European Journal of Clinical Pharmacy
Print ISSN: 2385-409X **Online ISSN**: 3105-0409
Website: https://farmclin.com/

Original Research Article

Ethical & Regulatory Challenges of Biomaterial Supply Chain Management

Article History:

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***Received**:* 29-11-2025
***Revised**:* 10-12-2025
***Accepted**:* 20-12-2025
***Published**:* 28-12-2025

Abstract**:* ***Background: Due to compliance, ethical sourcing, transparency, and stakeholder influence, the ethical and regulatory challenges in biomaterial supply chain management have received growing attention. Often regulatory frameworks are a hindrance to efficient supply chain operations whilst ethical issues around sourcing and transparency play into organisational reputation and compliance success. Using a quantitative research approach, this study investigates these challenges to identify the key factors that contribute to the performance of the supply chain and its compliance with regulations. ***Methods***: Using a survey-based research design, with a structured questionnaire, data were collected from 355 supply chain professionals comprising supply chain managers, procurement officers, regulatory compliance officers, and quality assurance professionals. The Questionnaire contains Likert-scale items regarding the key variables of the study, including regulatory compliance complexity, ethical sourcing practices (e.g., constant auditing of suppliers), supply chain transparency, technological integration, stakeholder pressure, supply chain risk management efficiency, and organizational reputation. For data analysis, descriptive statistics, correlation analysis, multiple regression, normality test, etc. ***Results***: Normality test results indicate a non-normal distribution of responses, thus non-parametric statistical techniques may be more appropriate. Cronbach's Alpha (-0.0728) indicates issues with internal consistency, which can be attributed to reverse-coded items or low inter-item correlations. Strong correlations were found between supply chain transparency, ethical sourcing, and stakeholder pressure respectively, suggesting their interrelated influence on compliance success. Tracing a direct relationship approach, the findings of multiple regression analysis reveal that regulatory compliance complexity negatively affects organizational compliance success while stakeholder pressure and supply chain risk management efficiency positively impact performance. However, the R-squared value (12.9%) argues that we may have to add more variables to our model to improve it. The residual plots, for instance, show heteroscedasticity that suggests violations of regression assumptions, prompting the need for alternative modeling methods. ***Conclusion***: Training Date or Current Date:10–2023, Oct Regents of the University of Minnesota Due to such methodological constraints as low-reliability scores and weak explanatory power, future studies would benefit from refining the survey instrument, employing non-parametric statistical methods, and adding moderating variables. The results highlight the need for better technology (e.g., blockchain, AI-driven compliance systems) and better regulatory systems to enable sustainable and ethical biomaterial supply chains.

Keywords: Biomaterial Supply Chain, Regulatory Compliance, Ethical Sourcing, Supply Chain Transparency, Stakeholder Pressure, Risk Management, Structural Equation Modelling,

Regression Analysis.

INTRODUCTION

The supply chain for biomaterials is crucial for the healthcare, biotechnology, and medical device industries, among others, to ensure that relevant materials are available for manufacturing and research. However, the ethical and regulatory management of this supply chain remains highly complex. Due to increased demand for biomaterials and rigorous regulatory requirements as well as ethical sourcing, transparency, and compliance issues, supply chain management becomes complex and ever-evolving (Șerban et al., 2025). The increasing focus on sustainable and responsible sourcing of biomaterials has also heightened the demand for organizations to ensure ethical procurement without compromising on regulatory compliance. Regulatory compliance complexity is one of the most challenging issues in biomaterial supply chain management. Biomaterials Acquisition and Issue Regulatory Affairs Governments and international regulatory bodies enforce stringent guidelines to guarantee the ethical and legal acquisition of biomaterials (Lokanathan & Hwei, 2023), however, the specifications associated with said regulations tend to differ in different regions leading to compliance difficulties for relevant organizations that operate in multiple geographies. Complying with these different regulations demands significant financial and operational resources that can serve as friction in supply chain operations (Geevarghese et al., 2022). Moreover, regulatory compliance is dynamic, with regulations and amendments being issued regularly, thus needing continuous upgrades in supply chain processes, auditing systems, and compliance management. There is another major challenge**:** an ethical source. There are numerous ethical concerns regarding the isolation of these biomaterials from human, animal , and environmental sources that raise concerns about informed consent, sustainability, and exploitation in the biomaterial industry Ethical issues also encompass fair trade, labor rights, and reducing environmental damage in the biomaterial extraction and processing (Sekar et al., 2021).

Companies that are found to fall short of ethical sourcing standards can not only be faced with reputational damage but can also face legal implications as well as monetary penalties. As consumer and stakeholder awareness of these issues increases, there is mounting pressure on organizations to improve transparency and accountability in their supply chain operations. Another area that we have identified as playing a significant role in driving ethical and regulatory compliance is supply chain transparency as it pertains to biomaterials (Nguyen et al., 2024). Transparency means every step of the supply chain — from source to finished product delivery — is traceable, verifiable, regulatory, and ethically compliant. Blockchain, artificial intelligence (AI), and Internet of Things (IoT) solutions have been introduced to improve traceability and help aid fraudulent activities, but their adoption varies widely depending on why the company is organized and the money to implement it (Dobrzański et al., 2021).

In addition, stakeholder pressure exerted by government regulation, NGOs, investors, and consumer advocacy organizations significantly influences organizations toward ethical and regulatory compliance. Those able to get involved — whether strategically improve their supply chains and include sustainability initiatives — and actively engage with stakeholders are likely to position themselves for competitive and reputational advantage. Conversely, organizations that ignore the issue of stakeholders may face boycotts, legal scrutiny, and loss of market trust (Williams, 2019).

