DICKSON
Environmental Monitoring + Compliance Experts

HANDBOOK

HOSPITAL & HEALTHCARE ENVIRONMENTAL MONITORING

BY DICKSON

Environmental Monitoring
+ Compliance Experts

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OVERVIEW

The healthcare industry is always evolving. With the constant innovation and regulations necessary to keep the field moving forward, the industry is filled with a myriad of challenges. Those challenges become more and more dangerous the less you're prepared for them. While an outsider may only see the patient focus of the field, here at Dickson we know that for a business to succeed in this industry they must also consider the healthcare professionals that make up the field, the facilities they work in, and the regulatory agencies that govern them.

Each of these aspects must be accounted for in order to be successful in this fast-paced market. Healthcare spending is increasing across the board, making this a lucrative market if you approach it correctly with the right insights from industry experts.

This handbook will take you through the current industry trends and the key factors, sectors, challenges, and regulations that make up modern healthcare. We'll teach you how to better understand your healthcare monitoring needs and prepare for audits, as well as guide you through the importance of thermal mapping. Our industry insights will help you find any further knowledge that you need to succeed.

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KEY FACTORS

There are many key factors that go into a successful healthcare business. Understanding, and properly accounting for, the below will allow you to find the right fits for your business.

FACULTY

From small-town private practices of physicians to the most well-known leaders in the industry, doctors, nurses, and other trained professionals are the fuel that keeps the healthcare engine running. They are instrumental not only in patient care, but also regulatory compliance. Access to continued development, employing burnout prevention tactics, and regular community outreach all assist your healthcare team in doing their job.

FACILITIES

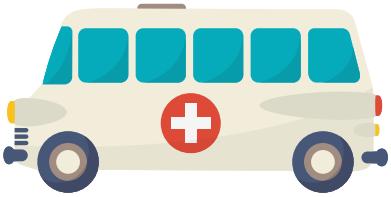
Just as there are many different types of healthcare professionals, there are a multitude of facilities that provide the backbone of the industry. Patient care does not stop in the office – healthcare facilities are found everywhere throughout our lives. These include hospitals, clinics, nursing homes, laboratories, pharmacies, and medical device manufacturing facilities among many others. With the increasing surge of telehealth and virtual care, even the patient's home can be involved in regular healthcare support.

REGULATORY ORGANIZATIONS

With public health and safety at risk, the healthcare field requires checks and balances. Businesses and professionals in the healthcare industry are subject to the review and validation of regulatory organizations. These include major governmental organizations like the FDA and CDC, as well as private organizations like the JCAHO. We'll go more into the regulations that these organizations impose latter on in this handbook.

KEY SECTORS

The modern healthcare field is divided into multiple sectors, each important to the overall success of the industry.

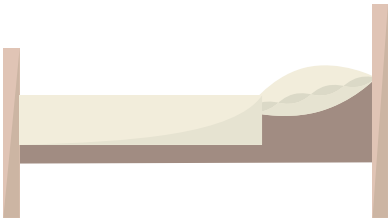


AMBULATORY

The ambulatory sector provides healthcare services to ambulatory patients directly or indirectly, typically through outpatient methods. This sector does not typically provide inpatient services. Ambulatory care includes physicians, dentists, outpatient care centers, home health care services, and diagnostic laboratories. A popular sector for incoming healthcare professionals, the ambulatory sector accounted for 95% of new US healthcare hires in July 2019.

HOSPITALS

Home of inpatient care, hospitals are instrumental to care coordination/integration and play a key role in supporting other healthcare sectors. They're critical to research and often provide a setting for clinician education. Hospitals must be resilient and maintain the ability to scale their services in emergency situations. They are usually funded by the public sector, healthcare organizations, insurance companies, or select charities.



NURSING/RESIDENTIAL CARE

As our population ages, more and more people require full-time monitoring, assisted living, or need to move to a residential facility. Facility-based long-term care services include board and care homes, assisted living facilities, nursing homes, and continuing care retirement communities. Different levels of care are typically offered throughout these services according to the patient's level of independence.

