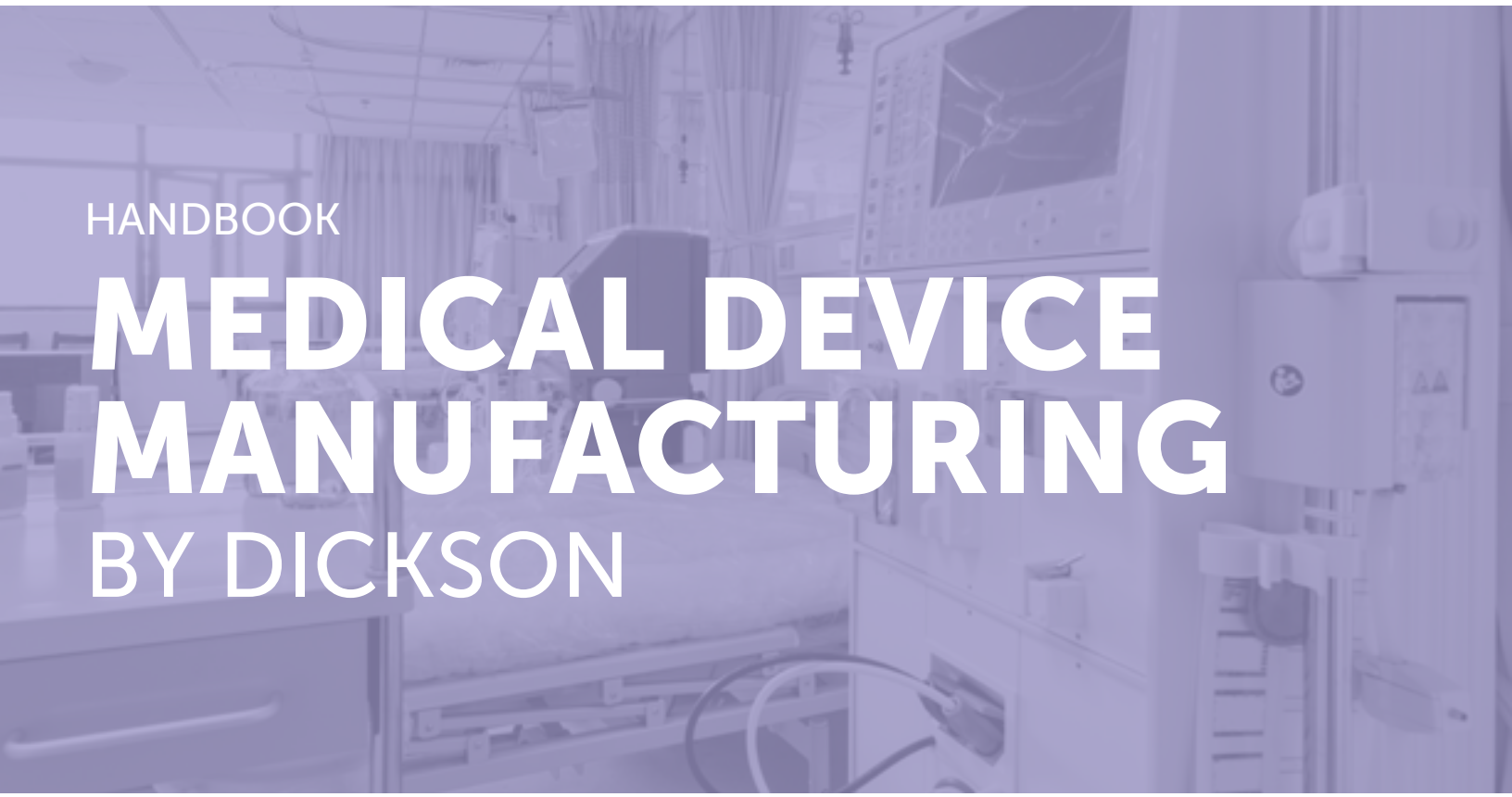
DICKSON
Environmental Monitoring + Compliance Experts



HANDBOOK

MEDICAL DEVICE MANUFACTURING
BY DICKSON

Environmental Monitoring
+ Compliance Experts

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THE PULSE OF THE INDUSTRY

New advancements in medical technology over the past several decades have led to a significant increase in average life expectancy. In the United States alone, the average age increased from 47 years in 1900 to 78 years in 2016. People are living longer, healthier lives. Much of this is due to medical device innovations that help clinicians more accurately diagnose and treat chronic illness and disease.

