Design and Validation Strategy for Medical Device Product Transfer

Adiel Hernández Santiago
Manufacturing Engineering
Carlos González-Miranda, PhD.
Industrial and Systems Engineering
Polytechnic University of Puerto Rico

Abstract *— The transfer of medical device products from development to manufacturing presents multifaceted challenges that demand meticulous planning and execution to ensure product quality, regulatory compliance, and cost-effectiveness. This article proposes an integrated approach leveraging principles of lean manufacturing and Six Sigma methodology to streamline the design and validation processes during product transfer. The application of lean manufacturing principles enables the identification and elimination of non-value-added activities, thus optimizing the transfer process for efficiency and resource utilization. Concurrently, Six Sigma methodology offers a structured framework for reducing variation and enhancing product quality through data-driven decision-making. This article outlines a comprehensive strategy encompassing key stages of product transfer, including design transfer planning, process validation, and risk management. Each stage is systematically analyzed and optimized to achieve seamless transition while meeting regulatory requirements and customer expectations.*

Key Term *− Design validation, Lean manufacturing, Product transfer, , Six Sigma.*

INTRODUCTION

In the ever-evolving landscape of medical device manufacturing, the transfer of product lines between facilities is a common occurrence, driven by factors such as cost optimization, capacity expansion, and strategic reorganization. However, this seemingly straightforward process often encounters significant obstacles when there are gaps in the design and validation strategies between the originating and receiving facilities. These gaps, stemming from differences in processes, standards, or interpretations, can lead to inconsistencies in product quality, regulatory compliance, and overall operational efficiency.

At the heart of these challenges lies the imperative need for a cohesive approach that seamlessly integrates lean manufacturing and Six Sigma methodologies. While lean principles focus on eliminating waste and optimizing processes, Six Sigma provides a structured framework for reducing variation and enhancing product quality. When applied in tandem, these methodologies hold the promise of not only bridging the gaps but also driving continuous improvement across the entire transfer process. In this article, we delve into the complexities of medical device product transfer between manufacturing facilities, identifying the key challenges posed by gaps in design and validation strategies, and proposing an integrated approach that harnesses the power of lean manufacturing and Six Sigma to navigate these obstacles effectively.

Problem Statement

The transfer of medical device products between manufacturing facilities poses significant challenges when there are gaps in the design and validation strategy. Such gaps may manifest in inconsistencies in product specifications, manufacturing processes, or quality standards, leading to variations in product performance and regulatory compliance. Without a robust strategy integrating lean manufacturing and Six Sigma methodologies, these discrepancies can escalate, resulting in delays, increased costs, and compromised patient safety.

Furthermore, the lack of alignment in design and validation approaches between the originating and receiving facilities exacerbates the problem, exacerbating communication breakdowns and hindering seamless knowledge transfer. These discrepancies may arise due to differences in organizational cultures, resource capabilities, or regulatory interpretations. Without a synchronized strategy, the transfer process becomes fragmented, impeding the achievement of key objectives such as efficiency improvements and regulatory compliance. Addressing these gaps requires a holistic approach that not only identifies and bridges the disparities but also establishes standardized procedures and metrics to ensure consistency and continuous improvement across manufacturing sites.

Research Description

The goal of this research is to optimize the design and validation strategy for the transfer of medical devices, thereby reducing the time required to execute validation activities and increasing product reliability and standard compliance.

Research Objectives

The goal of this project is to improve the time it takes to complete validation and reduce rework tasks. Reducing the duration of validation execution aids in getting product manufacturing back on track, which lowers lead time and product backorder.

Research Contribution

This project seeks to reduce the validation activities execution and gaps between manufacturing facilities. This improves product reliability, quality, and standard compliance as per 21CFR Part 210 and 211. The reduction of gaps between manufacturing facilities will improve the manufacturing process, reducing product inspection time.

Literature Review

Modern businesses have been searching for strategies to withstand the ongoing shifts in the market since the economic crises of the 1970s. Although lean manufacturing has been around since 1950, its methods and ideas were first published in publications in 1990. The brilliant minds behind the Toyota Production System (TPS), designed and developed the first methodology based on "Lean" concepts, was put into practice at Toyota. This way of thinking then started to spread around the globe. In fact, as Taiichi Ohno stated, the goal is to produce an increasing amount with a decreasing amount. By establishing control in the process [1], bypassing hierarchy, and implementing strategies that assign authority and specific tasks to various personnel, the goal is to increase production and profit. The operators possess a significant portion of the knowledge, not the engineering teams.

