## **BioReliance**®

Pharma & Biopharma Manufacturing & Testing Services





# Roadmap to success

#### **Provise™ Viral Clearance Services**

Accessibility and availability of viral clearance services is critical when it comes to on-time filing with regulators. Finding a partner with the capacity to meet your needs in a timely fashion and superior quality can be a challenge.

#### The Evolution of Demand

Demand for Provise<sup>™</sup> Clearance increased during the pandemic due to travel restrictions. From study design and tech transfer all the way through to support with regulatory questions, Provise<sup>™</sup> Clearance offers:

- Ability to focus on high value-added activities at your own facility
- · Reduced risk: No need to stock virus in-house
- Cost savings including travel expenses

#### **Our experience:**

- Monoclonal antibodies
- Recombinant proteins
- Novel and biosimilar products
- Vaccines
- Gene therapy vectors

## Team of expert scientists trained in:

- Virus reduction filtration
- Column chromatography
- Ethanol fractionation
- Viral inactivation by treatment with solvent/detergent and extreme pH
- Column re-use studies





### Trust Provise™ Clearance Services

We do it for you, keeping you informed along the way



Discuss your clearance needs with an expert partner you can trust?

SigmaAldrich.com/provise

#### **Understanding Your Molecule**

Our Provise™ Clearance Services offer a team of expert process scientists with years of experience in viral clearance studies who work with you to design your IND- and BLA-enabling studies to assess your manufacturing's ability to remove or inactivate viruses.

Most importantly you will develop a close relationship with your dedicated team of experts, who will be in regular communication to keep you informed of your study's progress along the way.

Collaboration sessions include among others:

- · Technical discussions to understand every detail of your process
- · Advice on study design
- Preparing workbooks, SOWs and study designs
- Updates from your study including: Cytotoxicity, mock runs, and process steps

When the study is complete, you will receive a final report and support through your regulatory journey.

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The cover image was produced before the Covid19 crisis started. We take our responsibility seriously and fully comply with all protection rules.

