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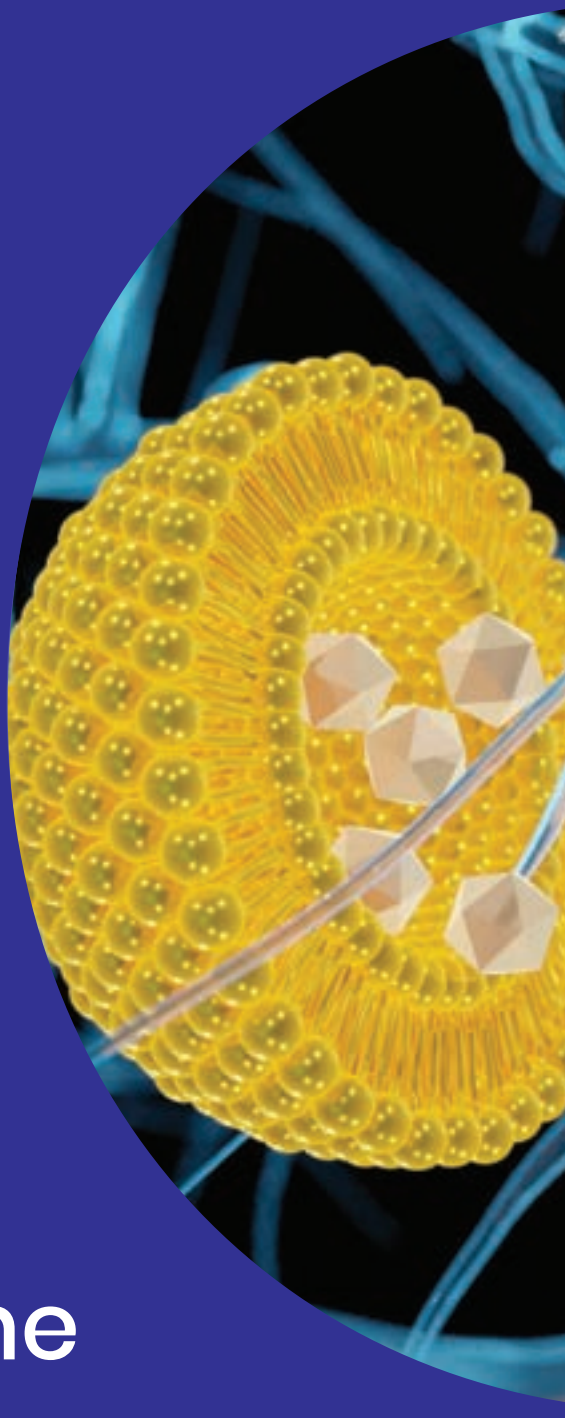

Nanomaterials for cancer nanomedicine

Case studies

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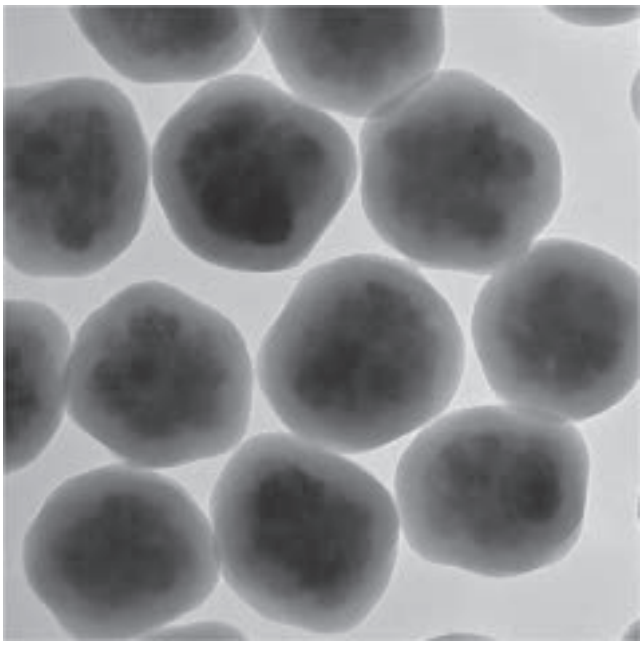
Targeted Silica Coated Iron Oxide Nanoparticles for *in vivo* Delivery to Tumors

Magnetic-cored silica-shelled nanoparticles were functionalized with an antibody against a prostate-specific membrane antigen. Antibodies were bound via a covalent strategy to create particles that targeted PSMA-positive cell lines. Off-target effects can be minimized by successfully targeted formulations. The antibodies were covalently linked to the silica surface via the addition of antibody-conjugated polyethylene glycol molecules.



In vivo data showed targeted delivery and tumor reduction when the magnetic nanoparticles were heated via an applied alternating magnetic field.