Typically, the purpose of a medical device is not determined by pharmacological, immunological, or metabolic means. Medical devices are any instrument, machine, apparatus or article that is used in "the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose."

The manufacturing of medical devices is a highly complex and highly regulated industry that is continually changing. Rapid advances in technology, although promising for the industry, present a fair amount of challenges for manufacturers. As designs become more intricate, the number of components used in devices is higher than ever before. This requires manufacturers to be much more diligent in production and inspection standards to ensure that the product performs as intended each time.

As a medical device manufacturer, you understand the importance of product quality in a world of changing technology, consumer demands for greater visibility, and ever-evolving regulations. This handbook on medical devices is for industry newcomers and seasoned pros alike. We explore trends that are shifting the market, essential regulations governing the industry, and how this translates to best practices.

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REGULATIONS HISTORY (USA)

1933

THE FDA RECOMMENDS AN UPDATE

The Food and Drug Administration (FDA) decides it wants to overhaul the original 1906 Food and Drugs Act, as that Act is now obsolete.

1966

THE FAIR PACKAGE AND LABELING ACT

Legislation is introduced that forces all consumer products in interstate commerce to be labeled properly, with the FDA enforcing medical device products.

1976

MEDICAL DEVICE AMENDMENTS

These amendments require medical device manufacturers to register with the FDA and follow quality control procedures. Some devices must meet performance standards before they can be released to market.

1990

THE SAFE MEDICAL DEVICES ACT IS PASSED

This act requires medical facilities to report to the FDA incidents that a medical device contributed or caused the death or injury to a patient. This act more importantly allowed the FDA to order medical device product recalls.

1997

FOOD & DRUG MODERNIZATION ACT

The Food & Drug Modernization Act was enacted to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, among other purposes.

2002

THE OFFICE OF COMBINATION PRODUCTS IS ESTABLISHED

This office is created to oversee the review of products that fall under multiple jurisdictions of the FDA, including the medical device jurisdiction.

2016

BREAKTHROUGH DEVICES PROGRAM

The Breakthrough Devices program was initiated to allow patients earlier access to devices that may have a positive effect on their health. Breakthrough Devices are subject to a Premarket Approval Application (PMA), only if it determines there are reasonable assurances of safety and effectiveness. This also signals that the FDA may accept a higher degree of uncertainty regarding the benefit-risk profile of new devices.

2018

MEDICAL DEVICES SAFETY ACTION PLAN

This plan aims to improve patient safety, explore regulatory solutions, and advance medical device cybersecurity nationwide. It seeks to accomplish this by requiring that medical devices be capable of being updated and receiving security patches and may force companies to publicly disclose cybersecurity issues that are detected, among other changes.

CATEGORIZING DEVICES

Medical devices span many different types and applications, and their complexity ranges from as simple as tongue depressors to massive large-scale imaging machines such as MRI's. As such, several sub-categories make up the broader medical device market.

Diagnostic: Endoscopic devices, ultrasound, and magnetic resonance instruments are examples of this sector. Key technologies include imaging, IT, and micromanufacturing.

Surgical: One of the largest segments, the surgical industry includes dilators, sutures, and surgical robotics. Key technologies include micromachining, surface treatments, and materials.

Cardiovascular: This highly competitive sector includes pacemakers, defibrillators, and drug stents. Key technologies include power sources, micro-molding, and assembly.

Orthopedics: As one of the fastest-growing sectors in medical device manufacturing, orthopedics includes reconstructive devices, spinal implants, arthroscopy, orthobiologicals, hip implants and knee replacements. The process of machining, casting, grinding, polishing metal injection molding and rapid manufacturing is utilized for production.

Diabetes: Continuous glucose monitoring (CGM) is a leading example of this sector. Key technologies include nanotechnology, sensors and assembly.

Dental: Imaging equipment, implants, drills and instruments. Key technologies include machining, additive manufacturing and 3D imaging.

Other: Spinal devices, catheters, syringes and hypodermic needles, blood transfusion and IV equipment, internal fixation devices, neuromodulation devices and urology devices.

