Transforming lives through science, innovation and collaboration

Supporting the delivery of innovative life-changing treatments to patients

Cell and gene therapy services

Who we are

We are RSSL

We're a cutting-edge Contract Research Organisation, pushing the boundaries of science and innovation to support our clients developing life-changing treatments for patients. Our clients trust us to deliver innovative solutions to real-world problems facing the global life sciences, pharmaceutical, healthcare and personal care sectors.

From our state-of-the-art facilities in Reading, UK, our multi-disciplinary team works hand-in-hand with our clients to develop drug products that are safe, innovative and capable of transforming lives around the world. We offer a diverse range of biological, microbiological, chemical and physical analytical services and bespoke training and consultancy to deliver tailored solutions.

More than

30 years of analytical excellence

More than

200 dedicated staff

8 State-of-the-art laboratories

MHRA and FDA-approved facilities

Over 700 delegates trained in 2021

Who we are

Your analytical and regulatory partner

The world of medicine is changing. Recent developments in the field of Advanced Therapy Medicinal Products (ATMPs) have led to innovative treatments for a variety of often life-limiting diseases, ranging from cancer to genetic disorders.

However, with change comes uncertainty. From the complexity of cell and gene therapies, the lack of single, all-purpose analytical solutions and the unique, rapidly evolving regulatory environment, developers and manufacturers can find this a challenging landscape to navigate, impeding the rapid development of promising therapeutics.

We're here to help you navigate the scientific, technical and regulatory roadblocks to support the delivery of next-generation biotherapeutics. With more than 30 years of experience of pharmaceutical analysis and cutting-edge laboratory services, we have the insight, experience and capabilities to support you at every stage of the cell and gene therapy development and manufacturing process.

WATCH OUR CELL AND GENE THERAPY SERVICES VIDEO

'With highly experienced multi-disciplinary teams and state-of-the-art technologies, we can support every stage of your drug product lifecycle.'

Who we are

Intelligent collaboration

‘We’re proud of our work and the role we play in helping our clients deliver innovative life changing treatments to patients.’

Our key service areas

Raw materials testing

Application of pharmacopeial monographs and bespoke testing methods for raw material characterisation.

Biosafety testing

Comprehensive sterility and safety testing for product and process-related impurities.

Product characterisation

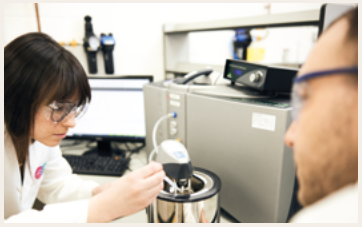
Combination of classic biopharmaceutical and cell and gene therapy-specific testing capabilities to help accurately characterise ATMPs.

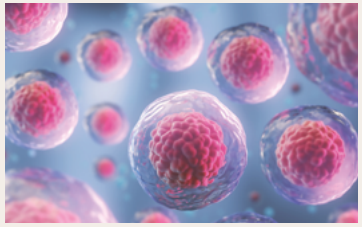
Stability testing and storage

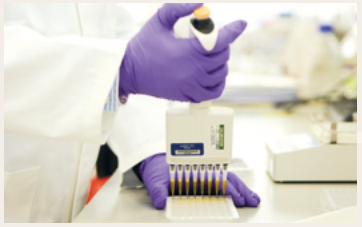
Sub-zero storage capabilities and subsequent analytical testing to assess changes to product safety, efficacy and quality.

Regulatory and training support

Expert consultancy and accessible training services for developing skills and addressing regulatory challenges.







Service areas

Raw material testing

Our testing services combine highly experienced chemists and biochemists with our strict GMP quality systems so you can have complete confidence in all the pharmacopeial, complex and biological raw materials used in clinical and commercial cell and gene therapy products.

We have in-depth knowledge of current monograph requirements as well as extensive experience of chromatography and other wet chemistry techniques. This enables us to develop bespoke, cost-effective and regulatory-compliant methodologies to meet your project's unique raw material testing requirements.

RSSL in action

A client approached us in June 2020 to conduct raw material characterisation and prepare a dossier submission to help progress their promising ATMP to clinical trials.

Over a period of eight months, using a wide range of analytical techniques and leveraging our extensive experience of biopharmaceutical testing, we rapidly developed 69 testing methods which helped progress the therapeutic to a pivotal clinical trial. The next step will be a larger study ahead of regulatory approval and future commercialisation to transform the lives of patients.

READ MORE ABOUT THIS PROJECT

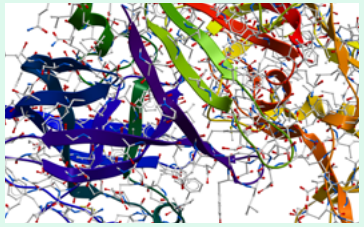
Service areas

Raw material testing

SAMPLE TYPE	TESTING REQUIRED	TECHNIQUE
Serum	ID	SDS-PAGE/Western blot. CE-SDS for protein profiling can be implemented if available sample volume is restricted
Serum free cell culture media		
Defined protein components	ID and/or Quantitative	ELISA
	Functionality	Bioassays Flow cytometry bespoke ELISA
	ID and characterisation	HPLC – Mass spectrometry
		HPLC – Protein
		HPLC – N-linked Oligosaccharides, following release using PNGase F
	Microbiological assays	Sterility, Bioburden, Endotoxin, and microbiological testing
Buffers	Presence/absence of: Sugars Vitamins Amino acids Other chemically synthesised small molecules Ions	HPLC – Small molecule Coupled to UV, fluorescence, CAD, ELSD, PED/PAD, MS) or combinations of detectors
	Ions or heavy metals	ICP-MS
	Microbiological assays	Sterility, Bioburden and microbiological testing
Defined nucleic acid targets	ID and/or Quantitative	qPCR







Service areas

Biosafety testing

Sterility

Maintaining the sterility of therapeutic products throughout their development and the manufacturing is a vital regulatory requirement and essential to protect patient health.

