

Navigating Training Needs: A Study of Medical Devices Industry Laboratories

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Graduate Project EXPO, October 2024

Abstract — *Imparting effective training for laboratory personnel in the medical device industry is crucial for ensuring operational excellence and reducing quality-related incidents. This article, therefore, explores the relationship between the adequacy of training for laboratory personnel and the frequency of quality-related incidents affecting operational excellence. The goal is to identify gaps in existing training programs and propose solutions to enhance them. A mixed-methods approach was employed, combining quantitative survey data with qualitative interviews to assess current training practices. The results indicate that, although training is generally perceived as effective, recurring incidents—such as documentation errors and testing inaccuracies—reveal gaps in the depth of the training. This research highlights the need for tailored training solutions that address technical and soft skills, fostering continuous improvement and minimizing costly quality-related errors. Future work will focus on refining training programs and assessing their effectiveness in reducing incidents and improving overall operational performance.*

Key Terms — *ISO 17025, Laboratory Personnel, Medical Device Industry Quality Assurance, Training Program.*

INTRODUCTION

The medical device industry operates within a highly regulated and quality-driven environment, where operational excellence is crucial. This industry heavily depends on industrial quality laboratories to verify the safety and effectiveness of their products. However, a significant challenge persists within these laboratories: the inadequacy of personnel training. Despite the critical nature of their work, many laboratory staff members do not receive comprehensive training tailored to their

specific roles. This deficiency can lead to various quality-related incidents, such as testing errors, contamination events, and regulatory non-compliance, which can have severe financial and reputational repercussions, such as regulatory fines, product recalls, reduced consumer trust, and tarnishing the brand.

This study is designed to explore the correlation between the adequacy of training provided to laboratory personnel and the occurrence of quality-related incidents. Its primary objective is to highlight the importance of tailored training programs and provide actionable insights for improving training practices within the industry. By achieving these objectives, the study aims to enhance operational performance, mitigate risks, and maintain the highest product quality and safety standards, thereby contributing to the overall improvement of the industry.

LITERATURE REVIEW

This literature review seeks to establish a direct correlation between the persisting problem of lack of adequate training among laboratory personnel and existing research. By examining studies on quality training needs, effectiveness assessment, and the impact of Total Quality Management (TQM), specifically within industrial quality laboratories, this review aims to explain the critical importance of comprehensive training programs. It delves into various aspects related to identifying training needs, assessing effectiveness, implementing TQM, and its implications for organizational performance in industrial settings, thus highlighting the urgent need for tailored training initiatives to address this industry-wide concern.