As a result, every operation's primary goal must be to satisfy its clients, which calls for a shift in perspective, structure, and methods of doing business that include thinking about standardization, collaboration, zero defects, and zero waste, among other things. Some companies opt not to innovate and update, some try and fail, and the remaining businesses work very hard through projects to use Lean improvement approaches [1]. Given the fact the tools and concepts may be tailored to suit any given situation, this philosophy is becoming more and more influential in company management globally. As a result, businesses' pursuit of profitability is propelling this methodology's adoption even further. According to Luís Cuatrecasas, the adoption of Lean management is not dependent on technology or resources because it primarily necessitates the determination and motivation of the company's members, especially its management [1]

He further believes that "the objective of the transformation of the process to Lean principles is to eliminate from the processes the activities that

do not add value (waste) and to introduce the necessary flexibility to adapt production to a fluctuating demand" [1]. Lean management, according to Uriel, "has as its essential objective that production flows at a continuous and smooth pace, a pace that is marked by customer demand, not by the availability or capacity of the machines"[1].

A lean manufacturing system eliminates any kind of activity that does not improve the product and delivers what the demand requests in the amount asked and at the time desired.

For his side, Luís Cuatrecasas claims that lean management has significantly improved processes, whether they are industrial or service-related, in terms of efficiency, competitiveness, speed of response, and adaptability. Additionally, technology has made it possible for businesses to provide a large range of goods at affordable prices, with excellent productivity, quick delivery, little inventory, and optimal quality. Cuatrecasas in the aforementioned article proposes a methodology for the implementation of Lean Management in a service production system and, to complete among many others, there is a study in which the effectiveness of Lean techniques in the construction sector is put into practice and tested [1], through a case study in which the implementation of Lean is successfully carried out, the authors reaching very special conclusions such as that the tools of Lean management are really applicable to their sector, that the commitment of the management is the most important factor. It reveals that workers enjoy being part of a structured planning and decision-making process, but above all that the training of workers is a key aspect for success.

Lean Methodology Implementation Steps

Implementing Lean methodology is crucial for organizations seeking efficiency and continuous improvement. The steps involved in Lean implementation are pivotal to its success. Firstly, defining value from the customer's perspective helps identify essential processes. Next, mapping the value stream exposes wasteful activities for elimination. Creating flow by streamlining processes and reducing bottlenecks enhances productivity. Establishing pull systems ensures resources are used only when needed, reducing overproduction. Finally, pursuing perfection through continuous improvement embeds a culture of excellence. Each step in Lean implementation is integral, fostering lean thinking and driving organizational success.

1. Identify Value = Identify the value adding from the waste activities. Value is everything that the customer is paying for the finished product. Waste activities fall into two categories: essential and pure. The primary distinction between them is that pure waste activities only interfere with the Lean flow of work, whereas certain waste activities are required to support the value-adding ones.
2. Map Value Stream = It is essential to visualize the path. An efficient tool for outlining each process step is a Kanban board. The value-adding activities are the main focus of value stream mapping.
3. Create Flow = Flow is a key concept, a major impediment to creating a smooth flow is the bottlenecks in the process. Pay attention to the critical path of the process flow. Alleviating the bottlenecks in the process is important for the creation of a smooth and lean process flow.
4. Stablish Pull = In industrial operations, a pull system minimizes waste. As a result, expenses are reduced, and storage expenses are maximized. Deliverables are made according to the just-in-time production approach, which prevents overstocking by meeting real demand.
5. Seek Constant Improvement = Every process should be continuously improved, with an emphasis on streamlining the tasks that add the most value for the client and cutting out as much waste as possible.[2]

Lean Six Sigma

Lean Six Sigma is a methodology that aims to increase productivity, decrease errors, and optimize processes by merging the ideas of Six Sigma and Lean Manufacturing. The following are some essential elements of Lean Six Sigma:

Customer Focus = A key component of Lean Six Sigma is comprehending and satisfying the needs and expectations of the customer. The end-user is considered in the design and improvement of processes.

Data-Driven Decision Making = The foundation of Lean Six Sigma is data analysis. To find the core causes of issues and make wise judgments for process improvement, it relies on statistical methodologies.

