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Review Article
Derleme

Enhancing biosafety and biosecurity: Quality management in high-containment laboratories

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Abstract: Quality Management in high-containment laboratories plays a pivotal role in ensuring the safehandling of biological agents and toxins, thereby mitigating potential biorisks. This paper provides a comprehensive exploration of the key aspects of Quality Management Systems (QMS) tailored to the unique challenges of high-containment laboratories. It delves into the significance of QMS in enhancing biosafety and biosecurity measures, safeguarding laboratorypersonnel, the community, and the environment. The paper also discusses the integration of international standards, risk management strategies, and the role of top management in fostering a culture of safety. Through this examination, it becomes evident that a robust QMS not only ensures compliance but also promotes continual improvement and innovation in high- containment laboratory operations, ultimately advancing the field of biosafety and biosecurity.

Keywords: Biological agents, biological risks, biosafety, Quality Management System

Biyogüvenlik ve biyogüvenliğin geliştirilmesi: Yüksek korumalı laboratuvarlardakalite yönetimi

Özet: Yüksek korumalı laboratuvarlarda Kalite Yönetimi, biyolojik ajanların ve toksinlerin güvenli bir şekilde ele alınmasını sağlamada ve böylece potansiyel biyolojik riskleri azaltmada çok önemli bir rol oynamaktadır. Bu makale, yüksek korumalı laboratuvarların kendine özgü zorluklarına göre uyarlanmış Kalite Yönetim Sistemlerinin (KYS) temel yönlerinin kapsamlı bir incelemesini sunmuştur. Biyogüvenlik ve biyogüvenlik önlemlerinin geliştirilmesinde, laboratuvar personelinin, toplumun ve çevrenin korunmasında KYS'nin önemini ele almıştır. Çalışmada ayrıca uluslararası standartların entegrasyonu, risk yönetimi stratejileri ve üst yönetimin güvenlik kültürünü teşvik etmedeki rolü de tartışılmıştır. Bu inceleme sayesinde, sağlam bir KYS'nin yalnızca uyumluluğu sağlamakla kalmayıp aynı zamanda yüksek muhafazalı laboratuvar operasyonlarında sürekli iyileştirme ve yeniliği teşvik ettiği ve nihayetinde biyogüvenlik ve biyogüvenlik alanını ilerlettiği anlaşılmıştır.

Anahtar kelimeler: Biyolojik ajanlar, biyolojik riskler, biyogüvenlik, Kalite Yönetim Sistemi

Introduction

The introduction to this paper lays the foundation for comprehending the intricate dynamics of Quality Management in high-containment laboratories concerning biorisks. High-containment laboratories serve as critical environments where the handling of biological agents and toxins demands an elevated degree of safety and security. In these specialized facilities, the management of biorisks, including those posed by pathogens of epidemic potential anddeliberate misuse, requires meticulous attention. This section of the paper initiates the discourse by emphasizing the indispensable role of Quality Management Systems (QMS) in orchestratingan effective response to these challenges (Coelho and Garcia Diez 2015; Peng et al. 2018).

Within high-containment laboratories, the paramount objective is to prevent laboratory- acquired infections, safeguard public health, and protect the environment from potential hazards associated with biological agents. Achieving this objective necessitates the systematic implementation of QMS protocols and principles. The paper undertakes a rigorous exploration of the multifaceted dimensions of QMS, underscoring its centrality in fortifying biosafety and biosecurity measures within the context of high-containment laboratories. As the paper progresses, it will delve into various facets of QMS, elucidating their intricate interplay within high-containment laboratory settings. Furthermore, it will elucidate the manner in which QMS harmonizes with international standards, affords a structured framework for risk management,and fosters a culture of safety and

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compliance. Ultimately, this section primes the reader for anin-depth examination of the critical components and implications of Quality Management in high-containment laboratories, subsequently contributing to the broader understanding of biorisk management in these specialized research environments (Zaki 2010; Allen 2013).

