The US FDA Modernization ACT 2.0 was signed into law in December 2022 with overwhelming bipartisan support in Congress. Passage of the act resulted in numerous popular news articles suggesting that animal testing is no longer required for new drugs. In reality, the law recognizes the many non-animal methods for novel drug assessment that may be used concertedly with animal testing and provides researchers the opportunity to use the most rigorous scientific methods available to bring safe and effective treatments to patients. In this session, the FDA Modernization Act 2.0 and its impacts on drug development will be outlined and approaches for reducing animal testing, such as virtual control groups, in vitro modeling systems, and new approach methodologies, will be discussed.

Co-Chairs: Alycia Fratzke, DVM, PhD, DACVP, Charles River Laboratories and Leah Schutt, DVM, PhD, DACVP, Genentech

1:30 PM–1:35 PM  Introduction

1:35 PM–2:10 PM  Overview of the US FDA Modernization Act 2.0 and Beyond: Intentions and Implementation
Jacob McDonald, PhD, ATS, Envol Biomedical

2:10 PM–2:45 PM  Virtual Control Groups: Too Good to be True or Triple Threat?
Lila Ramaiah, DVM, PhD, DACVP, Janssen Research & Development, LLC

2:45 PM–3:15 PM  Break

3:15 PM–3:50 PM  New Approach Methodologies (NAMs): Role of Pathologists
Radhakrishna Sura, DVM, MS, PhD, DACVP, Gilead Sciences, Inc.

3:50 PM–4:25 PM  Tox21 Program
David Reif, PhD, NIEHS/NTP

4:25 PM–5:00 PM  Q&A