- **Training Needs Assessment in Small Companies:** The study by Miros and Dale

- (1996) [1] examines the quality training needs of small companies, shedding light on the challenges faced in training personnel within limited resources. Small companies often encounter constraints in allocating resources for comprehensive training programs, leading to gaps in knowledge and skills among personnel. Such limitations could exacerbate the issue of inadequate training within industrial quality laboratories, particularly in smaller firms within the medical devices industry. Understanding the specific training needs and challenges faced by small companies can provide insights into designing tailored training interventions to address deficiencies effectively.
- **Assessment of Training Effectiveness:** The Talent Quality-Management System, as explored by Farn-Shing Chen, Shih-Wei Hsu, Min-Che Hung, and Yih-Chuan Wu (2016) [2] offers a practical framework for assessing training effectiveness within enterprises. This system not only equips personnel with the necessary skills but also contributes to organizational goals such as operational excellence. By utilizing a systematic approach to evaluate training outcomes, organizations can identify areas for improvement and optimize resource allocation. This framework can be particularly valuable for assessing the impact of training initiatives within industrial quality laboratories, enabling organizations to gauge their effectiveness in enhancing operational excellence.
 - **Impact of Total Quality Management (TQM):** The impact of Total Quality Management (TQM) practices on organizational performance has been extensively studied. The research by Ngambi, and Nkemkiafu (2015) [3] underscores the role of TQM in firm performance, particularly in fostering a culture of continuous improvement and excellence. Adherence to TQM principles can be a game-changer in the context of industrial quality laboratories in the medical devices industry. By prioritizing quality in all aspects of operations, organizations can mitigate risks associated with inadequate training and maintain the highest standards in product quality and safety.
 - **Knowledge, Attitude, and Practice Towards Occupational Safety and Health:** Ensuring occupational safety and health is essential in industrial settings, including quality laboratories within the medical devices industry. The review by Nayef Shabbab Almutairi, Shamsul Bahri Bin Md Tamrin, Ng Yee Guan (2020) [4] explores laboratory workers' knowledge, attitudes, and practice toward occupational safety and health, highlighting the importance of comprehensive training in mitigating workplace hazards. Inadequate training can not only compromise product quality but also pose risks to the well-being of personnel. Addressing gaps in knowledge and fostering positive attitudes towards safety through targeted training interventions can enhance overall operational excellence and contribute to a safer work environment.
 - **“Training Needs in Quality Systems: A Course on Standards ISO 17025:2017” [5]:** Rivera's study delves into the training needs concerning quality systems, specifically focusing on ISO 17025:2017 standards. This research is particularly relevant as it provides insights into the requirements and competencies necessary to comply with international quality standards. By incorporating findings from this study, the literature review can highlight the importance of tailored training programs that address the specific standards and regulations governing quality systems within the medical devices industry.
 - **“Impact of Training on Quality Management System - Case Study of a Tyre Manufacturing Company” [6]:** The case study presented in the Indian Journal of Training and Development by Padmalita

Routray and Sujata Mangaraj (2010) [6] explores the impact of training on the quality management system within a Tyre manufacturing company. While the industry differs from the medical devices sector, the principles of quality management and training effectiveness remain applicable. Integrating findings from this case study can supplement the literature review by providing real-world examples of how training initiatives can influence organizational performance and product quality. Additionally, it may offer insights into best practices for designing and implementing training programs tailored to specific industry requirements.

In summary, the literature reviewed underscores the critical importance of adequate training among personnel in industrial quality laboratories within the medical devices industry. Persistent deficiencies in training can have far-reaching implications, impacting organizational performance and jeopardizing product quality and safety. By understanding the specific training needs, leveraging effective assessment frameworks, embracing TQM principles, and prioritizing occupational safety and health, organizations can mitigate risks associated with inadequate training and strive towards operational excellence in the dynamic landscape of the medical devices industry.

METHODOLOGY

This study used a mixed-methods research design to explore the training provided to laboratory personnel in the medical devices industry and its effectiveness. The mixed-methods approach combined quantitative surveys and qualitative interviews to collect numerical data and contextual insights. This design offered a more comprehensive understanding of current training practices, their effectiveness, areas for improvement, and their impact on operational excellence.

Participants and Sample

- **Target Population:** Laboratory personnel (analysts and technicians) and laboratory managers in industrial quality laboratories of medical device companies.
- **Sampling Method:** The research employed purposive sampling to select participants with relevant experience and insights into laboratory training practices. This ensures that the data collected was representative of the target population and provided meaningful insights into the research questions.
- **Sample Size:** The survey's sample size was determined based on principles of statistical significance, aiming for enough responses to ensure the reliability of the findings. For the qualitative interviews, a smaller but diverse sample of laboratory managers and stakeholders were selected to provide a wide range of perspectives and experiences.

Data Collection

- **Quantitative Data:** A structured survey was designed to gather information on training practices, quality-related incidents, frequency of training sessions, content covered, and perceived effectiveness. The survey was distributed through in-person interactions and electronically to a sample of laboratory personnel in the medical devices industry.
- **Qualitative Data:** Laboratory managers and trainers were interviewed to explore their perspectives on training effectiveness, challenges, and suggestions for improvement.
- **Ethical Considerations:** Confidentiality was maintained, and participants' identities were anonymized in any reporting.

