nanoComposix

December 6, 2020

Subject: Scope applicability of the Quality Management System as it applies to customer products.

nanoComposix (NCX) is committed to ensuring the safety and reliability of our products and to continually improving products and processes to enhance customer satisfaction. This is accomplished through implementation, management, and improvement of our Quality Management System (QMS). We have developed and implemented a Quality Management System to document the company's best business practices, better satisfy the requirements and expectations of our customers, and improve the overall management of the company.

1 SCOPE

nanoComposix, a wholly owned subsidiary of Fortis Life Sciences, provides nanoparticles, contract development services, and scaled manufacturing to help our customers commercialize nanotechnology products in fields that include biodiagnostics, nanomedicine, and high-performance coatings. Our primary customers are utilizing our products for research and development applications. A small segment of our customers are medical device manufacturers or drug developers who integrate our products into their own finished products. Our products are distributed and used worldwide.

2 EXCLUSIONS

The QMS/QS described in the NCX quality manual applies **only** to Regulated Products designed, developed, and/or manufactured at NCX as defined by customer needs and applicable regulatory requirements. This includes custom designed, or regulated materials that have gone through full design or transfer to manufacturing processes at NCX. This also applies to materials manufactured by/for NCX as cGMP compliant materials.

2.1 ***Non-regulated Standard Products are excluded from the QMS/QS*** unless otherwise described in a Supplier Agreement, Quality Plan, or other purchasing contract agreement.

2.2 The scope of the Quality Management System is limited to the activities that are the responsibility of nanoComposix only.

2.3 For contracted projects, customer responsibility activities such as: Final Release of the product to the end user, coordination of clinical trials, post-market surveillance, and filings with regulatory bodies, are not nanoComposix' responsibility and are outside the scope of our Quality Management System.

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3 ORGANIZATION ROLE(S) AS DEFINED IN THE QUALITY MANUAL

3.1 nanoComposix is an OEM SUPPLIER of nanoparticle products that are used in our customers' end products. These consist of proprietary nanoparticles. We refer to these as "Standard Products". Many of these products were initially developed without formal design controls and are sold as Research Use Only (RUO) or Investigational Use Only (IUO) materials. While we stand behind the quality of our products, these items were not intended to be used in GLP or GMP products/devices.

3.2 nanoComposix is a SPECIFICATION CONSULTANT and COMPONENT MANUFACTURER for customers requiring unique applications of nanoparticle products for inclusion in the final customer finished product. Many, but not all, of these customers produce medical devices or accessories, or drug products. Our customer contracts define which elements of the development processes will be utilized in a specific customer project. These may include design and development, process controls, document controls, manufacturing, shipping, packaging, and/or labeling. Most of these projects are tailored to fit customer requirements.

4 REGULATORY REQUIREMENTS

nanoComposix is not currently required to site register with the FDA and none of our products require listing with regulatory agencies. We maintain a California Drug manufacturing license.

If you require the product(s) you purchase from NCX to be wholly covered by our Quality Management System, we welcome the opportunity to discuss our existing cGMP compliant products or transitioning your RUO/IOU product/application to a GLP/GMP compliant product.

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