# QSIT 20 YEARS LATER: THOUGHTS FROM AN ORIGINAL AUTHOR AND CAREER PRACTITIONER

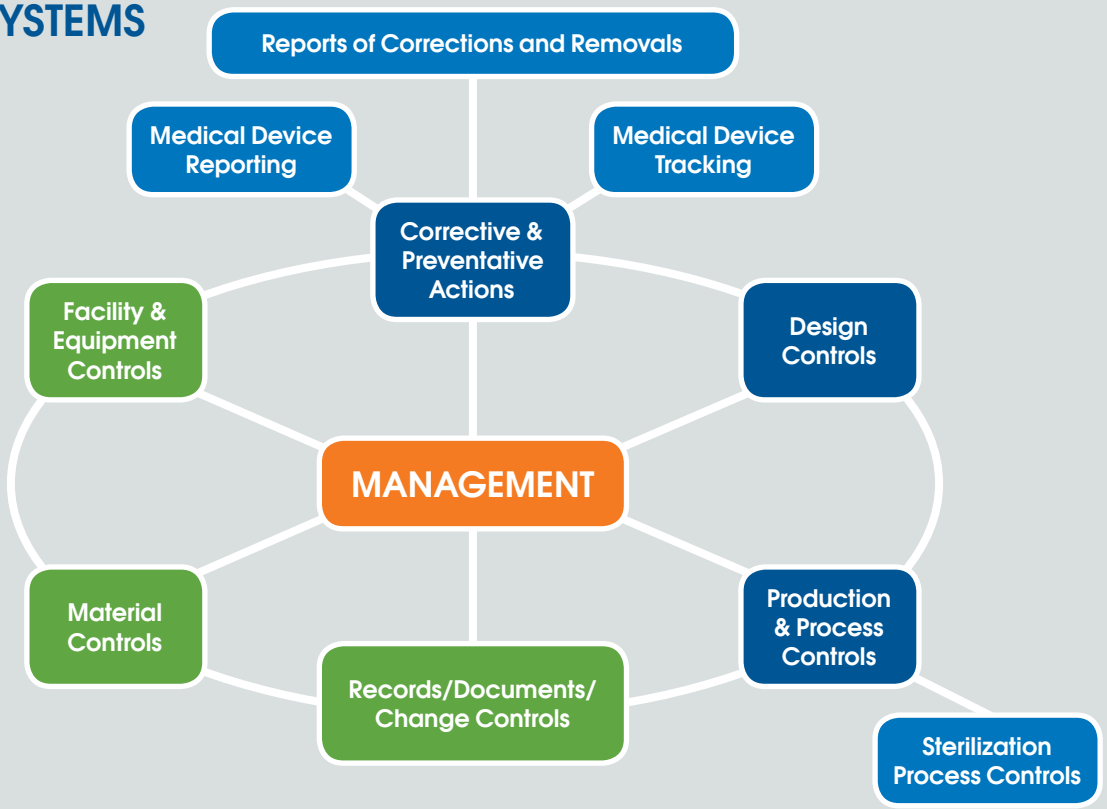
January 1, 2020 marks the 20th anniversary of the implementation of the FDA's Guide to Inspections of Quality Systems, more commonly referred to as the Quality System Inspection Technique (QSIT). This milestone provides an excellent opportunity to reflect on the value and history of the QSIT audit model, as well as its future utility in today's evolving regulatory environment.

## QSIT: WHERE IT ALL BEGAN

QSIT is the FDA's inspection model used by investigators to determine a manufacturer's compliance with a number of regulatory requirements including 21 CFR 820, the Quality System Regulation, 21 CFR 803, Medical Device Reporting, and 21 CFR 806, the Corrections and Removals Regulation.

QSIT divides a quality management system into four primary subsystems: management controls, design controls, corrective and preventive actions, and production and process controls. Additional QSIT subsystems that support, and may be inspected concurrently with, the four primary subsystems include records, documents and change controls, material controls, and facility and equipment controls. The primary subsystems are also supported by four "satellite" subsystems (i.e. sterilization process controls, medical device reporting, reports of corrections and removals, and medical device tracking).

## QSIT SUBSYSTEMS

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A number of "inspectional objectives" (tasks) are assigned to each QSIT subsystem. These tasks are supported by narrative discussions of how to accomplish each task as well as linkages to other regulatory considerations that may be germane to the task. These tasks are designed to allow an investigator to confirm compliance (or noncompliance) to applicable regulatory requirements relative to each subsystem. For example, during the inspection of the management controls subsystem, the investigator verifies that procedures for management review have been effectively defined, documented and implemented.

