

# *Integrating ThoughtSpot for Real-Time Analysis and Proactive Handling of Non-Conformance and CAPA*

*José Ortiz Cabrera  
Master of Engineering in Manufacturing Engineering  
Advisor: Rafael Nieves, PharmD.  
Industrial and Systems Engineering Department  
Polytechnic University of Puerto Rico*

---

**Abstract** — *This study addresses quality management issues at Ethicon, a Johnson & Johnson subsidiary in Guaynabo, Puerto Rico, utilizing advanced analytics and process optimization methods. Through the integration of the ThoughtSpot AI-powered platform and the DMAIC paradigm, the study achieves its objectives. ThoughtSpot enables real-time data analysis, facilitating swift assessment of non-conformances globally. Extensive stakeholder involvement and precise data gathering identify areas for optimizing the quality management system. Time studies reveal significant efficiency gains, with a yearly reduction of 468 analyst hours attributed to ThoughtSpot. Detailed time analysis graphics pinpoint process inefficiencies, enabling targeted improvements. ThoughtSpot's implementation accelerates problem detection and resolution, enhancing operational effectiveness and quality standards adherence. The study highlights the potential of AI-driven analytics to transform the medical device sector by streamlining decision-making and boosting operational efficiency.*

**Key Terms** — *CAPA, Data Analysis, DMAIC Method, Nonconformance, ThoughtSpot.*

## **PROBLEM STATEMENT**

The medical device company Ethicon, Johnson & Johnson in Guaynabo, Puerto Rico, is now having trouble with their site Quality Systems Metrics. The site's metrics are currently below 80%, which is a red flag for the business. As of right now, the Quality System Department is tracking and evaluating metrics regarding Non-Conformances, Corrective Actions, and Preventive Actions (CAPA) about Suppliers at locations across the globe. In order to attain the desired percentage in terms of metrics, each Nonconformance and

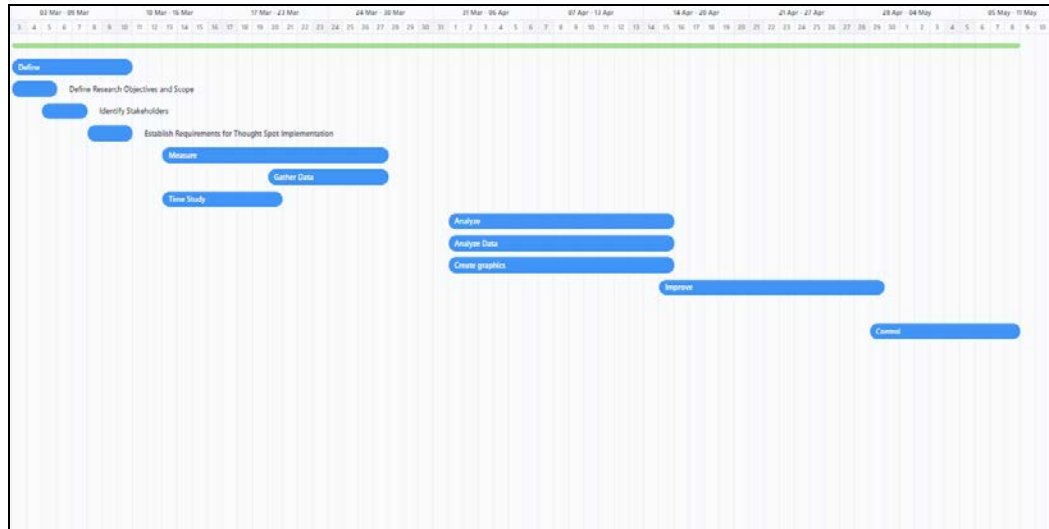
CAPA record must be closed within a specific time frame. They analyze and track all this data they continuously using an Excel sheet, which is not always precise and requires a lot of time to obtain the information. Since we will be getting real-time data from the cube rather than project metrics percent using potentially outdated or inaccurate data, ThoughtSpot is one of the finest possibilities for streamlining this process, which is why it is so critical. The Artificial Intelligence (AI)-powered analytics business ThoughtSpot enables anyone to generate customized insights to inform decisions and motivate action.

