TECH NH INCORPORATED

How to Choose the Right Medical Contract Manufacturer – Part 2

ASSURING QUALITY WITHIN THE PRODUCTION SYSTEM AND THE JARGON USED IN THE MEDICAL INJECTION MOLDING INDUSTRY

To assure that the highest standards are met on a consistent basis, all medical injection molders have Quality departments. In addition to this, a select group of injection molding companies have a key employee in the position of Management Representative who oversees the quality requirements, from a macro perspective. An industry rarity is a company that has a Management Representative and Regulatory Affairs staff overseeing all Quality and Regulatory requirements and activities.

The Management Representative reviews all ISO requirements (typically ISO 13485), and Regulatory Affairs reviews all FDA and other pertinent regulatory agency requirements, to support each Customer's production requirements. Any company that chooses to have a Management Representative and Regulatory Affairs as part of their staff demonstrates their corporate commitment to meet the Customer's Quality and Regulatory requirements.

Any Customer that utilizes their products within a regulated industry can be assured that the Management Representative and Regulatory Affairs will help them work through the requirements prior to production.

If you want the highest quality production environment, be sure that you choose a contract manufacturer that has a Management Representative and Regulatory Affairs on staff.

Common Terms within the Industry

Audit- a systematic, independent examination of a process that is performed at defined intervals and at sufficient frequency to determine if the process activities and results comply with stated requirements and that the process is implemented effectively, and suitable to achieve stated objectives.

AQL (Acceptable Quality Limit) – used in conjunction with and established sampling plan to determine the sample inspection quantity for a process. This limit determines the maximum allowable defects by lot quantity size.

FAI (First Article Inspection) – is a formal, documented, enumerated process by which parts from a mold are inspected to assure that all critical dimensions meet the specification on the print.

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cGMP (Current Good Manufacturing Practice) – the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of medical devices. These guidelines provide minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use.

IQ (Installation Qualification) – term used for the verification of the correct installation and function of the mold.

Metrology – the scientific study of measurement.

OQ (Operation Qualification) - is the establishment of the process window and verification standards within which acceptable parts can be manufactured.

PFMEA (Process Failure Mode and Effects Analysis) – an approach to review each step within a process to identify potential failure modes, with the goal of eliminating or mitigating the risks and effects of those failure modes on the process.

PQ (Performance Qualification) verification of the process using real production conditions.

Scientific (Decoupled) Injection Molding – A systematic approach to molding; it examines the principles behind plastics molding, the behavior of plastics during the molding process and the effect of process variables on part fill, pack and hold portions of the process.

Validation – process that verifies the stability of a process to produce an injection molded part.

Verification – evaluates plans, drawings and specifications to ensure the product meets established standards.

Check back soon for the next installment.