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Transforming Medical Regulations into Numbers: Vectorizing a Decade of Medical Device Regulatory Shifts in the USA, EU, and China

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Navigating the regulatory frameworks that ensure the safety and efficacy of medical devices can be challenging, especially across different regions. These frameworks often require redundant testing, slowing down the process of getting innovations to patients. This study leverages Natural Language Processing (NLP) to analyze 664 regulations and guidelines from the USA, EU, and China over the past decade, covering over 200 million tokens (individual words and sub-word units processed by Bidirectional Encoder Representations from Transformers's (BERT) tokenizer). We categorize regulations into key phases—such as animal studies, clinical trials, and other testing stages—and use BERT to perform Named Entity Recognition (NER), identifying key regulatory terms and entities. By converting these texts into numerical representations and segmenting them by phase, country, and year, we compare jurisdictional requirements and assess their alignment. Additionally, we apply Latent Dirichlet Allocation (LDA) for theme analysis to observe changes in regulatory focus over time, reflecting evolving priorities and challenges. Our analysis reveals notable semantic similarities and differences between countries and phases. For instance, the closest alignment in animal study regulations is between China and the USA, with a mean cosine distance of 0.33. These findings highlight the computational potential in regulatory science, offering valuable insights for researchers, policymakers, and industry professionals.

CCS Concepts: • **Applied computing** → **Health informatics**; • **Social and professional topics** → **Governmental regulations**; • **Computing methodologies** → *Natural language processing*; *Topic modeling*;

Additional Key Words and Phrases: natural language processing, regulatory affairs, topic modeling, LDA, BERT, longitudinal analysis, medical device regulation

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1 Introduction

Global regulatory authorities for medical products, such as the **Food and Drug Administration's (FDA)**, prioritize two pillars when reviewing medical device dossiers to determine market eligibility: safety and efficacy

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[1]. Safety ensures that medical products do not pose harm to patients, while efficacy confirms that the products achieve their intended indications when used. Although efficiency—the speed at which valuable devices reach patients—is also valued, it tends to receive comparatively less emphasis. Ensuring that high-quality devices reach patients worldwide remains critically important for those in need. However, products that successfully enter several markets often face significant challenges in accessing others, reflecting a disparity not always evident at first glance.

In 2018, Fractyl Laboratories' Revita DMR device, developed to treat insulin-resistant type 2 diabetes, received the FDA's Breakthrough Device Designation, intended to accelerate its development and review process [2]. However, despite the expedited pathway in the US, the device faced delays in launching in other markets due to differing regulatory requirements. These varying regulations across regions significantly impacted the timeline for global availability. After substantial investment in research and development, the regulatory approval process can become a bottleneck, delaying market entry, and limiting patient access. This highlights the critical need to understand and navigate the diverse regulatory landscapes to ensure that innovative treatments reach patients in a timely manner.

The hip implant scandal in the **European Union (EU)** has led to numerous recalls and reoperations for affected patients, highlighting serious safety concerns [3]. The European regulatory system for medical implants has come under intense scrutiny following several high-profile device failures and recalls, resulting in additional patient investigations and surgeries. Unlike the centralized authority of the US FDA, Europe relies on more than 30 decentralized notified bodies to assess the safety and efficacy of medical devices [3]. Investigations have revealed significant variations in regulatory practices, including differences in adopted standards, premarket evidence requirements, post-market surveillance, and factory audits. These inconsistencies create opportunities for manufacturers to take advantage of the approval process [3], demonstrating how regulatory frameworks can directly affect both the market entry and the safety of medical devices.

The **International Medical Device Regulators Forum (IMDRF)** seeks to accelerate the harmonization and convergence of global **Medical Device Regulations (MDR)** [4]. While the IMDRF has made notable progress in aligning regulatory frameworks, the rules remain complex and continue to evolve rapidly, making it difficult for stakeholders to manually track and understand the differences across regions [5]. These disparities in standards and requirements create a challenging regulatory landscape for manufacturers, often acting as barriers that delay or block patient access to medical products. As a result, patients may face delays or limited availability of innovative, potentially life-saving treatments. Bridging these regulatory gaps is crucial for streamlining approval processes, reducing time to market, and ensuring patients worldwide benefit from advancements in medical technology [6, 7].

To address this issue, our research seeks to answer the following question: How do regulatory requirements for medical devices differ across countries, and what are the practical implications of these differences for manufacturers? Specifically, how can manufacturers efficiently extract relevant information from the vast and continuously growing body of regulations and make informed decisions? Given the IMDRF's focus on convergence, how does each country align its regulatory framework across different phases, such as animal studies, clinical trials, and testing? Given the impracticality of manually reviewing all regulatory documents, we explore how **Natural Language Processing (NLP)** methods can assist in this process. Using real-world data, this study highlights the current state of regulatory harmonization and the challenges manufacturers face. By utilizing NLP methods, we are able to quantify and compare regulatory texts, offering a novel approach to measure of harmonization across regions.

2 Related Work

2.1 NLP Applications in Legal and Regulatory Texts

The application of NLP to legal and regulatory texts has become an active research area. One line of work introduced domain-specific transformer models such as Legal-**Bidirectional Encoder Representations from**

Transformers (BERT), pretrained on legal corpora, which achieved superior performance on document classification tasks and established important benchmarks for legal NLP [8]. Building on this, the MultiEURLEX dataset provided a large-scale multi-lingual benchmark for EU legislation, enabling cross-lingual analysis of legal texts [9]. Subsequent research developed hybrid approaches such as GAN-BERT for classifying pharmaceutical legal texts, combining adversarial learning with transformers to improve robustness on imbalanced datasets [10]. These studies demonstrate how domain-specific pretraining, multi-lingual resources, and hybrid modeling approaches can enhance the processing of complex legal and regulatory corpora.

2.2 Computational Approaches in Regulatory Science

In medical device domains, computational methods have increasingly been used to support regulatory science. Early works applied topic models and information extraction to regulatory documents and submissions. For example, one study applied machine learning to classify regulatory submission types, illustrating the potential of automated analysis in regulatory workflows [11]. Theoretical foundations for **Latent Dirichlet Allocation (LDA)** in policy text analysis were laid in earlier studies and later extended to medical device adverse event narratives [12, 13].

Since 2020, several works have advanced the use of NLP specifically for medical device regulatory science. One study proposed an NLP framework to automatically classify EU Field Safety Notices into device categories using **Named Entity Recognition (NER)** and transformer-based embeddings [14]. Another applied latent semantic analysis to FDA 510(k) device descriptions to identify substantially equivalent devices, demonstrating how semantic similarity measures can streamline equivalence assessments [15].

Further research used LDA to detect patterns of human-factor "use errors" in FDA adverse event narratives, providing insights into device usability and safety monitoring [16]. A benchmark corpus of annotated FDA adverse event reports was also released to support information extraction tasks, enabling structured analysis of failure modes and patient outcomes [17]. Recent comparative benchmarks have evaluated machine learning, deep learning, and large language models for medical device classification tasks, highlighting tradeoffs between accuracy, interpretability, and efficiency [18]. A **Retrieval-Augmented Generation (RAG)** system was proposed for cross-jurisdictional regulatory compliance, integrating semantic search over thousands of global standards with large language model reasoning to determine standard applicability [19]. Collectively, these studies illustrate the growing role of computational NLP in regulatory science, ranging from risk classification to compliance reasoning and post-market surveillance.

2.3 Our Contribution

A critical gap in the literature is the lack of large-scale, multi-jurisdictional computational comparisons of MDR. While prior studies have applied NLP to single-country corpora or to specific document types, no systematic attempt has been made to compare regulations across jurisdictions. By digitizing and numerically representing regulations from three major regions, our study establishes a scalable framework for cross-national analysis in medical device regulatory science. Building on this framework, we make three main contributions:

(1) *Large-scale, multi-jurisdictional analysis.* We address a critical gap in the literature by providing a computational comparison of MDRs across the USA, EU, and China. By digitizing and numerically representing regulations, we establish a scalable framework for cross-national analysis in regulatory science.
(2) *Phase-oriented analytical lens.* We introduce a segmentation of regulations into lifecycle stages such as animal studies, clinical trials, and testing. This perspective highlights the differentiated logics of evidence requirements, moving beyond prior work that treated regulations as homogeneous blocks.
(3) *Temporal dynamics of harmonization.* We quantify decade-long trajectories of regulatory alignment and divergence, reframing convergence as a dynamic process rather than a static outcome. This approach provides new insights into the pace, direction, and stability of global regulatory harmonization.

Together, these contributions shift the field from isolated, country-specific case studies toward a generalizable research agenda that integrates NLP, regulatory science, and policy analysis for international comparison.

3 Background and Motivation

Regulatory frameworks play a crucial role in ensuring the safety, efficacy, and quality of medical devices, governing every phase from preclinical testing to clinical trials and post-market surveillance. Regulatory affairs teams act as liaisons between companies and regulatory bodies, ensuring that products meet all legal and safety standards to facilitate market entry [20]. However, these frameworks vary significantly across regions due to differences in national regulatory environments, creating a complex landscape for stakeholders to navigate [21–25]. This complexity demands sophisticated analytical tools to effectively understand and manage the evolving regulations, as the challenge of regulatory complexity has been a topic of increasing scholarly interest [5, 26]. For manufacturers, researchers, regulatory professionals, and policymakers, keeping up with these changes is essential for compliance and fostering innovation.

Research has highlighted differences across various aspects of regulatory systems, such as quality systems, post-marketing requirements, and premarket approval processes. At the regulatory authority level, the U.S. FDA operates a centralized, adaptive process that allows rapid adjustments in device classifications based on new market data, facilitating the timely introduction of innovative technologies. In contrast, the EU's MDR relies on a more decentralized approach, using notified bodies to assess high-risk devices. While this ensures rigorous safety standards, it can lead to variability in enforcement across member states. Comparative studies of the U.S., EU, and Japan have documented these systemic differences [27].

From a procedural standpoint, gaining regulatory approval varies significantly across regions. In Canada, manufacturers must submit an **Investigational Testing Authorization (ITA)** to Health Canada for Class II, III, and IV devices. In the EU, manufacturers must notify the competent authorities of member states before conducting clinical investigations. In the U.S., approval processes differ based on whether a device is classified as **Significant Risk (SR)** or **Non-Significant Risk (NSR)**, which determines if an **Investigational Device Exemption (IDE)** or **Institutional Review Board (IRB)** approval is required [28]. On a product-specific level, even identical medical devices, such as contact lenses, face different regulatory requirements in the U.S., EU, and other countries, leading to varying compliance obligations [29]. These discrepancies illustrate the challenges manufacturers face when navigating global regulatory landscapes, impacting the timely availability of medical devices worldwide.

The global launch of medical devices is often hindered by the diverse and complex regulatory requirements across different regions. For example, even after successfully passing the U.S. FDA's rigorous review process, a medical device must still undergo additional approval processes to enter other markets, such as the EU or China, due to differing regulatory standards [30, 31]. These regional differences necessitate distinct approval procedures for manufacturers, complicating the regulatory process. In addition to initial market entry, manufacturers must also manage ongoing regulatory obligations such as device change control, complaint handling, vigilance, and recall activities during the product lifecycle in each region where their devices are registered [32].

The IMDRF has played a significant role in the harmonization of global MDRs by building on the foundation set by the **Global Harmonization Task Force (GHTF)**. Since its establishment in 2011, IMDRF has focused on aligning regulatory approaches and improving cooperation between regulatory bodies from various countries, including the U.S., EU, China, Australia, Japan, and others [6]. The IMDRF has made significant efforts to harmonize various aspects of MDR, including animal studies, while IMDRF's primary focus has been on clinical evidence and quality management systems.

IMDRF has published key documents such as the "Essential Principles of Safety and Performance of Medical Devices" and established working groups to address specific areas. The working focus includes harmonizing clinical evidence requirements and premarket submissions, which influence how animal studies and clinical

trials are conducted across jurisdictions. Specific guidance related to clinical evidence evaluation, such as clinical investigations, has been designed to ensure that trial data from one country can be accepted by others, promoting international data sharing and reducing redundancy in testing. Some of the key IMDRF publications related to clinical evaluations and safety include the frameworks the Clinical Evaluation Guidance (IMDRF/PMD WG/N56) [33] and Post-Market Adverse Event Reporting Guidance (IMDRF/NCAR WG/N14) [34], and so on.