## **RESEARCH DESCRIPTION**

The study aims to address Ethicon's quality management challenges by enhancing tracking and analysis processes. Quality Systems Metrics below the 80% threshold prompt the need for improvement. The study targets the analysis of non-conformances and corrective actions across international sites, currently managed via Excel, risking inaccuracies and delays. Integrating ThoughtSpot, an AI-powered analytics platform, for real-time insights aims to resolve issues promptly and maintain quality standards. This dynamic approach fills a gap in current methodologies, aligning with evolving quality management demands.

## **RESEARCH TIMELINE**

The research for the DMAIC method and how this supports the design and implementation of ThoughtSpot was completed in three months. Refer to the calendar of the March 2024 timeline for better reference in Figure 1. A period of one week, from March 3, 2024, to March 10, 2024, was



**Figure 1**  
**Project Timeline in January 2022**

established as the research period to learn more about the DMAIC methodology. During the weeks from March 10, 2024, to March 27, 2024, we investigated how the metrics team of the Quality System Dept. made their 2021 Metrics Overview and what type of analysis they do manually with the reports in the Excel sheet. The first two weeks, March 31, 2024, to April 15, 2024) were established as the analysis period of all the data gathered and submitted for approval. During the week of April 15, 2024, to May 01, 2024, improve period was performed, on the ThoughtSpot live-board. During the time of May 01, 2024, until May 9, 2024, we performed the Control Task to make sure this platform gathered accurate data.

### **RESEARCH CONTRIBUTIONS**

The implementation of ThoughtSpot at Ethicon promises accelerated decision-making and operational efficiency. Real-time access to live data reduces waiting time for reports, facilitating faster issue resolution and tracking of non-conformances. This shift from manual Excel-based analysis to ThoughtSpot's automated retrieval frees up time for strategic initiatives. ThoughtSpot's dynamic features enable swift adaptation to industry demands and legal requirements, ensuring compliance with changing standards. Users benefit

from instant access to customized insights, expediting continuous improvement programs and enhancing productivity. Overall, ThoughtSpot's deployment fosters agility, enabling Ethicon to identify, implement, and evaluate improvements swiftly, sustaining competitiveness in the medical device sector.

### **LITERATURE REVIEW**

Johnson & Johnson (J&J) is a globally renowned corporation with a focus on improving patient lives worldwide. Operating across consumer health products, pharmaceuticals, and medical equipment, J&J stands out for its diverse portfolio and commitment to innovation. In pharmaceuticals, the company's relentless pursuit of groundbreaking drugs underscores its dedication to advancing medical research. Meanwhile, its medical device segment showcases cutting-edge technologies that revolutionize patient care. With a product range addressing diverse health and wellness needs, J&J has become integral to daily life for consumers globally. In this competitive landscape, maintaining high standards is paramount. Quality, in the context of business, encompasses the excellence of raw materials, tools, and technological expertise throughout the production and delivery process. At J&J, quality management is indispensable,

requiring ongoing improvements to meet stakeholder expectations. This entails rigorous planning, assurance, control, and improvement efforts. Effective quality management ensures that J&J remains at the forefront of delivering superior products and services, reinforcing its position as a leader in the healthcare industry [1].

In today's data-driven landscape, the abundance of information poses challenges for risk managers and employees, who grapple with complex datasets. Extracting meaningful insights from this deluge of data is daunting and can lead to decisions based on easily collectible metrics rather than value-adding measures. To address this, robust data systems empower employees to set goals, effortlessly generate reports, and provide decision-makers with real-time, accurate information, mitigating the risks associated with relying on outdated data [2].

Effective data communication often relies on visual representations like graphs or charts, but manual construction of these tools is tedious and time-consuming. To streamline this process, advanced data systems offer one-click report building, presenting information in appealing and educational formats. This enhances stakeholders' ability to comprehend and utilize critical insights, thereby improving the overall efficacy of data-driven decision-making processes [2].

Artificial Intelligence (AI), a burgeoning field within computer science, aims to simulate and expand human intelligence through the development of theories, methods, and systems. Spanning robotics, language recognition, image processing, and more, AI endeavors to replicate human-like responses and intelligence [3]. In the realm of quality management, AI represents a paradigm shift, offering real-time insights and predictive analytics that revolutionize quality control procedures. Its robust algorithms empower businesses to sift through vast datasets, identifying trends, anomalies, and potential quality issues early on, thereby averting escalation [3].