Data Analysis

- **Quantitative Data:** Statistical methods were used to analyze survey data on training frequency, content relevance, and effectiveness. This analysis aims to identify correlations between reported training

adequacy and incident occurrence, which will provide valuable insights into the effectiveness of the training programs.

- **Qualitative Data:** Interviews were analyzed to identify recurring themes and patterns related to training practices and their impact on quality control.

RESULTS

The data collection process of this study entailed distributing a comprehensive 17-question survey to a representative sample of laboratory personnel within the medical devices industry. The survey was distributed through in-person interactions and electronically utilizing Google Forms over a two-week collection period (August 20, 2024 - to September 3, 2024).

The survey aimed to collect various aspects of training, including training methods, session frequency and content, and the perceived effectiveness of the training provided. Additionally, it gathered data on the frequency and nature of quality-related incidents occurring within the laboratories.

It is important to emphasize that the survey data analyzed in the following sections will assist in identifying potential correlations between the adequacy of training programs and quality-related issues in a laboratory setting. This analysis will offer valuable insights into the overall impact of training quality on operational performance and excellence within the industry.

Years of Experience Profile of the Participants

An important observation of this study was that almost half of the respondents had less than three years of experience, while the remaining half had over five years of experience, as shown in Figure 1. Analyzing the respondents' experience profiles was particularly important because it provided insight into specific training needs based on years of experience. This understanding was crucial for determining the impact of different types of training on quality performance, as some laboratories tend

to prioritize technical skills while others emphasize soft skills without considering the level of experience. Consequently, this finding could aid in developing a tailored training program to reduce errors, considering that more experienced personnel may require different training approaches than less experienced staff in certain cases.

How many years of experience do you have working in a laboratory setting within the medical device industry?

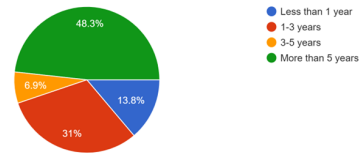


Figure 1
How many years of experience do you have working in a laboratory setting within the medical device industry?

Types of Quality-Related Incidents and Training Topics Covered

According to the respondents, Operational Procedures (86.2%) and Quality Standards and Controls (86.2%) topics are covered extensively during training sessions (Figure 2). Yet, process deviations (44.8%), testing inaccuracies (37.9%), and sample contamination (34.5%) were the most common quality-related incidents. Also, Regulatory Compliance was another major covered training topic with 65.5% (Figure 2); however, documentation errors were the most common quality-related incident at 82.8% (Figure 3). This data suggests a potential gap between training on these topics and the practical application, or it may indicate that the depth of training in these areas was insufficient to prevent these incidents.

Which topics are typically covered in your training sessions? (Select all that apply)

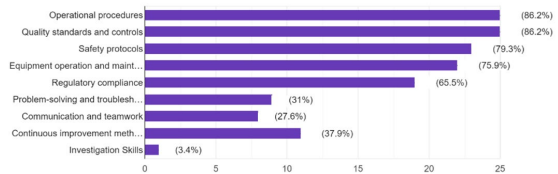


Figure 2
Which topics are typically covered in your training sessions?

What types of quality-related incidents are most common in your laboratory? (Select all that apply)

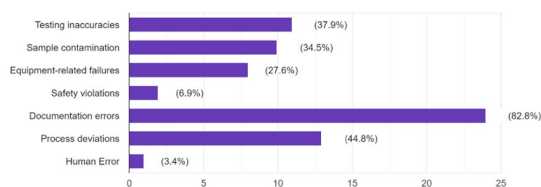


Figure 3

What types of quality-related incidents are most common in your laboratory?

