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Original Article

Risk-Based Approach in Medical Device Quality Management System in Covid-19 Pandemic

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Abstract *- This study helps to understand the impact of a risk-based approach in medical device quality management systems, especially during the Covid-19 pandemic period. It gives analytical information about the risk-based approach in the Quality system and pandemic Covid-19. This research study gives a solution to avoid failures in new product development in the medical device industry, especially COVID products. At the same time, it gives ideas and suggestions of Marketing COVID Products to solve the problem in commercialization as per regulatory.*

Keywords *- Risk approach, COVID, QMS, Medical Device.*

I. INTRODUCTION

The quality environment has evolved to require the use of a risk-based approach throughout the quality management system. ISO 13485:2016 Medical devices—Quality management systems –Requirements for regulatory purposes published March 1, 2016, characterizes risk to include two components:

- the safety or performance requirements of the medical device
- meeting applicable regulatory requirements.

The 2016 version of ISO 13485 has an increased focus on risk compared to the prior 2003 edition of the standard. Risk management is now required throughout the quality management system (QMS) rather than being specific to product development. A risk-based approach is needed for the control of QMS processes. In fact, the word risk was found 40 times within the body of the ISO 13485:2016, whereas the 2003 version only mentions risk on four occasions, all within Section 7, Product Realization.

There is also a clear focus on meeting regulatory requirements in the 2016 standard to assist users with inconsistent applications. It is difficult to meet all regulatory requirements in the Pandemic COVID situation. Regulatory requirement is a broad term that includes requirements in any law applicable to the user of the regulatory standard where a user of the standard could be a regulatory body, manufacturer, supplier, or medical device service provider.

II. OBJECTIVES OF THE STUDY

- To understand risk-based approach impact in Quality Management System in COVID related medical device products
- Understanding the application of risk techniques allows problems to be solved before they impact the quality of the COVID product
- To understand emergency route regulatory compliance related to COVID products
- To analysis about the 568 medical device companies' employees' opinions about employee suggestions in the Quality Management system

A. Limitations of the Study:

- The study is limited to only medical device manufacturing and distribution companies.
- The sample size is limited to 568, and that may be a bias of the study.
- The study period is around 3 months, and a deep analysis of the research cannot be made.
- Respondents may fail to express their opinions and beliefs.

B. Descriptive Study:

The present study attempts to assess the Quality Management System in the medical device manufacturing and distribution companies. It tries to assess the impact of a risk-based approach in medical device quality management systems and especially duringpandemic Covid-19. Hence it is a descriptive-analytical study.

C. Sources of Data:

Depending upon the sources of information available, data can be classified as,

- Primary data
- Secondary data

a) Primary data:

The primary data are those, which are collected for the first time by the researcher. It is the fresh data. It was collected by administering a standard communicable questionnaire from the employees and management.

b) Secondary data:

It refers to the already existing data. This study uses the internet, books, published articles, journals, and newspaper articles search to collect the data.

C. Data collection procedure used in the research:

a) Questionnaire: A questionnaire is used to collect the data for the study. One common questionnaire was formulated to collect the data respectively from middle management and executive-level management.

Types of sampling used for the study: Random sampling

b) Sample Size:

Using a random sampling method,568 respondents were selected from operational level employees, and 80 were selected from executive level management of the medical device manufacturing companies.

III. ANALYSIS AND INTERPRETATION

Table 1. Frequency Distribution of Employees' Qualification

Employees' educational qualification	Frequency	Percentage
Regulatory graduate	206	36.3
Graduate	241	42.4
Professional with MBA	121	21.3
Total	568	100.0

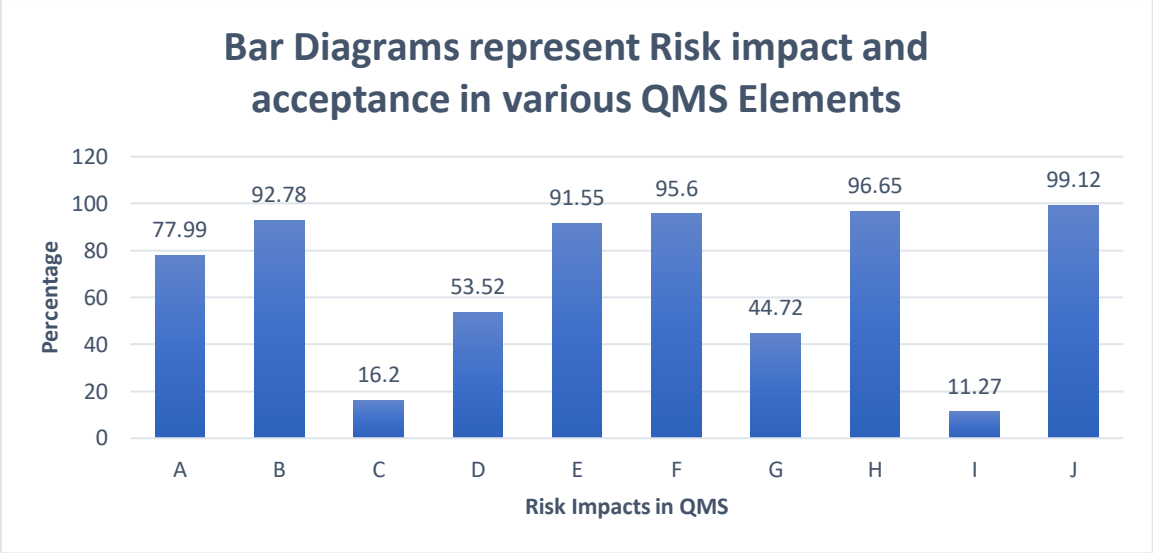
The above table explains that 36.3% of Regulatory graduates have given the data for this Research study, 42.4 % of Graduates have given the data for this research study, and 21.3 % M.B.A graduates have given the data for this research study.

