

HEALTHCARE SOLUTIONS FROM LUCIDEON

we'll give you the knowlEdge





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“LOOK AFTER THE HEALTH OF YOUR BUSINESS.”

You're reading this because you want to find out more about how we can help you. We are an international organization, a world leader in materials, product and process testing and analysis, and materials and technology development.

Our services and expertise cover the Medical Device, FMCG and Pharmaceutical industries.

At Lucideon innovation is our driving force. We optimize existing products and processes and develop novel technologies for our partners to turn into the products of the future.

What makes us unique? Our people.

Their expertise, their cross-industry knowledge, their solutions-driven approach, their attention to accuracy and quality, their innovative thinking - it's our people that provide the insights you need for success.

With our support and expertise you can differentiate your products from the competition with advanced quality and performance and with the reassurance that we understand how important regulations and safety are to the health of both your patients and your business.

We call it the knowEdge.

It's what makes Lucideon different, and makes all the difference to you.

LUCIDEON
insight creating advantage



Gemma Budd, Healthcare Business Manager.

This is Lucideon.

We're an international organization, a world leader in materials, product and process testing and analysis, and technology development and commercialization.

Our focus is on problem-solving and innovation.

We test to national and international standards, and also provide bespoke testing programmes.

We constantly invest in our facilities to ensure we offer you cutting edge technology and the latest techniques.

We have state-of-the-art ISO 17025-certified laboratories in the UK and USA, and Lucideon approved laboratories around the world.

In the UK we're a UKAS-accredited testing laboratory (No. 0013), and our pharmaceutical laboratories are accredited to cGMP by MHRA.

In the USA we're accredited by L-A-B.



These are our People.

- Over 200 in our team
- 1 in 8 have PhDs
- In total, they have 2204 years of experience!
- Materials and analytical expertise includes ceramics, glass, metals, polymers, composites, powders, gases and liquids
- Cross-industry knowledge and technology transfer
- Consultative approach
- Innovative thinking
- Right first time
- Accurate
- Quick turnaround
- Always at the end of the phone
- Your partner for testing and development
- We listen!

We help you:

- Understand materials and products through characterization
- Ensure consistent quality and performance
- Comply with regulations
- Understand failures quickly and prevent them reoccurring
- Optimize products and processes
- Develop the technologies of the future.



MEDICAL DEVICES

Safe, robust, optimized. Nobody goes further in healthcare testing.

You want your medical devices and processing routes to be safe, robust and optimized.
And you want to develop the medical materials, devices and technologies of the future.

Our experts will help you to achieve this. We use our materials knowledge and industry experience, backed up by comprehensive analytical and R&D capabilities, to ensure that your products reach the market quickly, keeping you ahead of the competition.



Testing and Analysis

The key to improving performance, developing future products and preventing failures is understanding the materials you use, their macro- and microstructure, surface characteristics and properties, and how they interact with each other and their environment.

We take an integrated approach using these capabilities to give you a complete picture of your material and how it influences product performance...

CHEMICAL

MICROBIOLOGICAL

THERMAL

PHYSICAL

MICROSTRUCTURAL

SURFACE ANALYSIS

Quality Control

At Lucideon we help you to maintain control of material, product and process quality, ensuring performance consistency and the timely resolution of any issues.

- Development of a quality assurance program
- Testing raw materials or materials from new sources
- Batch release testing of your manufactured components
- Validation of in-house quality control protocols.

Cleaning Validation

How clean is clean? We provide development and validation of your cleaning processes and end products for regulatory authorities, including the FDA.

Our proprietary VALIDATA service provides a simple, quantifiable "cleanliness index" so you can compare your product cleanliness either during process development or batch-to-batch.

We use a combination of extraction-based chemistry techniques and surface analysis to identify and quantify residual detergents, lubricants, oils and other contaminants - both those you can take off and those you can't.

In practice...

"I would like to thank all of the team that has worked on this file during the last few months for its great involvement in the project, strong expertise and excellent responsiveness. Your responsiveness to our questions really moved along the review of the file by FDA! It was a challenging key milestone that we have successfully managed thanks to our new partnership."