The successful implementation of AI spans various industries. In computer vision, for instance,

AI has significantly enhanced real-time quality control, enabling precise anticipation of nonconformities and cost reduction [4]. Similarly, at Cornell University, AI analysis of mass spectrometry data aids in understanding the past habitability of Mars, showcasing AI's prowess in data analysis and interpretation [5]. Moreover, AI has made remarkable strides in healthcare, where algorithms analyze medical data with exceptional precision, aiding in early anomaly detection and informed decision-making in patient care.

Addressing the need for streamlined data analysis and decision-making, ThoughtSpot emerges as a solution. Leveraging AI-powered analytics, ThoughtSpot facilitates intuitive data inquiries through natural language search capabilities, enabling instant access to live data from popular cloud platforms [6]. Its low-code platform, ThoughtSpot Everywhere, allows seamless integration of AI-powered analytics into existing products and services, empowering organizations to monetize data assets while ensuring user engagement. ThoughtSpot's web and mobile applications further enhance data accessibility and utilization, supporting effective decision-making across organizational hierarchies and locations [6].

ThoughtSpot, an AI analytics platform, prioritizes regulatory compliance and industry standards, particularly in sectors like medical devices. Recognizing the sensitivity of healthcare data, ThoughtSpot ensures data security and privacy by adhering to international standards and US regulations like HIPAA [6]. Compliance with FDA regulations is essential, and ThoughtSpot's architecture facilitates adherence by incorporating features for monitoring non-conformances and implementing corrective actions [7]. Through collaboration with regulatory specialists and obtaining relevant certifications, ThoughtSpot demonstrates its commitment to meeting industry standards. Businesses can rely on ThoughtSpot's vendor support and certifications as evidence of its dedication to regulatory compliance in the medical device sector. Additionally, ThoughtSpot offers

comprehensive training materials to ensure users understand and adhere to regulatory procedures, including guidelines for ethical data usage and industry rules.

## METHODOLOGY

We use the DMAIC methodology to execute the design and implementation of the ThoughtSpot for the Quality Systems team. The DMAIC framework, widely employed for process improvement, forms the basis of the technique. It offers a systematic approach to problem-solving, aligning with the study's objective of enhancing Ethicon, J&J's quality management system.



**Figure 2**  
DMAIC Methodology

DMAIC, an acronym for Define, Measure, Analyze, Improve, and Control, represents a systematic approach to process improvement widely utilized across industries. In the Define phase, the project's goals and scope are outlined, clarifying objectives and establishing a baseline for improvement. Following this, the Measure phase involves gathering data to quantify the current state of the process and identifying key metrics for evaluation. Subsequently, in the Analyze phase, data is scrutinized to identify root causes of inefficiencies or defects, often employing tools like root cause analysis and statistical analysis. Armed with insights from the analysis, the Improve phase focuses on implementing solutions to address identified issues, aiming for measurable enhancements. Finally, in the Control phase, mechanisms are put in place to sustain improvements, ensuring that the process remains stable and consistently delivers desired outcomes over time. The DMAIC methodology offers several

advantages, including its structured approach, which guides teams through each stage of the improvement process, fostering systematic problem-solving. Moreover, DMAIC emphasizes decision-making, enabling organizations to base improvements on empirical evidence rather than intuition. Additionally, the Control phase ensures that improvements are sustained, preventing regression to previous states. Overall, DMAIC serves as a powerful framework for organizations seeking to optimize processes, enhance quality, and drive continuous improvement initiatives.

- Define phase:** Research goals and objectives are clarified, focusing on enhancing the Quality Systems Metrics monitoring process at Ethicon's Guaynabo facility. Key stakeholders, including Quality System Department members and management staff, are identified to ensure project success. Conditions for implementing the ThoughtSpot platform are outlined, detailing data sources, user access, and integration with existing systems.
- Measure phase:** Collect data: At this phase, current process will be analyzed and studied. An analysis of the data will be done using a time study. A chronometer will be used to measure each step-in-minute for both the present process and the optimal procedure using ThoughtSpot. Charts and histograms will be developed.
- Analyze phase:** Analyze Data: To find patterns, trends, and the underlying reasons for inefficiencies in the quality management system, the data will be evaluated. We'll use statistical methods and tools to get a better understanding of the fundamental causes of low-quality measurements.
- Improve phase:** Implement the ThoughtSpot Platform. Real-time data analysis will be facilitated by the implementation of the ThoughtSpot platform. The implementation will be adjusted as needed in response to user and stakeholder input. Make Necessary Adjustments, feedback from users and stakeholders will be gathered to identify any

necessary adjustments to the ThoughtSpot implementation. This may include modifications to user access levels, system configurations, or data integration processes. Ensuring seamless integration with existing processes and systems is essential during this step.

