



Dr. Tim Farries

Director, Regulatory Affairs, Cell & Gene Therapies, ERA Consulting

Tim Farries is an expert in the development of Cell and Gene Therapy products with over 16 years commercial experience spanning employment in biotech and big pharma companies. Since 2013 he has been Director of Regulatory Affairs – Gene & Cell Therapies at ERA Consulting (UK) Ltd., where he heads a team of consultants focused on CMC regulatory, non-clinical and development matters for complex biological, cell & gene therapy therapeutics. This team supports cutting edge programs throughout the regulatory process (covering EU, US and Japan), including cellular immunotherapies, genome editing, and iPSC-derived products, and notably was pivotal for the first marketing authorization ever achieved in the EU for a product containing stem cells. Tim was previously responsible for managing regulatory, development and manufacturing aspects of the gene therapy development program of Ark Therapeutics Ltd., including liaising with EMA, FDA and other national regulatory authorities, and compiling CMC, non-clinical and environmental risk assessment documentation for marketing authorization applications. He has also held roles in management of advanced biotechnology programs at Gendaq Limited (acquired by Sangamo Biosciences) and Novartis Pharma, and holds a Ph.D. from Cambridge University.