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Guideline on the quality, non-clinical and clinical ...
O'Bryan has more than 25 years of regulatory experience including biologics, gene therapy and medical devices, most recently serving as Vice President of Regulatory Affairs and Quality Assurance at Lysogene where he led all aspects of global regulatory affairs.

About | SIO Gene Therapies
The FDA has recently published a draft guidance on interpreting the sameness of gene therapies under the orphan drug regulations (FDA 2020a), and several guidance documents specific to gene therapies in regards to Chemistry, Manufacturing, and Control (CMC) aspects relevant to gene therapies (FDA 2020b, f) and for various clinical indications such as hemophilia (FDA 2020c), retinal disorders ...

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1. Methods Mol Biol. 2009;542:397-421. Regulatory aspects for translating gene therapy research into the clinic. Laurencot CM(1), Ruppel S. Author information: (1)Surgery Branch, Center for Cancer Research, National Cancer Institute, National Institutes of Health, Bethesda, MD, USA. Gene therapy products are highly regulated, therefore moving a promising candidate from the laboratory into the ...

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Gene therapy (also called human gene transfer) is a medical field which focuses on the utilization of the therapeutic delivery of nucleic acids into a patient's cells as a drug to treat disease. The first attempt at modifying human DNA was performed in 1980 by Martin Cline, but the first successful nuclear gene transfer in humans, approved by the National Institutes of Health, was performed in ...

Gene therapy - Wikipedia
The European Medicines Agency's scientific guidelines on gene therapy help medicine developers prepare marketing authorisation applications for human medicines. For a complete list of scientific guidelines currently open for consultation, see Public consultations .

Multidisciplinary: gene therapy | European Medicines Agency
Comparison of regulatory stance for genome-editing products for gene therapy ... Guideline on the quality, nonclinical and clinical aspects of gene therapy medicinal products (2018.3) Guidelines for Gene Therapy Clinical Research (2019, 2) Long-Term Follow-Up After Administration of Human Gene Therapy Products (Draft, 2020.1)

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