Despite these efforts, challenges remain due to the diversity of regulatory institutions and the influence of various stakeholders, including industry, physicians, and scientific advisors [35]. A deep understanding of these regulations and strategic planning is essential for manufacturers to successfully launch products in multiple regions.

Machine learning involves training a computational model to perform tasks by leveraging data. Broadly, these tasks fall into two main categories: prediction and data exploration [36, 37]. Prediction relies on a specific branch of machine learning known as supervised learning, where data examples—like MDRs—include pairs of (i) predictor variables (such as a device's manufacturer or classification) and (ii) an outcome variable (for instance, whether the device achieved regulatory approval). With this structure, a model can learn to process new observations of the same predictor variables (e.g., a new device's manufacturer and classification) and predict its likely outcome (approval status).

Data exploration is often achieved using techniques known as unsupervised learning. Unlike supervised learning, unsupervised learning deals with data that only include observed variables without a designated outcome variable to predict. This allows for a larger pool of data since most datasets lack explicit outcome labels. For instance, there is a wealth of raw medical data available from various regulatory submissions. In the context of MDR, a task well-suited for unsupervised learning might involve identifying other devices with similar regulatory profiles or technical features to a given device.

Complementing these machine learning methods, NLP has become increasingly valuable for enhancing the efficiency and accuracy of regulatory analysis. As a branch of **AI**, NLP enables the automated understanding and extraction of information from regulatory documents, which is particularly useful when handling large volumes of text. Recent advancements in NLP have made it possible to automate the extraction of critical insights from massive collections of regulatory documents, allowing us to detect intricate patterns and trends that might be overlooked in a manual review [38]. Together, these computational approaches provide a more comprehensive toolkit for managing and analyzing regulatory data in a more efficient and insightful manner. As the regulatory landscape and medical devices evolve rapidly, maintaining harmonization across regions becomes more challenging, highlighting the growing importance of AI-driven tools [39, 40].

For example, NLP techniques like BERT have been employed to analyze regulatory texts within the EU, revealing that specific therapeutic areas align more closely with **European Medicines Agency (EMA)** guidelines than others [41]. In addition, unsupervised learning methods like LDA have proven effective in identifying and categorizing regulatory themes, such as safety, efficacy, and compliance, from large datasets [42]. These methods significantly reduce the manual effort involved in understanding complex regulatory frameworks. Machine learning approaches have also been applied to automatically classify regulatory submissions, improving efficiency and accuracy in the submission and review process [11]. NLP-based analysis of FDA approval letters, for instance, has helped to identify recurring themes and areas needing improvement, thus enhancing the regulatory review process [43]. Similarly, NLP tools have been used to extract key data from clinical trial registries, facilitating better analysis of trial designs and outcomes [44].

Furthermore, temporal analysis of regulatory documents, enabled by computational tools, offers insights into how regulatory priorities shift over time. This is particularly valuable in response to major events, such as the COVID-19 pandemic, during which regulatory agencies worldwide accelerated the approval processes for diagnostic and therapeutic devices, demonstrating remarkable flexibility [45]. Time-series analysis has also tracked growing emphasis on areas like cybersecurity and data protection in MDRs over the past decade [46].

Such computational analyses not only help stakeholders stay informed about changing regulatory landscapes but also allow them to better anticipate future trends, enabling proactive decision-making and strategic planning [47].

Our research tackles the challenges stemming from the lack of harmonization in MDRs, which often leads to delays in product approvals and can pose safety risks. Regulatory guidelines are typically communicated in written form to various stakeholders, including regulatory bodies, manufacturers, **Contract Research Organizations (CROs)**, and patients. Traditionally, researchers have manually compared regulatory frameworks and summarized their findings for the scientific community [48]. However, the rapid evolution of these regulations makes manual comparisons inefficient and prone to errors. By applying NLP techniques, we aim to transform regulatory texts into numerical embeddings, laying the groundwork for a more efficient, accurate, and scalable approach to analyzing global regulatory frameworks. This method holds the potential to reduce barriers to international market entry for medical devices, enabling faster and safer access to innovations. The yearly results of the LDA analysis across different countries also reveal shifts in regulatory themes within the medical device sector.

4 Methods

This study utilizes BERT embeddings and LDA [49] to analyze a comprehensive dataset of 664 regulations—over 200 million tokens (where tokens refer to individual words and sub-word units generated by BERT's tokenizer, including punctuation marks and special characters)—primarily comprising technical regulations and guidelines from the USA, EU, and China issued over the past decade. We categorize these regulations into distinct phases: animal studies, clinical trials, and other testing stages, allowing for a comparative assessment of each country's requirements and the degree of alignment among them. To achieve this, we employ specific keywords to filter and group phase-specific sentences, resulting in tailored corpora for each regulatory phase. We then leverage BERTSum, a summarization model built upon BERT [50], to gain insights into the underlying reasons for observed regulatory differences and their implications for manufacturers. BERTSum is particularly useful for extracting key points from extensive regulatory documents, providing a concise understanding of each region's regulatory focus.

4.1 Data Collection and Preprocessing

All regulations and guidelines were sourced from official government websites and databases specific to the USA FDA [51], EU EMA [52], and China NMPA [53]. These documents, manually downloaded, pertain to medical devices and, in some instances, combination products that include both devices and pharmaceuticals. The dataset encompasses laws, guidelines, and policies relevant to medical devices, available in English as well as the native languages of the respective regions. The collection period spanned from January 2013 to May 2024. Only documents directly providing regulatory guidance were included, while materials such as meeting minutes or surveillance reports were excluded. All documents were stored in a standardized format for subsequent analysis (Table 1).

To address potential language differences, Chinese regulations were translated into English by professional translation services and subsequently cross-checked through back-translation by two independent bilingual authors to ensure semantic fidelity. This process minimized translation bias and enhanced comparability across jurisdictions. Structural variations (e.g., numbering, formatting, section order) were also normalized to create a consistent textual structure.

All documents were then converted to plain text and subjected to a multi-step preprocessing pipeline. Boilerplate text (e.g., headers, footers, and repeated disclaimers) was removed, and the corpus was segmented, tokenized, and normalized. Stop words such as "the," "and," and "in" were excluded to reduce dimensionality and computational noise. To mitigate possible semantic loss, we retained legally significant connectors where they appeared in fixed regulatory expressions (e.g., "terms and conditions," "safety and efficacy") and verified that their omission did not materially affect the semantic similarity analysis. Alternative approaches, such as dependency-parsing-based stop word removal or domain-specific stop word lists, could further improve fidelity, and we highlight this as an avenue for future work (Figure 1).

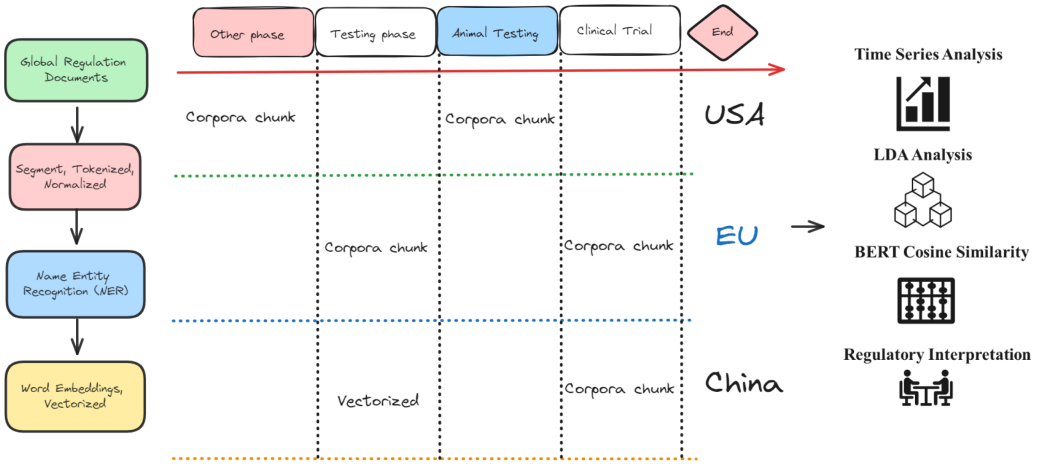

Fig. 1. The workflow of text cleaning and preprocessing.

In this study, "tokens" are defined according to the BERT WordPiece tokenizer (`bert-base-uncased`), which segments text into individual words and sub-word units, treats punctuation and special characters as independent tokens, and appends special markers (e.g., [CLS], [SEP]). Sequences longer than 512 tokens were truncated, while shorter ones were padded to standardize input length. This definition ensures reproducibility and clarifies the reported corpus size of over 200 million tokens (Figure 1).

4.2 NER

NER is a sub-task of information extraction that aims to locate and classify named entities from unstructured text into predefined categories such as names of persons, organizations, locations, expressions of time, quantities, monetary values, and percentages. NER is a fundamental component in NLP applications, including information retrieval, question answering, and machine translation. This process can be achieved through machine learning approaches and deep learning models.

In our study, NER is specifically applied to extract relevant biomedical terms from text, recognizing the unique nature of the biomedical field. We utilize SciSpacy, a Python package that provides language models optimized for processing biomedical, scientific, and clinical text. SciSpacy enables us to effectively identify entities in this specialized context [64]. Given that biomedical concepts are central to MDRs, applying NER allows us to capture a wide array of relevant biomedical names.

We applied NER to the corpora for each country, analyzing data on an annual basis. Additionally, SpaCy [65] was used for text preprocessing and NER analysis, while Matplotlib and Seaborn were employed for data visualization. To ensure clarity, we specify that our NER analysis covers 13 entity types defined by spaCy's schema, including `CARDINAL`, `ORG`, `DATE`, `LAW`, `PRODUCT`, and `GPE`. Across the full regulatory corpus, a total of 270,257 entities were extracted, providing a comprehensive representation of the regulatory terminology landscape.

4.3 Phase-Specific Segmentation

The development of medical devices is a complex and highly regulated process requiring rigorous testing and evaluation to ensure safety and efficacy before approval. The regulatory landscape aims to protect public health by enforcing stringent standards throughout the device lifecycle, from research and development to post-market monitoring. In this study, we categorize regulatory documents into four main phases relevant to the medical device lifecycle: preclinical testing (animal studies), clinical trials, testing phase, and other phases. This classification is informed by industry knowledge and reflects the characteristic stages of medical device development, highlighting

Table 1. Partial Overview of MDRs and Guidelines Issued by Authorities (2013–2024)

Year	Title	Authority
2024	Guiding Principles for the Registration and Review of Laparoscopic Surgery Systems, Animal Testing, Decision-making, Judgment and Requirements [54]	China NMPA
2023	Guidelines for the Registration Review of Medical Molecular Sieve Oxygen Concentrators [54]	China NMPA
2022	Single-Use Cervical Balloon Dilation Catheter Registration Review [54]	China NMPA
2022	Provisions for Supervision and Administration of Medical Device Manufacturing [54]	China NMPA
2021	Medical Diagnostic X-ray Equipment for Pediatric Applications [54]	China NMPA
2020	Hernia Repair Mesh Clinical Trial Guidelines [54]	China NMPA
2014	Renewal of EC Design-Examination and Type-Examination certificates [55]	EU EMA
2017	Designation and Notification of Conformity Assessment Bodies [55]	EU EMA
2019	Guidance Notes for Manufacturers of Class I Medical Devices [55]	EU EMA
2020	Post-Market Clinical Follow-Up (PMCF) Plan Template [55]	EU EMA
2022	MDCG Position Paper Notice to Manufacturers to Ensure Timely Compliance with MDR and IVDR Requirements [55]	EU EMA
2024	Guidance on Content of the Investigator's Brochure for Clinical Investigations of Medical Devices [55]	EU EMA
2013	Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to Borrelia Burgdorferi [56]	USA FDA
2014	Infusion Pumps Total Product Life Cycle [57]	USA FDA
2016	Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices [58]	USA FDA
2017	FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions [59]	USA FDA
2019	Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions [60]	USA FDA
2021	Safer Technologies Program for Medical Devices [61]	USA FDA
2023	Best Practices for Selecting a Predicate Device to Support a Premarket Notification Submission [62]	USA FDA
2024	Perform Servicing and Remanufacturing [63]	USA FDA

the significance of each phase within the regulatory framework. The boundaries between phases were determined using a purely keyword-based approach without human annotations, which may result in some misclassifications or overlapping content between phases.