- Control phase:** In order to measure important performance indicators and guarantee continued adherence to quality standards, monitoring and control systems will be put in place. The new procedures will be evaluated on a regular basis to see how well they work and to pinpoint any areas that still need improvement. Ensure Continuous adherence to legal and quality standards will be made guaranteed. If there are any deviations or problems, they will be quickly resolved to keep the quality management system intact. Over time, efforts will be made to maintain and improve the system's performance through continuous improvement.

## RESULTS AND DISCUSSION

This section presents the analysis of results and discussion of the problem established and how the design and implementation of the ThoughtSpot were achieved using the DMAIC methodology for this project.

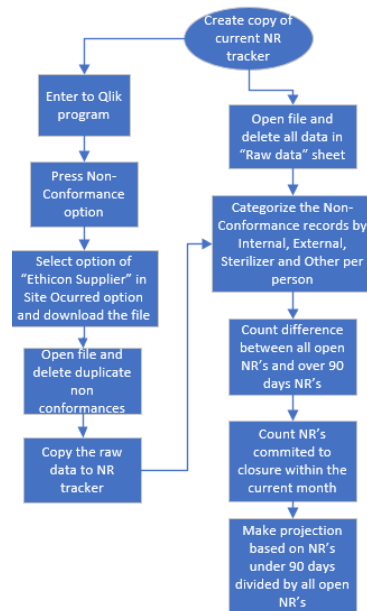
### Define

This section outlines the research goals using DMAIC methodology for AI implementation to replace current metric tracking methods. A new tracking form for CAPA and Non-Conformance is proposed, aiming to streamline the process currently managed through Excel sheets. This daily task consumes about 1.8 hours, totaling 468 hours/year. Stakeholders include Ethicon, Johnson & Johnson (Guaynabo site), the employee managing the task, and the Quality System Department. The ThoughtSpot platform offers real-time self-search, data exploration, and drill-down capabilities, enhancing response times for

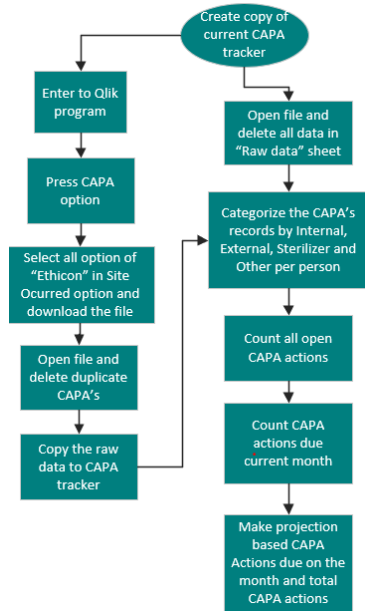
nonconformance and compliance issues. Access to the platform is initiated through EtQ, with J&J user requests translated into SQL statements sent to Azure Databricks.

### Measure

We conducted interviews with the Quality System Lead and Quality System Analyst to fully understand how we track metrics in our business. The data we acquired was crucial for describing the existing workflow. This thorough procedure is shown in the provided flowchart. We invested a significant amount of time and money in studying the process flow and examining the amount of time spent on each task connected to tracking metrics between March 13, 2024, and March 27, 2024. This comprehensive analysis assisted us in identifying areas for process optimization and enhancement. The following flowcharts are a thorough explanation of the metrics we monitor for non-conformances and corrective and preventive actions (CAPA). We can better comprehend the process of tracking and maintaining quality indicators in our operations thanks to this visual representation.