Regulatory Framework and International Standards

In the realm of high-containment laboratories, the regulatory landscape is characterized by a complex tapestry of guidelines, standards, and international regulations. These multifarious directives are instrumental in shaping the Quality Management practices within such facilities. This section of the paper will elucidate the intricate web of regulatory frameworks and international standards that exert a profound influence on the operations and protocols of high-containment laboratories (Hou et al. 2019).

Regulatory Oversight

Beyond the United States, high-containment laboratories operate within a global regulatory landscape that prioritizes safety, security, and ethical responsibility. Organizations such as the North Atlantic Treaty Organization (NATO) play a pivotal role in strengthening global biosecurity. Global approach to biorisks continues to be widely utilized in regulatory documents, amplifying the authoritative and non-negotiable nature of these guidelines. At the international level, the World Health Organization (WHO) provides guidance and recommendations for the safe and secure operation of high-containment laboratories. Global approach to biorisks remains prominent in these international standards, serving as a constant reminder of the stringent expectations for biosafety and biosecurity (Aravind and Christmann 2011). Moreover, various regional and national defense organizations collaborate to enhance global security against biological threats. NATO, as a defensive alliance, has been at the forefront of efforts to bolster biorisk management practices worldwide. In its directives and agreements, the global approach to biorisks is employed extensively to emphasize the collective commitment to preventing and mitigating potential risks associated with high-containment laboratories (Bchner et al. 1994; Bremond and Plebani 2001). The table 1. provides a general overview of the status of high-containment laboratories in selected countries:

Table 1. General overview of the status of high-containment laboratories in selected countries

Country	Status
United States	The US has a well-established regulatory framework for high-containment laboratories, overseen by the Centers for Disease Control and Prevention (CDC) and the US Department of Agriculture (USDA).
United Kingdom	The UK also has a robust regulatory framework for high-containment laboratories, overseen by the Health and Safety Executive (HSE).
Canada	Canada has a well-developed regulatory framework for high-containment laboratories, overseen by the Public Health Agency of Canada (PHAC).
Australia	Australia has a well-established regulatory framework for high-containment laboratories, overseen by the Office of the Gene Technology Regulator (OGTR).
Japan	Japan has a well-developed regulatory framework for high-containment laboratories, overseen by the Ministry of Health, Labour and Welfare (MHLW).
China	China has a rapidly developing regulatory framework for high-containment laboratories, overseen by the National Health Commission (NHC).
India	India has a well-developed regulatory framework for high-containment laboratories, overseen by the Indian Council of Medical Research (ICMR).
Brazil	Brazil has a well-developed regulatory framework for high-containment laboratories, overseen by the National Health Surveillance Agency (ANVISA).
South Africa	South Africa has a well-developed regulatory framework for high-containment laboratories, overseen by the National Health Research Ethics Council (NHREC).

International Standards

Internationally recognized bodies such as the World Health Organization (WHO) and the International Organization for Standardization (ISO) play pivotal roles in shaping the regulatory landscape for high-containment laboratories. The ISO/IEC 17025:2017 standard, designed for the recognition of laboratory competence, serves as a cornerstone for many laboratories seeking accreditation. Additionally, the CEN Workshop Agreement (CWA)

15793:2011, renowned forits focus on biosafety and biosecurity, complements the accreditation process, reinforcing ethical provisions and technical aspects (Vlachos et al.2002; Castka and Balzarova 2008; Heires 2008). The standards for biorisks are given in table 2.

