

BioPharma Services: Right Method/Right Solution

Our scientists are committed to applying an industrial forensics approach to the product life cycle. We use investigative materials research, environmental health and safety, and quality control principles to investigate, define, isolate and resolve biopharmaceutical problems. From foreign matter isolation and identification in raw materials to particulate analysis for quality control during the process, to evaluation of content uniformity in finished products, we work closely with our clients to understand the issues surrounding each situation.

Research and Development

Our experts can work independently or with our clients' internal R&D talent to provide critical assistance, always applying discretion to proprietary materials and processes. We are successful in assisting companies deliver their product to market by helping product engineers understand the micro-structure of materials and by responding to challenges within the marketplace.

We can assist in determining the suitability of the product as well as verification, validation, and manufacturing of the product or medical device. Our expert services at this level include:

- » Raw materials specification, selection, consistency and validation
- » Quality control testing
- » Device cleanliness assessments and impurity identification
- » Wear debris studies
- » Environmental health & safety issues
- » Technical support for FDA submittals and regulatory compliance

Quality Control

Our examinations in support of regulatory compliance and quality control encompass standard procedures developed internally as well as regulatory methods. Our established

quality system allows us to use and/or develop validated protocols and execute them in a cGMP level environment. These may be used alone or in conjunction with each other to provide the most comprehensive remedy and/or an entirely customized protocol.

Strategic Partnerships

Our partnership with NanoImaging Services enables us to expand our services and offer cryogenic electron microscopy analysis, tomography, and single particle averaging. These cryogenic techniques facilitate characterization of biological samples without drying or freeze drying (lyophilization).

RJ Lee Group provides the best leading-edge analytical technology to our clients. Our strategic partnerships with instrument manufacturers like Hitachi and Thermo Fisher provide us with the newest generation of electron microscopes and the distinction of being the only commercial laboratory

Our scientific expertise allows us to go beyond the delivery of data and facilitate the development of solutions.

in the U.S. to operate them. We are one of only a handful of U.S. laboratories using the Thermo Fisher K-Alpha XPS, a surface-sensitive analytical tool that also provides chemical information, and the

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Hitachi S-5500, the highest resolution electron microscope combining the best features of scanning electron microscopy (SEM) and scanning transmission electron microscopy (STEM). Our Hitachi S-5500 is the only one available in a commercial service laboratory.

Capabilities and Techniques

RJ Lee Group is an FDA-registered testing laboratory. We use appropriate analytical instrumentation to address each problem such as x-ray diffraction techniques for lot-to-lot equivalency, high resolution electron microscopy for particle morphology studies, energy dispersive mapping for elemental imaging of finished products and molecular spectroscopy for identification of organic materials. Our scientific expertise allows us to go beyond the delivery of data and facilitate the development of solutions.

- » USP Testing
- » CAPA Investigations
- » OOS Investigations
- » Content Uniformity Investigations
- » Contamination Identification
- » Source Determination
- » Surface Defect Analysis
- » Root Cause Analysis
- » Particle Morphology Evaluation
- » Particle Size Analysis

Environmental Health & Safety

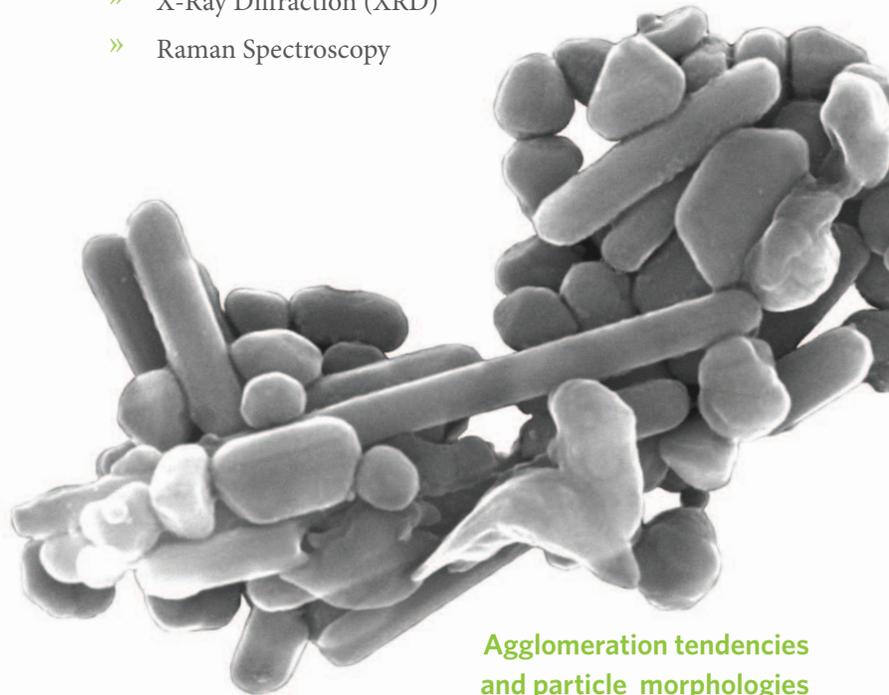
RJ Lee Group excels in the characterization of particulate. Our experts monitor, sample and analyze particulate matter in the workplace to assess air quality conditions for workers and to determine if any particulate produced during processing and manufacture affects workers or product. This is especially important in industries such as those that manufacture pharmaceuticals which can generate contaminants of concern down to the nano level. These unbound nanoparticles (UNP), whether man-made or naturally occurring, have a strong tendency to agglomerate

and form highly irregularly shaped structures that may exhibit unknown characteristics. By understanding particle behavior and having the expertise to investigate and identify particles, we bring together another level of competency to our clients.

Nanoparticles

RJ Lee Group experts use electron microscopy, diffraction and spectroscopy techniques to measure size, determine morphology and agglomeration state, elemental composition and the structures of new materials at the nanoscale. We work in collaboration with industry, government and academia to characterize nanoparticles and to prepare for their regulation. The instruments that we use to obtain information in the nano world include:

- » Scanning Electron Microscopy (SEM)
- » Field Emission Scanning Electron Microscopy (FESEM)
- » Scanning Transmission Electron Microscopy (STEM)
- » Transmission Electron Microscopy (TEM)
- » Energy Dispersive X-Ray Spectroscopy (EDS)
- » X-Ray Photoelectron Spectroscopy (XPS)
- » X-Ray Diffraction (XRD)
- » Raman Spectroscopy



Agglomeration tendencies and particle morphologies of silver nanoparticles.

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DELIVERING SCIENTIFIC RESOLUTION