Valéry Barbour, (former) Quality Assurance Customer Relation Manager, Greatbatch Medical.

Regulatory Submission Support

We provide quality data and technical support with full documentation.

With our expertise you can be confident that your medical device design will be guided to meet the required standards, giving you the best chance to achieve approval on your first submission.

Biocompatibility

We test for biocompatibility to ISO 10993 - an essential requirement for regulatory submission.

- 'Extractables and leachables' method development and testing
- Chemical, physical, morphological and topographical characterization of materials
- Identification and quantification of degradation products including sample preparation
- Benchmark analysis of your product versus a predicate - helping to avoid doing unnecessary in vivo trials.

Ageing Studies

Real-time testing is important, but often inefficient and sometimes impossible.

We develop, conduct and validate both real-time and accelerated ageing studies to understand and predict shelf life and potential failure modes, including developing simulated conditions to allow in vitro studies in early development stages.

Wear and Fatigue Testing

Using gold-standard simulators we provide hip and knee implant wear testing to ISO 14242 and ISO 14243, as well as impingement testing to ASTM F2582-14. We also develop methods for other joints that do not have official standards yet. This adds to our extensive mechanical testing capabilities, including dynamic fatigue.

We'll also help you to further understand the tribological properties of your product through our supporting analytical expertise in surface evaluation, materials characterization, and failure, debris and wear pattern analysis.

In practice...

"We have years of experience in the field. Outsourcing to us avoids overstretching or waiting for internal capacity, reducing delays to new product developments."

Dr Qianqian Wang,
Biomechanical Engineer.

Consultancy

Additive Manufacturing (AM)

It's all anyone's talking about, but there is a long way to go.

From characterizing your starting powders, to examining the microstructure, defects and debris that you generate during your AM process, to designing effective cleaning processes and optimizing the mechanical properties of your AM products – our experts can help.

Powder Processing

We have extensive experience in the fields of glass, ceramic and metal powders, providing consultancy, analysis and materials development.

We optimize products and processes at the front end to deliver maximum yields and the best quality products, by using the appropriate characterization techniques, and our knowledge of how powders behave in different environments.

Failure Analysis

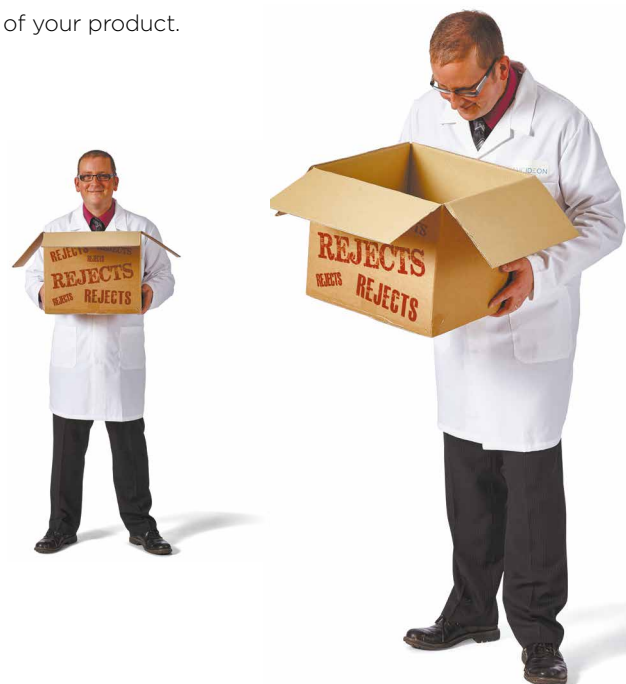
We understand the importance of reducing manufacturing downtime and preventing repeat incidents, so we will work with you to quickly and efficiently resolve and understand failures. We also analyze explants, to find the root cause of failure in-use. We:

- Investigate fracture, fatigue and delamination issues
- Evaluate corrosive failures
- Identify contaminants and their root cause
- Solve manufacturing and processing issues.