**Figure 3**  
Flowchart of the Process to Gather Metrics of Non-Conformances



**Figure 4**  
Flowchart of the Process to Gather Metrics of CAPA

We conducted a meticulous time analysis in collaboration with our employees, revealing that each assignment takes approximately 35 minutes to complete. This breakdown highlighted that non-conformance tasks require approximately 19 minutes, while tasks related to corrective and preventive actions (CAPA) take around 16 minutes. Considering the frequency of three completions per day, this equates to 1.8 hours of work daily and a significant 468 hours annually. This thorough examination illuminated potential areas for time optimization and efficiency enhancement. We can streamline operations and deploy resources more effectively by identifying these critical Key Performance Indicators (KPIs). Detailed results of the time analysis are provided below, offering insights into each job's time allocation.

**Table 1**  
Time Study of NC

Non-Conformance Process	Time in seconds	
Step 1	Create Copy of Current NR Tracker	0.3
Step 2	Enter to Qlik program	43
Step 3	Press Non Conformance Option	0.7
Step 4	Select option "Ethicon Supplier" in Site Occurred option and download the file	0.7
Step 5	Open file and delete duplicate non conformance	5
Step 6	Copy the raw data to NR tracker	0.9
Step 7	Open file and delete all data in "Raw data sheet"	27
Step 8	Categorize the non-conformance records by Internal, External, Sterilizer and Other, per person	288
Step 9	Count difference between all open NR's and over 90 days NR's	180
Step 10	Make projection based on NR's under 90 days divided by all open NR's	565
Total of seconds		1111
Total of seconds in minutes		18

**Table 2**  
Time Study of CAPA

CAPA Process	Time in seconds	
Step 1	Create Copy of Current CAPA Tracker	0.3
Step 2	Enter to Qlik program	43
Step 3	Press CAPA Option	0.7
Step 4	Select all option "Ethicon Supplier" in Site Occurred option and download the file	10
Step 5	Open file and delete duplicate CAPA	5
Step 6	Copy the raw data to CAPA tracker	0.9
Step 7	Open file and delete all data in "Raw data" sheet	27
Step 8	Categorize the CAPA records by Internal, External, Sterilizer and Other, per person	288
Step 9	Count all open CAPA actions	19
Step 10	Count CAPA actions due current month	4
Step 11	Make projection based on CAPA actions due on the current month and total CAPA actions	565
Total of seconds		969
Total of seconds in minutes		16

### Analyze

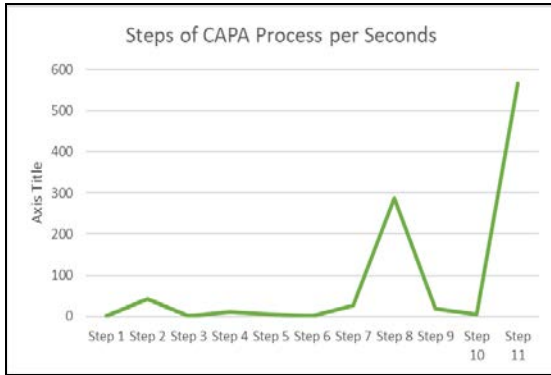
A comprehensive time analysis was conducted, revealing significant variations in time requirements across the Non-Conformance (NC) process. The graph illustrates these fluctuations, with early stages requiring minimal time, and escalating sharply in later phases. Step 8 stands out with the highest increase, indicating heightened complexity. This trend persists in Step 9 and peaks in Step 10, the most time-consuming phase. These findings emphasize the need for understanding and addressing underlying causes to optimize workflow efficiency. The analysis highlights the complexity and importance of this activity, underscoring the necessity of improving overall effectiveness.



**Figure 5**  
Graphic of Steps of NC Process per Second

The time analysis of the Corrective and Preventive Actions (CAPA) process reveals distinct trends and variations across its phases. Similar to Non-Conformances (NRs), initial CAPA steps are swift, with Step 1 taking a mere 0.3 seconds. However, time requirements increase notably as the procedure progresses, particularly in Steps 2, 7, 8, and 11. Step 8, in particular, stands out with a substantial increase to 288 seconds, indicating heightened complexity. Step 10 shows a significant

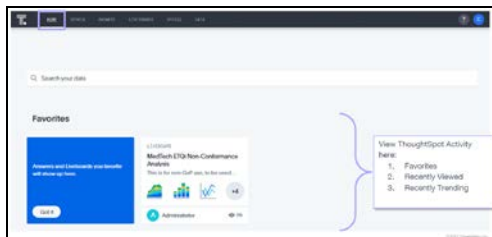
reduction in time, contrasting with Step 11, which remains the lengthiest phase at 565 seconds. Addressing these time disparities is crucial for optimizing the CAPA process and enhancing overall effectiveness.