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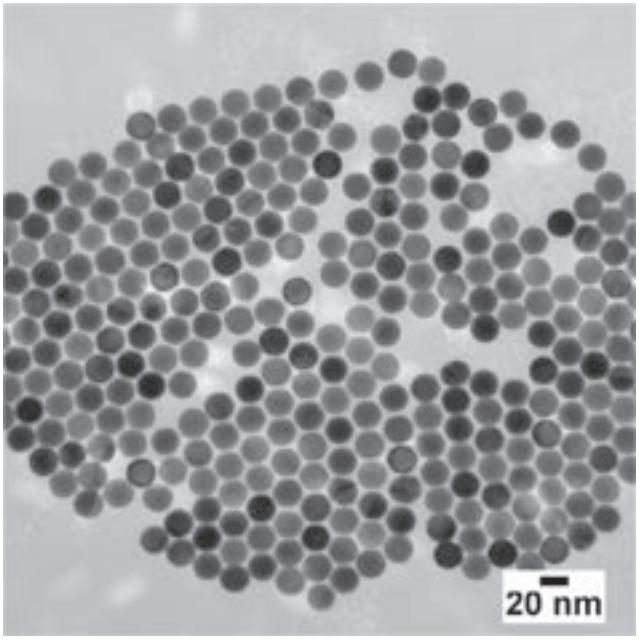
Oligonucleotide Conjugated Gold Nanoparticle Development for Cancer Therapy

A biotechnology company required a partner to develop a biofunctionalized gold nanoparticle for targeted delivery of a therapeutic oligo. The particle needed to be size appropriate for the application with a low coefficient of variation, offer high biocompatibility, and provide targeted delivery of the therapeutic molecule. Work at our end began by adapting a laboratory scale procedure provided by the customer and progressed to sweeping conjugation and loading conditions to determine the optimal procedure. Future work will select the best mode synthesis from the prior phase based on characterization data and functional testing and begin outlining the development effort to scale and GMP manufacture.



Development work included:

- Transfer of provided procedure to our facility
- Full characterization of synthesized particles, including:
- Hydrodynamic diameter by DLS
- Stability over time by DLS and UV-Vis
- Zetapotential by DLS
- Oligo loading by custom assay
- Functional verification of oligo binding by lateral flow assay
- Delivery of a 1 mL sample of each conjugate variant

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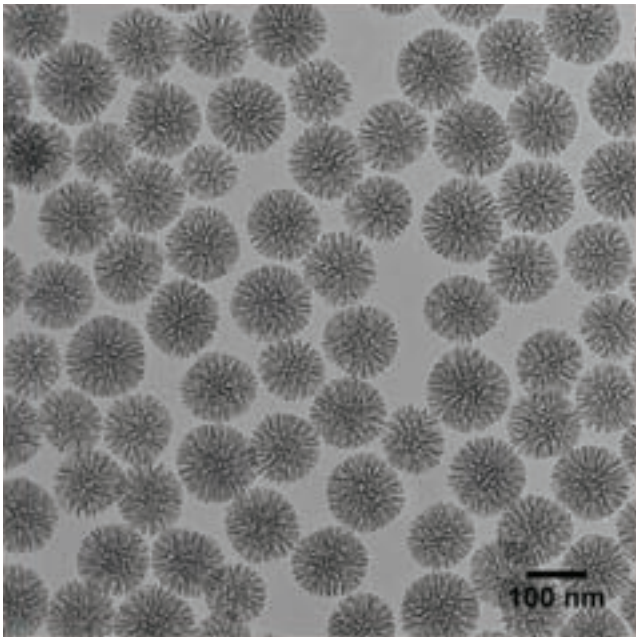
Mesoporous Silica-Based Therapeutic Development and GMP Manufacturing

Customer approached us for the development of a cell-based cancer therapy utilizing mesoporous silica. Following a feasibility scale synthesis that produced material meeting specifications, development progressed to scale up efforts, moving from mg scale to 50 gram batches. On-going work supports further scale up efforts with the implementation of design controls to move production under our QMS system for GMP manufacturing.



Development of cGMP documentation to support fabrication of materials for clinical testing included:

- Delivery of quality plan and analytics with Process Failure Mode and Effects Analysis (pFMEA) to identify the risks in the material manufacturing
- Bill of Materials (BOM-SPEC) with qualified suppliers
- Developing a Manufacturing Master Record (MMR), including Master Batch Records (MBR)
- Certificates of Analysis (CoAs) or Certificates of Conformance (CoC)
- Creation of process documentation including material specifications, SOPs, and work instructions.
- Transfer of scaled manufacturing process to GMP Compliant environment, including implementation of sterilization processes and sterility testing.
- Validation runs repeatedly producing the material under all the necessary controls to ensure the material meet all criteria of the formal Product Specification