Digital Imaging Correlation – 3DStrain

This allows you to image and quantify strain patterns under load without the need to test to failure. Some benefits of the service include the ability to:

- Predict and visualize failure modes e.g. fracture initiation points
- Validate Finite Element Analysis models to expedite product development
- Measure stress/strain on complex geometries – not just rely on unrepresentative test coupons
- Understand the impact of using multiple materials on the mechanical performance of your product.



Pioneering Innovation

At Lucideon we're leading the way in the development of novel materials technologies.

Our innovative products include:

BIOACTIVE GLASSES/CERAMICS

- **mxHA** - multi-substituted hydroxyapatite materials for bone/tooth repair and drug delivery applications with enhanced bioactivity
- **ICRT** - inorganic controlled release technologies for delivery of key actives including drugs and inorganic ions, e.g. Ca, Ag
- **Glass technologies** - manipulation of glasses to deliver tailored chemical and physical properties, e.g. solubility, porosity, strength.

BIORESORBABLE POLYMERS & COMPOSITES

Developing novel polymer chemistries and optimizing processing routes to strike the balance between mechanical strength and biodegradation rate.

TOUGHENED CERAMICS

Using our Field Enhanced Processing technology, we are developing ceramics with improved properties by controlling the microstructure of the materials.

POWDERS CONTROL

Optimization of processes to avoid agglomeration, enable foaming, and create formulations with strong cohesion within a matrix.

ANTIMICROBIAL MATERIALS

Incorporation of antimicrobial ions into the chemistry of our materials, using both polymers and ceramics for easy incorporation into your product.

PILOT SCALE PROCESSING

Development and production of novel materials at the pilot scale to build confidence in the scalability of our technologies.



FMCG

When you carry the burden of proof, we'll help compile all the evidence you need.

You want to ensure that your healthcare and homecare products meet the demands of the consumer market, as well as satisfying regulators.

From shampoos to toothpaste, cleaning products to laundry detergents, we have the experience and creativity to give you the insights you need.

Whether it's developing novel material formulations, proving product claims, optimizing performance, ensuring quality or finding the root causes of failures, our experts can help.



Quality Control Testing

Do you want to:

- Develop a quality assurance program
- Ensure product and material consistency and performance
- Test raw materials or materials from a new supplier
- Satisfy and validate in-house quality control protocols
- Receive regulatory approval
- Review your testing regimes and close any gaps for regulatory approval.

We provide high quality, reliable, fast and cost effective testing to meet your needs.



Packaging Failure Analysis

When packaging fails, the cost, in terms of time, money and consumer confidence, can be disastrous. With the high volume of products you make, it is essential you understand what has caused failure so you can implement a preventative solution.

From migration of actives between packaging and product, delamination, material integrity and storage concerns to compatibility of different components - we can help.

Method Development

Rarely are standard test methods available, so our experience can help you differentiate by making sure you get the right data.

We combine our expertise in analytical science with a sound understanding of what you are trying to achieve, to develop your solution.

Case Studies

Simulated contamination and mechanical stresses faced by denture pastes, to enable evaluation of the bond strength and quality of the "seal" between the denture and gum.

Simulated soap scum and artificially contaminated typical dishwasher surfaces, replicated dishwasher conditions with different treatments, and assessed the resulting cleanliness of the surface.

Tracked the penetration of actives into hair and measured the extent of deposition and penetration into the fibre, overcoming the obstacle of distinguishing "old from new".

Designed a dentine/enamel mimic to overcome the issue of dentine variability, developed a method of cycling the pH and other aspects of the environment, and assessed the extent of erosion on the surface following different treatments.

Product Claim Support

If you're a consumer healthcare manufacturer or supplier, it is important to instill consumer confidence in your brand and products, as well as satisfying the regulators that you can scientifically substantiate your claims. With independent testing from Lucideon, that's exactly what you get.

From shampoos to antimicrobial coatings, Lucideon's independent testing helps to support your claims, thereby giving you a competitive edge.