With our standardised and bespoke sterility testing methods, conducted in our purpose-built cleanroom, you can be completely confident in the sterility of your terminally sterilised or aseptic products.

24/7 Emergency Response Service

When something goes wrong, be it contamination or identification of foreign materials, it's crucial you act quickly to identify and resolve the problem. Our 24/7 Emergency Response Service provides rapid, rigorous analytical services, giving you access to round-the-clock dedicated technical support, to minimise the impact, protect your reputation and safeguard patients.

Service areas

Biosafety testing

Product and process-related impurities

Biological impurities	Our cell and gene therapy testing service provides solutions for a variety of potentially harmful biological impurities, including host cell proteins, residual DNA, and full and empty capsid ratio.
Biosafety	We not only test for sterility but also bioburden, endotoxin, cleaning validation and replication competency (subject to risk assessment)
Environmental monitoring	We offer comprehensive consultancy and on-site testing for environmental monitoring of manufacturing facilities. This includes air, surface and water testing, in addition to a cleaning validation service for equipment used in manufacturing processes.
Packaging and pathways analysis	We can conduct a full complement of extractables and leachable studies on all liquid-handling system components to identify any substances that may affect the efficacy or safety of your therapeutic product.
Subvisible particles	Our highly skilled microscopy team can detect and quantify sub-visible particles. We can also use complementary techniques, including Fourier transform infrared (FT-IR) spectroscopy and X-ray microanalysis, to identify particles and determine their source.

Services areas

Product specific characterisation

Our state-of-the-art equipment capabilities are being constantly updated to keep pace with fast-moving advances in cell and gene therapy. This constant evolution, combined with our highly skilled and experienced team, means we can offer a comprehensive range of testing for ATMP identity, potency and purity to enable accurate product-specific characterisation.

In addition to classic biopharmaceutical analyses, we also offer more complex testing, including full/empty capsid ratio analysis, capsid protein characterisation, tissue-tropism testing, viral genome analysis and more. As a part of these services, we can design bespoke combinations of tests, tailored to your specific project requirements.

Service areas

Stability storage and testing

Cold chain storage is an essential component of any cell and gene therapy project. It's vital to get it right at every stage – freezing, storage and thawing – to ensure product quality.

We offer secure, fully validated sub-zero storage facilities which are 21CFR-compliant and monitored 24 hours a day, with a dedicated out of hours response team on call in case of emergency.

Following storage, we conduct a full complement of tests, including cell-based assays and sterility tests, to assess any changes to quality, efficacy and safety so you can be confident of ICH-compliance and the product's safe onward delivery to patients.

Our stability storage conditions

-80˚C and -20˚C

5˚C

25˚C/60%RH

30˚C/65%RH

30˚C/75%RH and
40˚C/75%RH

Service areas

Additional analytical capabilities

With a comprehensive suite of analytical techniques, we can support every aspect of your R&D programme. With extensive expertise in developing and validating analytical methods, we provide robust and reliable data that you can trust at every stage of the drug product lifecycle.

Techniques available onsite include:

- Chromatography techniques: HPLC, GC, UPLC, IC, GPC/SEC
- Mass spectrometry: GC-MS, LC-MS, LC-TOF, ICP-MS, PTR-MS, GC-GC-TOF
- Elemental analysis: AAS, ICP-OES, XRF
- Spectroscopy: NMR, FT-IR, NIR, UV/Vis, and Colour (both reflectance and transmittance)
- Microscopy: SEM, LM, Confocal scanning laser microscopy, X-ray tomography, Confocal raman microscopy
- Image analysis
- Physical characterisation: DSC, PSD, Rheometers, TGA, DVS, Texture analysers, Zetasizer, XRPD
- Biochemistry: ELISA, PCR, Whole genome sequencing/ NGS, SDS-PAGE, CE

Services areas

Training and consultancy

We believe collaboration is essential to the constant evolution of science, which is why we provide training and consultancy services to help innovative companies navigate the complexities of the cell and gene therapy sector to bring their products to market, fulfil their potential and deliver safe and effective therapeutics to patients.

We offer over 50 training courses, including specific technical training around biologically derived products and ATMPs. To make our courses as accessible as possible, we offer both in-person training sessions and live online sessions through our e-learning platform. Our courses are pitched at different levels and can be customised to your individual requirements.

With a team of expert consultants with a deep knowledge of the ATMP regulatory landscape, we can also provide tailored support to help with regulatory document preparation and clinical trial submission to help you navigate this emerging and fast-evolving industry.

2022 Training course calendar

Download our 2022 interactive course calendar

RSSL in action

When facing a complex and evolving regulatory regime, it makes all the difference to have a team of experts on hand to anticipate any issues, provide insightful advice and resolve any problems. In 2021, we were contacted by a client to develop a long-term plan to train their staff and ensure regulatory compliance. The result? Our client was not only fully compliant but also impressed the MHRA at a recent inspection.

Supporting the delivery of innovative life changing therapies

For more information, please visit
www.rssl.com

Contact us to find out how we can support your cell and gene therapy research and development goals.

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