FDA MEDICAL DEVICE CLASSES

The FDA also provides the specific classification of medical devices based on their complexity and risk level to the patient:

Class	Risk Level	Explanation	Example
Class I	Low to moderate	Simpler in design; device is not life-supporting or life-sustaining and does not present a reasonable source of injury through normal usage	Stethoscope, elastic bandage, bedpan
Class II	Moderate to high	Most medical devices on the market are class II	Powered wheelchair, x-ray machine, suture material
Class III	High	Usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury	Pacemaker

MEDICAL DEVICE TECHNOLOGIES OF TODAY

Since medical devices are used to achieve such a myriad of patient outcomes, many technologies work together to create a final product. These technologies may accomplish minor tasks such as regulating speed, or something as complex as imaging a live heart in 3D. What follows are common technologies used in medical devices.

MEASUREMENT/INSPECTION

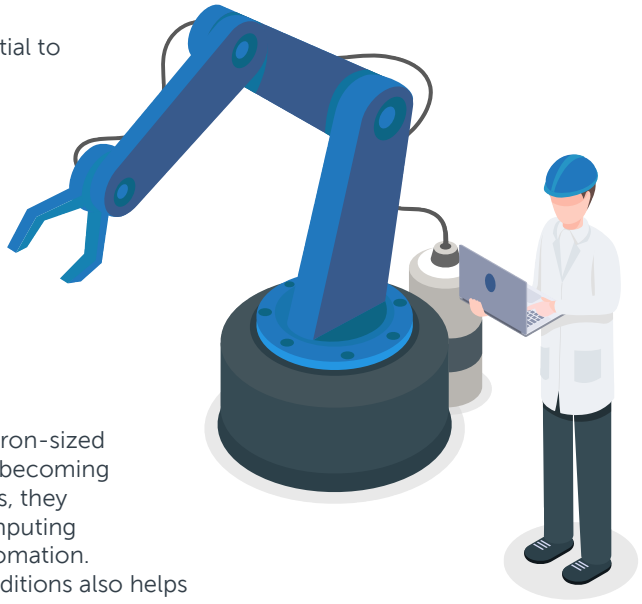
Maintaining medical device quality requires consistent, reliable, and verifiable measurement and inspection. With the need to measure and inspect down to micron and submicron levels, medical device manufacturers can face unique technology and process challenges. These challenges are made even more difficult when you can't touch or spray the surface of the device for the sake of sanitation. Using methods like computed tomography, manufacturers can take measurements of the internal as well as external features of intricate medical devices like inhalers or injection systems.

3D IMAGING

3D imaging is the rendering and display of objects in 3D. According to HealthTech Magazine, 3D imaging allows healthcare professionals to access new angles, resolutions, and details that offer an all-around better understanding of the body part in question, all while cutting the dosage of radiation for patients. For instance, it can provide clear images of bones or blood vessels, empowering more effective diagnosis and treatment. Combined with artificial intelligence, 3D imaging can even use measurements to supplement and support human diagnoses.

QUALITY SYSTEMS

In a highly regulated environment, quality systems are essential to medical device manufacturing. Technologies that help with failure mode and effects analysis (FMEA) give manufacturers a structured approach to discovering potential failures that may exist within the design of a medical device. The sooner a problem is detected, the less it will cost to fix it and the more lives you can protect from harm. With the industry's critical need for consistent quality, these technologies are found in more and more medical devices.



ASSEMBLY

From selecting appropriate joining methods to handling micron-sized components, medical device manufacturing assemblies are becoming more and more complex. With the nature of medical devices, they often require exceptionally clean environments. Precise computing is essential here, as it allows for efficient, detail-focused automation. Environmental monitoring of temperature and humidity conditions also helps ensure consistency during production and assembly – ensuring product safety and even helping companies remain compliant with industry regulations.

LASERS

Highly accurate and flexible, a narrow laser beam can cut, machine, mark or weld intricate details with micron-level accuracies. Laser welding and cutting technology can meet rigid standards for clean and hygienic surfaces, completely free of any material residue. Precision laser cutting is explicitly perfect for medical device machining applications that require superior edge quality, tight dimensional tolerances, and high-volume production, like thin wall metal tube cutting.