LABORATORY/RESEARCH

Clinical laboratories and research facilities are critical components of the healthcare industry. According to Kalorama Information, a research firm based in the healthcare market, approximately 80% of physicians' diagnoses are a result of laboratory tests. Common routine tests include testing for cholesterol levels, HIV, pregnancy, and substance abuse. Lab testing is also used to monitor diseases and the effectiveness of drug treatments. The importance of the clinical laboratory and research sector makes it a highly competitive market.

KEY CHALLENGES

In today's climate, the healthcare industry faces several important challenges and obstacles. Sometimes these challenges are direct threats to the industry, while other times they are the unfortunate, yet seemingly inevitable, byproducts of advancements in technologies and methodologies. These are the top challenges the healthcare industry faces:

AN AGING POPULATION

While it is certainly a sign of progress that we're living longer and longer, an increasingly older population comes with its own set of obstacles and challenges. Healthcare professionals must find efficient and cost-effective ways to care for the elderly. More funds and development are going to go into nursing homes and residential care, increasing the need for in-home care professionals. Our workforces are aging as well, changing the demographics of who is working in the industry.

MORE CHRONIC DISEASES

Closely related to our aging population is the increased prevalence of chronic diseases throughout society. With more people throughout the world, and those people living longer, the chances of them developing chronic diseases increases. While this is partially due to increased healthcare monitoring and the ability to uncover these diseases, the takeaway is the same: we need to provide sustained care for an increasing number of people around the world.

ADVANCEMENTS IN DIGITAL TECHNOLOGIES

Advancements in the digital technology and tools within the healthcare industry naturally provide a number of benefits. Advanced technology that's made its way into the industry include IoT, blockchain, and increased cyber-security capabilities. These innovations are leading to better disease diagnosis and treatment, care personalization, and the development of new drugs and devices, but all of this comes at a price... a literal one. Digital technologies are expensive, pumping up industry costs as the demand for quality healthcare increases form patients' free access to information.

VALUE-BASED CARE STRUCTURES

Value-based care structures reward healthcare providers for providing quality care to their patients. This differs from the typical capitated approach, where providers are paid based on the amount of services they deliver. Current political battles over insurance and coverage requirements are making the switch to value-based healthcare more and more likely. While this has the potential to be a good thing that could provide benefits for patients, clinicians, and providers alike, a value-based switch would require the industry to simultaneously deliver more customized quality care while aiming to keep overall costs down. Beyond this switch, the healthcare industry will likely continue to face the challenge of a shifting healthcare delivery model.

KEY REGULATION

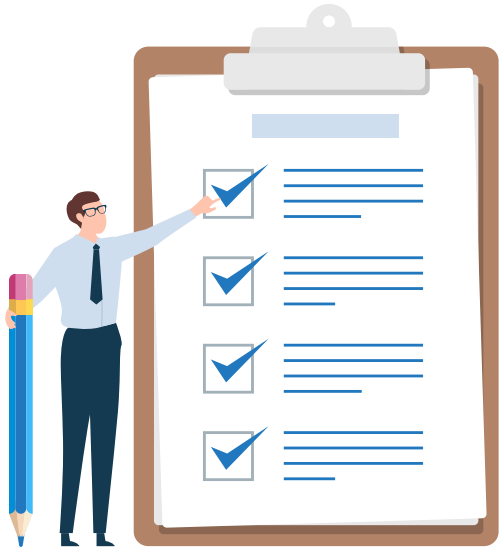
As the healthcare industry has grown, so have the governing bodies surrounding it. These are the leading regulatory organizations and their key regulations that you need to follow.

FDA

The Food and Drug Administration, or FDA, is responsible for protecting public health by prioritizing the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. The FDA's Code of Federal Regulations, or CFR, is a codification of the permanent general rules that were published in the Federal Register by the Executive departments and agencies of the Federal Government. The CFR is broken down into 50 titles representing important areas subject to regulation. These can further be broken into general sections, or parts:

- Parts 1-99: product jurisdictions, protection of human subjects, institutional review boards, etc.
- Parts 100-799: food, human and animal drugs, biologics, cosmetics
- Parts 800-1299: medical devices and radiation-emitting products
- Parts 1300-1499: controlled substances

Title 21 of the Code of Federal Regulations (parts 800-1299) is the most comprehensive set of rules surrounding drugs and medical devices.