We offer:

- Development of in vitro models to quickly screen new products before taking them to clinical trials
- Expert testing and analysis to help you gain insights into your product's properties
- 3D imaging of your product at work - a strong marketing tool for packaging and advertising
- Quantitative, scientifically-credible results for product claims.

Examples of past projects:

- **Toothpaste:** visualizing and quantifying the extent of remineralization of tooth enamel after treatment
- **Toothpaste:** visualizing and quantifying the penetration of whitening agents into the teeth, and their residence time
- **Hair conditioner:** chemically mapping the distribution of actives on the individual hair fibers at different regions and under different conditions
- **Hair conditioner:** confirming the presence of species that are similar in composition to the hair and imaging the penetration of those actives into the hair fibers by cross section
- **Skin care:** quantifying and imaging the effect of treatments on the smoothness of skin before and after shaving.



New product development

With our technologies you can differentiate and improve your offering and bring novel products to the market.

We optimize consumer products by:

- Adding or improving optical features e.g. color, refractive index
- Transforming physical properties e.g. porosity, state
- Changing reactivity e.g. solubility, stability in different environments
- Adding functionality e.g. antimicrobial, bioactivity, surface chemistry
- Extending shelf life
- Controlling the release of active ingredients.

iCRT

Our novel inorganic controlled release delivery platform (iCRT) can deliver active ingredients in a targeted manner with several advantages including tamper-resistance.

Using iCRT we have worked with our partners to develop products that deliver:

- Bioactivity to oral care products
- Desensitizing properties
- Encapsulation of harsh actives (e.g. bleach) until triggers stimulate release
- Improved stability of whitening agents to sunscreens
- Fast dissolution of solid films releasing active ingredients.

All of our materials are GRAS and can dissolve into biocompatible ions.



PHARMACEUTICAL

The best form of preventative medicine.

We work with pharmaceutical manufacturers, and the supply chain, to ensure that products meet regulatory requirements and are fit for purpose.

Our experts help you to optimize processing routes and solve problems, quickly and efficiently.

We're a pretty unique partner; we have a comprehensive range of advanced analytical capabilities, such as surface analysis.

And to that we add innovative thinking; we work with you to develop the materials, products, processes and technologies of the future.

We are fully cGMP certified for the testing of human and veterinary medicinal products. Our services are undertaken in compliance with EU guidance on GMP as it applies to contract QC testing laboratories.



Quality Control Testing

Whether you need to ensure quality, source new raw materials or ensure the purity and stability of your existing ones, we are here to help.

Pharmaceutical Chemistry

- QC (batch release) testing
- Raw materials testing
- Residual solvent testing
- Method development and validation
- Water analysis
- Heavy metals testing.

Pharmaceutical Microbiology

- Sterility testing
- Antimicrobial efficacy testing (AET)
- Microbial limits testing
- Bioburden determination
- Endotoxin testing
- Environmental monitoring and identification
- Water analysis.

Stability Storage and Accelerated Ageing

Our stability storage walk-in chambers, controlled to ICH guidelines, are monitored 24/7/365 and have built-in safeguards to give you peace of mind. Additional standalone cabinets enable us to offer alternative parameters including refrigerated, frozen and client-defined storage conditions.

The standard ICH conditions are:

- 25°C/60%RH - Real time storage condition
- 30°C/65%RH - Intermediate storage condition
- 40°C/75%RH - Accelerated storage condition

Our experienced staff can aid with study design, planning and management of stability storage testing. We can combine these facilities with the design of a more advanced accelerated ageing regime, combined with an evaluation and validation of the effect on your products vs. real-time and real-life conditions.



Method Development and Validation

Our experienced scientists can develop new methods for your products. These can be developed and validated to ICH guidelines which include the following parameters:

- Linearity
- Limit of detection (LOD)
- Limit of quantification (LOQ)
- Specificity (including stability of solutions)
- Precision (method, intermediate and system)
- Accuracy (recoveries)
- Robustness
- Forced degradation.

Failure Analysis

Lucideon helps to determine the root cause of failures in your pharmaceutical products and packaging and provide fast and effective solutions. We solve failures during and post manufacture to help ensure your customers' safety.