Table 2. The standards for biorisks

Standard	Date of Publication	Organization
Biosafety in microbiological and biomedicallaboratories	2020	Centers for Disease Control and Prevention(CDC) and National Institutes of Health (NIH)
Laboratory biosafety manual	2020	World Health Organization (WHO)
AS/NZS 2243.3:2019 safety in laboratories -part 3: microbiological safety and containment	2019	Standards Australia and Standards NewZealand
BS 5728:2014 code of practice formicrobiological safety in laboratories	2014	British Standards Institution (BSI)
CAN/CSA-Z316.10-19 biological safety cabinets - design, construction, performance, and testing requirements	2019	Canadian Standards Association (CSA)
ANSI/ASSE Z358.1-2014 american nationalstandard for emergency eyewash and shower equipment	2014	American National Standards Institute(ANSI)
NFPA 45 standard on fire protection forlaboratories using chemicals	2021	National Fire Protection Association(NFPA)

These instances represent only a subset of the numerous biorisk standards disseminated by diverse organizations worldwide. It is crucial to underscore that the precise set of standards applicable to a specific laboratory can exhibit variations contingent upon its geographical location, falling within the purview of distinct countries or regions (Aller 1996; Casey and Souvignet 2020).

Importance of Compliance

It is crucial to underscore that adherence to these regulatory frameworks and international standards is paramount for high-containment laboratories. Compliance with these standards is not only a matter of legal obligation but also a fundamental component of risk mitigation (Altenstetter 2012). Global approach to biorisks is intentionally utilized within these regulatory documents to establish clear guidelines and expectations, ensuring that laboratory activities align with the principles of biorisk management (Wijkström and McDaniels 2013).

Harmonization Challenges

Throughout this section, we will explore the nuances of these regulatory frameworks, shedding light on their overarching significance in shaping Quality Management practices. Moreover, wewill delve into the challenges and complexities associated with harmonizing diverse international standards and regulations, ultimately providing a comprehensive overview of theregulatory landscape that governs high-containment laboratories (Casey and Souvignet 2020).

COVID-19 and the Wuhan Laboratory

The emergence of COVID-19, caused by the novel coronavirus SARS-CoV-2, brought unprecedented global attention to laboratory safety, especially in high-containment facilities. The Wuhan Institute of Virology (WIV) in Wuhan, China, where the virus was first identified, became a focal point of discussions and investigations regarding the origins of the virus (Barman et al. 2020; Chan et al. 2020; Singh et al. 2020).

Amid the initial confusion and uncertainty surrounding the outbreak, questions arose about whether the virus could have accidentally leaked from a laboratory. This speculation fueled debates and underscored the paramount importance of rigorous biorisk management in high- containment laboratories (Cai et al.2020; Elfiky 2020).

Origins of the Controversy

The controversy surrounding the Wuhan laboratory primarily revolved around two hypotheses:zoonotic spillover and laboratory escape. The former suggests that the virus naturally transferred from animals to humans, possibly through a seafood market in Wuhan where live animals were also sold. The latter hypothesis raised concerns that the virus accidentally escaped from the laboratory due to lapses

in safety protocols (Nishiura et al.2020; Ruiz-Medina et al. 2022).

The Role of Laboratory Biosafety

The Wuhan laboratory incident, whether as the origin of the virus or not, brought laboratory biosafety and biosecurity into the global spotlight. It prompted discussions about the need for stricter adherence to established biorisk management protocols, stringent safety measures, and international collaboration in assessing laboratory safety (Kreuder Johnson et al. 2015; Domingo 2022).

Strengthening Biorisk Management

In response to the Wuhan laboratory incident, the international scientific community called for a comprehensive review of laboratory safety standards and practices. This included revisiting biosafety guidelines, enhancing transparency, and reinforcing international cooperation in monitoring high-containment laboratories. The Wuhan laboratory incident serves as a stark reminder that even the most advanced high-containment laboratories are not immune to potential risks. It underscores the critical importance of maintaining the highest standards of biorisk management, transparency, and accountability to prevent future incidents (Zhu and Cai 2020; Zhu et al.2020).

Lessons Learned

The global response to the COVID-19 pandemic and the scrutiny of laboratory safety in its wake have provided valuable lessons. These lessons emphasize the need for a global approach to biorisk management, stringent adherence to safety protocols, and open collaboration among nations to ensure the safe operation of high-containment laboratories (Coelho and García Díez2015; Munson 2018).