UNDERSTANDING YOUR HEALTHCARE MONITORING NEEDS

Environmental healthcare monitoring is the observation and collection of environmental data (temperature, humidity, pressure, etc.), typically to ensure consistent key operating parameters and meet regulatory requirements in this ever-visible industry. A common environmental monitoring device is an electronic data logging monitor. Devices like these are important to make sure that your systems are working and operating efficiently, your products are kept flowing, and your team and patients are kept healthy and happy.

Monitoring systems can also act as alarms, warning you as certain conditions go out of their desired range, allowing you to act before your systems or the efficacy of your products are impacted. Other benefits include higher drug quality, long-term ROI, audit compliance, higher operational efficiency, patient safety, and better research accuracy.

Having environmental monitoring systems in place can very well mean the difference between the success or failure of an audit, or even a failed treatment. Monitoring essential data throughout all stages of your business can help you protect your assets, your bottom line, and your patients.

To make sure you're getting the most out of your monitoring systems, ask yourself these questions:

- **Do I have the right tool(s)?** You can't have a proper healthcare monitoring system without the right tools. Medications are frequently exposed to a multitude of environments, from creation and testing, all the way to packaging, shipping, and on-site storage. You need to monitor every one of these environments so that you can alert the appropriate people of any environmental changes. Once in storage, site staff should be able to frequently monitor loggers in your refrigerators as well as have visibility of any excursions before dispensation.
- **What's my reporting structure?** Without a structured reporting system, all the valuable data that you acquire could go unused, misplaced, or even lost. Most loggers in use today, including DicksonOne data loggers, allow for the viewing of real-time data from any mobile device. This removes the need for your team to manually upload data, creating an automatic end-to-end monitoring solution everywhere in your supply chain.
- **What am I doing for temperature control monitoring?** Keeping a temperature-controlled environment is one of the most important aspects of environmental monitoring as many devices and medications break down or lose their effectiveness when you go outside of a certain temperature window. Placing temperature loggers within your systems and packaging them in with medication enables temperature tracking through shipment and storage. This end-to-end approach provides a complete temperature history of your medicine.

  Ask yourself these follow-up questions when designing a temperature control monitoring system:

  - Am I sure my temperature monitoring device is accurate?
  - Is adequate and timely attention being paid to critical storage temperatures?
  - Do responsible parties know what to do if temperatures move out of range and there is suspected damage to the stored items?
  - Is my record keeping system adequate to document critical storage area temperatures?

PREPARING FOR AN AUDIT

While it may not always be front of mind compared to the daily challenges of the healthcare industry, failing to properly prepare for an audit, whether planned or a surprise, can cost your organization valuable time and money in the long run. Here are a few important steps that you can take to make sure you're always ready for an audit... no matter what.

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

THERMAL MAPPING MINI-GUIDE

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 assistsin 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

GLOSSARY

ELECTRONIC DATA LOGGING MONITOR

A small portable device that measures and stores environmental data (temperature, humidity, pressure, etc.) at predetermined time intervals using an electronic sensor.

KEY OPERATING PARAMETERS

Parameters that must be maintained to process or produce products with consistent quality attributes and those that may have an impact on the proper operation of the equipment.

THERMAL MAPPING

Documented measurement of the temperature or relative humidity distribution within a storage area, including identification of hot and cold spots.

TEMPERATURE CONTROLLED

Includes any environment in which the temperature is actively or passively controlled at a level different from that of the surrounding environment within precise predefined limits.

VALIDATION

Documented testing performed under highly controlled conditions, demonstrating that processes, methods, and systems consistently produce results meeting predetermined acceptance criteria.

SUMMARY

Success in the healthcare industry is dependent on your ability to evolve with the industry itself and overcome the challenges that you'll face. Understanding the key factors, sectors, challenges, and stringent regulations that make up modern healthcare will allow you to make the right decisions and properly prepare for the industry's inevitable curveballs. You're going to need the right people, tools, and constant environmental monitoring in order to remain compliant, and have the data to pass any audits. With the information in this handbook, you'll be prepared to walk the line between standardization and innovation, allowing you to increase your bottom line while still staying complainant and ensuring 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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