The role of mechanical variation management in medical devices

A case study of drug delivery devices developed by Flex Health Solutions

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The development of medical devices presents unique challenges in terms of patient safety, regulatory compliance, technological innovation and the need for rigorous testing to ensure reliability and efficacy. These factors make the design and manufacturing process complex and require a multidisciplinary approach involving engineers, clinicians and regulators.

This applies to a wide range of devices, listed here by way of example, and which illustrate how challenging and unique work is in the medical sector, even though it shares pain points with products from other industries.

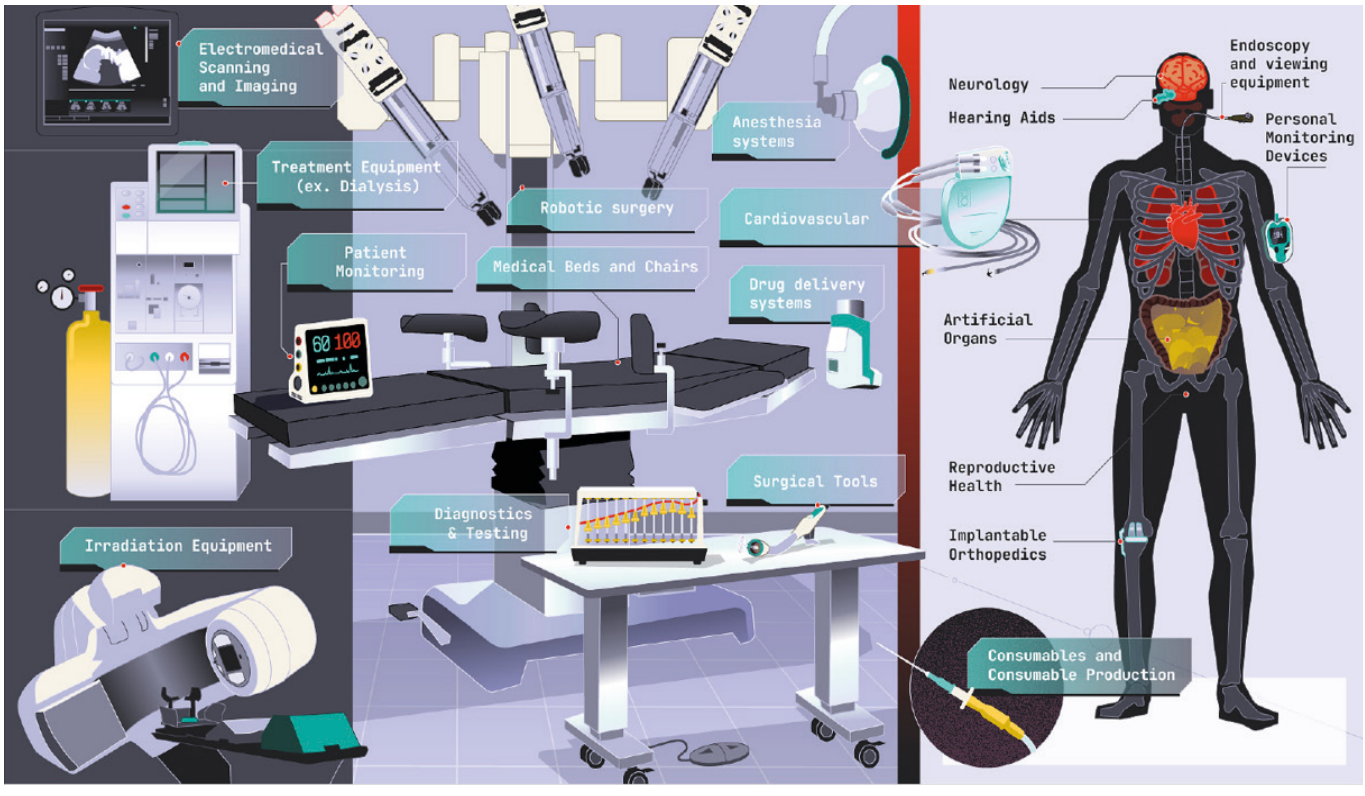
Types of medical devices:

- Diabetes care: testing and treatment equipment, personal monitoring devices, artificial pancreas
- Cardiovascular implants: implantable cardiac rhythm management devices, stents, surgical tools
- Diagnostics and testing: equipment for testing biological samples, molecular testing, genetic testing
- Orthopaedics: implants, surgical tools, surgical robots, endoscopy
- Life sciences: biological, molecular and genetic research equipment
- Gastrointestinal devices: surgical tools, surgical robots, biopsy harvesting devices, laparoscopic tools, endoscopy
- Urology: catheters, surgical tools
- Reproductive health: surgical robots, ultrasound devices, surgical tools, endoscopy
- Renal (kidneys) care: dialysis equipment
- Ear, nose and throat (ENT): scopes, surgical tools