Some of the issues we have helped our partners resolve include:

- Staining on pharmaceutical ovule blister packaging material
- Spot defects that have migrated into metallized pharmaceutical packaging film
- Heat seal strength reduction on drug foil packaging
- Issues with variable adhesion of X film bonding to glass beads
- Presence of brown spots on antibiotic tablets
- Crystallization and discoloration of tablets under different storage conditions.



In practice...

Product Validation

"We not only test for quality and performance, we also have a complete product validation service, and can provide patent infringement support, cleaning validation and counterfeit drug detection."

Nigel Rich,
Pharmaceutical Chemistry Manager.

Powder Consultancy

It is critical that your powder processing routes are optimized at the front end to provide maximum yields and the best quality products, whether they are ultimately pressed into a tablet, used in an aerosol, or added to a suspension.

We provide rheology, zeta potential and milling protocol development support as well as particle property characterization, pilot scale processing, Factorial Experimental Design and in-depth analysis of your downstream and intermediate products.

Expert Witness

When facing legal challenges, it is essential you have independent, credible scientists behind you.

Our analysts provide accurate and reliable data, backed by the expertise to justify their findings. Our experts have worked on multiple cases including patent infringement and counterfeiting claims.

iCRT

Drug delivery technologies

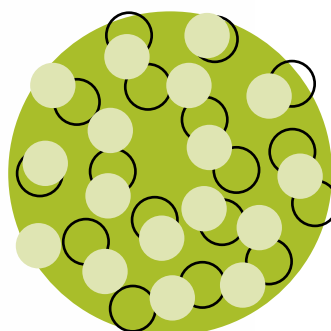
We have developed novel and innovative technologies for the effective delivery of drugs using inorganic matrices. Some of the advantages of our iCRT platforms include:

- Controlled release of challenging APIs for immediate or sustained release
- Particulate nature allows blending of two formulations for combination products
- Flexible physical form, e.g. powder, soluble film, suspension, granulate, tablet
- GRAS and IID approved materials
- A green manufacturing process
- Tailored solubility and porosity of the carrier controls drug release.

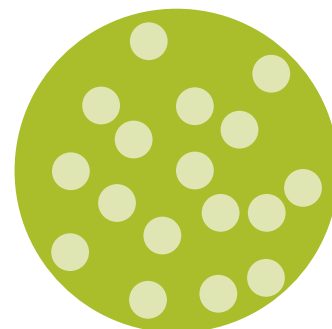
iCRT-deter

Abuse deterrent technology

- Retarded release in alcohol and other household solvents - deters extraction
- Extremely high melting point - deters melting for injection
- Hard physical structure - difficult to crush
- Particulate nature - retains controlled release features if tablet is crushed
- Large particle size - difficult to inject.



POROUS MATRIX
(DIFFUSION MEDIATED)



NON POROUS MATRIX
(DISSOLUTION MEDIATED)

We work with you to develop market leading products using our novel in-house technologies, based on your needs and desired applications. All our work is supported by our industry experts, IP and know-how, and an extensive suite of cGMP analytical capabilities.

Strategic partnerships

Lucideon forms strategic partnerships with healthcare product manufacturers and suppliers internationally. We have our own specialist processing labs with pilot scale facilities to develop and produce novel materials and optimize existing materials and products.

How we work:

You tell us what you are trying to achieve and why - both strategically as a business and specifically for that product.

We hold an innovation session internally to brainstorm ideas and form some options, selecting the most experienced scientists for the application to work on the project.

We discuss those technology options with you, highlighting pros and cons and gaining feedback on which are most relevant to your needs.

We perform a feasibility study to prove the platform is viable.

Lucideon works with you from start to finish to implement the new technology and process into your product portfolio - starting with development scientists to design the prototype, then transferring the technology to the chemical engineers to scale up the process, and finally to process engineers to implement it into your manufacturing line - we know what you need to do to make our technology work!

... and then we start on the next one!



Contact Details

Your regional sales contact should be your first port of call if you want to talk to us about anything.

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And our Customer Liaison Group are always on hand should you have a query or need any more information.

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