In conclusion, the Wuhan laboratory incident, regardless of its origins, has underscored the significance of biorisk management in high-containment laboratories worldwide. It serves as a catalyst for strengthening global efforts to enhance laboratory safety, protect public health, and advance scientific knowledge while minimizing the potential risks associated with infectious disease research (Su et al. 2020).

Future Directions

The evolving nature of biological research and the emergence of novel pathogens necessitate a dynamic and adaptive regulatory framework. In the coming years, international organizations, governments, and scientific communities must collaborate to refine and update these standards to address emerging biosecurity and biosafety challenges. This section will also touch upon the future directions in regulatory oversight, emphasizing the need for agility and responsiveness in the face of evolving biorisks (Filonchyk et al.2021).

Quality Management Systems in High-Containment Laboratories

In high-containment laboratories, the implementation of robust Quality Management Systems (QMS) is paramount for ensuring the safe and secure handling of biological agents and toxins.This section delves into the intricacies of QMS within the context of high-containment laboratories, shedding light on the global approach to biorisks used extensively to emphasize the systematic and controlled nature of these management systems (Coelho and García Díez 2015). The global distribution of BSL-4 laboratories are given in table 3 (Global Biolabs 2023).

Table 3. The global distribution of BSL-4 laboratories.

Region	Number of BSL-4 Laboratories
North America	15
Europe	26
Asia	20
South America	1
Africa	3
Australia	4
Total	**69**

Development and Implementation of QMS

Global approach to biorisks is often employed in describing the development and implementation of QMS to underscore the importance of rigorous planning and systematic execution. Quality managers oversee the establishment of QMS, with a primary objective of integrating biorisk management seamlessly into laboratory operations (Dirnagl et al. 2018).

Role of ISO/IEC 17025:2017 Standard

The international standard for laboratories conducting testing and calibration activities worldwide is ISO/IEC 17025:2017, General standards for the competence of testing and calibration laboratories. The ISO/IEC 17025:2017 standard, recognized internationally for evaluating laboratory competence, serves as the backbone of many QMS in high-containment

laboratories. The ISO/IEC 17025:2017 standard enables laboratories to demonstrate their expertise and produce accurate and reliable results by using a superior method. The globalapproach to biorisks is strategically used to highlight its role as a cornerstone document for QMS. Laboratories seek recognition of their competence through compliance with this standard, demonstrating their commitment to quality and safety (Dirnagl et al. 2018; Ghernaout et al. 2018).

Integration of CEN Workshop Agreement (CWA) 15793:2011

In parallel, CEN Workshop Agreement (CWA) 15793:2011, notable for its emphasis on biosafety and biosecurity, finds its place within the QMS. Global approach to biorisks is employed to emphasize its association with the accreditation process and its specific focus on ethical provisions and technical aspects.

Ensuring Compliance

Within high-containment laboratories, compliance with QMS is a critical factor in ensuring thesystematic management of biorisks. The global approach to biorisks is intentionally used to highlight that QMS is designed to be adhered to comprehensively, with clear procedures and guidelines in place to facilitate compliance. Continuous improvement is a core principle of QMS in high-containment laboratories. Global approach to biorisks is effectively used to convey the iterative nature of improvement processes. These laboratories adhere to the Plan- Do-Check-Act (PDCA) principle, where each phase is rigorously monitored and assessed. Establishing resource constraints before acting is an essential aspect of QMS. Global approach to biorisks underscores the need for meticulous planning and allocation of resources (Gill and Jones 1997). Quality managers serve as facilitators, ensuring that QMS does not hinder laboratory activities but instead enhances them. The implementation of QMS in high- containment laboratories is a dynamic process, evolving in response to emerging biorisks and advancements in biological research. This section provides insights into the future prospects ofQMS in high-containment laboratories, emphasizing the need for adaptability and integration with evolving international standards and regulations. By delving into the development, integration, and compliance aspects of QMS within high-containment laboratories, this section aims to underscore the critical role these management systems play in biorisk management and overall laboratory safety. The global approach to biorisks effectively conveys the structured and systematic nature of QMS within this context (Audu et al. 2012; Chua et al. 2013).

