Directive Agenda
Product Tooling

Scope:

This document discusses the product tooling used in the manufacture and testing of medical devices, pharmaceuticals, and other biotechnology products.

Objective:

To present the concepts of product tooling design and control by transforming general concepts into concrete directions and steps that a company can take to continuously improve its effectiveness and performance in this area.

Disclaimer:

This is presented by Atzari Consulting, L.L.C. to its existing and prospective customers as a way to review and assess their current state and use this as a tool to guide their efforts in this area. It is not intended to replace existing guidance for regulatory compliance in this area.

Philosophy and Discussion:

Product-specific tooling must be designed to sustain design control requirements, especially all end-product features that are formed or shaped by that specific tool. While the quality of the tool can be measured and analyzed from the parts it makes, its quality must be built into the design and maintained with the process parameters in which it operates. Forming tools act by displacing material either into a cavity, through a die or away from a cutter, hence good design is necessary to ensure that the form of the tool is preserved and that there is an adequate path for the material to travel. By their nature, these tools are often exposed to intense heat supplied by heaters, heating fluids or by the friction of material being displaced or sheared. For this reason, the coolants, heaters, speeds and feeds all play a major role in tool life and in the quality of the product material being formed. No tool qualification is complete without taking into account its associated process. Milling is affected by speeds, feeds and coolants as well as by rake angle, clearance angle and pitch. Injection molding is affected by screw speed, mold temperature, molding pressure as well as by venting, gate design and draft angles for part release.

Philosophy and Discussion (continued):

Displacement of product material is a function of gate design, venting and preventing obstruction of the scrap. While these parameters do not directly impart the form into the product, they do affect tool wear and the heat history of the product material. Preservation of tool life is also a function of tool material.

To control tooling, it is important to examine the stages of product tooling development. Prototype tooling is often utilized until a product design is frozen. This can take the form of soft tools, mock-ups and rapid prototyping methods using stereolithography and CNC. Clinical build units are often fabricated using such soft tooling before the funds and lead times are committed to hard tooling. Since this tooling can be of a different material than the final hard tooling, the parameters and process associated with soft tooling may differ from what is used with hard tooling. The appropriate adjustments must then be made in order to preserve tool life and product material properties.

Tool control begins with a controlled drawing where all features that form or fit the functional characteristics of the product are closely traceable to the product drawing. For example, no changes must be made to the core pin diameters for a mold unless these are necessary to achieve the existing product drawing specifications. Due to shrinkage or expansion, tool dimensions may differ from the final product dimension.

Molds and dies are specialty tools made with hardened material and are often fabricated by outside suppliers. In cases where the tool drawing is controlled by the supplier, statistical analysis and process validation must be performed. It will then be up to the supplier to make any necessary tooling changes. It must be kept in mind that the tool is only one factor in the process and that material selection and process parameters also play a role. To supplement the dimensional analysis, a process validation with the cumulative high, low and nominal parameters should be performed and the material characteristics analyzed for brittleness, hardness and crystal structure.

Philosophy and Discussion (continued):

Statistical analysis of parts can be performed when an outside supplier supplies both the tool and the parts it makes. It is in the company's interest to audit the supplier's validation program for both the process using that tool as well as well as the tool itself.

Other tools such as cutters must be serviced by sharpening or refurbishing at regular intervals or at established wear points. A program of statistical process control (SPC) can detect when a tool is starting to wear so that corrective action is taken.

It is not enough to control the drawing. When a tool is released to the production floor, evidence must be provided that this tool has been qualified and is the correct revision. In cases where multiple tools exist that were made to the same drawing, a unique serial number (similar to a calibration sticker) must be either engraved or permanently attached to the tool or its container. The tool number must also be referenced in the Device Master Record so there can be no doubt that the correct tool is being used. It is important to always distinguish experimental tooling from that of final release. One way is to do this is by assigning unique and distinct numbers to each. Another way to control this is through its revision, although that may not make it obvious that a new tool has been released. A color-coded sticker can indicate the qualification status of a tool, although these must be secured, otherwise they can fall off.

Tool dimensions and quality are the responsibility of the machinist or toolmaker that either made the tool or is re-sharpening it. Monitoring product quality, however, is the responsibility of the manufacturing operation.

Directive Agenda
Product Tooling

Stages of Development—Hierarchy of Needs:

Startup—Vital Level:

(1)Do your company's products have specifications and/or drawings, which establish their form, fit, and function?
(2)Does your company follow design controls, which determine design inputs and design outputs?
(3)Has your company/plant identified all tooling, and classified it as to whether or not it directly forms, creates the fit, or affects the function of the final product?
(4)Does your company's new product introduction process include provisions for product tooling?

Operation—Functional Level:

(1)Have First Article Inspections (FAIs) been performed to verify that product tooling provides the correct product dimensions, form, and fit?
(2)Have Installation Qualifications (IQs) established that product tooling is and can be correctly installed onto the manufacturing equipment?
(3)Have Operational Qualifications (OQs) established that the tooling and equipment work together as a system to create the correct product dimensions, form, and fit?

Systems Integration—Interactive Level:

(1)Are product tooling specifications and/or drawings controlled in such a way to ensure that changes to product result in applicable changes to tooling?
(2)Are mating parts of related products controlled in such a way that changes will also ensure updates to the product tooling of the mating part?
(3)Are fixed measurement gauges for product dimensions controlled to properly measure changes to product form, fit, and/or function?
(4)Are product tooling and related gauges inspected and calibrated as applicable as part of a preventive maintenance program to ensure continued accuracy?

Future Growth—Developmental Level:

(1)Do future product introductions account for new or existing product tooling?

Directive Agenda
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Strengths, Weaknesses, Opportunities, and Threats (SWOT):

Strengths / Weaknesses (Internal):

(1)Product tooling is fairly new and robust
(2)Plant has a history of compliance with existing design control standards
(3)Plant has a strong preventive maintenance program
(4)Assuming manufacturing cells have the ability to create and inspect their own gauges, are these controlled as part of design controls?
(5)Does your company use mating parts as gauges? If so, are these mating parts under design controls to ensure that these will keep up with product design changes?

Opportunities / Threats (External Opportunities or Challenges):

(1)Your company is being acquired by another company, or is acquiring another company.
(2)Introduction of new drawing templates may have different tolerances on the title blocks, which would render existing drawings inaccurate?
(3)A major client is coming to audit you
(4)Your new product has just been approved (PMA or 510(k) and your plant will soon be audited
(5)Have your suppliers changed their product tooling? If so, have they informed you of this?
(6)Has your marketing forecast increased, causing significant new challenges for your process output, hence the need for additional product tools?

Directive Agenda
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Proposed Direction for Improving Product Tooling at Your Company:

(Examples)

(1)Create a master list of all product tools.
(2)Ensure that First Article Inspections are correct and up-to-date.
(3)_____
(4)_____
(5)_____
(6)_____
(7)_____
(8)_____
(9)_____

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