Our comprehensive validation approach combined automated processing with systematic quality assurance measures. We performed extensive validation, including: (1) data completeness verification for all 664 documents, (2) statistical analysis of 270,257 NER entities across jurisdictions, (3) LDA topic coherence validation through interactive visualizations, (4) BERT embedding quality assessment using UMAP dimensionality reduction, and (5) temporal trend validation using Prophet time-series analysis. All major outputs were exported for manual inspection and cross-validated using alternative methodologies. In Figure 3, we visualize each chunked corpus. To enhance clarity, we excluded other corpora due to their volume, allowing for a clearer view of the animal, testing, and clinical corpora in this figure.

Animal Studies. The phase of animal studies focuses on preclinical evaluations of safety and biological effects [66]. These studies gather preliminary data on the interactions between the device and living tissues, assessing factors such as toxicity, biocompatibility, and potential side effects. Insights gained from animal testing are crucial, as they cannot be ethically or feasibly obtained through in vitro (lab-based) tests alone. We filtered relevant text from the corpus using keywords such as "animal testing," "animal models," "animal toxicity tests," "animal ethics," and "animal." The extracted sentences were compiled into a corpus for subsequent analysis.

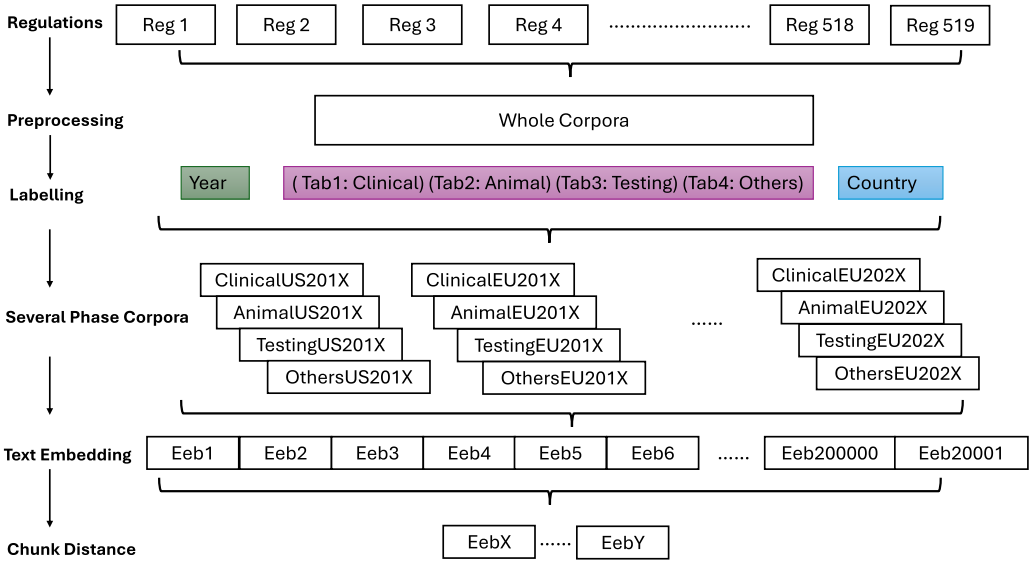

Fig. 2. Segmentation of regulations: labeling, chunking, embedding, and distance calculation.

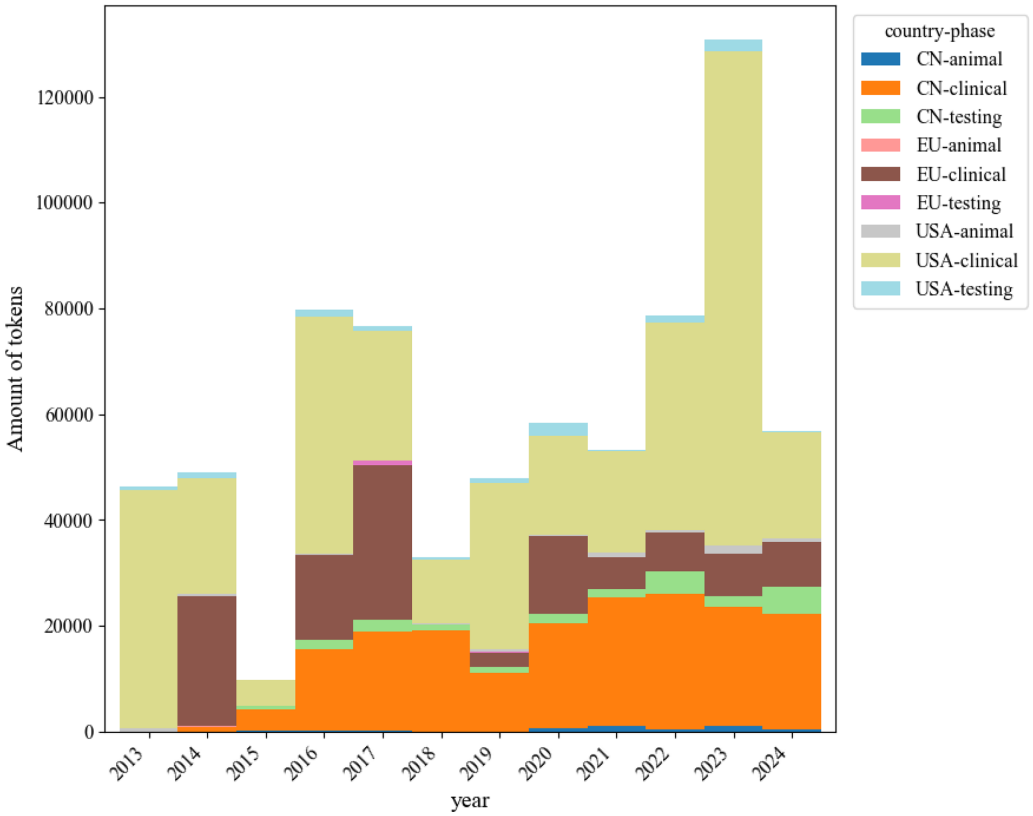

Fig. 3. Quantitative corpora amount of different chunks.

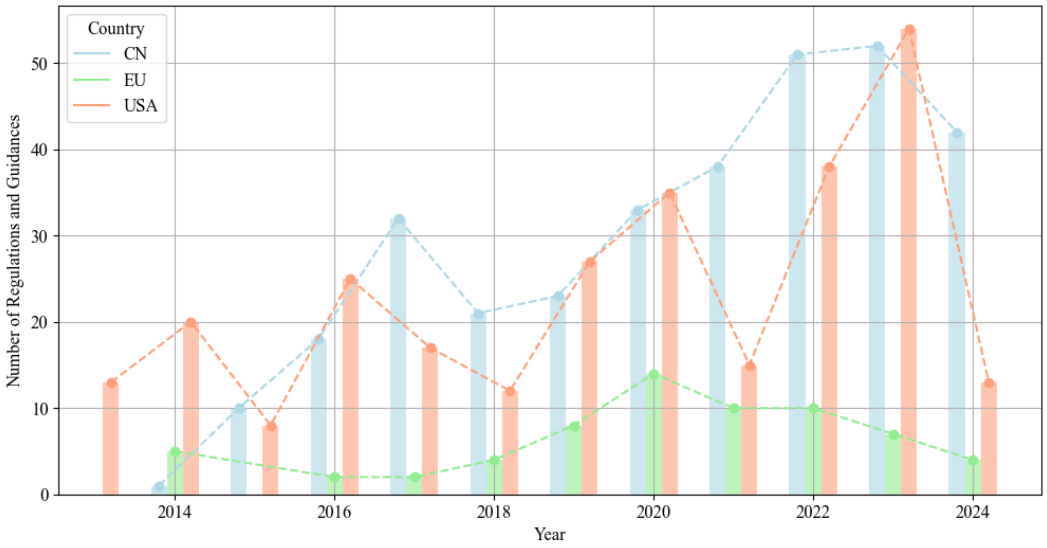

Fig. 4. Quantitative analysis of regulation amount in past decade.

Clinical Trials. The clinical phase involves testing the medical device on human subjects to assess its safety and effectiveness in real-world settings [67] (Figure 4). This phase encompasses various stages of clinical trials, ranging from small pilot studies to large randomized controlled trials. Human trials are indispensable for understanding device performance and identifying potential risks. To ensure comprehensive coverage of pertinent documents, we employed keywords including "clinical," "clinical research," "patients," "clinical evaluation," "randomized controlled trial," "safety assessment," "efficacy," "pharmacodynamics," "side effects," "subjects," and "human trials." These trials are rigorously regulated to protect participant rights while generating robust data for regulatory approval.

Testing Phase. This phase includes all activities related to lab testing, quality control, testing methods, and procedures conducted before the registration of medical devices. It also involves ongoing monitoring to ensure that devices consistently meet safety and performance standards after the market release [68]. We captured relevant regulatory documents using keywords such as "testing methods," "quality control," "analytical methods," "laboratory testing," "test standards," "testing equipment," "calibration," "sample collection," "data analysis," "instrument validation," "standard operating procedures," and "testing." These documents guide manufacturers and regulatory bodies in maintaining high standards of device quality and patient safety.

Other Phases. Documents that do not fit into the predefined phases are classified under "Other Phases." This category includes various regulatory and compliance-related activities that support the overall lifecycle of medical devices but do not strictly fall into animal testing, clinical trials, or post-market testing. Including an "Other Phases" category ensures that no pertinent regulatory information is overlooked, allowing for a comprehensive analysis that captures broader regulatory compliance, risk management, labeling, and other essential activities contributing to the safe and effective use of medical devices.

4.4 BERT Embeddings and Similarity Analysis

As illustrated in Figure 2, the entire set of regulations was preprocessed into a comprehensive database referred to as the whole corpus. Each document within this database was labeled with various keywords to filter and segregate the text into distinct phases of regulation. While the initial processing pipeline is automated for scalability, multiple validation steps were implemented throughout our analysis to ensure data quality and analytical rigor, including

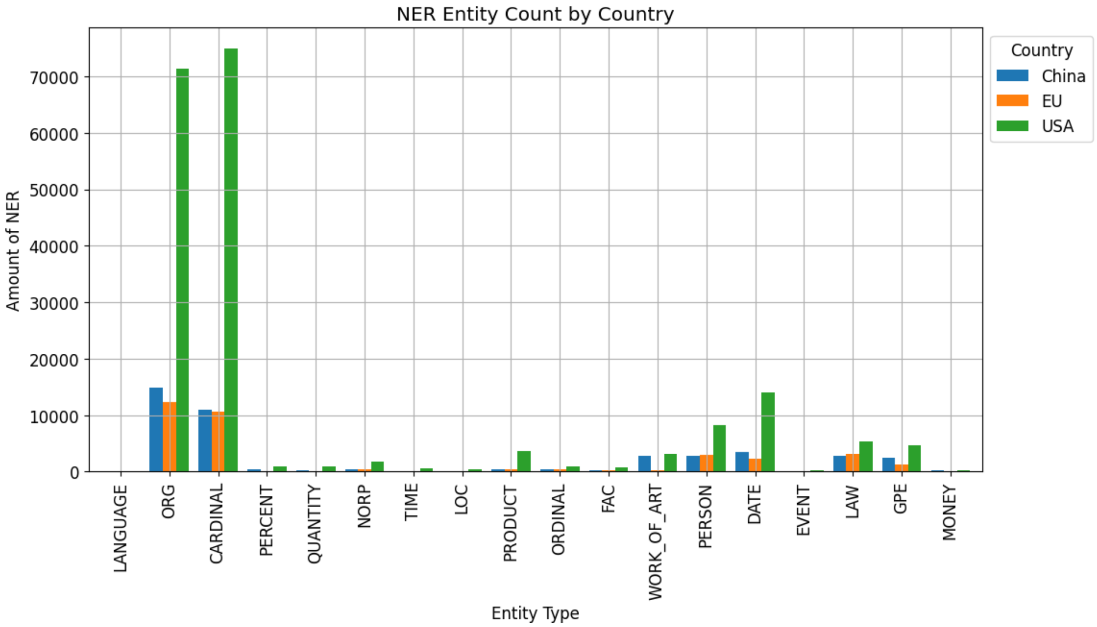

Fig. 5. Quantitative analysis of regulation amount in past decade.

statistical distribution analysis, cross-validation using alternative methodologies, and systematic quality checks of all major outputs. Additionally, documents were tagged with country and year information, allowing the creation of several smaller, distinct corpora. For instance, a corpus labeled `Clinical_CH2011` includes all clinical-related paragraphs and words from Chinese regulations in 2011.

