Roslin CT
your advanced therapy solution

– GENERAL INFORMATION –

Company Trading Name	RoslinCT
Company Registered Name	Roslin Cell Therapies Ltd
Originally Founded	2006
Registered Address/HQ	NINE Edinburgh BioQuarter 9 Little France Road Edinburgh, UK EH16 4UX

GMP Facility Location	GMP Manufacturing Facility Scottish Centre for Regenerative Medicine 5 Little France Drive Edinburgh, UK, EH16 4UU
GMP Manufacturing and Storage Facility Specifications	Approximately 250m^2 clean room space (3 clean rooms); QC laboratory suites; technology transfer suite; raw material and final product storage
Process Development Suites	200m^2 laboratory suite dedicated to process development and analytical assay development
Team	Approximately 40 employees Range of experience across all aspects of process development, manufacturing, quality control, quality assurance, supply chain management and project management
Key Departments	GMP Process Development, GMP Manufacturing, Quality Control & Quality Assurance
Customer Support & Project Management	Personalised customer service and dedicated project management designed to deliver quality service in budget and on time

– BUSINESS MODEL –

RoslinCT is a UK-based contract manufacturing organisation focused on providing an integrated pipeline of Process Development, GMP manufacturing solutions for companies developing cell-based therapeutics for clinical trials

–LICENCES –

Medicines and Healthcare Products Regulatory Agency	Human Tissue Authority (HTA 22631)	ISO 9001:2015
Manufacturer's and Importer's Authorisation for Investigational Medicinal Products (MIA(IMP) 45803) and a Manufacturer's 'Specials' licence for Advanced Therapy Medicinal Products (ATMP)	For the procurement, testing, processing, storage, distribution and import/export of human tissues and cells intended for human application	

– SERVICES –

Process Development
Gap Analysis
GMP Translation
Process Scale Up and Automation
Analytical Assay Development & Optimisation
Cryoformulation & Cryopreservation Studies
Generation of Test Material for Pre-Clinical Studies

GMP Manufacturing
GMP Technology Transfer
GMP Process Validation
GMP Batch Manufacture for Clinical Trials
Cryoformulation & Cryopreservation
Fill/Finish

Quality Control
Analytical Assay Qualification
In-Process Critical Control Point Testing
Identity, Safety and Final Product Release Testing
Stability Programme Design

Product Storage & Logistics
GMP Cryogenic Storage
Packaging for Temperature Controlled Shipping Validation
Supply Chain Management

Quality & Regulatory
QA Batch Release
QP Batch Certification for Clinical Trials in Europe
Regulatory Support
CMC Support for IMPD and MAA Submission