COATINGS AND SURFACE TREATMENTS

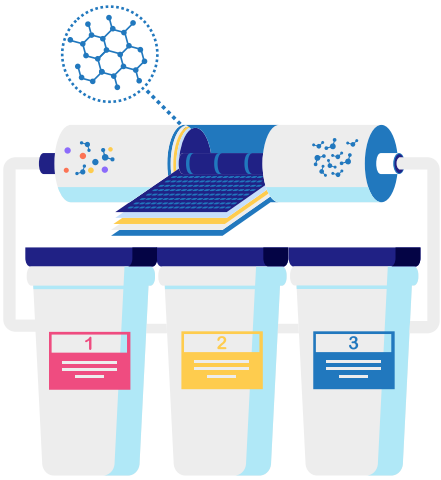
Coatings serve numerous functions, such as increased wear resistance, increased bone in-growth, reduced friction, and enhanced abrasion. Biocompatible coatings are used for passive and drug-eluting applications on cardiovascular stents and a broad range of other implantable medical devices. The ultra-thin coating on implantable devices is designed to protect surrounding tissue from potentially harmful interactions with bare metallic stents.

MICROMANUFACTURING

Medical devices continue to get smaller and smaller. Features and components the size of just a few microns require the specialty processes of micromanufacturing, which includes micromachining and micro molding. These allow you to simplify devices into more compact designs by combining multiple components or will enable you to increase the capabilities of the device without taking up any more space. When going inside the body, micromanufacturing technology can reach areas not accessible without miniaturization, and smaller cuts/intrusions mean faster healing time and improved patient comfort.

NANOTECHNOLOGY

Nanotech involves the manipulation and manufacturing of materials and devices on the atomic, molecular, and supramolecular scale. From new materials and coatings to drug delivery systems, the use of nanotechnology in medical devices and medicine is expected to grow. Smaller versions of needles, electrical devices, and tubing are all possible with nanotech. Nanorobotics, which aims to develop microscopic robots smaller than a strand of human hair, could have numerous medical applications in and out of the body.



POWER SOURCES

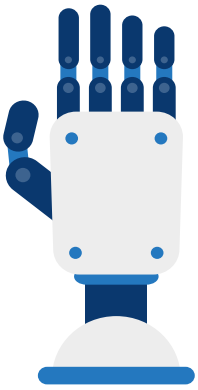
With the advancement of implantable devices for patient monitoring and treatment, the selection and development of power sources have become a critical part of medical manufacturing. Referred to as "active" medical devices, many of today's devices require a power source to function, including pacemakers and insulin pumps. Smaller batteries and power supplies, along with wireless sources of power, allow for more compact devices, easing the physical burden on patients.

"Maintaining medical device quality requires consistent, reliable, and verifiable measurement and inspection."

TRANSFORMING PATIENT CARE THROUGH TECHNOLOGY ADVANCES

Every medical device that is prescribed to a patient is a path on their journey to wellness. To ensure better patient outcomes, manufacturers of medical devices are finding new ways to transform their journey of care. Understanding industry challenges and needs of a growing global market is key to keeping this commitment. Technology will play a significant role in this transformation.

As healthcare goes digital, manufacturers of medical devices need to follow suit. High-precision medical devices are only successful if they are consistently manufactured according to defined specifications. The digitization of manufacturing is key to success. It's critical to adapt the design of medical devices to the changing technology demands. Below we explore some of the technologies that are transforming patient care:



AI

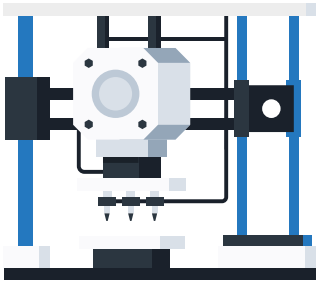
Artificial intelligence is the capability of a machine to perform tasks that would typically be done by a human. Through machine learning, computers are taking in data and learning mistakes while enhancing the jobs of engineers in the manufacturing process. A predictive algorithm can gather data about a medical device that was taken out of a production line because of a problem with the device. Then, using data and performance records, AI can determine the probability of that device being scrapped.

IOT

The Internet of Things, or IoT, is the concept of connecting any device with an on and off switch to the Internet (and/or to each other). In healthcare, one major example of IoT is the emergence of electronic medical records. According to Machine Design, "provides medical engineers with wireless sensor technology, remote and continuous monitoring, microscale actuation and motor tools, mobile connectivity, and 3D printing capabilities of living tissue." This can reduce treatment costs and the chance of clinical error. Additionally, as more and more patients begin to rely on medical devices for ongoing monitoring or treatment, they will likely want these devices connecting to their smartphones and computers to keep track of essential data. A few examples include wearable fitness trackers, smart continuous glucose monitors, and even connected inhalers.