BERT is a pretrained transformer model specifically designed to understand the context of words in a sentence by considering the surrounding words [69]. We selected BERT as our embedding method because bag-of-words does not account for word order or context, and TF-IDF also overlooks the nuanced relationships between words by focusing solely on term frequency and document rarity [70]. By applying BERT to segmented corpora, such as Clinical_CH2011, we generated embeddings for each document. Subsequently, we assessed the similarity between these corpora using cosine similarity measures. Detailed statistical analyses on these similarity scores allowed us to identify patterns and draw meaningful conclusions about the relationships between different phases.

The categorization of regulatory documents into these distinct phases provides a structured approach to analyzing the complex landscape of MDR. By focusing on the Animal Phase, Clinical Phase, Testing Phase, and Other Phases, we can thoroughly examine all relevant guidelines and requirements, facilitating a comprehensive understanding of the regulatory environment governing medical device development and post-market monitoring. As shown in Figures 5 and 6, we visualized the corpus chunks for different phases in each country across various years.

4.5 Topic Modeling with LDA

Following the embedding process, we utilized LDA [42] to uncover the underlying topics within the regulatory documents. LDA posits that each document is a mixture of several topics, with each word attributable to one of these topics. This probabilistic model helps us discover the hidden structure of the text by grouping words that frequently co-occur, thereby delineating distinct themes.

We applied LDA to the entire corpus to identify overarching topics relevant to MDR. Additionally, we conducted a time series analysis, performing LDA on the corpora from each country for each year. This analysis enables

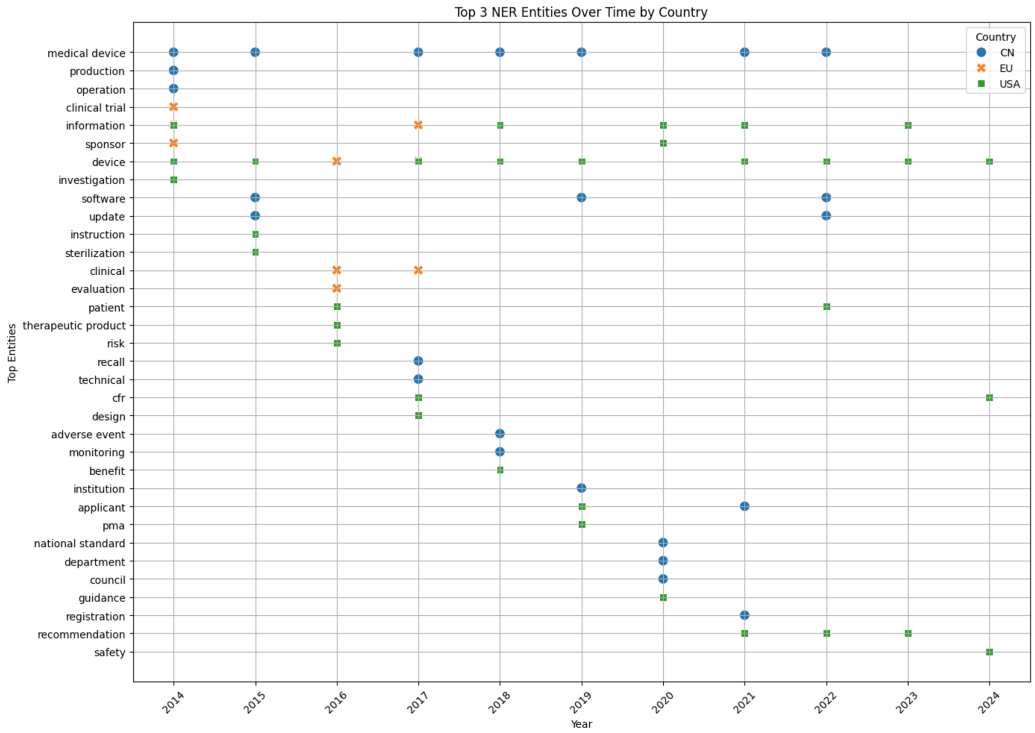

Fig. 6. Top 3 NER corpora by year and country.

us to examine how topics have evolved over time across different regions. Initially, the LDA model was trained using the preprocessed text data, and the number of topics was determined by evaluating the coherence score, which assesses the interpretability of the identified topics [42].

Each topic was carefully reviewed and labeled according to its most representative words. To facilitate better understanding, we categorized these topics under broader themes. Furthermore, visualization tools were employed to graphically represent the topics, enhancing the interpretability of the results [71]. This methodical approach ensures a robust analysis of the regulatory documents, providing valuable insights into the underlying thematic structures within the regulatory landscape.

5 Results

We labeled all regulations by their respective year and country, then visualized the trend in Figure 5. The line graph illustrates changes in the number of regulatory documents issued by China (CN), the European Union (EU), and the United States (USA) from 2013 to 2024. Each line represents the trend of document issuance for one of these regions. The graph reveals an upward trend for every region, indicating that the number of regulations published annually has increased across all three jurisdictions.

5.1 Increasing Trends in Regulatory Issuance across the USA, EU, and China

From data shown in Figure 5, we found the United States exhibits a volatile trend in regulatory document issuance. The most pronounced increase occurs between 2020 and 2022, reaching the highest peak among the three regions. Conversely, China demonstrates a fluctuating trend characterized by a general increase over the years. Starting with a moderate count in 2014, the issuance in China displays noticeable peaks and troughs, with significant

growth observed after 2020, culminating in a peak around 2022. This suggests intensified regulatory activity in recent years, potentially driven by evolving industry standards and regulatory requirements. In contrast, the trend for the EU is relatively stable, with only minor fluctuations.

The trend of increasing regulatory guidelines issued by the FDA marks a significant shift in the agency's approach to managing medical device approval and oversight. Historically, the number of guidelines remained relatively constant; however, since the mid-2010s, there has been a notable surge [72]. This surge can be partly attributed to the COVID-19 pandemic and the proliferation of digital health technologies. During this period, authorities issued numerous new guidelines to ensure the safety and efficacy of emerging technologies and emergency medical devices. The increase is not limited to COVID-19-related emergency authorizations but also encompasses regulations for digital health devices and other medical innovations [72].

This rapid increase reflects the FDA's efforts to address public health emergencies and adapt to the evolving landscape of digital health technologies. As technology continues to advance and medical devices evolve, we expect that global authorities will continue to expand their issuance of guidance to address the challenges and opportunities presented by these new technologies.

5.2 Regulatory Focus in Medical Devices: Insights from NER Analysis

The analysis of NER entities over time in the medical device sector for China, the EU, and the United States from 2013 to 2024 reveals significant trends and patterns in regulatory focus across these regions. Our NER analysis covers 13 distinct entity types following the spaCy English language model's classification schema: CARDINAL (numerical values), ORG (organizations), DATE (temporal references), PERSON (person names), LAW (legal references), GPE (geopolitical entities), PRODUCT (objects/products), NORP (nationalities/groups), ORDINAL (ordinal numbers), PERCENT (percentages), FAC (facilities), QUANTITY (measurements), and LOC (locations). For the frequency of various types of entities extracted from the analyzed text corpus, there are total of a 270,257 entities identified across all countries' regulation documents.

Our analysis of NER in the medical device sector reveals that the most frequently identified entity types are CARDINAL and ORG, comprising 35.7% (n = 96,531) and 36.4% (n = 98,481) of the total entities recognized, respectively. Following these are DATE entities, accounting for 7.4% (n = 19,880), and PERSON and LAW entities, which constitute 5.3% (n = 14,200) and 4.1% (n = 11,201), respectively. Geographic and product-related entities, represented by GPE and PRODUCT, make up smaller proportions at 3.1% (n = 8,290) and 1.7% (n = 4,520), respectively. Other entity types, such as NORP (0.96%), ORDINAL (0.70%), and PERCENT (0.51%), each constitute around 1% or lower. This distribution highlights the diverse range of entity types present in regulatory and technical texts related to the medical device field, with a notable emphasis on numerical and organizational references.

This distribution emphasizes the strong presence of numerical values and organizational references, alongside temporal, personal, and legal elements within the analyzed corpus. Less frequent entities such as NORP (nationalities or religious/political groups), ORDINAL (ordinal numbers), PERCENT (percentages), FAC (facilities), QUANTITY (measurements), LOC (locations), TIME (specific times), MONEY (monetary values), EVENT (named events), and LANGUAGE (languages) further illustrate the varied nature of the text. The high frequency of CARDINAL and ORG entities indicates that the corpus contains substantial numerical data and organizational references, while the presence of DATE, PERSON, and LAW entities highlights a focus on temporal information, personal names, and legal content. This distribution provides valuable insights into the thematic emphasis and contextual framework of the content.

From Figure 6, the NER results indicate that in the USA, there was an early focus on "technical" terms and "CFR" (Code of Federal Regulations), which suggests strong regulatory activity around technical standards and compliance from 2014 to 2016. A noticeable increase in terms like "software" and "update" reflects the growing importance of digital health technologies and the need for updated regulatory frameworks during 2017–2019, as

Table 2. Top Words and Their Derived Topics

Top Words	→	**Theme Inferred**
mdr, mdcg, annex, article, notified, authority, designating, group, pediatric, nb	→	Theme 0: Regulatory Framework and Compliance
article, device, investigation, irb, consent, subjects, mdr, informed, asca, accreditation	→	Theme 1: Clinical and Ethical Guidelines
registration, guidelines, equipment, applicants, indicators, production, diagnostic, reagents, packaging, trial	→	Theme 2: Registration and Diagnostic Equipment
software, functions, updates, algorithms, documentation, business, cybersecurity, hardware, environment, mobile	→	Theme 3: Software and Cybersecurity
clinical, study, trial, sponsor, article, member, reviewer, sponsors, author, benefit	→	Theme 4: Clinical Trials and Sponsorship
study, recommend, tissue, subjects, population, sample, statistical, tests, disease, protocol	→	Theme 5: Research and Statistical Analysis
market, premarket, study, model, predicate, recommend, market, software, submissions, modification	→	Theme 6: Market Approval and Recommendations
market, device, submissions, decision, approval, data, premarket, new, program, submitter	→	Theme 7: Regulatory Decisions and Data
combination, constituent, applicant, device, reporting, pma, premarket, manufacturing, drugs, program	→	Theme 8: Combination Products and Manufacturing
animal, recommend, biocompatibility, tissue, material, iso, coating, tests, chemical, testing	→	Theme 9: Biocompatibility and Material Standards

the FDA issued several guidance documents that year. This trend is consistent with observations made by other researchers [73, 74]. In the period from 2020 to 2022, peaks in mentions of "medical device" and "safety" are likely driven by the COVID-19 pandemic and the urgent need for safe and effective medical devices.

The EU and the USA show a strong focus on "clinical trial" and "evaluation," particularly around 2016–2017, reflecting an emphasis on clinical trials and the evaluation processes crucial for medical device approvals. This trend aligns with the implementation of the EU Clinical Trials Regulation No. 536/2014, which aimed to streamline clinical trial processes and ensure participant safety [75]. Entities such as "sterilization" and "safety" are also prominent, highlighting the EU's emphasis on maintaining high hygiene standards and ensuring device safety during the 2018–2020 period.

In the USA, terms such as "risk," "recall," and "safety" emphasize the importance of risk management and proactive measures to address defective or unsafe devices. Furthermore, China's frequent mention of "national standard," "department," and "council" points to efforts to align MDRs with both national and international standards, ensuring consistency and regulatory compliance. Understanding these trends will help regulatory authorities and manufacturers navigate the evolving landscape of MDRs. For regulatory bodies, it highlights areas requiring continuous improvement and alignment with global standards. For manufacturers, it underscores the importance of adhering to clinical trial data, robust software development practices, and stringent risk management protocols.