Continuous Improvement = Lean Six Sigma continuously seeks to optimize processes to get rid of waste, errors, and variability. The culture of companies using Lean Six Sigma is deeply embedded with this idea.

Waste Reduction = A key component of lean concepts is the elimination of waste in operations, which includes excess inventory, motion, waiting times, unnecessary transportation, overproduction, overprocessing, and defects. This is enhanced by Six Sigma, which lowers process variances.

DMAIC Methodology = Define, Measure, Analyze, Improve, and Control are the acronyms for these phases. Lean Six Sigma efforts apply this methodical approach to problem-solving to systematically address process issues and produce quantitative improvements.

Standardization = In order to guarantee consistency, lower mistake rates, and support continuous improvement initiatives, Lean Six Sigma advocates for process standardization.

Cross-Functional Teams: People from several departments or fields of expertise frequently work in cross-functional teams as part of Lean Six Sigma projects. This approach encourages teamwork and introduces a variety of viewpoints to the process of addressing problems.

Leadership Support: Strong leadership commitment and support are necessary for the successful implementation of Lean Six Sigma. Setting objectives, allocating resources, and promoting a continuous improvement culture are all critical tasks performed by leaders.

Put Quality First: Six Sigma seeks to reduce faults to a level that satisfies customers to attain near-perfect quality. It highlights how crucial process competence and quality control are.

Visual Management: To make information clear and encourage team communication, Lean Six Sigma frequently uses visual management tools like performance dashboards, process maps, and Kanban boards.

Kaizen: Kaizen, or constant progressive improvement, is an ideology that Lean Six Sigma promotes. It involves suggestions for little, steady process changes coming from all the organization's personnel.

The methodical approach to process improvement, focus on data-driven decision-making, dedication to customer satisfaction, and culture of continuous learning and improvement that define Lean Six Sigma as a whole.[3]

METHODOLOGY

Lean Six Sigma is a powerful methodology that combines the principles of Lean Manufacturing and Six Sigma to improve processes, reduce defects, and enhance efficiency[4]. Here's an overview of the Lean Six Sigma methodology (see Figure 1).

Figure 1
DMAIC

Define: The goal and scope are precisely defined at this phase. This requires identifying the

issue or area in need of change, comprehending the needs of the client, and establishing project goals that are specific and measurable.

Measure: To assess the process's current state, the Measure phase is centered on obtaining data. Methods of data gathering are decided upon, along with key KPIs. Measuring process performance and pinpointing areas for improvement generally involves the use of process mapping and data analysis techniques like histograms, Pareto charts, and process capability analysis.

Analyze: The purpose of the Analyze phase is to find the underlying reasons for process problems or variation using the data gathered during the Measure phase. Failure mode and effects analysis (FMEA), cause-and-effect diagrams, and hypothesis testing are a few of the tools used to methodically investigate possible causes and rank improvement chances.

Improve: In the Improve phase, remedies for the core issues found during the Analyze phase are created and put into action. To come up with and evaluate possible solutions, creative problem-solving methods like benchmarking, design of experiments (DOE), and brainstorming can be employed. The objective is to put changes into place that will enhance process performance in a way that can be measured.

Control: The purpose of the Control phase is to make sure that the advancements achieved during the Improve phase are maintained over time. Regression to prior performance levels is avoided by implementing control measures like standard operating procedures (SOPs), visual controls, and mistake-proofing strategies. To ensure that the process is stable and keeps achieving its objectives, ongoing measurement and monitoring are done.

A systematic technique for problem-solving called DMAIC (Define, Measure, Analyze, Improve, Control) is frequently used throughout the Lean Six Sigma process. A methodical framework for leading initiatives from problem description to long-term process improvement is offered by DMAIC.

Lean Six Sigma also highlights the value of employee involvement, leadership support, and a continuous improvement culture. Various levels of training and certification programs, such as Yellow Belt, Green Belt, and Black Belt, are offered to provide people with the knowledge and abilities required to successfully lead Lean Six Sigma projects.

By following the Lean Six Sigma methodology, organizations can achieve significant improvements in quality, efficiency, and customer satisfaction while reducing costs and waste in their processes.

Results and Discussion

In this section is described the steps of the DMAIC methodology to capture all variables using the Lean Six Sigma Principles.