- Oncology: radiation equipment
- Vascular devices: surgical robots
- Eye health: diagnostic and surgical tools
- Neurology: implantable neuromodulation devices, surgical tools, endoscopes
- General: infusion devices, surgical tools, robotic surgery and telemetry systems, endoscopes and viewing devices, non-invasive patient monitoring, anaesthesia systems, ventilators, needles
- Pharmaceuticals: drug delivery systems, inhalers, consumables manufacturing and testing equipment
- Patient management: medical beds, examination chairs, dental chairs, patient monitoring equipment
- Audiology: hearing aids, diagnostic equipment
- Cosmetic surgery: surgical tools
- Allergy solutions: diagnostics, vaccines

The reasons are easy to understand:

- Medical products require a responsible approach to product development to ensure product traceability and reliability: Due to the liability associated with medical devices, designers can be held accountable for every aspect of design, analysis, documentation, validation, and even component production.
- Product failure can have serious consequences: patient pain, and/or loss of life in the most severe cases. This can result in significant business impacts: major legal disputes or class actions inevitably impact corporate reputation.
- Competition for cheaper and more innovative solutions: Patents on medical devices have an expiration mechanism that allows competitors to enter the market as time passes. This makes it essential to be the first to patent solutions in order to tap into the initially high profit margins protected by the patent, and it is equally important to seek "cost-effective" product/process solutions once the patent expires in order to maintain a competitive advantage over new players entering the same market. For instance, patents for surgical robots began expiring in 2016 and were fully phased out by 2022. Potential competitors, both new and established, have been trying to enter the market with lower-cost offerings, some of which include partnerships with tech giants such as Google. There is, therefore, strong emphasis in the medical device sector on being first to market with pre-market approvals and patent applications.
- Customized, low-productivity, high-cost manufacturing and assembly processes because the problems these products must solve are often complex and multidisciplinary requiring the development of small parts and complex mechanical systems and/or intricate geometries that will fit inside the human body, and the use of inert materials that do not cause allergies/rejection by the body, all of which have a major impact on manufacturing and quality control processes. One cannot always rely on established manufacturing processes. In addition, the likelihood of production waste is significant, and it is extremely important that quality control is able to intercept any defective components.
- Manufacturers must overcome specific challenges in managing manufacturing and testing costs: parts that require unique materials and complex processes can be extremely expensive to manufacture and test and can have high scrap rates.
- Complex assembly processes can result in long production and delivery times. Extremely small parts and surfaces and uniquely shaped geometries can be difficult to inspect.



Clearly, these issues have a significant impact on the cost of product development itself.

Mechanical variation has a significant impact on all of the above. It is imperative that this impact is properly managed, monitored and documented.

What are mechanical variations and why do they impact these products so significantly?

All manufacturing processes inevitably produce "imperfect" products that deviate from the perfect nominal model, which only exists at the design level (3D CAD model). The actual geometry and/or size of all manufactured components will always deviate from the ideal counterpart. Therefore, to evaluate whether this deviation is acceptable and does not negatively affect the functionality of the final product to be assembled, it is necessary to introduce an acceptability criterion. This criterion is expressed in the technical drawings by assigning tolerance values to the various sources of geometric/dimensional variation. Once these tolerances have been defined, it is then possible to assess whether a component, produced by any manufacturing process, conforms to the requirements based on whether or not it conforms to the tolerances indicated on the drawing.

The evaluation of conformity involves making measurements on the manufactured parts. From a design and product development point of view, defining the tolerances to be included in the technical drawing is one of the most critical points because tolerances that are too wide negatively affect the quality and functionality of the product. Conversely, tolerances that are too tight increase the cost of manufacturing and testing components, with the risk of eroding profit margins once the product is on the market. It is therefore necessary to find a compromise between these two conflicting requirements. Mechanical Variation Management does just that.

What are the requirements for proper management of mechanical variation and its impact on the product?

Clearly, it is not just a matter of common sense. Several international regulations require the certification and pre-approval of medical devices before they can be placed on the market. Meeting the requirements of these regulatory frameworks is mandatory, otherwise the product will not be certified and cannot be marketed.

Regulatory oversight is required for most medical devices, particularly for Class III devices, which require full pre-market approval. Some of these regulations require the submission of detailed engineering studies that demonstrate that failure modes have been considered along with the variations in systems critical to their function. Some of these regulations include:

- FDA 21 CFR 820.30 and ISO 9001, clause 4.4 (www.fda.gov/media/116573/download). Page 25 of this document states that a tolerance stack should be performed as part of the design validation phase for complex systems or subsystems.
- FDA 501(k) (www.fda.gov/media/82395/download) discusses the criteria for approval. In 2014, the FDA issued revised 510K guidelines that refer to dimensions and design tolerances. This meant that medical device companies had to demonstrate that they had exercised due diligence on the potential impact of mechanical variation. Page 19 specifically mentions tolerances.