5.3 Topic Modelling: LDA Topics and Their Themes

We applied LDA to the entire corpus to uncover the major themes present in regulatory documents. The optimal number of topics (K = 10) was determined through coherence score optimization and manual inspection of topic interpretability. Each topic is represented by the top 10 most probable keywords, selected based on their highest probability weights within each topic distribution. Table 2 summarizes the top keywords for each identified topic, providing insights into the thematic structure of the texts.

It should be noted that some keywords (e.g., "device," "subjects," "premarket," "article") appear across multiple topics, which is inherent to the probabilistic nature of LDA. This overlap does not create ambiguity in topic

Fig. 7. LDA of China corpora over years.

specification but rather reflects the interconnected nature of regulatory themes. Each topic represents a distinct probabilistic distribution over words, and the presence of common regulatory terms across topics indicates their fundamental importance in the medical device regulatory domain. The appearance of overlapping keywords is theoretically sound and practically beneficial. For instance, "device" appears with different probability weights across topics: lower probability in Topic 0 (general regulatory framework) but much higher in Topic 3 (software-specific regulations), indicating context-specific importance. Similarly, "premarket" appears in Topics 6, 7, and 8 but with different co-occurring terms that distinguish between K submissions, PMA applications, and combination products. This probabilistic overlap allows our model to capture the nuanced ways regulatory concepts interconnect across different domains, providing a more realistic representation of the complex regulatory landscape than artificially separated keyword clusters would achieve.

We then applied LDA to each year's corpus from the different countries individually, generating a series of LDA topics. The results are visualized in Figures 7–9, representing the term frequencies for China, the EU, and the USA over time. These visualizations reveal how the focus of each country changes from year to year, allowing us to observe shifts in thematic emphasis.

The numbers in each cell of the figures indicate the frequency of specific terms in the regulatory documents for that year, with cell colors corresponding to the term frequency. Darker colors represent higher frequencies, while lighter colors indicate lower frequencies. By tracking changes in color intensity and the associated numbers over

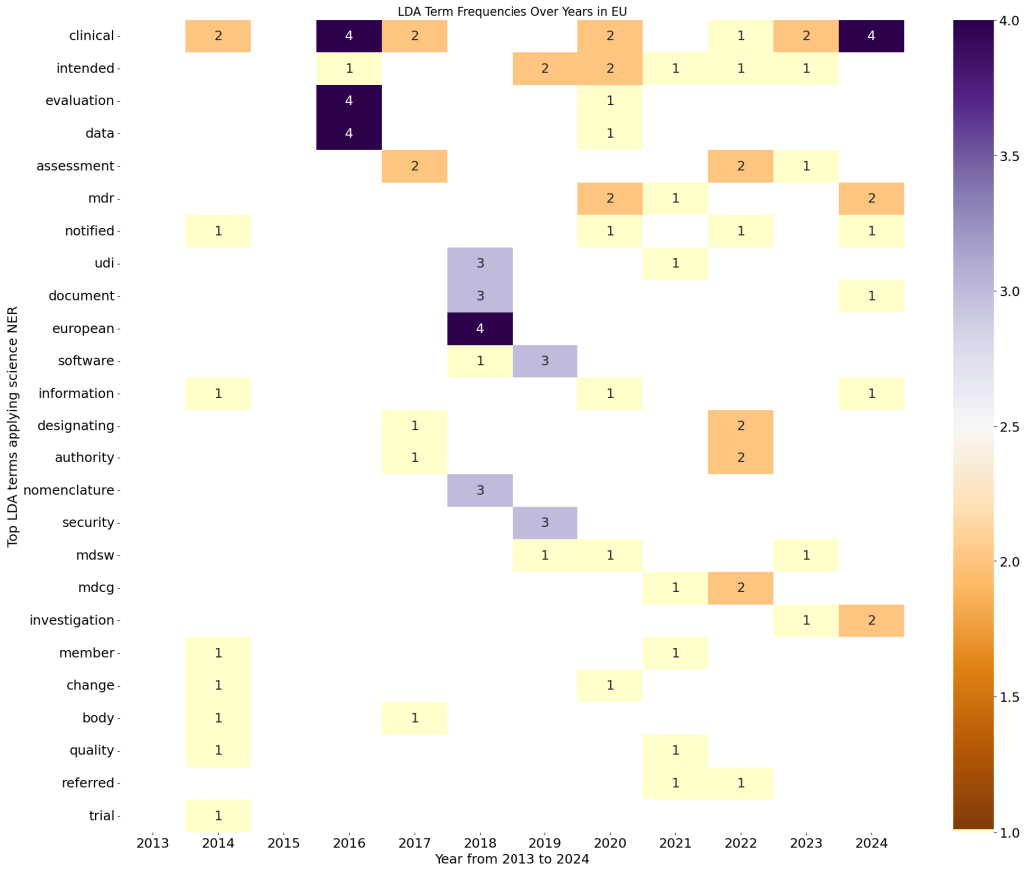

Fig. 8. LDA of EU corpora over years.

time, we can identify trends in the topics emphasized within each country's regulatory framework. For example, the term "clinical" shows high frequency in the years 2013, 2015, 2016, 2019, and 2023, indicating a consistent focus on clinical topics during those periods. Similarly, terms like "evaluation" and "data" have high frequencies in 2015 and 2016, suggesting that these years saw heightened emphasis on regulatory evaluation and data-driven decisions. The term "software" shows moderate frequency in 2018 and 2019, reflecting a growing attention to software-related regulations during those years.

The LDA results for the EU show a particular emphasis on clinical evaluation, which aligns with findings from previous research [76], confirming a regulatory focus on clinical aspects in EU documents.

In the USA, terms such as "clinical," "data," and "study" dominate the landscape, reflecting a consistent emphasis on clinical trials, data management, and study protocols. The frequent appearance of "CFR" underscores the reliance on the Code of Federal Regulations, highlighting the importance of codified rules in the regulatory framework. The terms "guidance" and "instructions" appear regularly, indicating ongoing updates and clarifications in regulatory guidelines to adapt to new developments and ensure compliance.

The EU heatmap reveals a strong focus on "clinical," "evaluation," and "data," emphasizing the importance of clinical assessments and data-driven evaluations in the regulatory process. The prominence of terms such as "mdr," (Medical Device Regulation), "udi" (Unique Device Identification), and "European" highlights regulatory initiatives

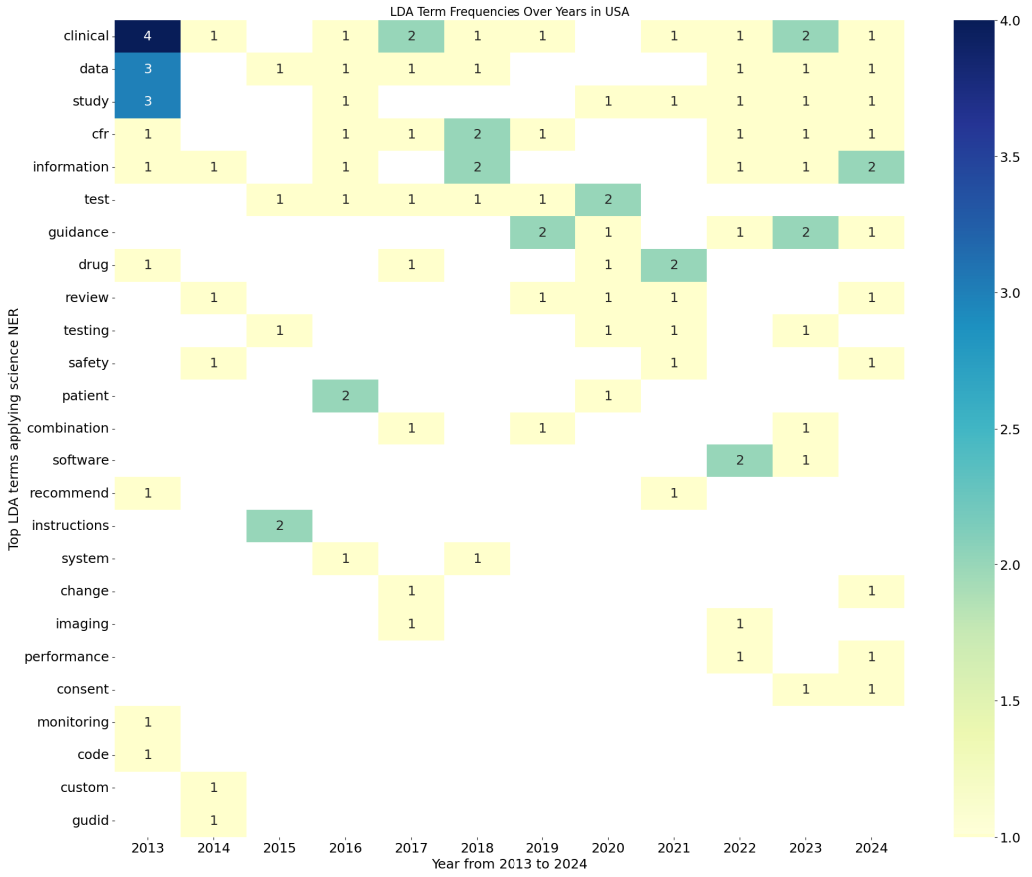

Fig. 9. LDA of USA corpora over years.

specific to the EU. Additionally, the terms "document," "software," and "security" reflect a focus on documentation requirements, software regulation, and cybersecurity, respectively. The presence of the "investigation" and "authority" terms underscores the roles of regulatory investigations and authoritative bodies within the EU's regulatory framework.

In China, the heatmap shows a significant focus on "clinical," "requirements," and "registration," indicating a strong emphasis on clinical requirements and the registration processes for medical devices. The frequent appearance of "data" highlights the importance of data in regulatory processes, while "administration" reflects the role of regulatory administrative bodies. The term "research" underscores the focus on medical research. Additionally, terms such as "adverse," "monitoring," and "technical" indicate a focus on adverse event reporting, post-market surveillance, and technical standards. The presence of "production," "equipment," and "quality" highlights the emphasis on manufacturing standards and quality control within China's regulatory framework.

Comparatively, all three regions consistently emphasize clinical terms, indicating the universal importance of clinical trials and evaluations in MDR. Both the USA and the EU demonstrate a strong focus on "data" and "document," reflecting rigorous data management and documentation requirements. In contrast, China places additional emphasis on "administration" and "requirements," highlighting its regulatory structure and focus on administrative compliance. The EU's focus on terms like "mdr" and "udi" underscores its unique regulatory

initiatives, while the USA's consistent reference to "CFR" indicates a reliance on federal regulations. China's emphasis on "administration" and "requirements" further reflects its specific regulatory priorities.

The analysis also highlights the EU's proactive approach to regulating digital health technologies and cybersecurity, as evidenced by the frequent occurrence of terms like "software" and "security." While the USA and China also address these areas, their emphasis appears less frequent compared to the EU.

5.4 Keyword Extraction across Regulatory Landscapes

Keyword Extraction is a technique used to automatically identify the most relevant or important words from a text. It enables summarization of the main themes or topics and is commonly applied in information retrieval, content classification, and text summarization tasks.

To enable quick checks of words or themes within a country's regulations and highlight notable trends in regulatory focus and interest, we developed a model called "RegulTermAnalyzer [77]." This model performs keyword and key theme frequency analysis of specific terms across different countries. As illustrated in Figure 10, we searched some words; for example, we can see the term "real world evidence" shows significant variation, with the USA exhibiting a prominent peak in 2022, indicating a surge in interest or regulatory emphasis on **Real World Evidence (RWE)** during this period [78]. This trend is consistent with the USA's increasing integration of RWE into its regulatory framework for medical devices and pharmaceuticals. In contrast, the EU and China show minimal occurrences of this term, suggesting either less emphasis or the use of different terminologies in these regions. According to research, the United States is currently the only country that has explicitly defined RWE within its formal regulatory framework [78]. Similarly, the term "evaluations" displays distinct patterns across the regions, with varying frequencies that reflect different regulatory activities and interests over the years. The term "post-market surveillance" demonstrates a significant presence in the EU, especially around 2018, indicating a strong focus on monitoring medical devices post-market entry. The USA and CN show lower frequencies, reflecting different regulatory priorities or terminological preferences. The term "new" reveals substantial peaks in the USA, aligning with periods of increased regulatory activity or the introduction of new regulations. Lastly, the frequency of "risk management" shows notable fluctuations, with the USA peaking around 2022, highlighting a heightened focus on regulatory risk management practices during that period. The model developed in this study provides professionals with a valuable tool for examining the frequency and evolution of specific terms within regulatory frameworks of individual countries. It is important to note that the accuracy of the analysis depends on the exact terminology used in the regulations. For instance, querying "real world evidence" will yield accurate results, while using semantically similar terms, such as "true world proof," will not produce correct or relevant data.