Equipment operation and maintenance (75.9%) is another well-covered topic during training sessions (Figure 2). Still, equipment-related failures account for 27.6% of incidents (Figure 3), indicating that while training is frequent, further reinforcement or hands-on practice may be needed to reduce equipment failures. On the other hand, 79.3% of the participants also acknowledge that safety protocols (Figure 2) were addressed during training sessions. However, the documented safety violations were relatively low per the 6.9% of the respondents (Figure 3), suggesting that the emphasis on safety training is more effective and positively impacts incident reduction.

Training Effectiveness and Incident Frequency

Many respondents (72.4%) rated the effectiveness of the training they received as either "Very Effective" or "Effective," indicating a generally positive perception of the training's ability to support their roles in the laboratory (Figure 4). This positive perception of the training effectiveness could be supported by the fact that 41.4% of the respondents perceive quality-related incident occurrence as rare (Figure 5).

However, a closer examination of the data contradicts this, as quality-related incidents occur at a 27.6% monthly rate or 20.7% quarterly rate, representing almost half of the respondents (48.3%) who reported incidents as happening at relatively high frequency (Figure 4). This suggests that despite an effective training perception, there is room for improvement in the training programs or other related operational practices since quality-related incidents remain common in laboratories.

In particular, the relatively high frequency of incidents reported by 48.3% of respondents may be linked to the most common type of quality-related incident—documentation errors—reported by 82.8% of respondents (Figure 3). This connection underscores the importance of addressing specific training gaps to mitigate such issues.

How would you rate the overall effectiveness of the training received in supporting your role in the laboratory?

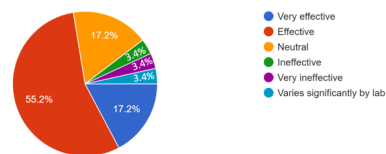


Figure 4

How would you rate the overall effectiveness of the training received in supporting your role in the laboratory?

How often do quality-related incidents occur in your laboratory?

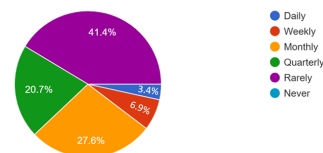


Figure 5

How often do quality-related incidents occur in your laboratory?

Moreover, on occasion, the effectiveness of the initial training could be rated as effective. Still, ongoing training, refresher courses, or updates to address new challenges might be lacking, as 51% of the respondents perceived (Figure 6). Over time, without continuous improvement, the effectiveness of the training could diminish, and incidents may occur more frequently as employees encounter new situations that weren't covered in their original training. Even if initial training is solid, failure to reinforce best practices over time can lead to complacency or errors, increasing the likelihood of incidents. This could explain the relatively frequent occurrence of incidents despite the overall positive view of training.



Figure 6

What challenges do you face when applying the training to your job in the laboratory?

CONCLUSION

This research thoroughly examined the connection between the quality of training provided to industrial quality laboratory personnel in the medical devices field and the occurrence of quality-related incidents that affect operational excellence, highlighting several critical findings through a mixed-methods approach and contributing to a deeper understanding of the challenges laboratories face regarding training adequacy. These findings were the following:

- The training is perceived as effective but does not entirely prevent frequent incidents such as documentation errors, process deviations, and testing inaccuracies.
- The depth of training in certain areas may be insufficient to prevent recurring quality incidents effectively.
- Based on years of experience, the laboratory personnel may require different training approaches to maintain high-quality standards.
- Focusing on specific training needs, such as technical skills, soft skills, or both, can positively impact quality performance.

In conclusion, this research provides valuable evidence-based insights into the importance of comprehensive training programs tailored to the specific necessities of laboratory personnel in the medical devices industry. By addressing the gaps identified in this study, organizations can reduce quality-related incidents and, thus, costs associated with errors, product recalls, and non-compliance, improve operational efficiency, and promote an environment of continuous improvement. Future

research should concentrate on creating standardized training procedures, exploring innovative training solutions, and investigating the long-term effects of continuous training on operational performance. The findings of this research have the potential to significantly improve training practices within the industry, contributing to higher standards of quality and operational excellence.

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