3D PRINTING

3D printing creates a three-dimensional object by building successive layers of material. Each layer is attached to the previous one until the object is complete. Objects are produced from a digital 3D file, such as a computer-aided design (CAD) drawing or a Magnetic Resonance Image (MRI). The flexibility of 3D printing allows designers to make changes quickly without the need for additional equipment or tools. It also enables manufacturers to create devices matched to a patient's anatomy or devices with very complex structures. Some common medical uses are in orthopedics and cranial implants.



BIO-PRINTING

Bio-printing is the exciting ability for scientists to create artificial organs and body parts for patients. An extension of 3D printing, bio-printing offers hope to patients in need of transplants, grafts, or those dealing with rare conditions. Bio-printing deposits layers of biomaterials (e.g., living cells) to build biological structures. Some applications also require the use of a support medium to help cells stabilize in the correct form. Bio-printing is still in its early stages, being used to develop skin, tissue, blood vessels, and even bone. As the technology continues to advance, more and more complex structures, such as fully functioning organs.

KEY CHALLENGES

The medical device industry is no stranger to challenge. Manufacturers over time have dealt with increasing regulatory oversight, technology complexity, and new diseases to address. But what challenges are currently facing medical device companies?

SOCIOECONOMIC CHANGES AND AN AGING SOCIETY

Over 15% of the population in 2015 was in the geriatric category, and that number is expected to reach 25% by 2023. As the population ages, there is a much greater demand for medical device products. Baby Boomers might be more active than their predecessors, but they are not necessarily the healthier generation. They are more likely to be obese, have high blood pressure, or have diabetes than previous generations at similar ages. People are living longer but are not necessarily living better.

15%

OF THE POPULATION IN 2015 WAS IN THE GERIATRIC CATEGORY

With advancing technology in the medical industry, equipment can often be complicated and challenging to build and operate. It is becoming increasingly popular for patients to self-medicate; especially when diseases such as Type II Diabetes are on the rise. The inability for older people to use or access public transport is also spurring the development of telemedicine devices, creating a need for doctors to consider remote treatment options.

MEETING PATIENT EXPECTATIONS

Today's patients are more informed about healthcare than ever before. Information on chronic disease and the latest treatment plans is readily available through a variety of vehicles, most notably the internet. This has created a new opportunity for consumers to become their own advocates when it comes to their healthcare decisions. Although this is powerful for the patient, it can be a challenge for healthcare providers to manage their heightened expectations.

With their newfound knowledge, patients are often demanding minimally invasive procedures that would put them back on the path to wellness in a much shorter amount of time. They also expect complete transparency throughout the process. Add to the mix that many of these patients are suffering from lifestyle-associated conditions from poor eating habits, smoking, and non-physical activity and it's no wonder that healthcare providers are struggling to keep up with the demands. All of this presents an excellent opportunity for medical device manufacturers to develop new solutions to meet these challenges.

CHRONIC DISEASES

Finding new ways to manage chronic disease is critical for the healthcare industry as more than 29 million people in the U.S. alone are diagnosed with life-altering conditions such as diabetes. By seamlessly connecting patients, healthcare providers, and care teams, technology has the potential to improve access to medical records, update caregivers on how their loved ones feel, monitor treatment adherence, and work in countless other ways to aid patient wellness.

29

MILLION PEOPLE IN THE U.S. ALONE ARE DIAGNOSED WITH LIFE-ALTERING CONDITIONS

CYBERSECURITY

All medical devices carry a certain amount of benefit and risk. Since medical devices are increasingly connected to the Internet, hospital networks, and other medical devices, the chance of a cyber-attack is very likely if the right precautions are not in place. Medical device manufacturers have a significant role in helping to prevent this from happening by designing devices that will protect critical patient data. The best way to mitigate threats to your device is to assess your device's vulnerability early in the design process.

PRODUCTION OUTSOURCING

The global medical device outsourcing market size was valued at USD 94.2 billion in 2018. It is expected to grow at a CAGR of 11.92% from 2018 to 2023. This growth is spurred by the high prevalence of chronic disorders, the increasing demand for medical devices, and the need to remain price competitive in the market. All of this is putting added pressure on design engineers to balance complexity, reliability, and costs. Because of this, companies are shifting their focus to innovation and outsourcing non-essential activities to keep up with the demand.