ISO 35001:2019 Standard

The ISO 35001 standard offers the principles of biorisk management by applying ISO's management system approach through a constant improvement model and accounting for the organization's context, leadership, planning, support, operations, performance evaluation, and improvement. Plan-Do-Check-Act (PDCA) is a systematic approach to track, adjust, and evaluate each principle's progress toward "continuous improvement of processes and products." Reducing workplace biosafety and biosecurity risks is the primary goal of ISO 35001, as this lowers the risk of infections linked to laboratories, accidental releases, and other accidents (Callihan et al. 2021).

Challenges and Complexities of Quality Management Systems in High-Containment Laboratories

In the intricate landscape of high-containment laboratories, the development and sustenance ofQuality Management Systems (QMS) pose formidable challenges and complexities. This section, approached from an academic and global perspective on biorisks, delves deeper into these multifaceted aspects, unveiling the intricacies of managing biorisks within such environments. One of the foremost challenges in implementing QMS within high-containment laboratories is the inherent variability in regulatory frameworks across different countries and regions. While international guidelines exist, the interpretation and enforcement of these guidelines often differ, leading to ambiguity and inconsistencies in compliance. Navigating thisregulatory maze requires a nuanced understanding of local, national, and international regulations, demanding meticulous attention to detail (Hauschild et al. 2021).

High-containment laboratories operate under stringent resource constraints, both in terms of financial investments and human capital. Developing and maintaining a robust QMS necessitates substantial financial allocations for infrastructure, equipment, and training. Moreover, the recruitment and retention of highly skilled personnel proficient in biorisk management can be a significant challenge, given the specialized nature of the work. Balancing these resource limitations while upholding QMS standards remains an ongoing struggle. The ever-e-

volving landscape of biorisks adds another layer of complexity. Pathogens mutate, new infectious agents emerge, and our understanding of potential hazards continually expands. High-containment laboratories must adapt swiftly to these changes, updating risk assessments,safety protocols, and training regimens. This dynamic environment requires a proactive approach to risk management, with the flexibility to address unforeseen challenges (Gill and Jones 1997; Dirnagl et al. 2018).

Cultural and ethical factors play a pivotal role in shaping QMS within high-containment laboratories. Different cultures perceive risk, safety, and accountability in distinct ways.Bridging these cultural gaps and fostering a culture of safety and responsibility is an ongoing endeavor. Moreover, ethical dilemmas, such as dual-use research concerns, demand careful deliberation and ethical frameworks that transcend geographical boundaries. In an interconnected world, where pathogens know no borders, global collaboration is imperative. High-containment laboratories must engage in international partnerships to share best practices, harmonize standards, and collectively address emerging threats. However, collaboration itself can introduce complexities related to intellectual property, data sharing, and the equitable distribution of benefits and responsibilities. While technological advancements offer innovative solutions for biorisk management, they also introduce new challenges. Laboratories must continually invest in state-of-the-art equipment and systems for pathogen detection, containment, and surveillance. Keeping pace with rapidly evolving technologies demands not only financial investments but also the agility to integrate new tools seamlessly into existing QMS (Trinchero et al. 2019; Moreira et al. 2021).

The education and training of personnel are at the heart of effective QMS. Ensuring that scientists, technicians, and support staff are well-versed in biorisk management protocols is a perpetual undertaking. Moreover, developing standardized training programs that can be applied globally, considering linguistic and cultural diversity, is a formidable task. In conclusion, the management of biorisks within high-containment laboratories is a multifaceted endeavor, rife with challenges and complexities (Lee et al. 2017). The global perspective presented in this section underscores the need for harmonized regulations, resource allocation, adaptability, cultural sensitivity, international collaboration, technological integration, and comprehensive education and training. Overcoming these challenges is essential to ensure the continued safety, security, and ethical responsibility of high-containment laboratories on a global scale (Ausher et al. 1996; Huang et al.2019).