5.5 Vectorization and Comparative Analysis of Corpora

The vectorization technique is a multi-step process used in NLP to transform text data into numerical representations and subsequently compare multiple text corpora. This technique involves two main phases, including vectorization and cluster comparison. In the vectorization phase, textual data is transformed into vectors, which are numerical representations of words, phrases, or entire documents.

As shown in Figure 2, all regulatory documents were preprocessed into individual tokens with multiple labels. The entire corpus was divided into smaller segments, each labeled with three attributes: year, phase (clinical, animal, testing, and other phases), and country. For example, "ClinicalCH2011" represents the Chinese regulatory guidance corpus for the clinical phase of medical devices in 2011. These smaller corpora were then processed for text embedding.

The preprocessed text was then embedded using BERT, a pretrained transformer model adept at understanding the context of words within a sentence by considering the surrounding words. Each chunk of text was converted into a high-dimensional vector representation, encapsulating its semantic meaning. Subsequently, the cosine

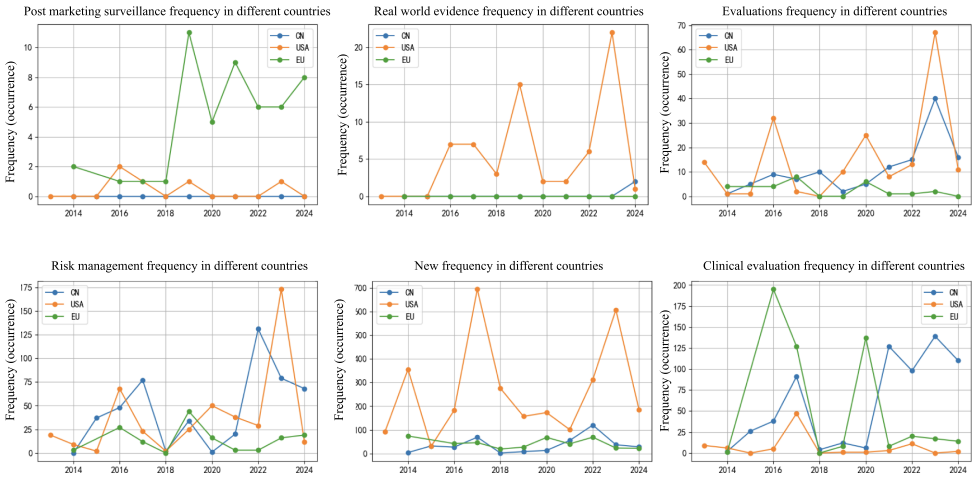

Fig. 10. Different keywords' frequencies over the years.

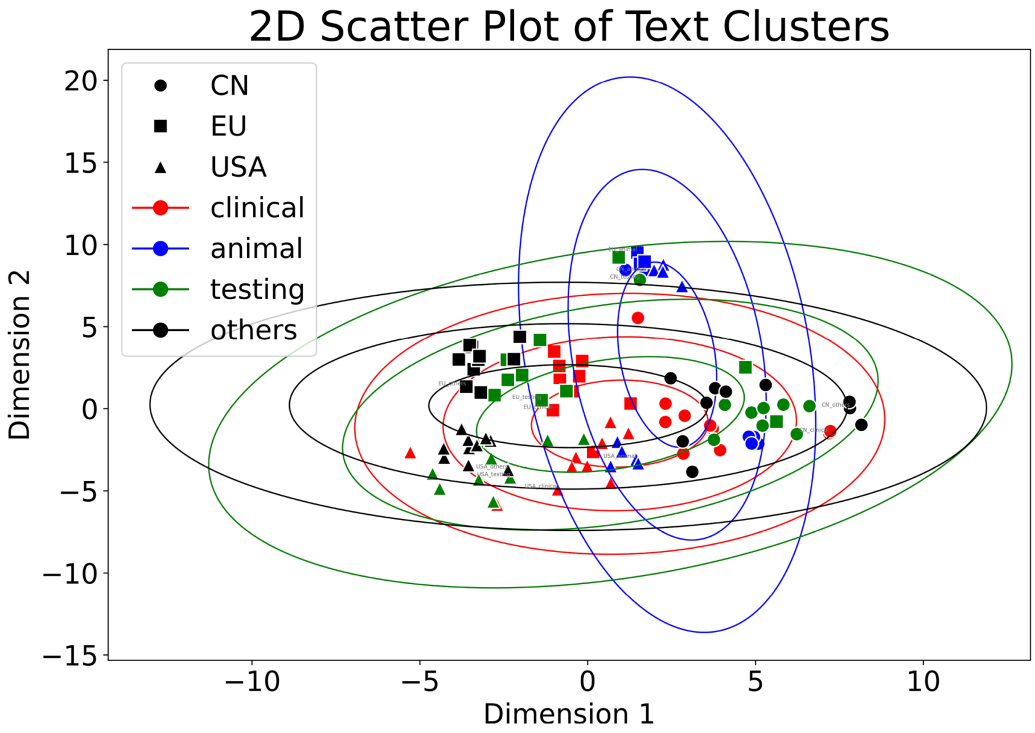

Fig. 11. Visualization of 2D data for NERs points.

similarity between these text embeddings was computed to assess the semantic similarity of different text chunks. Clustering techniques were then applied to group similar text chunks, providing a visual representation of thematic proximity (Figure 12). After that, we use cosine similarity to measure the cosine angle between two vectors, helping assess how similar the corpora are in terms of content or topic distribution.

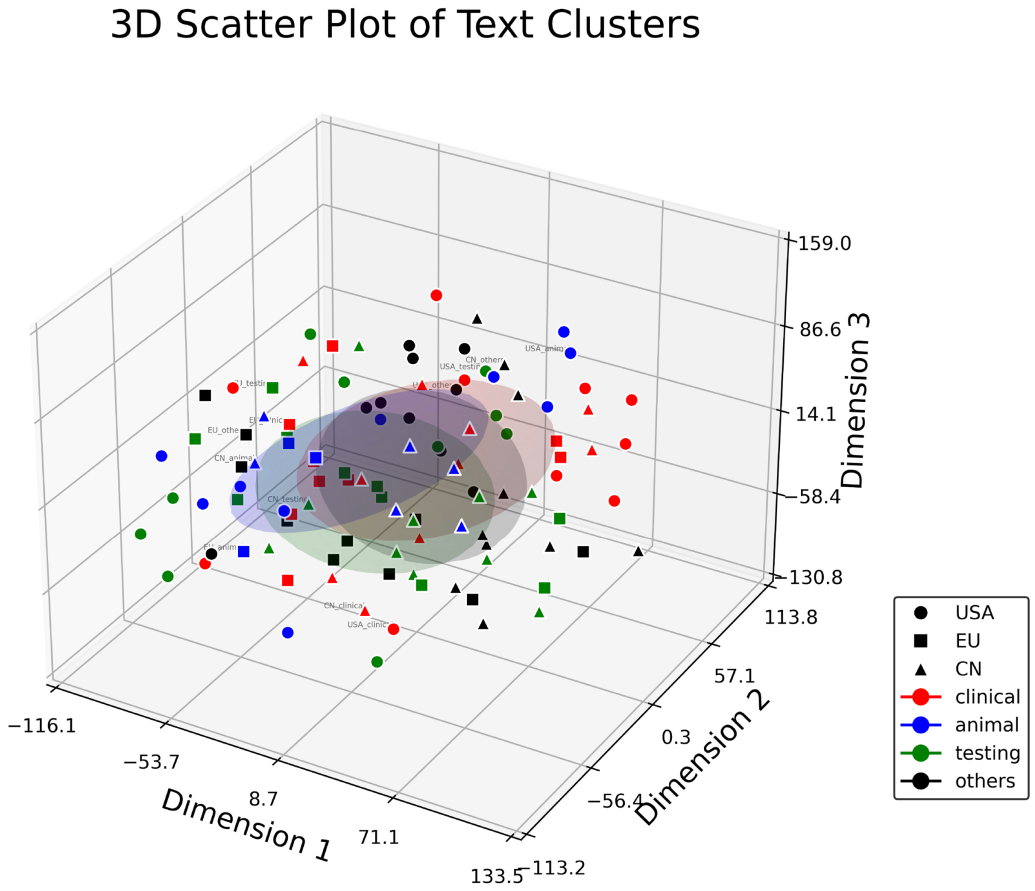

Fig. 12. Visualization of 3D data for NERs points.

We have visualized these corpora using 2D and 3D matrices as shown in Figures 11 and 13. In these visualizations, each point represents a distinct country and a different phase of the process. The results of cosine similarity are shown in Table 3.

Among all the pairs, we filtered and present the closest pairs as follows in Table 4. This is for the whole decade's corpora together.

In Table 5, we analyzed regulatory text from the closest pairs identified using mean cosine distance calculated from embedded text vectors. Each pair was condensed into representative chunks, articulating the essential regulatory meanings. We then interpreted the machine-generated similarity by examining the shared regulatory focus across regions. This approach reveals thematic parallels in global regulatory frameworks, enabling a nuanced understanding of common regulatory goals and interpretation. By presenting the interpretations, the table elucidates why certain points align closely from tons of regulations, which are hard to interpret.

5.6 Cosine Similarity Shifts over Consecutive Years

After the IMDRF began releasing guidance documents in 2011, their focus evolved year by year to address critical areas in MDR. In the early years, they concentrated on foundational frameworks in 2013 and continued expanding into clinical evaluations and quality management systems. By 2017, there was a noticeable shift towards advancing clinical evaluations for SaMD, with the IMDRF/SaMD WG/N41 document providing guidance on this emerging

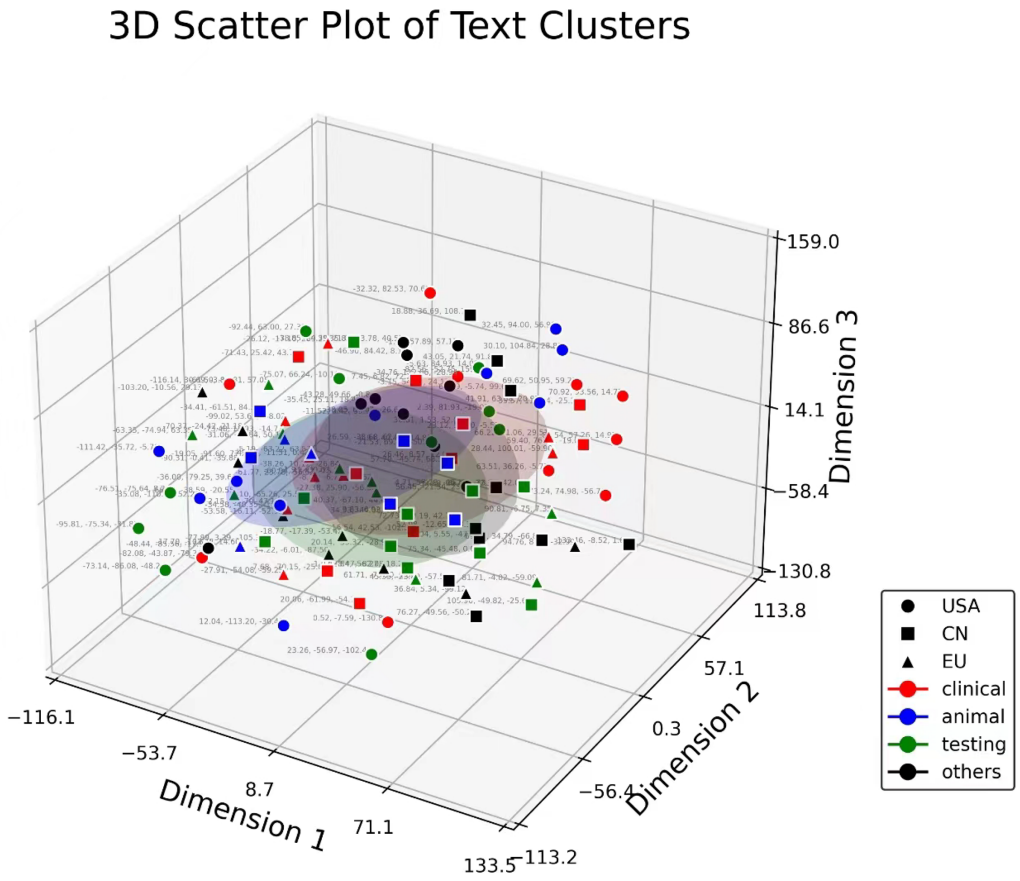

Fig. 13. Visualization of 3D data points for NERs with numerical axes.

technology. Over time, IMDRF documents have increasingly emphasized post-market surveillance and safety, as seen in updates like the Post-Market Adverse Event Reporting Criteria (2023, IMDRF/NCAR WG/N14). We have shown a list of regulations in Table 6.