QSIT relies on judgement and statistical based sampling (e.g. binomial sampling) to accomplish each applicable inspection task. Intelligence gathered from the inspection of one subsystem may drive the inspection of subsequent subsystems. For example, complaints reviewed during the inspection of the corrective and preventive action subsystem may indicate a potential weakness with the design control process or a production process. These potential weaknesses can be investigated during the subsequent inspection of the design controls or the production and process controls subsystems.

Part III of **Compliance Program (CP) 7382.845 Inspection of Medical Device Manufacturers** – FDA's playbook for the inspection and regulatory follow-up relative to medical device manufacturers – describes two inspection types that rely primarily on the QSIT model: Level I or abbreviated inspections and Level 2 or comprehensive inspections. Level 3 or compliance follow-up inspections, special "for cause" and "risk-based workplan" inspections are primarily directed by inspectional guidance, but also rely on elements of QSIT. In addition, according to Part III of Compliance Program 7383.001, medical device premarket approval and postmarket inspections also rely on the use of the Quality System Inspection Technique.

## QSIT TODAY

As successful and robust of an inspection model QSIT has proved to be over the past twenty 20 years, it is not without its weaknesses. For example, the inspection of purchasing controls is almost an afterthought.

There are no specific inspection tasks associated with purchasing controls. The only substantive inspectional guidance on the subject contained in the four primary QSIT subsystems appears in the narrative discussion of production and process controls, tasks 2 and 5, respectively:

- **Task 2:** "This verification must include a review of the purchasing controls and receiving acceptance activities regarding at least one component or raw material (preferably determined essential to the proper functioning of the device." A similar task appears in the sterilization process controls satellite subsystem.
- **Task 5:** "For example, for software developed elsewhere, confirm that appropriate software and quality requirements were established and provided to the vendor and that purchasing data (and validation results) support that the requirements were met."

In my opinion, these narratives are hardly a comprehensive challenge of such an important process within a medical device manufacturer's quality management system – particularly in light of the application of purchasing controls to external and internal suppliers.

In addition to purchasing controls, another weakness inherent to QSIT is the inspection of risk management.

Considering how far risk management has evolved in the past 20 years, the description of contemporary risk management principles -- contained in the preamble to the Quality System regulation (response to comment 83) and in the QSIT design controls subsystem (Task 3) -- could best be described as "abridged."

The terminology relative to risk used in QSIT may also confuse today's medical device quality professional. In the context of the Quality System regulation and QSIT, the term "risk analysis" is understood as a comprehensive term rather than one element or tool for risk assessment within a comprehensive risk management program – as is the contemporary understanding.

The application of contemporary risk management principles and risk-based decision-making throughout a device's lifecycle are essential to establishing and maintaining a robust, dynamic quality management system.

## BUILDING ON QSIT

These facts are not meant as a condemnation of QSIT. I have always been a steadfast proponent of QSIT. However, it may also be time to revise QSIT or consider an alternative – now that one exists.

The Medical Device Single Audit Program (MDSAP) has been a viable alternative to routine FDA inspections since January 2017. As CDRH continues to signal its intent to transition its medical device quality management regulatory requirements (inspection criteria) from the Quality System regulation to ISO 13485:2016, now appears to be a good opportunity to consider revising QSIT to align with the standard. Let's discuss one option.

MDSAP was designed, developed, challenged, implemented and is being maintained by a coalition of five equal regulatory authority partners representing Australia, Brazil, Canada, Japan and the United States. Official observers to the program include the European Union (through the UK and Ireland) and the World Health Organization's (WHO) IVD Prequalification Program. MDSAP is governed by a Regulatory Authority Council (RAC) consisting of two high-ranking regulatory representatives of each participating regulatory authority. The RAC rotates its chair every three years – currently Health Canada chairs the RAC.

