

Viral Clearance Services

*Unsurpassed experience, science
and compliance*





What We Do

BioReliance has conducted thousands of Clearance studies for clients around the globe. These studies are required by regulatory authorities to assess the ability of a manufacturing or cleaning process to produce a product that is safe for use in humans.

Manufacturers of biologics, such as blood products, monoclonal antibodies, recombinant proteins, tissue derived products, inactivated/subunit vaccines, and some medical devices, are required to evaluate their downstream manufacturing process for the ability to inactivate or remove potential contaminants.

In addition to downstream process validation services, BioReliance also offers also cleaning validation services and validation of processes for inactivation of potential contaminants in raw materials.

Example of our capabilities:

- Viral clearance (virus validation) studies
- Transmissible spongiform encephalopathy (TSE) clearance studies
 - Western blot assay
 - Bioassay
- Mycoplasma clearance studies
- Bacterial clearance studies
- DNA clearance studies
- Cleaning validation studies
- Disinfection efficacy studies
- Facility disinfection programs

BioReliance has performed studies on the widest range of biological therapeutic types and process steps. Our experience allows us to advise our clients on designing the most appropriate study to ensure regulatory compliance.

Experience Matters

For viral clearance studies, BioReliance's experience is unsurpassed.

- Over 12,000 studies performed
- Scientific staff has over 300 years of direct experience designing and performing studies
- Scientists and associates each have an average of 8 years of viral clearance experience
- 70% of scientific staff have advanced degrees in the life sciences
- Dedicated Project Management team
- Local language support

We have a database of several thousand studies to draw from, allowing us to provide our clients unrivalled process information on which to base downstream study design decisions. Our Process experts have unique and extensive industry experience which allows us to provide expert advice to our clients.

With the highest quality data and the deepest experience in the industry – BioReliance is the clear choice to perform your critical study.

Quality You Can Rely On

We continually strive to provide the highest quality service for our clients. Our viral clearance studies are conducted according to ICH Q5A Guidelines and other appropriate international regulatory standards. Our Quality and Regulatory Affairs experts continually update our standard procedures to ensure compliance.

In addition, BioReliance utilizes advanced Quality systems and in-process auditing of studies to ensure the reliability of results. We have been successfully audited by the FDA, EMA and other government regulatory authorities. Finally, we host hundreds of client audits per year.

Our Quality is based on over 30 years of experience in biologic manufacturing process safety testing. You can rely on us to provide the critical data you need to advance your product development.



UK Facility - Stirling, Scotland

BioReliance's facility in Stirling, Scotland has been serving the Viral Clearance market since 1991 and has a highly experienced and long serving team, several of whom have been in the field since its time of origin. Our Clearance Services laboratories are completely refurbished and have ample capacity. In addition, we have invested in state-of-the-art equipment, which together with a modular lab design, provides the maximum flexibility to successfully conduct your study.

BioReliance is a leader in the field of Biologics Safety testing, and globally, has been conducting viral clearance studies for clients since 1984. Many biotech products such as plasma derivatives, monoclonal antibodies, recombinant proteins and medical devices that have been licensed around the world relied upon data generated at BioReliance.

The Clearance Services group at our facility in Stirling, Scotland has performed over 6,000 clearance studies including virus, TSE, bacteria, mycoplasma and DNA clearance. This extensive experience helps us to design the most successful studies for our clients. We have performed both virus and TSE clearance studies on a wide range of different products and different process steps allowing us to advise our clients on optimal study design and on the most appropriate process steps to validate.

Features include:

- Dedicated process staff
- HDMI access point for guest presentations
- Modular lab configuration
- Full IT support
- Dedicated client lounges with coffee making facilities and refrigerators

Our goal is to give our clients maximum flexibility by offering the bespoke solutions required for clearance studies. The UK facility offers a full range of ÄKTA™ systems, including ÄKTApurifier™, UPC-10, ÄKTAexplorer™ and Avant and Pure units. These systems are modular and therefore easy to adapt for every study we perform.



