Quality

Sierra Coating Technologies LLC has been a trusted manufacturing partner for over 20 years. From the start, we base our decisions on making quality product that protects our customers' brands. We invest in laminating and coating equipment that produces highly consistent quality coated and laminated products. Our product development and definition process is an in-depth program to review, define and test to determine the best options. In order to achieve repeatable manufacturing processes we include tests for specific critical specification to ensure consistent quality results. This process and all work performed is fully tracked by documentation, software systems and product retention programs.

The Basis of Our Quality System

The quality systems at Sierra® are based on the foundation of the FDA, NSF and ISO. We maintain quality through administrative and regulatory compliance, following good manufacturing practices (GMPs) to ensure sanitation and good housekeeping, rodent and pest control, inventory control, process and product evaluations, proper packaging and labeling, storage and shipping. Our quality parameters and documentation are established during product design and development validation, and maintained during production through employee training, preventive maintenance, supplier management, data analysis, corrective actions, problem-solving and safety. We reinforce this process with customer satisfaction reviews and formal reviews of any issues through documentation and problem-solving.

Our philosophy is based on allowing customers to determine standards for their products. We then achieve and maintain those standards with full compliance through any requested documentation and testing. Over the years, Sierra has manufactured products to many quality standards.

Sierra compliance with FDA CFR 21 as relates to production that falls under these regulations

Sierra complies with 21 CFR Chapter 1, part 110, Current Good Manufacturing Practices in Manufacturing, Packaging, or Holding Human Food as it relates to the production of products that fall under Chapter 1, part 174 Indirect Food Additives. This regulation prescribes conditions under which food additive substances may be safely used under this part and parts 175, 176, and 177 and their definitions.

Sierra past compliance with additional FDA products

Sierra had been registered with the FDA to apply an over-the-counter medication (OTC). We completed the Validation Master Plan (VMP) that included the Installation Qualification (IQ), the Operation Qualification (OQ), the Performance Qualification (PQ), and the Process Validation (PV) necessary to produce a product that complies with the FDA’s OTC pharmaceutical programs and the necessary CGMPs. This also included on-site audits by the FDA inspectors related to this product. The registration for this product is

mandatory.

There is a voluntary registration for other cosmetic products. Sierra has produced a number of products for cosmetics usage, but Sierra does not register because products were not labeled for resale by Sierra.

Sierra compliance with ICC-ES certified product

ICC-ES reports state that: “The inspector must use the ICC-ES supporting documents, the manufacturer’s current quality documentation and operating procedures, and the manufacturing process records, to evaluate the implementation and effectiveness of the facility’s quality management system.”

> ***Summary:*** *The product is certified by ICC-ES. The audit is performed by QAI Laboratories. Our quality systems have been evaluated and approved as being effective and meeting all ICC-ES requirements.*