Specifically, how can mechanical variation management strategies be applied to product development?

These strategies can be applied to product development through dimensional management, an engineering methodology.

- Dimensional management promotes a continuous dialogue between designers, manufacturers, and inspectors of components through the exchange of information based on the geometric/dimensional requirements of the product, the "capability" of the various manufacturing processes (Pp, Cp, Cpk indices) to achieve the required precision, and the results of measurements made during dimensional inspection (scans, tomography, CMM, etc.). The aim is to find the best compromise solutions between often conflicting requirements.
- It uses predictive analysis (simulations) to anticipate and resolve potential product non-conformities before technical drawings are released to production, with a view to what is sometimes referred to as robust design (in this case, related to the geometric/dimensional domain).
- It is supported by measurement campaigns to evaluate the conformity of the manufactured parts with respect to the drawing requirements, and to monitor the behaviour of the production processes involved to identify potential savings in production costs and possible risks of drift in the stability of the production processes themselves.

Some tools are vital to successfully implement dimensional management.

Standardized technical language

It is essential to produce technical documentation that ensures unambiguous interpretation of the technical drawing. Today, this language is defined by international standards and regulations such as ISO-GPS (Geometric Product Specification) or ASME GD&T (Geometric Dimensioning & Tolerancing). Adopting such a language in technical drawings is not without its challenges: not only must designers and technical drafters be adequately trained to draw according to the rules of these standards, but those who receive the drawings must also be adequately educated about the implications from a manufacturing process and quality control perspective, including the impact on the hardware/software tools that must be used to verify the compliance of the components produced. The entire supply chain is certainly no exception in this regard.

Tolerance analysis

This is currently the only tool available to designers to evaluate tolerance widths and thus avoid under- or overestimating their impact on product quality. In fact, the analysis of the tolerance chain (stack-up analysis) makes it possible to anticipate the occurrence of potential non-conformities due to tolerances and their propagation, and to eliminate them before the product is industrialized, by means of real preventive corrective actions. Possible effects include increased productivity, greater repeatability of assembly processes (essential to avoid frequent stoppages of automatic lines), fewer production rejects, fewer non-conformities to manage and resolve, minimization of repairs/rework, etc.

Tolerance analysis is often performed in the wrong context and using outdated calculation approaches. In terms of context, it is useful to remember the importance of performing these calculations before the components are manufactured: performing post-production checks to understand the extent of an out-of-tolerance impact that has already occurred is reductive and leads to little or no benefit in reducing cost or time to market. As far as calculation approaches are concerned, it is useful to emphasize that simplified calculation models are often used (the most common being the one-dimensional model of the "worst case") because they are extremely easy to apply (manual calculations or supported by electronic spreadsheets).

Such approximate models are mistakenly believed to be sufficient to obtain useful information for use in practice, only to be confronted with reality: simplified calculation models practically always produce results that are partly or completely unreliable, proposing tolerance values to include in the drawing that are so tight that they paradoxically make the product itself uneconomical (with production process costs higher than the sales price of the final product). It goes without saying that such tight values do not represent the real functional requirements of the product but are derived from an inherently overly cautious calculation approach.

These considerations also form the basis of the widely held perception that tolerance analysis is of little use in product development: why should I spend time and resources developing calculation models that have marginal (or no) impact in practice? The reality is that tolerance analysis is fundamental and has potentially very significant impact. The only way to make it truly useful is to get it right. Calculation models must therefore represent reality to produce reliable results that can be used to support decisions.

Reality is three-dimensional: chains always contain dimensional and geometric tolerances; these tolerances have error-amplifying effects in 3D; the real behaviour must be described by variables that are probability distributions (statistical models), etc. In short, you cannot deal with such complexity by imposing hugely influential simplifying assumptions on calculation models! The complexity makes it impossible to conduct tolerance analyses manually: dedicated software such as CAT (Computer Aided Tolerancing) facilitates the work, allowing analysts to perform very complex 3D analyses with statistical variables in a relatively simple manner and within an acceptable timeframe for today's development times.

Some further considerations on implementing Dimensional Management models

Bottom-up initiatives are often proposed: designers, engineering, and R&D feel the need to "do something" to manage tolerances and try to make do with what is available. Such attempts are almost always doomed to failure because they underestimate the problem.

Many believe that it is sufficient to make ISO-GPS compliant drawings and do tolerance chain calculations; it is not. This "compartmentalized" way of working is often counterproductive and creates more problems than it solves. In fact, one must remember that the technical drawing "travels" during the product development process, ending up in the hands of those who must produce the product, and afterwards in the hands of those who must check the component. Can you be certain that the people who receive the drawing can read, understand and interpret it correctly? Are you certain that they have the hardware and software tools to collect and process data compliantly with international standards?