Define

During the design and validation strategy of a medical device transfer, process gaps were encountered during the initial development steps. Inadequate part measuring at the sending facility is a serious risk to product integrity and quality control. Operators may unintentionally pass defective components as acceptable when parts are not measured in accordance with Geometric Dimensioning and Tolerancing (GD&T) fundamentals [5]. The dependability of quality inspections is compromised by this disregard for GD&T standards, which may permit defective components to pass through production or assembly processes undetected. Consequently, if faulty parts find their way into finished goods, this oversight may result in a rise in rework or scrap, a decrease in customer satisfaction, and a breach of safety standards (see Table 1). It is impossible to overestimate how important it is for the sending facility to have precise measurement protocols since they have a direct effect on the general dependability and quality of the manufactured

parts that are dispatched throughout the manufacturing process.

Table 1
Problem Statement

Affected Process:	Medical Device Transfer
What is the problem? Why?	The sending facility does not measure the parts according to GD&T guidelines. The operator can pass bad parts as good parts by not measuring the parts properly.
What is the goal?	Measure the parts according to GD&T fundamentals
Staff:	Manufacturing Engineer, Operators, Programmers, Quality Engineer, Project Manager, Tool Engineer, and Engineering Manager

Measure

In this phase, a thorough data collection procedure was put in place to obtain specific information about the amount of scrap produced during development activities. Using the defined Standard Operating Procedure (SOP) by the sending facility, we were able to properly measure the variation between acceptable parts and defective parts by systematically collecting this data. This required careful documentation of the results, including units that did not meet the drawing specifications and units that were acceptable and met the drawing specifications.

Using the actual inspection SOP from the sending facility, 3 lots of 50 parts were selected, and 5 different operators remeasured them to see if any bad parts were accepted as good parts. (See Figures 1, Figure 2, Figure 3 and Figure 4).

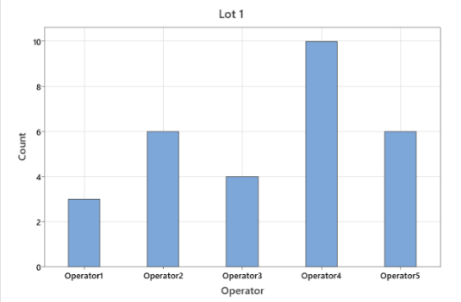

Figure 2
Bad Parts Identified from Lot 1

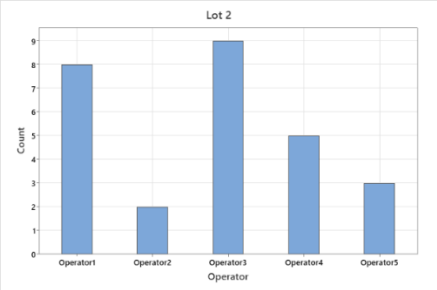

Figure 3
Bad Parts Identified from Lot 2

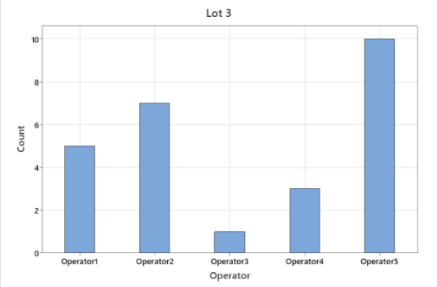

Figure 4
Bad parts identified from Lot 3

Analyze

This phase aims to investigate how inadequate measurement practices allow operators to pass defective parts as acceptable ones. By analyzing the root causes and consequences of this problem, we can lay the groundwork for effective solutions that enhance measurement protocols and ensure quality standards are met. (See Figure 5).

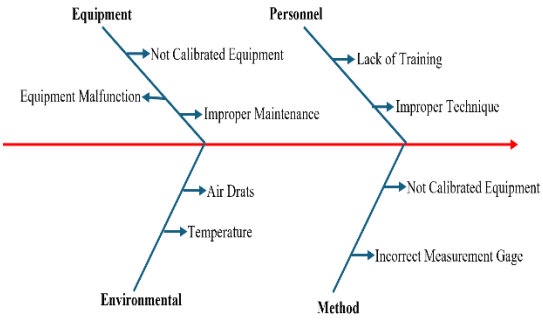

Figure 5
Cause and Effect Diagram

Equipment

Equipment calibration, operation, and maintenance must be done correctly to achieve precise measurements. Significant measurement

mistakes might result from improperly calibrated equipment. Calibration guarantees measurement reliability by ensuring that instruments are accurately calibrated to accepted standards. Unpredictable errors can be introduced by equipment defects, such as sensor drift or electronic failures, which compromise the quality of the data. Furthermore, poor maintenance over time can affect precision and cause performance to gradually deteriorate. Regular maintenance is necessary to maintain equipment accuracy and increase its longevity. This includes cleaning, calibration checks, and repairs.