**Figure 5**  
Graphic of Steps of NC CAPA Process per Seconds

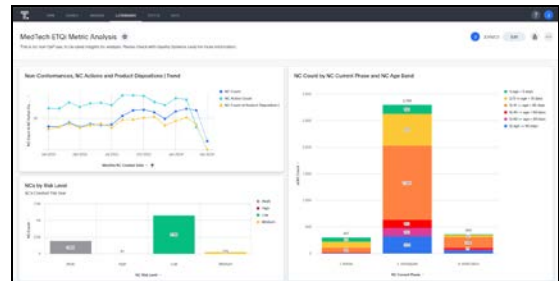
**Improve**

Steps 10 and 11, focused on non-conformances and CAPA, respectively, are critical phases demanding attention due to their time-intensive nature. Efforts to optimize efficiency and streamline operations center around the Improvement step, where strategic changes are implemented, emphasizing creative ideas. Integration of the ThoughtSpot platform facilitates real-time data analysis, enabling swift and effective decision-making. This dynamic implementation process ensures alignment with operational needs and organizational goals, with feedback driving modifications. Quality and Compliance teams benefit from self-search capabilities, expediting responses to non-conformance and compliance issues. ThoughtSpot's architecture will be detailed in upcoming images, summarizing its features and implementation process.



**Figure 6**  
ThoughtSpot Home Page

ThoughtSpot's real-time data display, with auto-updating features, ensures users access the latest insights, improving decision accuracy. A Liveboard collects site metrics efficiently, combining CAPAs and non-conformances. Authorized users easily locate open records with due dates, crucial for maintaining positive metric outcomes. The search bar simplifies data retrieval, reducing daily Excel tasks. Management focuses on Non-Conformance Trends by BU, NC Progression, NC Count, and Risk Level. Detailed figures present the Liveboard with Non-Conformance information, enhancing data accessibility and management efficiency.

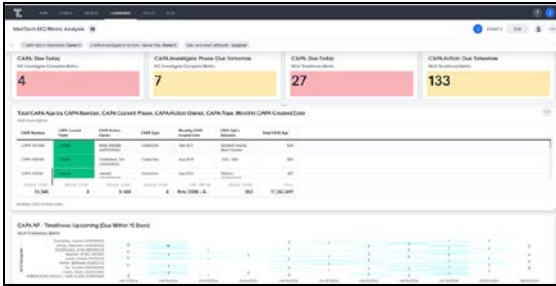


**Figure 7**  
Non-Conformance Live Board

Live boards provide managers with daily updated statistical analytics, aiding in goal measurement and enhancing managerial insight. Real-time updates enable quick pattern recognition and data-driven decision-making, fostering responsiveness and agility. Proactive management becomes easier, facilitating swift remedial action if performance deviates from goals. Live boards promote a culture of continuous improvement and long-term profitability. Addressing open Non-Conformances (NRs) is a priority, necessitating careful monitoring of closure targets and NR owners. Real-time counts aid in identifying operational influences, especially with Supplier Quality Engineers (SQEs), facilitating cooperative resolution initiatives, and continuous quality improvement processes.

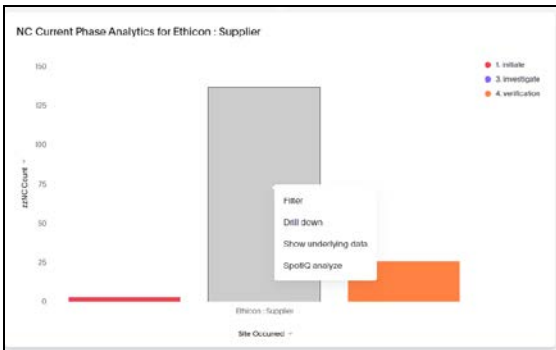
The following Live Board covers all topics related to Corrective and Preventive Actions (CAPAs). CAPAs that are due today and those that

are the subject of an investigation are shown in this part of the board.



