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Ensuring successful technology transfers for clinical manufacture

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Successful technology transfers can be defined by the ability to provide well documented evidence of the routine manufacture of the therapeutic product using a reproducible manufacturing process and quality control testing regime, measurable against a pre-defined set of specifications. Key to success is the establishment of an effective overarching technology transfer framework at both the transferring and receiving sites, in addition to a full understanding of the process before transfer. In this presentation we present a practical case study on the transfer of a process for production of human embryonic stem cell lines for the manufacture of cell therapy products to treat Parkinson's and Huntington's disease. We will detail the steps involved in the translation of the research protocol through to a fully GMP compliant process. We will highlight the main drivers for success, including the generation of an effective communication strategy and a technology transfer protocol which covers the technical gap analysis, quality risk management, qualification of methods, facilities, equipment, analytical assays and regulatory strategy. We explore the key stages of the process and its challenges and discuss mechanisms to ensure that the transfer is successful.

Biography

Janet Downie is the Chief Executive Officer for Roslin Cell Therapies, a leading cell therapy contract manufacturer and process development company based in Edinburgh. She has completed her BSc in Biological Sciences with over 20 years' experience within the life sciences industry in Scotland with many years' experience in cell therapy manufacturing and GMP translation. She was previously worked as Chief Operating Officer for Roslin Cells where she spent 8 years setting up and developing the cell therapy division before the Roslin Cell Therapies subsidiary was formed to enable investment and company growth. She is the Human Tissue Authority, Designated Individual and MHRA License Holder for the Roslin Cells GMP Cellular Therapy Facility within the Scottish Centre for Regenerative Medicine. She is a Member of the BIA Manufacturing Advisory Committee and the Research Quality Assurance (RQA) GMP Committee.

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