Need materials for proof of concept clinical trials, scaled production, or cGMP manufacturing? We can help! We offer a comprehensive nanoparticle solution which includes development, fabrication, and final formulation.

**Why partner with nanoComposix?**

- **Customized GMP Solutions:** Because each project is unique, we work through a multi-stage process with each client to collaboratively develop a GMP Project Plan customized for the target application while maintaining cost efficiency and compliance.

- **Nano Experts:** nanoComposix has been manufacturing nanoparticles for over 14 years. Our lead scientists have 80+ years of collective experience in nanomaterial fabrication, with an emphasis in metals and metal oxides like gold, silver, and silica.

- **GMP Experience & Capabilities:** Our facility offers cGMP/ISO13485 compliant production and provides scaled nanoparticle manufacturing for medical devices, topical therapeutics, and combination (drug/device) products for preclinical and Phase I/II clinical trials.

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**FROM CONCEPT TO COMMERCIALIZATION**

**Our lab space includes:**
- 8,000 ft² of R&D and production labs
- BSL-2 safety lab and low humidity dry room
- ISO 8 cleanroom with chemical fume hood
- Process and procedures in compliance with ISO 13485 and FDA guidelines

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**Pre-GMP**
- Concept
  - Determining product’s feasibility & identify the scope of the project
- Research & Development
  - Defining user needs and identify corresponding design inputs

**Early GMP: Initiate Design Controls**
- Design Development
  - Identifying the stages, activities, responsibilities, resources, & verification methods for design & development
- Product Development
  - Establishing a product design with detailed associated specifications

**Clinical GMP**

**Design Transfer**
- Transfer the process from development to commercial scale manufacturing: ensure all of the design requirements & product specifications can be met in commercial production, and identify potential problems before transfer to commercial GMP

**Verification & Validation**
- Verification: Examining objective evidence to confirm specified requirements are met
- Validation: Obtaining objective evidence to assure that a product meets the intended user needs
Sienna Biopharmaceutical partnered with nanoComposix to co-develop a photothermal acne treatment made of nanoparticles. The technology is made possible by highly concentrated silica coated silver nanoplates that are introduced into the hair follicles of over-productive oil glands. Standard dermatology lasers are then used to locally heat and impair the nearby sebaceous glands, reducing oil production and acne. In order to make this therapy successful, the silver nanoplates needed to be protected from the skin’s local environment. NanoComposix worked closely with Sienna to design and optimize the silica encapsulation, maximizing the formulation's stability on skin and thereby increasing treatment efficacy.

Transfer to GMP Manufacturing Under QMS

NanoComposix developed a working prototype and helped Sienna define a formal Product Specification, a critical early phase of GMP development. The transfer to GMP manufacturing for clinical supply and preparation for commercial production included:

- Repeatedly producing the material under all the necessary controls to ensure the material meet all criteria of the formal Product Specification
- Establishing a process flow diagram based on the R&D process and control points for In Process Quality Control (IPQC)
- Developing a Manufacturing Master Record (MMR), including Master Batch Records (MBR) and a Bill of Materials with qualified suppliers
- Process development to increase the standard batch size 100x
- Process Failure Mode and Effects Analysis (pFMEA) to identify the risks in the material manufacturing
- Several iterations of robustness work to ensure a consistent manufacturing process at commercial scale
- Successful audits of nanoComposix to ensure QSR & ISO13485 requirements were met

NanoComposix is currently producing clinical supply material on-demand for this client and preparing for commercial production.