IV. ANALYSIS OF RISK-BASED APPROACH IN QUALITY MANAGEMENT SYSTEM IN COVID RELATED MEDICAL DEVICE PRODUCTS

Table. 2 Frequency Distribution of Employees' Opinion About the Risk-Based Approach in QMS

The risk-based approach in different QMS elements	No		Yes		Total	
	Count	%	Count	%	Count	%
1. Risk based approach in purchasing raw material	125	22.01	443	77.99	568	100.00
2. Risk based approach in training	41	7.22	527	92.78	568	100.00
3. Risk approach in marketing	476	83.80	92	16.20	568	100.00
4. Risk in document control	264	46.48	304	53.52	568	100.00
5. Risks in production	48	8.45	520	91.55	568	100.00
6. Risks in design and development	25	4.40	543	95.60	568	100.00
7. Risk approach in planning	314	55.28	254	44.72	568	100.00
8. Risk approach in vigilance	19	3.35	549	96.65	568	100.00
9. Risk approach in marketing material	504	88.73	64	11.27	568	100.00
10. Risk based approach in distribution especially COVID- 19 pandemic	5	.88	563	99.12	568	100.00

(Source: From Medical device manufacturer / Distribution employees -Primary data)



- The risk-based approach in purchasing raw material
- The risk-based approach in training
- Risk approach in marketing
- Risk in document control
- Risks in production
- Risks in design and development
- Risk approach in planning
- Risk approach in vigilance
- Risk approach in marketing material
- The risk-based approach in distribution, especially COVID- 19 Pandemic condition

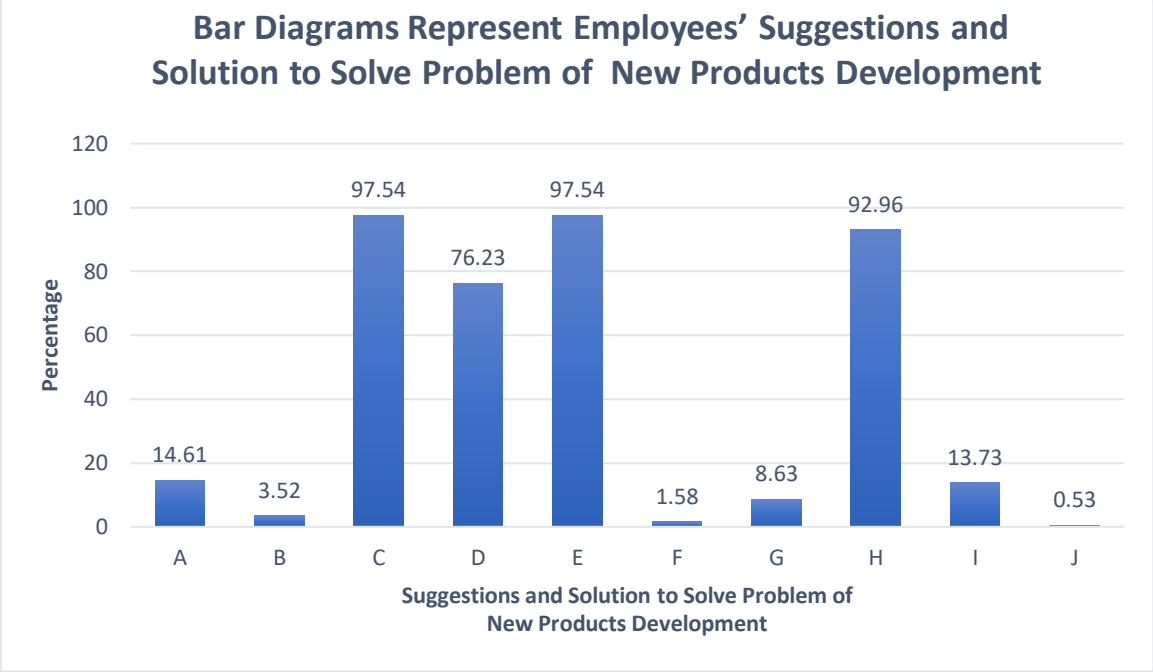
The above table and bar diagrams explain the risk-based approach started practice by medical device companies in training (93%), production (92%), design of the new product (96%), and vigilance (97%). The risk-based approach focused more on distribution practice (99%) due to the pandemic situation of COVID-19 and the need for this device in the market. Risk focus is moderate in document control (54%) and planning (45%). Risk focus ware low in marketing 16% and marketing material (11%).

