tasks of the responsible for the Quality Control of production of Advanced Therapy Medicinal Products (ATMPs) for all medical disciplines.

The Area for Clinical Production is involved in the following processes:

- Cell-based therapeutic products, including cell vaccines.
- Gene therapy products and lentiviral production in our GMP facility.
- Tissue engineering products and production of artificial scaffolds.
- Human cell production for research, drug screening and toxicological studies.
- GMP and UNE-EN-ISO:9001 protocols, AEMPS certifications.

This work will be performed at the **Creatio's Clinical Area** in close contact with the laboratory of **Stem Cell and Regenerative Medicine** at the Department of Biomedical Sciences at the Faculty of Medicine and Heath Sciences, University of Barcelona. Creatio is integrated in the Spanish network of neurodegenerative disorders (CIBERNED) and the Spanish Advance Therapies network (RICORDS; TERAV). These two networks provide a collaborative environment to successfully achieve our objectives.

Main Duties

Quality Control Manager in the Area for Clinical Production of the Production and Validation Center of Advanced Therapies (Creatio), develop appropriate protocols for quality control, perform/supervise quality control tests for the clinical productions and product release.

Requirements

Applicants are required to hold a biomedical degree, with background experience in GMP and UNE-EN-ISO:9001, and Quality Systems.

- Experience in Quality Control procedures
- Ability to work with other team members.
- Organized, methodical, proactive and motivated.
- Experience in ATMP production such as cell culture, molecular biology and virus production.

Expression of interest

People interested in this position should send a CV and presentation letter to: Felipe Chiappe, e-mail: felipe.chiappe@ub.edu and Dr. Josep M Canals, e-mail: jmcanals@ub.edu

With the support of: ACCIÓ Generalitat de Catalunya

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ABOUT CREATIO

Creatio is the Production and Validation Center of Advanced Therapies at the Faculty of Medicine of the University of Barcelona. Our mission is to deliver solutions based on advanced therapies with the goal of increasing the efficiency of the sanitary system and the quality of life of society. Creatio is a center of excellence that is technologically specialized in advanced therapies. Creatio has an experienced multidisciplinary team with great experience in Advanced Therapies that work under high quality standards. We establish strategic alliances with companies, research centers and hospitals to develop new projects and/or products in this innovative medical field.

SERVICES

1. Production of Advanced Therapies for Clinical Use

Creatio produces medicines for advanced therapies (ATMPs) for clinical investigation under a high standard of quality according to Good Manufacturing Practice (GMP) requirements (both EMA/FDA).

Creatio supports all aspects of production and testing of clinical material under current GMP guidelines. We ensure that all projects are **compliant with applicable GMP guidelines and/or UNE-EN-ISO 9001**, and the Creatio Quality System.

The Creatio Quality System **provides comprehensive documentation of policies and procedures** that cover all aspects of facility operation, manufacturing, and quality control testing.

The resulting manufacturing batch records and associated documents provide **full traceability and records** that are critical in demonstrating GMP compliance and **supporting Investigation New Drug (IND) and Investigation Device Exemption (IDE) applications**.

2. Process and Documents Development

Creatio develops protocols and all necessary documents for production under GMP conditions: Standard operating procedures, *specification of sources, intermediary and final product*, production guidelines and validation protocols amongst others.

- **Legal documentation development** - Development of protocols for the production of ATMPs for clinical application, including gene therapy, cell culture and cryoprotection of stem cells, and tissue engineering with natural or artificial scaffolds.
- **Process Development** - Full support for clinical process development. We have expertise in clinical trials involving cell culture and cryoprotection, cellular vaccines, lentiviral production for *ex vivo* gene therapy, and *in vitro* manufactured tissues.
- **Quality Control** - Comprehensive product testing and analytical methods development/qualification/validation to support process development and cGMP release testing.
- **Quality Assurance** - Review of GMP batch records and release, full quality system support, and vendor audit support.

3. Scientific & Technical Advice and Training

Expert advice in the development of new activities and processes in the fields of advanced therapies, preclinical and clinical tests, compliance with the standards of GMP and UNE-EN-ISO 9001, as well as its implementation and monitoring.

Creatio specialists will train your technical team involved in the production process under compliance of GMP rules wherever necessary.

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4.

Creatio can facilitate and accelerate your preclinical research. We have a team of experts to develop in vitro and in vivo models using a broad range of rodent and human cell lines and animal models.

The Creatio research team has various cell culture platforms available to test your **new drugs and to validate research hypotheses**. We have experience in testing efficacy of drugs based on animal models and human cells for neurodegenerative disorders:

- Processing of tissue and isolation of primary human cells.
- Culturing and differentiation of pluripotent and somatic human stem cells.
- High throughput screening for immunohistochemistry and gene expression.
- Brain-on-chip systems.
- Gene therapy *in vivo* and *ex vivo.*
- Pharmacological and genetic mouse models of neurodegenerative diseases.
- Cell transplants; chimeric human/mouse models.
- Motor and cognitive behavior platforms.
- Neuroimaging for animal models.

All our activities and processes are performed according to high quality standards under compliance of ISO 9001:2015 rules.

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