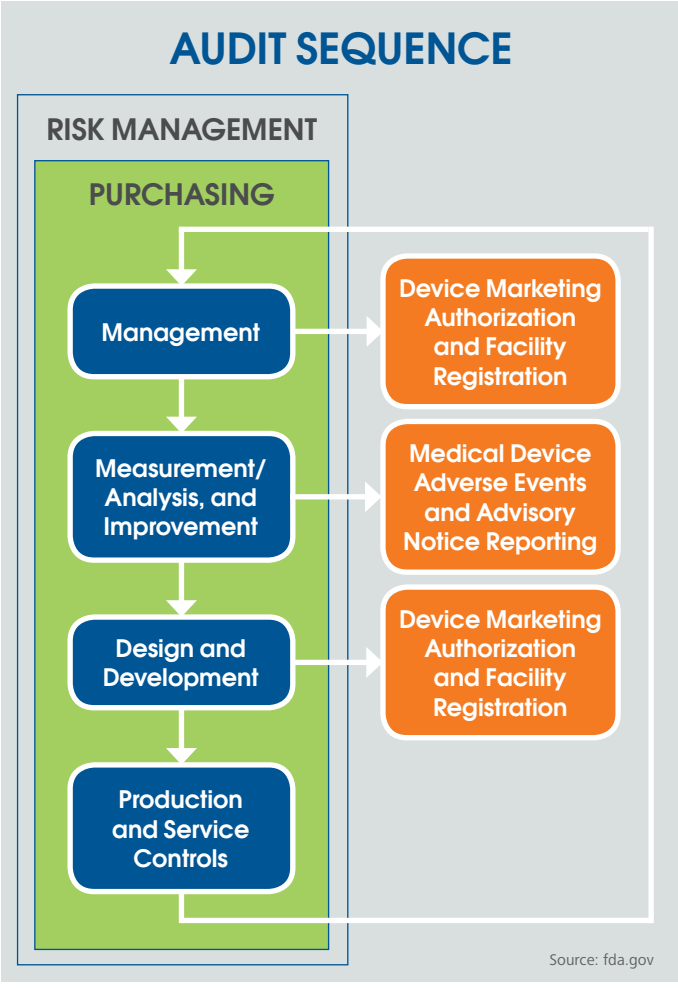
MDSAP was developed so that a single regulatory audit of a medical device manufacturer's quality management system could satisfy the requirements of each participating regulatory authority – reducing the number of audits or inspections a manufacturer would be exposed to if each regulatory authority or its surrogate were to audit or inspect independently.

The **MDSAP Audit Model** and **Companion Document** were developed to provide auditors with an efficient and effective audit model that challenges the applicable medical device regulatory requirements of all participating regulatory authorities. The MDSAP audit model is a task-based audit model similar to QSIT. It uses ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes as its foundational audit criteria, supplemented with country-specific audit criteria as necessary.

The fact that the MDSAP audit model is based on ISO 13485:2016 should make it (or a derivative) an attractive QSIT alternative should CDRH transition to ISO 13485:2016 as expected.

The MDSAP Audit Model and Companion Document identify seven quality management system processes (similar to QSIT subsystems) including five primary processes: management; measurement, analysis and improvement; design and development; production and service controls; and purchasing. During MDSAP audits, risk management is integral to each of these processes and is expected to be applied throughout the quality management system and over the entire lifecycle of the device.

The five primary processes are supported by two additional processes: device marketing authorization/ facility registration and medical device adverse events/ advisory notice reporting. These supporting processes are designed to fulfill specific requirements of participating MDSAP regulatory authorities. For example, FDA facility registration and medical device reporting.

