

Services for
the Pharmaceutical,
Biotechnology, Healthcare
and Cosmetic Industries



science with service



Head Office – The Reading Science Centre

About RSSL

Reading Scientific Services Ltd (RSSL) is a specialist scientific consultancy providing cutting edge solutions and answers to your problems.

We provide unrivalled expertise in analysis and training to the global pharmaceutical, biotechnology, healthcare and cosmetics industries to assist clients in developing world-leading brands. We help you to ensure that raw materials and finished products meet legislative and safety requirements thereby achieving your commercial objectives.

We continually invest in technology and people to ensure our business maintains its foundation in scientific excellence. Our multi-disciplinary scientific teams guarantee to meet your needs for rapid results, expert personal interpretation and sound advice to resolve all your product problems/issues. Results are available within minutes of project completion through our Results Online.

As your partner, we have a flexible approach and we strive to understand your needs and issues.

Quality, Health and Safety

As a business we are committed to Quality, Environment, Health & Safety.

We operate within a framework of accredited quality systems, ensuring you can have confidence in the quality of our results. We have gained extensive regulatory compliance, including:

- Medicines and Healthcare Products Regulatory Agency (MHRA) inspected
- UK Good Laboratory Practice Monitoring Authority
- US Food and Drug Administration (FDA) inspected
- United Kingdom Accreditation Service (UKAS) accredited

Our departments can work to the following quality standards:

- cGMP (Current Good Manufacturing Practice)
- GCP (Good Clinical Practice)
- GLP (Good Laboratory Practice)

To demonstrate our commitment for excellence, our management has received Institution of Occupational Safety & Health (IOSH) Leadership training and our scientific team has undertaken Working Safely training.



We also provide services to the food and associated industries



Emergency Response Service

A membership based service which provides you with a range of analytical services for the rapid resolution of your product emergencies.

- Immediate access to emergency analytical services for 'troubleshooting' and product contamination issues
- Multi-disciplinary team of scientists skilled in resolving the widest range of contamination cases
- Simple contact strategy
- Services provided 24 hours a day, 365 days a year (depending upon membership level)
- Priority service for registered clients
- Registration and membership covers all company sites

Analytical Services

A comprehensive range of services which help you develop, manufacture and ensure the integrity of your products from raw materials to market.

Services include:

- Pharmacopoeial testing (EP, USP, BP, JP) of raw materials and finished products
- Sub-visible particle analysis
- Drug release profiling
- Release testing
- Residual solvent analysis
- Analysis of body fluids for drug metabolites
- Dissolution testing
- Cytotoxic and controlled substance analysis
- Development, validation and optimisation of analytical methods





Stability Storage Management

Comprehensive and cost effective stability management services carried out according to cGMP and in line with recommended ICH guidelines.

- Stability chambers are 21CFR compliant
- A full range of storage conditions
- Photostability and other stress conditions
- Protocol preparation
- Development of stability indicating methods
- Method validation
- Partner for disaster recovery plans/overflow



Microbiology

A range of services to monitor the microbiological safety and efficacy of your raw materials and products.

- Harmonised microbial testing for specific pathogens, bacteria, yeast and mould
- Preservative efficacy testing
- Endotoxin testing
- Environmental monitoring
- European suspension tests
- Method development



Biopharmaceutical Analysis

Access to a pool of expertise to develop, interpret and carry out biopharmaceutical testing to support your needs.

- Bioanalytical services
- Immunochemistry validation
- Process and product related impurity analysis

Investigative Analysis

A multi-disciplinary scientific approach ensures we are the specialist investigative laboratory of choice to assist our clients. A range of advanced analytical services available for complex characterization and problem solving to support you in resolving your issues around:

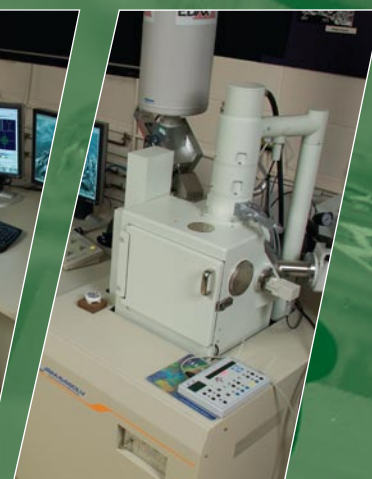
- Accidental or deliberate contamination
- Manufacturing and processing failures
- Counterfeit and adulteration

Extensive knowledge and regular assessment of complex product matrices.



Spectroscopy, Trace Analysis and Analytical techniques are used to provide:

- Expert spectroscopy services including FT-IR, NMR, GC-MS
- Method development using HPLC, GC, LC-MS
- Identification of off-flavours and taints
- Impurity identification in raw materials and finished products
- Identification of process, trace and environmental contaminants
- Screening for toxic materials
- Metals analysis by AA and ICP-MS



Microscopy and Physical Science techniques to assist in:

- Light and scanning electron microscopy
- X-ray microanalysis and x-ray microfluorescence
- Foreign material identification
- Particle sizing morphology, crystal structure and characterisation
- Rheology and texture analysis
- Thermal transition methods (DSC)
- Karl Fisher, water activity and density measurements



Dietary Supplement and Natural Product Testing

Expertise in analysis and method development to assist with claim substantiation, labelling and ingredient stability.

- Expertise includes:
 - Vitamins
 - Natural products
 - Herbal products
 - Functional lipids (omega 3, stanols, sterols, phospholipids)
- Matrix specific method development undertaken



Product and Formulation Services

A highly skilled team can assist you with development of new products and line extensions. Services include:

- Product development and formulation optimisation of OTC pharmaceuticals, dietary supplements and herbal products
- Taste masking and flavour modification
- Dose formats include tablets, powders, granules, liquids and emulsions
- Development of novel concept products

Clinical Sciences

Clinical trials and healthcare studies conducted to the aims and principles of, or full ICH Good Clinical Practice (GCP) to demonstrate the safety, efficacy, acceptability and preference of products.

- Protocol design and development
- Independent Ethics Committee approval
- Single or multi-centre trials
- Dermatological testing to support claims such as 'suitable for sensitive skin', 'hypoallergenic' and 'dermatologically tested'
- Photoreaction testing/sun protection factor testing
- Cognitive performance
- Satiety and health claim studies



Training

A comprehensive and broad based schedule of training courses provided for industry professionals.

- Highly interactive training by industry experienced tutors
- Over 28 different courses available
- Range of topics covered including:
 - Good Manufacturing Practice
 - Stability
 - Good Distribution Practice
 - Pharmaceutical Lead Auditor
 - Internal Auditing
 - Biotechnology
 - Train the Trainer
- Cost effective and tailored in-house and bespoke training offered



Qualified Person (QP) Training

- Recognised by the UK professional assessment bodies
- Short courses of 1 – 2 days duration
- All modules presented in one calendar year
- Stimulating and practical workshops

Consultancy

A range of quality and technical consultancy services available for manufacturing and laboratory operations including:

- Technical support
- Third party quality assurance auditing
- Validation
- Company training management
- Gap analysis
- Remedial auditing
- Pre-regulatory audit support





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