We calculated the cosine similarity number between consecutive years for different phases and countries to assess how consistently the IMDRF's focus shifted or remained stable over time (see Figure 15). For example, we visualized the cosine similarity between 2021_US_clinical and 2022_US_clinical, which helped us identify trends or changes within the same regulatory area year by year. From 2014 onward, there is a noticeable upward trend in similarity values, with mean cosine similarity increasing from 0.511 in the early period (2014–2017) to 0.824 in the later period (2018–2022) (Mann-Whitney U test, $p < 0.001$; linear regression $R^2 = 0.784$), providing robust quantitative evidence that regulations became increasingly aligned from one year to the next. In the animal phase, all countries showed a consistent increase in similarity between consecutive years, indicating that regulations are becoming more harmonized. In the clinical phase, China's similarity values remain consistently high, around 0.9, reflecting a stable and continuous regulatory framework.

A notable exception is the sudden increase in similarity between 2016 and 2017 for China's clinical phase, which aligns with significant regulatory reforms during that time. These reforms included the acceptance of foreign clinical trial data, which reduced the burden on multi-national pharmaceutical companies, as well as stricter requirements for clinical trial registration and transparency. Moreover, China's preparations to join the

Table 3. 3D Mean and Standard Deviation of Cosine Distances for Different Comparisons

Comparison	Mean Cosine Distance	Std Cosine Distance
CN_animal vs. EU_animal	0.718346	0.194819
CN_animal vs. USA_animal	0.326863*	0.471442
CN_clinical vs. EU_clinical	0.166742	0.524871
CN_clinical vs. USA_clinical	0.104228	0.503762
EU_clinical vs. USA_clinical	−0.089216*	0.548269
CN_testing vs. EU_testing	0.220312	0.483452
CN_testing vs. USA_testing	0.172389	0.568923
EU_testing vs. USA_testing	−0.001876*	0.530034
CN_others vs. EU_others	0.212934	0.544109
CN_others vs. USA_others	0.052984	0.487163
EU_others vs. USA_others	−0.139752*	0.520475

Closest pairs are marked with an asterisk (*). Negative values indicate that the vectors are pointing in opposite directions in the high-dimensional space, suggesting fundamental differences in regulatory approaches rather than measurement errors.

Table 4. Closest Pairs of Regulatory Text by Mean Cosine Distance

Closest Pair	Mean Cosine Distance
CN_animal vs. USA_animal	0.326863
EU_clinical vs. USA_clinical	−0.089216
EU_testing vs. USA_testing	−0.001876
EU_others vs. USA_others	−0.139752

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use in 2017 likely contributed to this alignment, as the country aimed to standardize its regulations with international norms. These factors explain the sharp rise in similarity between 2016 and 2017. We also compared the corpora between different countries for the same year and phase to explore how regulations vary across regions. This analysis provides insights into how different countries govern the same aspects, such as clinical trials or animal studies, during the same period, highlighting the degree of alignment or divergence between regulatory frameworks (see Figure 14). In the figure, we observe that the corpora for testing and animal phases between China and the USA show the highest similarity values in each year.

5.7 Summarization of Clinical Trial Regulations by Region

Summarizing is a sophisticated technique that leverages the pretrained language model to create coherent and contextually rich summaries of complex texts. While sentiment analysis, text summaries, and topic modeling aim to provide a high-level understanding of a document collection, the language summarizing function refines this by generating concise summaries specific to fine-grained regulatory details.

We employed the SumBERT function to summarize the clinical trial requirements from different regions, as shown in Table 7. Given the importance of clinical trials globally, our goal was to see if AI tool, for example, SumBERT can accurately capture key points in each country's regulations. If it works well, this could pave the way for future advancements in digitizing regulatory documents, enabling a more streamlined comparison of international requirements and potentially supporting regulatory harmonization.

Table 5. Similar Points Based on Pairwise Distances and Shared Focus

Country	Phase	Details	Shared Focus
Pair 1			
CN	Animal	The regulation describes the regulatory requirements for "Preclinical Animal Testing and Clinical Evaluation," stating, "Confirming the composition and structural information of the product is key to determining whether the product can undergo preclinical and clinical research." It specifies that "all preclinical safety studies should be completed before conducting clinical research except for carcinogenicity reproductive, and developmental toxicity tests," which may be exempted based on factors like genotoxicity test results. The passage emphasizes that animal testing should be dosed up to "10 times the highest human dose." Additionally, it notes that "the requirements for product packaging and packaging integrity should comply with the standard requirements of GBT" and further details guidelines for "preclinical animal testing" and other research materials. The principles for animal testing involve "Replacement, Reduction, and Refinement (3R)" and indicate that non-animal methods should be prioritized when available.	Both emphasize preclinical animal testing for medical devices, with allowances for reduced testing if alternative evidence exists. They both stress documentation in animal study reports and ethical testing considerations, with the U.S. using "validated animal models" and China applying the "3R" principles.
USA	Animal	The regulation covers FDA's regulatory expectations for animal testing. For example, the FDA may require "continued animal testing of implanted devices at 6 months, 1 year, and 2 years after implant." It specifies that animal study reports must detail "purpose, test method, sample selection, results, discussion of the acceptability of the results, and clinical applicability." The passage explains that the FDA requires "animal studies to support the initiation of an early feasibility study," using validated animal models whenever available. It is also noted that when starting pivotal trials, long-term animal studies may be performed concurrently with feasibility	

(Continued)

Table 5. Continued

Country	Phase	Details	Shared Focus
		studies "to demonstrate complete healing at the implant site." For certain device evaluations, an animal study may include protocols such as "study design, species, strain, and number of animals used," and should ensure "anatomic, physiologic, and procedural similarities to humans."	
Pair 2			
EU	Clinical	EU regulation outlines the necessary steps for clinical trials, specifying that "groups of subjects rather than individual subjects are allocated" in some trials. It highlights that for these studies, "simplified means for obtaining informed consent will be used." Details on investigator suitability are provided, including submission of a "current curriculum vitae and other relevant documents," as well as information on "previous training in the principles of good clinical practice." Clinical sites need to include descriptions of "the suitability of facilities, equipment, and human resources." Additional components such as "financial and other arrangements" should also be documented, with details of "compensation paid to subjects and investigator sites." A substantial modification may be requested for multiple clinical trials by a sponsor, using the EU trial number and "substantial modification code number." Reporting serious adverse events is mandatory, and unblinding should only occur if it is "relevant to the safety of the subject."	Both require thorough documentation for clinical trials, including investigator qualifications, ethical considerations, and facilities. They emphasize ongoing safety assessment, with methods suited to each regulatory landscape.
USA	Clinical	USA regulation discusses FDA's approach to clinical testing for implanted devices, which may continue "at 6 months, 1 year, and 2 years after implant." Detailed requirements for individual test reports are specified, including "test method, sample selection, results, and discussion of the acceptability of results." If pediatric use is intended, additional animal testing might	

(Continued)

Table 5. Continued

Country	Phase	Details	Shared Focus
		be needed. A long-term animal study is recommended "to demonstrate complete healing at the implant site." The passage emphasizes that animal testing should occur only when "non-animal testing methods are insufficient." FDA guidance highlights that the animal study "should involve a validated animal model when available."	
Pair 3			
EU	Testing	The notified body must prepare a Clinical Evaluation Assessment Report (CEAR), covering details like device description, intended purpose, and classification. The CEAR assesses the clinical evaluation and equivalence assessments if relevant, clinical investigation plans, and the benefit-risk profile. The notified body verifies that the device meets essential requirements, checking the quality system for procedures in clinical evaluation, risk management, and PMCF. It ensures clinical data integrity and justifies decisions for compliance with EU directives.	Both regulatory processes focus on evaluating and approving medical devices to ensure safety and efficacy. They involve assessments by relevant bodies and collaboration between device and drug manufacturers to streamline development while meeting clinical and safety standards.
USA	Testing	This guidance assists sponsors in the simultaneous development of antimicrobial drugs and AST devices, aiming to clear AST devices around the same time as new drug approvals. It outlines collaborative efforts between drug sponsors and device makers, covering interactions with both the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health. The document includes AST device types such as qualitative disc diffusion and other growth-based systems, emphasizing that coordination won't impact the independent review timelines mandated by MDUFA and PDUFA.	
Pair 4			
EU	Others	EU regulations, including AIMDD Essential Requirements, demand that any undesirable side effect must represent an	Both frameworks stress rigorous post-market surveillance and documentation to

(Continued)

Table 5. Continued

Country	Phase	Details	Shared Focus
		acceptable risk when weighed against device performance. The EU emphasizes extensive documentation, such as the Clinical Evaluation Report (CER), which covers device equivalence, risk management, and an ongoing PMCF. Furthermore, devices classified for unmet medical needs must comply with Essential Requirements and, in some cases, may be permitted market access with limited clinical evidence if they fulfill significant health benefits.	manage risks. They allow expedited pathways for unmet medical needs, aiming to balance public safety and innovation.
USA	Others	The USA regulations under 21 CFR outline a rigorous framework for reporting, including 15-day and 5-day Reports for adverse events, malfunction reports, and requirements specific to combination products. Devices must comply with post-market surveillance regulations, including requirements from the MDR and the FD&C Act for tracking safety issues. Additionally, devices classified under specific codes must adhere to performance controls or meet equivalent safety standards through the 510(k) pathway for modifications.	

6 Discussion

This study provides significant insights into the regulatory landscapes for medical devices in China, the USA, and the EU, demonstrating how computational methods can illuminate both alignment and divergence across jurisdictions. The application of LDA revealed phase-specific themes that characterize the regulatory lifecycle. In the preclinical testing phase, topics were centered on safety, toxicology, and compliance, reflecting regulators' commitment to minimizing risks before human use. In the clinical trial phase, human testing protocols, efficacy, and safety monitoring dominated, highlighting the balance between protecting trial participants and producing robust clinical evidence. Post-market surveillance focused on device performance, adverse event reporting, and regulatory updates, emphasizing the need for continuous oversight once devices are in real-world use. Collectively, these results illustrate the multi-dimensional nature of MDR, spanning premarket, clinical, and post-market considerations.

The LDA-derived themes also underscore the complexity of regulatory texts. Terms related to regulatory frameworks and compliance (e.g., "MDR," "notified authority"), clinical and ethical guidelines (e.g., "IRB," "consent," "subjects"), and diagnostic registration requirements (e.g., "registration," "equipment," "guidelines") all appear as key topics. This diversity of emphasis shows how regulations embed both technical and ethical considerations, guiding manufacturers not only on device safety and efficacy but also on broader responsibilities toward patients and healthcare systems.