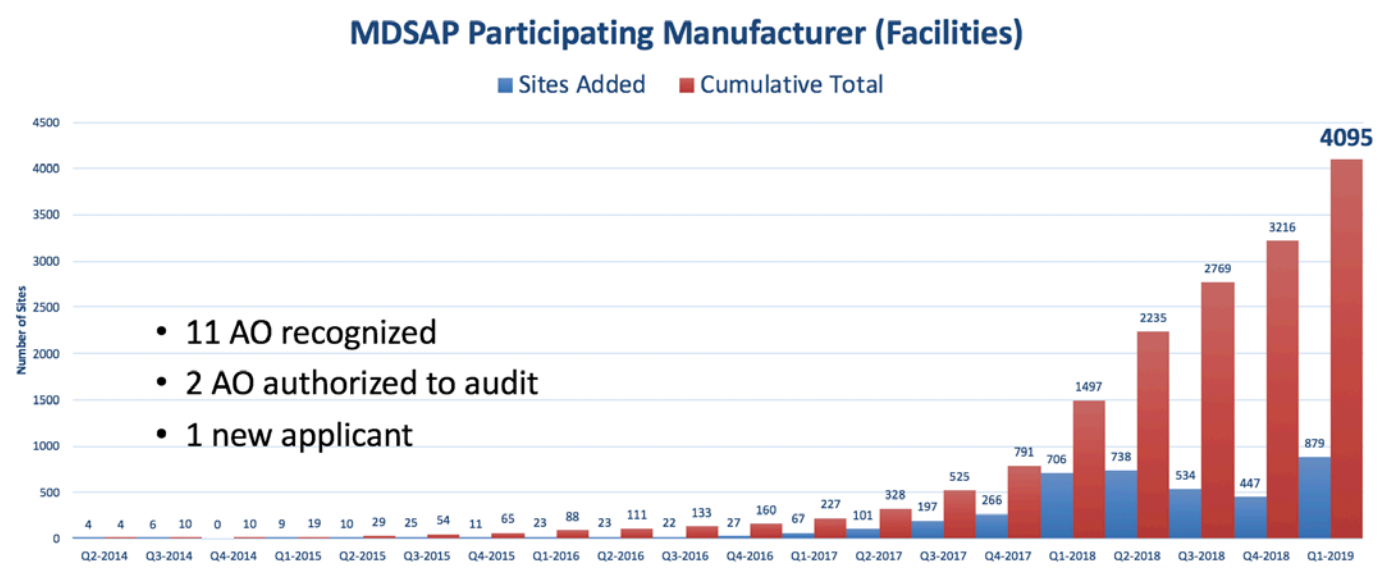


Similar to QSIT, an MDSAP audit of each process is guided by audit tasks and narrative discussions relative to accomplishing those audit tasks – with color-coded links to other germane processes including interrelationships to applicable risk management activities. Also similar to QSIT, intelligence gathered during the audit of one process is used to drive the audit of subsequent processes.

Unlike QSIT, MDSAP provides a great deal of focus on a manufacturer's purchasing process – dedicating an entire chapter to the subject. In addition, the expectation of the application of contemporary risk management principles is clearly stated in the forward of the MDSAP Audit Model: "Audits performed under the MDSAP program will be process based, focusing on several defined processes, a defined method for linking those processes, and built on a foundation of requirements for risk management." MDSAP appears to have addressed two major weaknesses in QSIT (purchasing controls and risk management).

From January 2014 through December 2016, MDSAP underwent a comprehensive pilot to assess many factors including the utility of the MDSAP audit model. In June 2017, a **report** summarizing the analysis of the pilot was published recommending the MDSAP program remain viable.

By the end of March 2019, over 4,000 medical device manufacturing facilities were participating in MDSAP.

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So in a sense, QSIT 2.0 (or whatever the FDA eventually elects to call its new inspection model) already exists. The MDSAP audit model has been validated in a three-year pilot and in hundreds of MDSAP audits conducted since January 2017. If FDA were to extract from the MDSAP Audit Model and Companion Document the audit tasks and narrative discussions relative to FDA regulatory requirements, the new FDA inspection model would be the result.

A new FDA inspection model based on the existing MDSAP audit model would provide at least three benefits to FDA by:

> Addressing two significant weaknesses in the original QSIT audit model (purchasing and risk management)

> Providing a ready-made inspection model for the inspection of quality management systems against ISO 13485:2016

> Aligning FDA inspections with MDSAP audits conducted by third-party auditing organizations, providing more consistent coverage of the medical device industry overall

As noted with QSIT, the MDSAP Audit Model and Companion Document are not perfect. The development of a new inspection model would allow FDA an opportunity to adjust the audit model as deemed necessary – an exercise that would likely result in strengthening not only FDA's new inspection model, but the MDSAP audit model as well. Topics I would like to see addressed or better addressed in a next-generation inspection model are data integrity, data security, and good data collection, storage and analysis practices. Over the years I have seen more often than I'd like to admit the lack of understanding with respect to data available to manufacturers for analysis (and/or a lack of understanding of the utility of available data), the misuse of data analyses, or the misrepresentation of data or data analyses.

In conclusion, as QSIT enters its third decade, it should be celebrated as a time-tested, robust and effective audit model. However, considering the contemporary regulatory environment including the FDA signaling a transition to ISO 13485:2016, now appears to be an excellent time to revisit and revise the QSIT inspection model, which the FDA is likely already considering.

## ABOUT THE AUTHOR

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