THE GLOBAL MEDICAL DEVICE OUTSOURCING MARKET WAS VALUED AT

94.2

BILLION DOLLARS (USD)

MANUFACTURING CONSISTENCY

The increased complexity of devices and the use of production automation systems has introduced new challenges in manufacturing. Coupled with more stringent regulations and patient demands, ensuring medical device quality has never been more critical. Consistency throughout the manufacturing process is an essential step. Monitoring temperature and humidity is a simple, yet impactful way to guarantee that your products are being manufactured in the required conditions, every time.

"By seamlessly connecting patients, healthcare providers, and care teams, technology has the potential to improve access to medical records, update caregivers on how their loved ones feel, monitor treatment adherence, and work in countless other ways to aid patient wellness."

KEY REGULATIONS

As medical devices have modernized, the regulations governing these products have also evolved. Below are some of the key regulations in the industry:

FDA

510(K)

One of the most significant efforts to modernize medical device regulations is the FDA's 510(k) program, which outlines the pathway for evaluating and approving new devices. Manufacturers must notify the FDA at least 90 days before marketing new medical devices. Additionally, major changes to existing devices that impact the safety or effectiveness must also submit a new 510(k) notification. According to FDA Commissioner Scott Gottlieb, the revisions to 510(k) "recognize that medical devices exist across a continuum of complexity and risk and that the scope of premarket review should reflect this risk continuum."

2018 MEDICAL DEVICES SAFETY ACTION PLAN

The Medical Devices Safety Action Plan outlines how the FDA will encourage innovation in the medical device industry to help improve safety, detect safety risks earlier, and keep doctors and patients alike better informed. The key actions the FDA described are:

- Establishing a robust medical device patient safety net in the US
- Exploring regulatory options to streamline timely implementations of post-market mitigations
- Spurring safer medical device innovation
- Furthering the cybersecurity of medical devices
- Integrating the Center for Devices and Radiological Health's (CDRH's) premarket and post-market activities to help advance the use of the Total Product Life Cycle (TPLC) approach to the safety of medical devices

2016 BREAKTHROUGH DEVICES PROGRAM

The Breakthrough Devices Program is a voluntary program from the FDA for certain medical devices or device-led combination products, allowing manufacturers to work with FDA experts through several different program options. The goal is to address topics as they come up and let manufacturers receive FDA feedback during the premarket review phase rather than wait until an issue is harder to rectify, and significant time/money was lost.

FDA 21 CFR PART 820 AND CGMP

Title 21 of the Code of Federal Regulations is the most comprehensive set of controls surrounding any drug or medical device. Chapter I, Subchapter H (series 800), deals specifically with medical devices. It includes an overview of medical devices, outlines premarket approval processes, and defines specific devices and their classifications.

As part of the FDA's Current Good Manufacturing Practices program (cGMP), 21 CFR Part 820 outlines the regulations around medical device quality systems (QS). The QS regulation "provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device."

Part 820, Subpart G deals specifically with environmental conditions: "(c) Environmental control. Where environmental conditions could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures to adequately control these environmental conditions. Environmental control system(s) shall be periodically inspected to verify that the system, including necessary equipment, is adequate and functioning properly. These activities shall be documented and reviewed."

It is important to note that the FDA has expressed overwhelming support of ISO13485:2016 and has announced that it will use the international regulation as a basis for future quality system legislation. We'll discuss more on ISO 13485:2016 later in this chapter.

PILOT PROGRAMS

Currently, the FDA's most prominent pilot program is Software Precertification (Pre-Cert) Pilot Program. This regulatory model pilot, which is limited to software-based medical devices manufacturers, is meant to assess both the safety and effectiveness of software technologies without restricting patients' access to them. The goal of this pilot is to work toward establishing a future model that will provide more streamlined, timely, and efficient regulatory oversight of medical devices that rely on software.

INTERNATIONAL

ISO 13485:2016

ISO 13485 is an internationally agreed standard that sets out the requirements for a quality management system (QMS) specific to the medical devices industry, in order to help manufacturers better guarantee product quality across the board. According to ISO, "the quality of product includes not only their intended function as well as safety and performance but also their perceived value and benefit to the customer. From the perspective of the medical device industry, this includes the therapeutic benefit to a patient."