Table 6. A Series of Publications from IMDRF

Document Name	Description	Year
Clinical Evaluation (IMDRF/PMD WG/N56) [79]	Framework for assessing clinical data related to the safety and performance of medical devices	2022
Post-Market Adverse Event Reporting Criteria (IMDRF/NCAR WG/N14, Edition 4) [80]	Guidelines for reporting adverse events post-market to promote global data sharing	2023
Software as a Medical Device: Clinical Evaluation (IMDRF/SaMD WG/N41) [81]	Clinical evidence requirements for software-based medical devices (SaMD)	2017
General Principles of Premarket Clinical Evaluation (IMDRF/MDCE WG/N47) [82]	Principles for premarket clinical evaluation of medical devices	2018
Optimizing Standards for Regulatory Use (IMDRF/STAND WG/N51) [83]	Best practices for using standards in the regulatory evaluation of medical devices	2019
Good Regulatory Review Practices (IMDRF/RPS WG/N49) [84]	Guidance on best practices for medical device regulatory reviews to ensure consistency	2018
Definitions for Personalized Medical Devices (IMDRF/PMD WG/N49) [85]	Framework defining key concepts around personalized medical devices	2020
Principles for Clinical Evidence (IMDRF/PMD WG/N55) [86]	Outlines requirements for clinical evidence supporting regulatory submissions of personalized medical devices	2021

Regional comparisons revealed distinct regulatory approaches. China emphasizes detailed compliance and structured submission protocols, reflecting its rapidly evolving system aimed at aligning with international norms. The USA prioritizes clinical trial management and ethical safeguards, underscoring participant protection and rigorous evaluation. The EU balances safety, efficacy, and data privacy, consistent with its broader governance framework under the MDR and GDPR. For manufacturers, these differences present challenges when entering multiple markets, requiring careful adaptation to heterogeneous requirements. For regulators, they highlight the difficulty of achieving harmonization, though initiatives such as the IMDRF demonstrate ongoing efforts toward greater convergence.

Cosine similarity analysis quantified these dynamics. In animal studies, China and the USA showed moderate alignment (mean distance 0.33), suggesting opportunities for harmonization. Clinical trial regulations displayed higher variability, with the EU and USA as the closest pair (−0.089), reflecting shared principles but divergent implementation. Testing regulations revealed near-perfect alignment between the EU and USA (−0.002), suggesting strong potential for mutual recognition. In the "others" category, the EU and USA again emerged as the closest pair (−0.14), indicating shared elements that could form a basis for future alignment despite residual differences. Importantly, the temporal analysis revealed turning points: China's reforms between 2016 and 2017 led to notable shifts in similarity, while the EU's MDR implementation in 2021 produced a marked increase in alignment, particularly in clinical regulations. These findings demonstrate how major regulatory updates can drive convergence across jurisdictions.

The broader implications of these findings are twofold. First, computational methods such as BERT embeddings and LDA provide a scalable way to capture the thematic and semantic structure of regulations, offering regulators and manufacturers a new lens for monitoring convergence. Second, identifying areas of high alignment, such as animal studies or testing between the USA and EU, suggests practical opportunities for harmonization and cooperation. At the same time, the substantial variability in clinical and "other" categories underscores the persistence of divergence and the need for further dialogue.

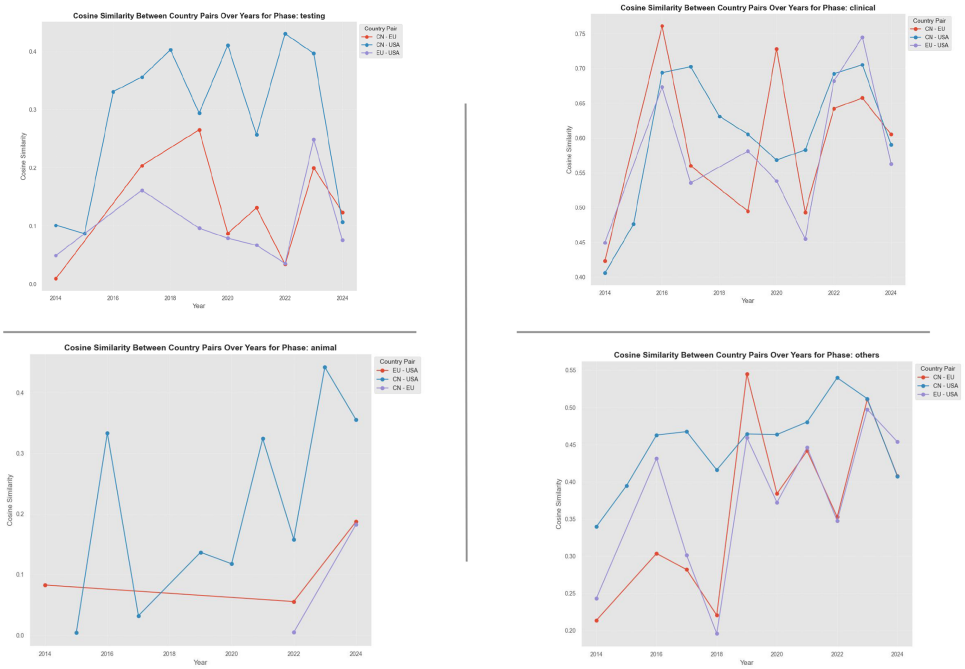

Fig. 14. Cosine similarity number between different countries.

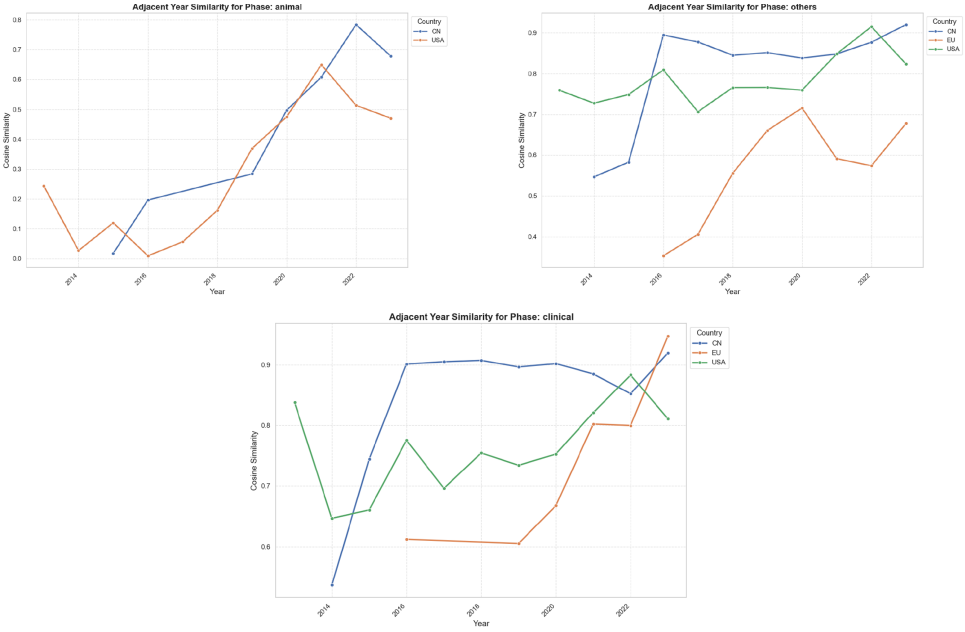

Fig. 15. Cosine similarity number between consecutive years.

Table 7. BERTSum Summaries of Country-Specific Clinical Trial Regulations

Region	Summary of Clinical Trial Requirements	Key Points
EU	The EU regulations emphasize the autonomy of Member States in managing clinical trial authorizations, ensuring the involvement of ethics committees, and relying on specialized expertise for assessments. However, sponsors may face challenges in providing complete application information across different Member States.	—Member State Responsibility for assessing clinical trial applications. —Assessment based on appropriate expertise. —Incomplete applications across Member States.
China	China's regulations focus on the need for localized clinical evaluation data to address specific differences in demographics and clinical practices. If the imported data does not suffice, conducting clinical trials within China is mandatory. Strict compliance with local guidelines for both local and overseas data is required.	—Imported software needs local clinical evaluation data. —Mandatory local trials if overseas data is insufficient. —Compliance with "Good Clinical Practice" and overseas data guidelines.
United States (USA)	The USA regulations highlight the importance of comprehensive data collection for certification and disclosure purposes. The FDA emphasizes the potential impact of data from all investigators on study results and requires thorough financial disclosures from clinical investigators.	—Data collection for certification and disclosure. —Investigator data can impact overall results. —FDA reviews financial disclosure information.

Finally, the rapid regulatory adaptations seen during the COVID-19 pandemic demonstrate that regulatory systems can adjust swiftly in response to global health emergencies. Integrating computational tools into such adaptive processes could enhance regulators' ability to anticipate, compare, and align evolving requirements. Future research should extend this approach to emerging markets such as Brazil, India, Russia, and South Africa and develop automated pipelines capable of real-time monitoring of regulatory changes. In doing so, computational approaches can help bridge regulatory gaps, streamline approval processes, and ensure timely patient access to safe and effective medical devices worldwide.

7 Conclusion and Future Work

This study demonstrates the transformative potential of computational methods in analyzing MDRs across major jurisdictions. By applying NLP techniques, including BERT embeddings, NER, and LDA to 664 regulations from the USA, EU, and China, we have uncovered patterns of regulatory convergence and divergence that would be difficult to identify through traditional manual analysis.

Our findings reveal increasing regulatory harmonization from 2014 onward, demonstrated through comprehensive statistical analysis of temporal patterns, thematic convergence through LDA, and quantitative document similarity trends. The identification of distinct thematic clusters through LDA analysis provides valuable insights for stakeholders navigating the complex regulatory landscape. These computational approaches offer a scalable framework for continuous monitoring of regulatory evolution and can facilitate more efficient global market access for medical devices.

The methodology presented here can be extended to other regulatory domains and additional jurisdictions, potentially accelerating the development of internationally harmonized standards that balance innovation with patient safety.

This study offers critical insights for researchers, policymakers, and industry professionals, facilitating a more navigable regulatory environment. By leveraging NLP and other AI approaches, we systematically analyzed a large corpus of regulatory documents, uncovering patterns and trends that would be difficult to detect through traditional manual methods. In particular, tracking the evolution of LDA topics over time revealed shifting regulatory priorities, providing manufacturers with actionable intelligence to anticipate changes, adapt compliance strategies, and streamline approval processes.

Our methodology combined automated text processing with systematic validation. Multi-stage quality assurance measures—including statistical verification, complementary methods for cross-validation, and manual spot checks—helped ensure scalability and rigor. Future work could further enhance accuracy by integrating real-time expert feedback and employing active learning strategies to better address edge cases in regulatory text interpretation.

Despite these strengths, several limitations should be acknowledged. First, the regulations were manually downloaded from official repositories, introducing potential human error or inadvertent omissions. Second, the keyword-based classification of four regulatory phases (animal, clinical, testing, and others) may not have been exhaustive, and some relevant documents may have been misclassified or excluded. Third, the preprocessing pipeline excluded common stop words such as "the," "and," and "in" to reduce dimensionality. While this improves computational efficiency, we acknowledge that removing connectors (e.g., "and," "or") may alter the conditional structure of certain requirements. Although legally significant connectors in fixed expressions (e.g., "terms and conditions," "safety and efficacy") were retained, the risk of reduced interpretability remains and is noted as a limitation.

Another limitation arises from the intrinsic challenges of applying NLP to legal and regulatory texts, which are often ambiguous, jargon-heavy, and vary across jurisdictions. While BERT embeddings provide powerful semantic representations, they cannot fully replicate the nuanced reasoning of human experts. For example, understanding provisions such as rolling review procedures requires contextual and procedural knowledge that extends beyond text similarity [87]. Current models thus remain less sophisticated than expert interpretation, underscoring the need for hybrid human–AI approaches.

Finally, this study focused on three major jurisdictions (USA, EU, China). While these represent significant markets, the exclusion of emerging economies such as Brazil, India, Russia, and South Africa limits the global generalizability of our findings [88, 89]. Expanding future analyses to include these markets will provide a broader understanding of global regulatory dynamics and harmonization opportunities.

Despite these limitations, our work demonstrates the feasibility and potential of applying NLP to regulatory science. By showing that regulations can be digitized, structured, and compared across jurisdictions, we lay the foundation for data-driven regulatory harmonization studies. Future advances in NLP and domain-specific modeling will likely yield tools that are not only more accurate and interpretable but also capable of supporting real-world regulatory decision-making across diverse global contexts.

Data Availability and Ethics

The regulatory documents analyzed in this study were obtained from publicly available government websites and databases (FDA, EMA, NMPA). While the raw regulatory texts are publicly accessible, some country-specific device security standards and confidential regulatory submissions are not included in our dataset due to privacy and security considerations. The processed NER dataset and extracted regulatory features could be made available to the research community upon reasonable request and in compliance with relevant data sharing guidelines and institutional policies.

All regulatory documents were obtained from official public sources, and no human subjects were involved in this computational analysis. The study focuses purely on publicly available regulatory texts and does not involve any patient data or confidential information.

Conflicts of Interest

The authors affirm that there are no conflicts of interest to declare.

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