When looking at the problem from an organizational perspective, it is not sufficient to perform the assigned task within the engineering office alone. Rather, the problem must be tackled in its entirety and complexity, considering all potential interactions.

The emblematic example is procurement: if the engineering department adopts ISO-GPS technical language for producing engineering drawings, one of the criteria for qualifying new potential suppliers (or auditing existing suppliers) must be based on their ability to process this type of information. It seems trivial, but all too often these considerations are completely ignored.

For all these reasons, it is extremely important that the managment executives of companies are made aware of the issue and understand its potential impact on the business. In fact, they should be the ones to support and promote dimensional management initiatives within companies with a top-down approach, knowing that to achieve concrete (economic) results requires staff training, the adoption of appropriate tools (investments), and redefinition/control of business processes.

Flex Health Solutions case study: drug delivery device

Drug delivery devices, which are devices specially designed and developed to enable the dosage and subsequent administration by injection of drugs such as insulin for the treatment of diabetes,

or the latest generation of drugs to treat obesity.
These devies can be purely mechanical (i.e. with springs) or electrical, where the actuators are managed by software. They are portable and must meet requirements for ease of use, accuracy of dose delivery and, of course, cost.

Therefore, the precision of the components, miniaturization and electrical consumption for the duration of any batteries are of fundamental importance. From a mechanical point of view, these devices can be compared to a plastic resin CNC machine the size of a smartphone.

Dimensional Management as described in this paper has been successfully implemented by Flex Health Solutions over the last few years, along with the use of ISO-GPS technical language in its technical drawings, and the dissemination of skills to independently perform complex

Fig. 1. Technology demonstrator of an autoinjector. This is not an actual product.

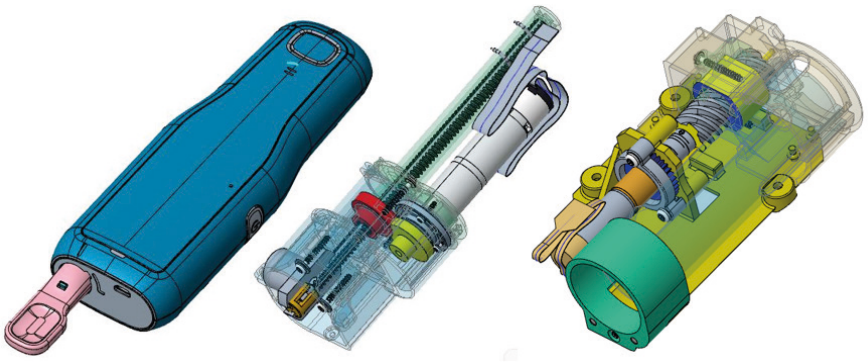


Fig. 2. Technology demonstrator of an autoinjector - CAD model.

tolerance analyses using CAT Cetol 6σ software from Sigmetrix. Throughout this process, EnginSoft has played an important and continuous role, not only supplying the software, but also providing various face-to-face training sessions for Flex Health Solutions staff at the company's Milan facility, and consulting activities. This has made it possible to achieve concrete results to support product and process improvement decisions.
The identification of the dimensions to be included in the drawings of mechanical components follows a process that starts from the functions that the component must perform and the iterations that it has with the other components.

This "functional" approach to the identification of dimensions implies a wide use of geometric tolerances for the definition of component specifications and has been made possible by:

- implementing a rigorous dimensional management system using the ISO/GPS standard;
- using new prediction tools such as Sigmetrix Cetol 6σ and verification tools such as computed tomography.

This has allowed us to identify and focus only on the really important dimensions that have a functional impact, with the

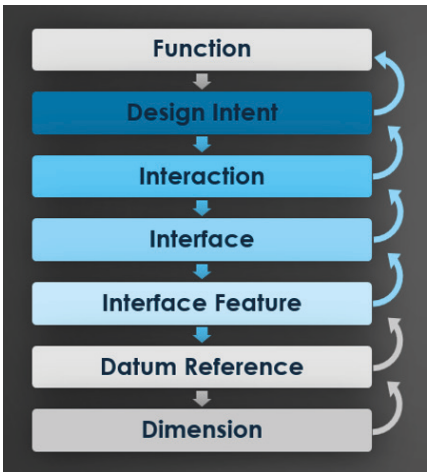


Fig.3. Design process that illustrates the link between functions and feature dimensions.

double benefit of improving quality by predicting the impact of tolerances and reducing production costs by requiring dimensional checks only where necessary and relaxing them elsewhere.

"The use of Cetol allowed us to identify the most critical dimensions to meet the requirements and, thanks to the complete integration with CREO, this was done in real time from the design phase", declared Maurizio Volpe, Mechanical Engineering Manager at Flex Health Solutions.

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