

Jeffrey C. Baker, PhD

Deputy Director of the Office of Biotechnology Products in the Center for Drug Evaluation and Research at the FDA (retired in April 2021)

Senior Fellow in the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)

Title

Impact of the Global Pandemic on Bioprocess Manufacturing: Regulation, Resilience, and the Nature of Rubber Bands

Abstract

The biopharmaceutical community's global pandemic response has in largest part been one of unprecedented cooperation in patient centered, risk-based decision making in the context of strained supply chains and profoundly disrupted business practices. As we move forward, it may be worth asking whether elements of crisis management are assuming the role of precedent and whether they anticipate (should anticipate?) changes to policy and practice. This talk will address strains upon our regulatory and quality management systems and ask whether pre-pandemic principles of practice are resilient to many months of repeated exceptions and whether these exceptions are a de facto basis for a new normal.