QMS standards outline requirements for good management practices to ensure medical device quality, generally without referencing any specific product type. Certification to the standard is not required of companies but can be beneficial in ensuring successful compliance. Additionally, a 2016 update placed increased emphasis on risk management.

MEDICAL DEVICE SINGLE AUDIT PROGRAM

The Medical Device Single Audit Program (MDSAP) allows an auditing organization that the program recognizes conduct a single regulatory audit of a medical device manufacturer. This audit can satisfy any relevant requirements of the regulatory authorities that participate in the program. The FDA also accepts MDSAP audit reports as a substitute for routine agency inspections.

EU MEDICAL DEVICE REGULATIONS

The European Medical Device Regulation (EU MDR) provides strict safety and quality standards for medical devices being produced in or supplied into Europe. Manufacturers must demonstrate that their medical devices meet the MDR requirements through a conformity assessment, which depends on the device's classification. If it passes, you can place a CE mark on the device to show that it is compliant. By May 2020, even some products that don't have an intended medical purpose will also be required to comply with these new standards to help regulate the market.

"One of the most significant efforts to modernize medical device regulations is the FDA's 510(k) program, which outlines the pathway for evaluating and approving new devices."

PREPARING FOR AN AUDIT

One of the biggest issues pharmaceutical companies have is complying with and passing audits – whether planned or surprise. If you're not ready, this can make for a difficult situation and even cost the organization in both lost time and money. Don't stress though; there are plenty of steps you can take that will make it easier to always be audit ready. Follow the helpful checklist below:

1. REVIEW ALL DOCUMENTS

- A list of all documents related to the audit should be prepared
  - Batch manufacturing data
  - Master formula records
  - Facility and equipment maintenance records
  - Calibration records
  - Stability testing data
- Review qualification documents
  - Equipment and instruments used for production & quality control
  - Process validation and analytical method validation
  - Facility validation records

2. PREPARE GXP AUDIT PLAN

- Prepare an audit plan and agenda
- Address all applicable departments
- Note all strengths and weaknesses of each respective department
- Perform audit tasks by starting on the areas with the greatest needs
- Review notes of historical audits to address any corrective actions that may still be open
- In large matrixed organizations ask other departments if they have experience with a particular auditor

3. IDENTIFY KEY PERSONS

- Identify 1 or 2 persons from each department with knowledge of documents and have them available for the audits
- These persons shall explain things to the auditors

4. ASSIGN AUDIT RESPONSIBILITIES

- Assign tasks to every area identified in your audit plan
- Head of department(s) should ensure completion of assigned tasks

5. CONDUCT ROUTINE INTERNAL AUDIT(S)

- Routine internal audits are part of every good quality system and help you get in the routine of an audit, as well as prepare for any unexpected audits

MANUFACTURING CONSIDERATIONS: UNDERSTANDING ENVIRONMENTAL MONITORING

As a manufacturer of medical devices and technology, you know that transparency and accuracy are essential to your products' successful development. The rise of IoT, an evolving regulatory landscape, and increasing demands for visibility make this process even more complicated. That's why it's critical to have the right tools to ensure compliance.

Environmental monitoring is the observation and collection of data (e.g., temperature, humidity, pressure), typically to ensure consistency in the conditions and meet regulatory requirements. Monitoring systems can also act as alarms, warning companies as certain conditions may go out of their desired range, so that action can be taken before product efficacy is impacted.

Whether producing devices for diagnosis, testing or treatment, consistent quality in the medical devices industry is mandatory. Having environmental monitoring systems in place can mean the difference between business as usual and a failed audit, or even failed treatment. Monitoring essential data from R&D to production can help protect assets, the bottom line, and patients.

THE BENEFITS OF MONITORING

PRODUCT QUALITY When you're manufacturing medical devices, there need to be assurances that your product identity, strength, and quality are not compromised. Temperatures that are too hot or too cold can impact the effectiveness of certain components. Humidity can also introduce moisture and damage. Finding the right temperature monitoring system can guarantee audit compliance and patient safety.

LONG-TERM ROI Upgrading your environmental monitoring system to a more automated, cloud-based solution can save manufacturers money in the long run. These systems reduce the chance for human error and provide real-time excursion alerts – preventing costly product loss and freeing up employees to handle other tasks. The automation and long-term savings offered by these systems can help companies realize a significant return on their initial investment.

