

Medical Manufacturing Quality Suite

In medical technology production facilities, the requirements governing end-to-end reproducible documentation are particularly demanding.

Achieving the highest possible and uniform standards of quality across all production stations is the basic requirement for installing a validated quality assurance process. Whether for implants, prosthetics or medical instruments and appliances a manufacturer must be able to verify full compliance for all quality-related features.

If the manufacturer also wishes to make these high-quality products at competitive prices an efficient tool management system is essential.

In the central Zoller tool database 'z.One', the key to tool management is to organize tool data over the entire life cycle. From production planning to CAD/CAM, warehouse, tool presetting and measuring or inspection machine and the production machine itself, tool data is available at all times. Even CAM systems can access this central database directly via Web service technology.

Achieving actual tool data formatted to suit the control unit in an entirely process-safe manner begins with the machine's NC control unit, for example in the form of data matrix code such as Zoller identification 'zidCode', by file transfer via post-processor, RFID or primary production control systems.

The consolidation of all tool data in the central database achieves transparency across all production steps, and this guarantees an economical and process-safe machining process. Seamless traceability and logging is assured at all times during the process.



Successful quality assurance begins with the tool components being used. Dimensional integrity, the concentricity and face runout of the complete tools and all decisive parameters relating to cutter

geometry need to be measured, inspected and documented continuously. The changing accuracy of the toolholder systems and the resultant measuring accuracy have a major influence on the end product and on process safety.

Zoller's high-performance universal measuring device known as 'smarTcheck' is designed for tool inspection and

can be used before and after sharpening for measurement work in transmitted

light and vertical lighting contexts. This makes it easy to check and measure all tool geometries and to log results in accordance with applicable regulatory directives.

Another universal measuring machine, the 'genius 3,' is well-suited for documenting quality features on external geometry measured in transmitted light, and for the detailed parameters resulting from grinding geometry (e.g., face geometries on drilling tools or other detailed information). As well as specific individual criteria, this universal measuring machine can be put to day-to-day use performing fast, precise, fully-automatic and operator-independent complete checks of tools. Interfaces to tool grinding machines for direct data exchange and for automatic correction of the grinding machine are all now state-of-the-art technical features. High-tech materials assure a high level of measuring stability and optimum suitability for use under production conditions, even when not used in an air-conditioned room.

As well as the requirement for process safety, the medical sector is specifying increasingly filigree components. These are being produced using exceptionally small tools. Further challenges include tight production tolerances and materials that are frequently difficult to machine. To achieve the required quality and precision levels on a continuous basis, high-quality tools with optimum settings are essential.

For example, precisely preset thread-whirling tools help assure long tool lives and burr-free machining outcome.

Whirling tools can be set up using the 'hyperion' system, eliminating the need for elaborate precision adjustments. This speeds up the setup operation substantially.

Also, the small component sizes often required for medical parts often present an operator with challenges during the setup process. Precise adjustment of the tip height is essential because the tip height on the machine is exceptionally difficult to set, and the operation is almost impossible to reproduce accurately. However, it is possible to resolve this problem on a tool-presetting device before fitting a tool to the machine. This reduces the setup time and improves quality.

Zoller Inc.

Ph: 734-332-4851

Web site: www.zoller-usa.com