US Facility - Rockville, MD

BioReliance opened a new, custom designed Clearance Services Facility on August 1, 2013 at BioReliance's Rockville location. This investment reaffirms our commitment to enhancing the client experience and providing a 'total solutions' service offering. During the design phase, consideration was given to the direct feedback received from our clients, enabling BioReliance to incorporate many features which enhance the overall experience. The new location is five minutes from our main offices and is situated within walking distance of hotels, shops and restaurants.

Modular design is the key feature of our new facility. This provides 100% functionality and flexible lab layouts tailored to each individual client's requirements. This has also enabled introduction of our new 'SmartLab' concept - where technology and lab design has been integrated to increase capacity and workflow efficiency.

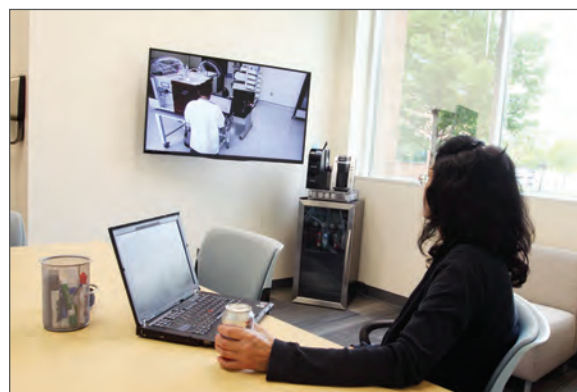
Features include:

- Modular lab configurations available, based on client specifications
- Ceiling panels with power & data for 360° access to modular equipment where required
- Dedicated client lounges with secure touch screen technology for lounge-to-lab monitoring
- Smart TV technology with end user capability to connect to smart devices
- HDMI or VGA access point for ease of guest presentations
- Remote ÄKTA™ monitoring from the lounges (concurrent quad screen format on single display)

BioReliance has also invested in ÄKTA™ Avant systems to provide our clients with the most up-to-date platforms for their studies.

The benefits of our novel facility design also extend to our Complete Clearance offering where SmartLab technology allows clients to remotely access their data.

Coupled with our high quality team of scientists, extensive experience with a diverse product base for global regulatory submissions, and the redundancy provided by our recently re-designed UK Clearance facility, BioReliance provides the most advanced Clearance service offering within the industry.



BioPure Virus™

BioReliance offers two grades of virus spikes for use in viral clearance studies. Our standard, purified virus – BioPure Virus™ - is the benchmark that has been used industry wide for over 25 years. Our BioPure Virus stocks are available for approximately 30 virus types, at >7log titre. We have been producing all our virus stocks in serum-free conditions for over 20 years, using a fully characterized viral banking system. Our BioPure virus stocks are validated, fully characterized and include many virus types not typically available such as Feline calicivirus, West Nile Virus and Avian Leukosis Virus. Our new, highly purified and characterized BioPure Virus™ GOLD is designed specifically for use in nanofiltration studies. BioPure Virus™ GOLD MMV, XMuLV, REO and PPV are available for studies performed in both our US and UK laboratories.

BioReliance excels in bringing new methods and technologies to the marketplace. To demonstrate this, and build on our depth in virology, we now offer Porcine Circovirus (PCV) for use as a model virus in clearance studies. We have designed and validated a PCV infectivity assay to offer as a novel small, single-stranded, non-envelope DNA virus.

Complete Clearance™

Typically, when virus clearance studies are performed, staff from the manufacturer's DSP department work alongside our viral clearance staff to conduct the spiked process runs. Studies have been performed this way to ensure that the process steps perform as expected. This on-site process monitoring may require the manufacturer to have staff at BioReliance for 1–2 weeks, leading to an impact on their own internal R&D or manufacturing schedules. The costs for flights and accommodation while at our facilities also need to be considered. As an alternative, BioReliance offers Complete Clearance™ service, where our highly experienced process scientists will perform all process steps on behalf of the client. These include inactivation, filtration and chromatography studies. Data generated during these studies can be monitored by the client in 'real-time' from their own facilities to ensure successful study performance.



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