AUDIT COMPLIANCE Continuous monitoring and digital logs can help you easily adhere to regulatory requirements and reduce the risk of non-compliance during audits. By having ongoing data on critical environmental conditions, you can provide documentation on consistency as well as evidence on how excursions were addressed.

OPERATIONAL EFFICIENCY Cloud-based solutions eliminate the need to manually go to each sensor and collect charts or download data. Instead, environmental data is pushed automatically to a central location that can be accessed by anyone with permissions, from anywhere, at any time. Cloud options also save time and resources for internal IT teams, who no longer need to dedicate extended periods on maintaining servers and software.

R&D ACCURACY In the laboratory, results must be repeatable, and you need to understand the exact conditions that resulted in your success. Environmental monitoring solutions can be the difference between an IND application and going back to the drawing board.

PATIENT SAFETY Since environmental monitoring tracks essential environmental conditions, you can ensure that your products are consistent throughout the entire process – from R&D to patient use. This helps guarantee that the end users-the patients who will benefits from your products-are safe and that their treatment is effective.

INSIDE THERMAL MAPPING

Mapping the differences and changes in temperature and relative humidity within a three-dimensional space can provide valuable data. Thermal mapping services offer a data-driven rationale for permanent monitoring placement to protect environmentally sensitive products. Periodic mapping of a facility can also assist in determining whether your preventive maintenance activities are effective at maintaining your environmental control systems.

HOW DO YOU GO ABOUT PERFORMING A THERMAL MAPPING TO ENSURE YOU GET THE DATA REQUIRED AND DOCUMENTATION REQUIRED BY YOUR AUDITING BODY?

1. Create a test plan or protocol to define requirements such as critical areas to be mapped, data logging sample interval, length of study, data logger placement and acceptance criteria
    a. Use risk-based decisions on where to place data loggers and guidance from the World Health Organization, USP, or ISPE
    b. The more you understand your product storage requirements, the better the rationale will be for quantity and placement of the data loggers
2. Select and prepare your data loggers:
    a. Calibrate to a NIST traceable standard
    b. Ensure adequate memory to cover your intended study period. Most data loggers today are capable of handling multiple weeks of data storage depending on your sample rate
    c. Choose a data logger with the appropriate sensor and range
    d. Choose a logger that is Part 11 compliant, if you're working in an FDA compliant environment
    e. Label all data loggers with their specific location
3. Begin placing your data loggers according to the documented test plan
4. Remove loggers after the defined test period and begin downloading and analyzing data
5. Perform post-calibration verification to ensure your data loggers remained in calibrated state
6. Write a Summary Report:
    a. Summarize details of data logger setup, time and dates of study, any notes that were taken during study period
    b. Include tables and graphs to easily summarize data. Include all data for a specific area within 1 graph or table to assist in determining if data meets acceptance criteria
    c. Determine all high and low points within your study. These points are typical points for permanent monitoring as they bracket the operating range of the facility
    d. Document deviations from acceptance criteria and corrective action(s) for those areas. Corrective actions may entail avoiding storage in specific areas, adding ventilation to specific areas, or even adjusting HVAC systems
7. Use your summary report as justification for permanent monitoring locations (high and low points) and as supportive data for preventive maintenance tasks that have been performed or need to be performed
8. Perform mapping in extreme weather conditions for your area (e.g. summer and winter) to ensure the facility environmental control systems (e.g. HVAC) can perform at these extremes

SUMMARY

The safe and successful manufacturing and distribution of medical device products require constant environmental monitoring to remain compliant. There are very stringent regulations in place from a variety of government agencies to ensure that all medical devices are safe and effective for patients.

It's critical for medical device companies to understand these regulations and to have the right tools in place to adhere to them. That requires navigating a rapidly changing industry, adhering to ever-evolving regulatory standards and addressing increasing patient demands. To succeed, companies must be rigorous and standardized in their processes but also flexible enough to respond to innovation while ensuring ongoing compliance and patient safety.

ABOUT DICKSON

Since 1923, Dickson has been changing the way organizations monitor their temperature, humidity, and pressure-controlled environments. By incorporating the best and newest innovations, Dickson enables organizations to manage compliance, asset protection, data analysis, and quality control with confidence.

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