Developing a Product for Clinical Use Is Not Only About the Cool Science

Research to develop products intended for clinical use is exciting and challenging, but it is only the beginning. Clinical product development and use requires quality systems, coordinated management, regulatory knowledge, trained personnel, cost of goods, raw materials sourcing, manufacturing, testing, stability, packaging, logistics and storage. These elements for optimizing commercialization to use should be integrated into scientists' training and thinking from the beginning—not considered as secondary elements. Intellectual property, funding, contracting, collaborations and partnering are on-going considerations.

Mary Pat Moyer, PhD, CTBS Founder, CEO, and Chief Science Officer, INCELL