

Químic - Tissue Operations Expert

Escrito por Novartis

Sábado, 03 de Marzo de 2018 17:00 -

Tissue Operations Expert BARCELONA (BARCELONA) Empresa: Novartis Descripción: Responsibility for ensuring high quality consistent supply of human cells & tissues (HCT) intended for use as manufacturing starting material in GMP manufacturing of cell therapy products through selection, approval, initiation, and monitoring of hospitals/sites that will collect and process HCT. Verify sites comply with applicable regulations / accreditations, and ensure HCT capabilities and capacity. ? Ensure business and quality agreements are implemented and maintained. ? Lead onboarding of sites, with accountability as the primary technical operations point of contact, ensuring ongoing operations are according to Novartis requirements: o Maintain clear technical/operational requirements (i.e. specifications, manuals, SOPs) o Training of sites to Novartis requirements o Coordinate internally for site quality assessments, audits, inspections, and perform operations performance reviews (i.e. collecting data on trends, KPI, and driving continuous improvement) o Key point of contact externally for all technical questions on apheresis and cryopreservation o Management of change control, deviations, investigations, and CAPA. Within the organization: ? Support implementation and maintenance of local SOPs. ? Ensure management is kept informed of all critical and major issues. ? Ensure coordinated contact and collaboration is maintained with other functions (e.g. QA, Clinical, Sourcing, Legal, Supply Chain, Regulatory, Manufacturing Operations). ? Coordinate with other field personnel on ongoing site needs. Personal development and People development ? Maintain current knowledge of regulatory requirements for HCT ? Maintain knowledge of latest collection and preservation techniques Minimum requirements Education: University degree with an advanced degree in science preferred (e.g., MS, PhD., Pharm. D., MD, RN) Languages: English required 10+ years of GxP pharmaceutical experience or at least 5 years pharmaceutical experience and experience in GTP ? Wo Relació laboral: LABORAL INDIFERENT Nombre Hores: 0 Salari mensual des de: 0 Salari mensual fins a: 004/03/2018

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