V. ANALYSIS OF THE SOLUTION TO SOLVE PROBLEMS IN COVID -19 RELATED PRODUCT COMMERCIALIZATION

Table. 3 Frequency Distribution of Employees' Suggestions and Solutions to Solve the Problem of New Products Development

Solution for Problem in NPD	Yes		No		Total	
	Count	%	Count	%	Count	%
1. Good brand name	83	14.61	485	85.39	568	100.00
2. Less adverse reaction	20	3.52	548	96.48	568	100.00
3. USFDA/CE/WHOapproved under emergency use	554	97.54	14	2.46	568	100.00
4. India approved	433	76.23	135	23.77	568	100.00
5. Raw material availability to Manufacture	554	97.54	14	2.46	568	100.00
6. Strategy for competitions	9	1.58	559	98.42	568	100.00
7. Good market strategy	49	8.63	519	91.37	568	100.00
8. Service intention in pandemic COVID Situation	528	92.96	40	7.04	568	100.00
9. Post market surveillance	78	13.73	490	86.27	568	100.00
10. Employees sincerity and service	3	.53	565	99.47	568	100.00

(Source: From medical device manufacturer/distribution employees - primary data)



- Good brand name
- Less adverse reaction
- USFDA / CE / WHO approved under
- emergency use
- India approved
- Raw material availability to manufacture
- Strategy for competitions
- Good market strategy
- Service intention in pandemic COVID
- situation
- Post-market surveillance
- Employees sincerity and service

The above Table and Bar diagram explain 14.61 % of medical device companies employees suggest "good brand name" helps solution to solve the problem of new products in the medical device industry. 3.52 % of pharmaceutical companies' employees suggest "less adverse reaction" gives a better solution to solve the problem in new products development in the medical device industry.

97.54 % of medical device companies employees suggest "USFDA/CE/WHO approved under emergency use" gives a better solution to solve the problem in new products development in the pandemic covid-19 situation. 76.23 % of medical device company's employees suggest "Indian drug authority approved products" gives solution to solve the problem in new products development in the medical device industry. 97.54% of medical device companies' employees suggest "raw material availability to manufacture" gives solutions to solve the problem in new products development in the medical device industry.

1.58 % of medical device companies' employees suggest "strategy for competitions" gives solution to solve the problem in new products development in the medical device industry. 8.63 % of medical device companies' employees suggest a "good market strategy" gives a solution to solve the problem in the commercialization of new products in the medical device industry.

92.96 % of pharmaceutical companies' employees suggest a "good work culture" gives solutions to solve problems in the commercialization of new products in the medical device industry. 13.73 % of medical device employees suggest "post-market surveillance" gives a solution to solve the problem in the commercialization of new products in the medical device industry.

0.53% of medical device companies' employees suggest "employees sincerity" gives a solution to solve the problem in the commercialization of new products in the medical device industry.

A. Risk Techniques

The tool most commonly used to conduct a risk analysis was an FMEA (failure mode effects analysis). Not a new or unique technique for the medical device industry. ISO 14971 is the standard accepted throughout the world for medical device risk management.

The medical device regulatory agencies have accepted ISO 14971 and expect to document risk management activities throughout the entire product lifecycle. From device inception through obsolescence.

B. Emergency route regulatory compliance related to COVID products:

Regulatory authorities are committed to ensuring that patients and health care providers have timely and continued access to high-quality diagnostic and therapeutic medical devices to respond effectively to the COVID-19 pandemic. On the basis of this determination, the authorities declared that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices and COVID-related medical devices during the COVID-19 outbreak.

International Medical Device Regulators Forum (IMDRF) countries as per WHO (World Health Organization)website (https://www.who.int/diagnostics_laboratory/200408_imdrf_covid19_listing_update_8_april_2020.pdf) announced national authorities emergency route approval to commercialize COVID-19 products to avoid short supply.

C. Suggestions:

- A risk-based approach throughout the entire product life cycle implementation leads to High-performance products and fewer errors in the medical device industry.
- Due to the risk concept "benefits overweight the risks", many COVID -19 products are released in the market to handle the pandemic situation. Risk concept in design and development contributing big impact in pandemic period especially medical device industry.
- New products should be approved by Regulatory Authorities by emergency route to avoid failures in new product development as suggested by employees in the quality management system.

VI. CONCLUSION

A risk-based QMS means applying a process to assess risk to each of these processes. A QMS is our architecture for demonstrating all the things we do to comply with regulations. Those actions tend to be good business practices, too. Appropriate implementation of a risk-based approach in the product life cycleleads to fewer errors in the Quality Management system, especially medical device industry, as per demonstrated data. To ensure success, the whole organization, especially executive management, middle management, and workers should commit and undertake Risk Management to improve productivity. Despite an internal desire to undertake risk management, some aspects of organizational culture prevented these from reaching full potential. Data has confirmed that customer satisfaction and product quality performance have increased due to the Risk-based approach in the selected manufacturing firms.

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