Biopharmaceutical Services

From concept to market

rssl
science with service

Welcome to RSSL

RSSL provides analytical, investigational, consultancy and training services to clients in the global biopharmaceutical, pharmaceutical and healthcare industries. We help our partners to develop drug products that are safe, innovative and of the highest quality.

Our GMP compliant facilities are located in Europe and with our team of more than 200 dedicated scientists, we ensure that every project is performed with our absolute commitment to outstanding quality, scientific excellence and customer satisfaction.

We offer a large portfolio of biological, microbiological, chemical and physical services to ensure the identity, purity, safety and quality of your biopharmaceutical through the full drug product life cycle.

Quality You Can Trust

Quality is at the heart of everything we do, ensuring you can trust and have confidence in the quality of our science and analytical data. We deliver work of the highest technical standard, supported by an extensive quality system. Our regulatory compliance includes certification by MHRA and inspection by the FDA.

Biological Road Map – from concept to market

The success of your biopharmaceutical product is dependent on it meeting regulatory requirements for safety, efficacy and quality. Our multidisciplinary expertise and extensive portfolio of analytical methods will help you navigate your biopharmaceutical challenges beginning with:

1. Raw materials testing

Where analysis is needed for QC testing of raw materials for batch release, the correct methods and latest technologies need to be applied to ensure that your raw materials are suitable for the manufacture of your biologic. Our scientists' have extensive experience of chromatography/wet chemistry techniques and detailed knowledge of monograph requirements.

2. Biopharmaceutical characterisation

Biopharmaceutical characterisation is a regulatory requirement (ICH Q6B) and necessary to gain a full understanding of the biochemical and biophysical attributes of your product. The effects of drug manufacturing processes, purification and storage can affect the final properties of your molecule. A combination of molecular characterisation along with forced degradation studies is used to identify the Critical Quality Attributes (CQA's). Knowledge of the CQA's for a product leads to successful definition of an analytical testing regime for both in-process testing as well as final release testing.

3. Safety testing

Safety testing builds on biopharmaceutical characterisation focussing on product related and process related impurities. We can provide analytical solutions to both host cell DNA and Protein impurity analysis all validated to ICH Q2(R1). In addition we use rapid PCR mycoplasma testing to ensure the integrity of your WCB and offer solutions to demonstrate the removal or reduction of many common process additives listed under the regulatory guidelines. Where necessary we provide expert mass spectroscopy analysis to quantify product related impurities, with product aggregates being assessed by various particle sizing techniques. Our suite of microbiology services will help ensure your product is safe for release. We offer Endotoxin, Bioburden testing and Preservative Efficacy Analysis.

4. ICH Stability testing

Our stability storage and testing services include a range of monitored temperature, humidity and light chambers covering ICH requirements for climatic zones I to IV. In addition we have low temperature storage; -80°C and -20°C. We have expertise in developing and validating stability indicating methods and can support with the production of stability protocols and trending reports.

5. Release testing

Release testing of your finished biopharmaceutical product is important, to ensure the quality control of proteins, monoclonal antibodies (mAbs), antibody drug conjugates (ADC's) or biosimilars. We can supply a range of tests as part of release testing activities to address the purity, potency, concentration, consistency, identity and biosafety of products and have extensive experience in developing, validating or transferring methods.

6. Troubleshooting and contaminant identification

Whether you are facing product contamination issues, the presence of foreign material in a product, manufacturing and process failures, adulteration of raw materials or product development difficulties, we can support you. We investigate structural issues by analysing microstructure and particle size, investigate taints, and help you to solve systems and process problems.

1. Raw materials testing

- Pharmacopoeial testing (EP, USP, BP, CP, JP)
- Ninhydrin-positive substances
- Microbiological analysis including endotoxin analysis
- Method verification
- Chromatography media characterisation
- Protein identification

2. Biopharmaceutical characterisation

Comprehensive range of analysis to ICH Q6B and EMA Guidelines:

- Comparability
- Method development & validation
- Molecular weight or size
- Protein or peptide sequencing
- Post translational modification (PTM)
- Disulfide-mapping
- Forced degradation studies
- Immunochemical properties by ELISA or western blot
- Glycosylation analysis
- Amino acid composition
- Aggregation studies
- Bioassay for potency
- Bioassay for ELISA
- Troubleshooting & investigations

3. Safety testing

- Extractables & leachables
- Microbiological analysis
- Host cell DNA & Protein
- Mycoplasma by PCR
- Container testing (USP & EP)
- Particulate investigations
- Sub-visible particle analysis
- Elemental impurities
- Process & product related impurities

4. ICH stability testing

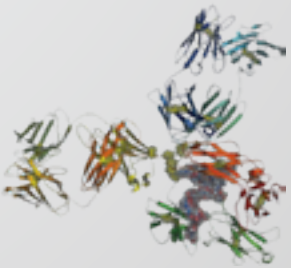
- Formulation support
- Forced degradation studies
- Method development & validation
- Stability storage & testing

5. Release testing

- Peptide mapping
- Protein identification
- Glycosylation (monosaccharide analysis, oligosaccharide profiling, mass spectrometry of glycans)
- Disulfide bonds
- Oxidation and deamidation
- Size exclusion (aggregation analysis), ion exchange, reverse phase chromatography
- Pharmaceutical microbiology including endotoxin analysis
- Sub-visible particle analysis
- Chemical modifications (pegylation, linkers)
- USP 129 and EP 2031
- SDS/IEF PAGE
- Bioassay for potency
- Capillary electrophoresis - cSDS/cIEF
- Multi-Attribute monitoring (MAM)
- Chromatographic purity
- Troubleshooting & investigations

6. Troubleshooting and contaminant identification

- Aggregation
- Foreign body identification
- Counterfeit investigations
- Problem solving & contamination identification
- Impurity isolation and sample purification
- Consultancy
- Training
- 24/7 emergency response service



Additional Support

Consultancy

With access to a large team of industry leading consultants, we are well positioned to help with troubleshooting or continuous improvement. The combination of technical skill, industry knowledge and resourcefulness means you can rely on us to support you in solving problems, either in conjunction with our analytical services or as standalone consultancy.

Training

We have an outstanding reputation as a trusted training provider. Our tutors are all industry specialists bringing current and future thinking to knowledge content. All of our training courses can be tailored and run at a location of your choice.

Popular courses include:

- Biotechnology issues and sterile manufacturing
- Good manufacturing practice
- Qualified person
- Cleaning validation
- Responsible person
- QMS auditor/lead auditor

24/7 Emergency Response Service

In a product contamination situation you need fast, reliable analysis you can trust to make the right decisions to ensure patient safety and to protect your brand and reputation. Our ERS gives you access to a multidisciplinary team of scientists and testing facilities 24 hours a day, 365 days a year.

For further details contact us:

Tel: +44 (0)118 918 4076
Email: enquiries@rssl.com
Web: www.rssl.com

Reading Science Centre , Whiteknights Campus, Pepper Lane, Reading, RG6 6LA