**Figure 8**  
**CAPA Count Live Board**

The system integrates all relevant activities, enhancing analysis and tracking efficiency. Various chart options facilitate data representation. Instant drill-down capabilities enable investigation based on criteria like NC number, phase, and CAPA due date. This streamlines meetings and provides easy access to specific CAPA or Non-Conformance Reports (NRs) within the platform, saving time and improving overall productivity.



**Figure 8**  
**Options in CAPA or NC Charts**

**Control**

Following the implementation of the ThoughtSpot platform, Ethicon's Quality System Department will establish robust monitoring and control systems to ensure ongoing efficacy and adherence to quality standards. These systems will support continuous improvement initiatives, maintain compliance, and evaluate performance metrics.

**Monitoring and Control Mechanisms:** Ethicon will implement monitoring and control mechanisms to assess key performance indicators (KPIs)

associated with the quality management system. Metrics such as closed non-conformance and CAPA records, data analysis precision, and user satisfaction with ThoughtSpot will be monitored. Periodic assessments will identify areas for enhancement.

**Ongoing Compliance:** Proactive measures will ensure continued compliance with legal and quality requirements. Ethicon will periodically evaluate industry rules and standards relevant to the medical device sector. Deviations will be promptly addressed to maintain system integrity.

**Continuous Improvement:** Ethicon recognizes that improvement is an ongoing process. User and stakeholder feedback will drive the optimization of the ThoughtSpot platform. Regular audits and assessments will identify areas for improvement and ensure ongoing system enhancement.

**CONCLUSION**

The integration of the ThoughtSpot Platform with Ethicon's quality management system offers numerous advantages. Real-time data access replaces reliance on outdated Excel sheets, ensuring decision-makers have the most current information for informed choices. ThoughtSpot's AI-powered analytics enhance accuracy by reducing errors in tracking non-conformances and CAPA records. These efficiency gains enable staff to focus on strategic projects rather than data manipulation, boosting overall operational efficiency. Issues can be identified and addressed more quickly, improving quality control processes and meeting industry standards proactively. Customized insights empower swift decision-making, enhancing responsiveness and agility. Additionally, ThoughtSpot's deployment accelerates continuous improvement initiatives, facilitating quicker identification of improvement opportunities, more effective changes, and faster outcome assessments. This integration maintains Ethicon's competitive advantage in the dynamic medical device market, leveraging AI-powered analytics for operational excellence. Modifications are made to ensure

seamless integration with existing systems and processes, with monitoring and control mechanisms implemented to track performance metrics and ensure ongoing adherence to quality requirements. Overall, the ThoughtSpot implementation enhances operational performance, enabling Ethicon to stay ahead in the competitive landscape.

## REFERENCES

- [1] M. Dziak, "Quality Management," in Salem Press Encyclopedia, 2022, 3 pages. Item: 100259291. Available: <https://research.ebsco.com/c/sygyvy/viewer/html/nzcyi2gi z>.
- [2] R. Webb. (2020, Nov. 25). *12 Challenges of data analytics and how to fix them* [Online]. Available: <https://www.clearrisk.com/risk-management-blog/challenges-of-data-analytics-0>.
- [3] A. Ettalibi, A. Elouadi, and A. Mansour, "AI and Computer Vision-based Real-time Quality Control: A Review of Industrial Applications," in *Procedia Computer Science*, Jan. 2024, vol. 231, pp. 212–220. doi:10.1016/j.procs.2023.12.195.
- [4] Hindawi, "Artificial intelligence edge computing for innovative applications," Hindawi. <https://www.hindawi.com/journals/mpe/si/392784/>
- [5] I. Nasios, "Analyze mass spectrometry data with artificial intelligence to assist the understanding of past habitability of Mars and provide insights for future missions," in *Icarus*, Jan. 2024, vol. 408, pp. 115824. doi:10.1016/j.icarus.2023.115824.
- [6] ThoughtSpot. (2024, Jan. 30) *ThoughtSpot | the AI-Powered analytics platform* [Online]. Available: <https://www.thoughtspot.com/>.
- [7] U.S. Food and Drug Administration, Office of the Commissioner. (2024, March 20). *Artificial Intelligence and Medical Products* [Online]. Available: <https://www.fda.gov/science-research/science-and-research-special-topics/artificial-intelligence-and-medical-products>. [Accessed: May 17, 2024].