Personnel

The lack of training in GD&T fundamentals and improper techniques among operators can significantly impact the accuracy of measurements in manufacturing processes. GD&T provides a standardized method for defining and communicating engineering tolerances, ensuring parts are produced to required specifications. Without adequate training, operators may misinterpret GD&T symbols, leading to incorrect measurement techniques and ultimately flawed parts. Improper techniques, such as applying too much pressure or not maintaining a stable environment during measurement, can introduce additional variables that skew results. Ultimately, the quality and reliability of measurements heavily rely on the expertise and diligence of the operator.

Environment

Air draft and surrounding temperature can have significant effects on measurement accuracy. Moving air currents, or air drafts, can introduce variables that affect measurements. These drafts may introduce unintentional movement or interference, causing variations or instability in sensitive measuring instruments and influencing readings. The precision of measurements is also greatly influenced by temperature. Temperature variations have the potential to expand or contract the materials used in equipment, changing their dimensions, and influencing calibration. Therefore, keeping a stable and regulated environment with minimum air drafts and consistent temperature levels is crucial to guaranteeing reliable and precise measurements.

Method

Measurement accuracy may be severely impacted by improper gage selection and an inadequate standard operating procedure. The procedure is more likely to be inconsistent and prone to error in the absence of explicit instructions and steps for taking measurements. When various people perform the same measurement, this might result in differences in outcomes. Furthermore, systemic mistakes or biases may be introduced if the wrong gage is used for a particular measuring activity. For example, readings that do not accurately reflect the value being measured may arise from choosing an instrument with too coarse or fine resolution for the necessary precision.

As a result, choosing the right gage and focusing meticulous attention on SOP details are essential to assuring precise measurements.

Improve

Implementing effective solutions is critical for improving measurement accuracy and adherence to standards. Fostering a culture of continuous improvement and accountability within the organization can encourage adherence to standards and drive sustainable improvements in measurement practices. By systematically addressing root causes and implementing these solutions, organizations can optimize measurement accuracy, enhance product quality, and mitigate risks associated with non-compliance with GD&T guidelines.

Equipment

After implementing the improvement of using calibrated equipment and maintaining proper maintenance procedures, the accuracy of measurements noticeably improved. Calibrating

measuring instruments regularly ensured that they were operating within specified tolerances, reducing the risk of inaccuracies due to instrument drift or wear. Additionally, establishing a schedule for equipment maintenance and upkeep helped prevent unexpected breakdowns and maintained the integrity of measurement tools. These measures resulted in more consistent and reliable measurements.

Personnel

The implementation of training sessions for operators on GD&T and proper techniques with gages proved to be highly beneficial. During these sessions, operators were educated on the fundamentals of GD&T. They were also trained in the correct usage of various gages and measuring instruments specific to the needs of the product. As a result of this training initiative, operators demonstrated improved proficiency in accurately measuring parts according to GD&T guidelines, leading to enhanced precision and consistency in measurement outcomes.

Environment

Several crucial steps were taken to successfully implement the improvement of lowering air drafts and controlling temperature to increase the accuracy of taking measurements. Initially, in order to reduce air drafts within the measurement area, air leaks surrounding doors and windows were located and plugged. To regulate temperature variations, the measurement room's insulation was also modified. To keep a steady temperature range appropriate for accurate readings, HVAC changes were made. These upgrades helped create a controlled environment that reduced outside influences on the measurement equipment, which led to accurate and reliable measurements across.

Method

The improvement in developing a more detailed SOP and ensuring correct selection of inspection gauges yielded positive results. The team worked collaboratively to enhance the existing SOP, incorporating specific guidelines for measurement procedures according to GD&T standards. This included detailing the appropriate selection and calibration of inspection gauges based on the required precision for each measurement task. As a result of these improvements, measurement consistency and accuracy notably increased, reducing variability in recorded data, and ensuring alignment with geometric tolerancing specifications.

