

# SERVICES FOR ORTHOPAEDIC IMPLANT MANUFACTURERS



Product Lifecycle	Bespoke Service	Example Applications	Benefit
R&D	Material Selection	Selection of a new ceramic material formulation for a femoral head.	Improved product performance relating to strength and durability.
	Material Characterization	Understanding of the chemical make-up of a coating	Is a chemical reaction occurring between materials and affecting the properties/biocompatibility of components?
	Material Development	Development of substituted HA, high strength ceramics for implants and bioactive materials including polymers.	Reduction in coating thickness, increased bioactivity, etc., providing differential advantage in the market place.
Pre-Production	Performance Testing	Long term performance/shelf-life setting through short-term testing (creep, fatigue, load, shelf/environmental ageing, accelerated ageing, wear testing, mechanical testing, debris analysis).	Validated understanding of shelf-life and long term performance to support regulatory approval.
	Regulatory Approval Testing	Complete testing of a HA coating for an FDA master file submission.	Independent assurance that data is accurate and complete for FDA approval/CE marking submissions.
Production	Raw Material Qualification	Routine testing of any materials utilised in the manufacturing process.	Ensure conformity of raw materials, reduce problems in production, save cost on recalls/rework/failures.
	Troubleshooting	Contamination identification and product/material failure investigations.	Understanding of problem causes and facilitation of correct action.
	Process Improvement	Plasma HA coating of implants.	Improved yields and reduced costs.
QA/QC & Validation	Materials Testing	QC of batches against pre-defined protocols or bespoke Lucideon-designed protocols.	Independent confirmation of batch consistency.
	Cleanliness Validation	Residue testing, gravimetric, direct surface analysis, extraction.	Independent confirmation of cleanliness.
	Product Testing	Physical testing of implants.	Ensures products meet specification and confirm with regulatory requirements.
After-sale	Failures and Returns	Product/material failure investigations including issues around contamination and physical properties (fractures).	Prompt and independent identification of causes to support remedial action and client engagement.
	Expert Witness	Expert Witness to support legal disputes.	Independent support.