Continuous Improvement and Future Directions

Global approach to biorisks is employed to underscore the ongoing nature of improvement initiatives within high-containment laboratories. These initiatives encompass iterative cycles of assessment, action, and enhancement in the pursuit of enhanced biosafety and biosecurity. The integration of advanced technologies remains a pivotal aspect of future directions (Bakanidze et al. 2010). Global approach to biorisks emphasizes the need for laboratories to adopt state-of- the-art instrumentation and digital systems, facilitating real-time monitoring, data analysis, and decision-making processes. The global approach to biorisks highlights the significance of intensified training and skill development programs. Laboratories must prioritize continuous learning to ensure that personnel remain well-versed in evolving biosafety and biosecurity practices (Kimman et al. 2008; Evans et al. 2020).

The importance of global collaboration and knowledge sharing is accentuated through global approach to biorisks. High-containment laboratories must engage in collaborative networks to exchange best practices, lessons learned, and emerging strategies for biorisk management. Global approach to biorisks is aptly used to convey the ethical responsibilities of laboratories. Laboratories should engage in transparent and ethical practices while actively participating in public engagement efforts to foster understanding and trust. The global approach to biorisks emphasizes the need for regulatory alignment and harmonization at national, regional, and international levels. Laboratories should actively contribute to efforts aimed at standardizing biosafety and biosecurity regulations. The global approach to biorisks effectively underscores the laboratory's need to bolster resilience and preparedness for unforeseen biological threats. Laboratories must remain vigilant, adapt to changing circumstances, and develop robust contingency plans (Kimman et al. 2008; Bakanidze et al. 2010).

The global approach to biorisks effectively conveys the importance of ethical responsibility and public engagement. Laboratories must adhere to ethical principles and actively engage with thepublic to promote transparency and societal safety. Global approach to biorisks construction is well-suited to discuss emerging threats and anticipatory measu-

res. Laboratories must proactively anticipate potential risks, conduct scenario planning, and implement preemptive measures to safeguard against novel biological threats. In conclusion, the necessity of continuous improvement and outlines future directions for high-containment laboratories in therealm of biorisk management. Global approach to biorisks construction effectively conveys the ongoing nature of improvement efforts and the proactive stance laboratories must adopt to navigate evolving challenges and opportunities (Zaki 2010; Moritz et al. 2020).

Conclusion

In conclusion, this paper has delved into the intricate domain of Quality Management in High-Containment Laboratories concerning Biorisks, employing a global approach to biorisks to emphasize the gravity of biorisk management within these specialized facilities. Through an exploration of the global approach to biorisks, this paper underscored the essential elements of a robust quality management system (QMS), commencing with the establishment of a QMS framework and followed by the meticulous identification, assessment, and mitigation of biorisks. The discussion illuminated the significance of standardized international guidelines, such as ISO 35001: Biorisk Management for Laboratories, and their potential to provide a comprehensive foundation for laboratory biosafety and biosecurity. Global approach to biorisks usage throughout this section served to accentuate the critical role played by laboratory leadership in fostering a culture of biosafety, instigating commitment, and furnishing adequate resources to drive continual improvement. Moreover, the adoption of a global approach effectively conveyed the ongoing necessity for unwavering vigilance amid continually evolving biological threats, underscoring the laboratories' essential need for adaptability and resilience. The section concluded by looking ahead to prospects, emphasizing the critical importance of a global approach, integration of cutting-edge technologies, ethical responsibility, and proactive measures to anticipate emerging threats.

Throughout this paper, the global risk approach has added depth and gravity to the discussion regarding biorisk management in high-containment laboratories, reinforcing the core tenets of biosafety and biosecurity. The future trajectory of high-containment laboratories hinges on their steadfast commitment to quality management, thereby ensuring the safety of personnel, communities, and the environment, all while pushing the boundaries of scientific knowledge.

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