Using the improved inspection SOP developed from the receiving facility, 3 lots of 50 parts were selected, and 5 different operators measured them to test the accuracy of the measurements after the improvements were implemented.

The graphs represent the improvement of bad parts identified after the implementation of several controls in the machining process. (See Figures 6, Figure 7 and Figure 8).

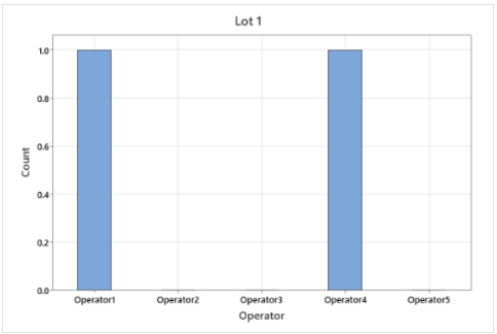

Figure 6
Bad Parts Identified from Lot 1

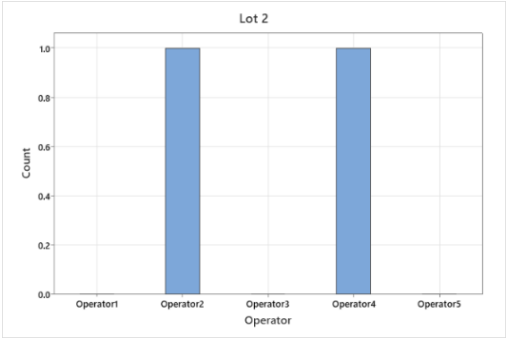

Figure 7
Bad Parts Identified from Lot 2

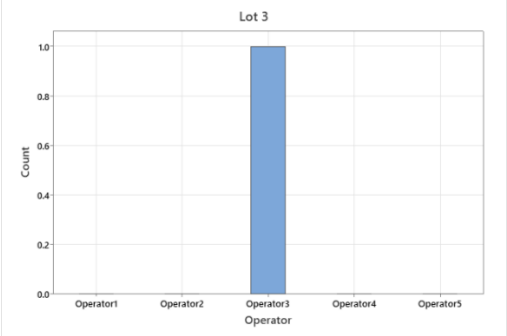

Figure 8
Bad Parts Identified from Lot 3

Control

The emphasis turns to preserving reliability and consistency. Regular audits will be performed to ensure compliance with SOPs and gage calibration schedules. Key performance indicators (KPIs) such as process capability indices and defect rates will be regularly tracked. Any deviations will be handled promptly using approved corrective action processes. Furthermore, continuing training programs will be implemented to reinforce best practices and keep operators informed of any procedure changes. By employing these control methods, the goal is to maintain the improvements that were obtained.

CONCLUSION

The root causes for the high variability and large number of defective parts that were dispatched as good ones were found throughout this investigation. Both manufacturing facilities implemented the results after sharing them with the sending facility. This ensures that every product shipped out from both facilities are being dimensionally inspected accurately in accordance with GD&T guidelines. DMAIC allowed for the identification of the root causes of the problem, improvement, and assurance that the two manufacturing plants were maintaining the improvements made.

REFERENCES

[1] P. Gómez. (2010, Jul.) "Lean Manufacturing: flexibilidad, agilidad y productividad," pp. 1–14. Available: https://ciencia.lasalle.edu.co/gs/vol3/iss2/7/

[2] The 5 Lean Principles: Reduce Waste and Drive Growth. (2014). Kanban Software for Agile Project Management. [Online] Available: https://businessmap.io/lean-management/implementing-lean-principles#:~:text=The%20five%20principles%20of%20Lean,and%20striving%20for%20continuous%20improvement

[3] Arthur, Jay. 2011. "What Is Lean Six Sigma?." Chap. 1 in Lean Six Sigma Demystified. 2nd ed. New York: McGraw-Hill.

[4] DMAIC Process: Define, Measure, Analyze, Improve, Control | ASQ. (2023). Asq.org. [Online] https://asq.org/quality-resources/dmaic

[5] Cogorno, Gene R. 2020. "Dimensioning and Tolerancing Fundamentals." Chap. 2 in Geometric Dimensioning and Tolerancing for Mechanical Design. 3rd ed. New York: McGraw-Hill Education.