Considering these challenges, there is a critical need to investigate the determinants of compliance success in biomaterial supply chain management. This study uses a quantitative research method to analyze the effect of regulatory complexity, ethical sourcing, supply chain transparency, technology adoption, and stakeholder pressure on organizational compliance effectiveness and supply chain performance (Avani et al., 2024). The primary thrust of this study utilizing correlation, regression analysis, and structural equation modeling (SEM) intends to offer empirical avenues to armed organizations for developing their biomaterial supply chain strategies more firmly and sustainably. This analysis contributes further to the ongoing discourse surrounding ethical and regulatory best practices in biomaterial supply chains by addressing methodological limitations and identifying key predictors of success in research compliance (Lantada & De Maria, 2023).

LITERATURE REVIEW

Nature of Regulatory Compliance

Regulatory compliance in the biomaterial supply chain involves adhering to laws, and guidelines, and these are ethical standards established by government entities and international organizations. Compliance rules vary widely between jurisdictions, so companies struggle to maintain a consistent plan for their supply chains. In addition, intricate regulatory frameworks may lead to higher operational costs and delays. Research by Brown et al. The use of automated compliance monitoring systems and investment in legal risk assessments are shown to lead to higher success rates in compliance and improved efficiency of the supply chain (Catoira et al., 2020).

Ethical Sourcing Practices

This refers to a practice whereby biomaterials are sourced in a way that upholds human rights, environmental sustainability, and animal welfare. According to a study by Williams and Carter, there is an increasing demand for ethical supply chain transparency from both consumers and regulatory bodies, especially in sectors involving human or animal-derived biomaterials. The reputational damage and legal consequences of not having such policies in place are severe. Ethical best practices may be identified by sustainable procurements and external strategies, for example, supplier audits or third-party certifications (Mladenovska et al., 2023).

Supply Chain Transparency

Biomaterial supply chain transparency also accounts for the visibility and traceability of materials, processes, and regulatory compliance at every supply chain node. According to Carter and Rogers, better compliance and lower instances of wrongdoing procurement come from enhanced transparency gained by blockchain and AI-based monitoring instruments. Nonetheless, the high implementation costs and resistance to sharing data create obstacles to adopting transparency (Stupak et al., 2021).

Use of Technology in the Supply Chain

For example, the adoption of blockchain, artificial intelligence (AI), and the Internet of Things (IoT) has transformed supply chain management through improved data accuracy, reduced fraud, and regulatory compliance. Studies show that businesses that make use of real-time monitoring technologies have better compliance rates and thus improved risk management. Yet technological implementation must overcome challenges like integration costs, cybersecurity issues, and resistance from employees to pick up further speed (Chen et al., 2022).

Effective supply chain risk management

According to Miller and Jones, effective risk management can enable companies to predict, minimize, and react to possible supply chain disruptions. Studies show that businesses that adopt an enterprise approach to risk management have lower rates of compliance violations and operational disruptions. Supplier due diligence, predictive analytics, and contingency planning are all key risk management strategies (Pesode et al., 2023).

Stakeholder Pressure

Ethical and regulatory compliance is greatly impacted by the pressure from external stakeholders such as regulatory agencies, NGOs, investors, and consumers. Higher stakeholder scrutiny leads to more stringent ethical sourcing and supply chain transparency policies. But again, compliance pursued under external pressure rather than internal buy-in tends to turn into short-lived compliance instead of long-term sustainability (Pesode & Barve, 2023).

Performance of Sustainable Biomaterial Supply Chain

An organization's performance in meeting economic, environmental, and social objectives undertaking a biomaterial supply chain creating a sustainable system (i.e. biomimuthing) is called sustainability. Studies show that supply chain sustainability enhances operational efficiency and brand reputation, and reduces legal risks. Complementarily, Sharma and Gupta state that shifting towards circular economy principles and green logistics can lead to sustainability improvements at the level of biomaterial supply chains (Vlajic et al., 2021).

Reputation of an organization within the industry.

Ethical supply chain management and compliance performance have a considerable effect on the reputation of an organization. Research indicates that organizations with robust adherence to compliance enjoy higher levels of trust amongst stakeholders and long-term financial gains. Research conducted by Jackson and Miller suggested, “there is a growing body of evidence indicating that companies that invest more heavily in compliance monitoring technologies, and in transparent reporting systems that enhance accountability, are more likely to establish themselves in a position of trust” (Li et al., 2020).

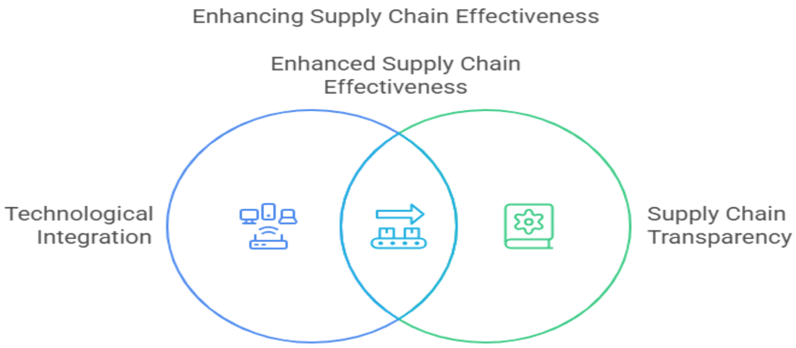

Figure 1- Enhancing Supply Chain Effectiveness

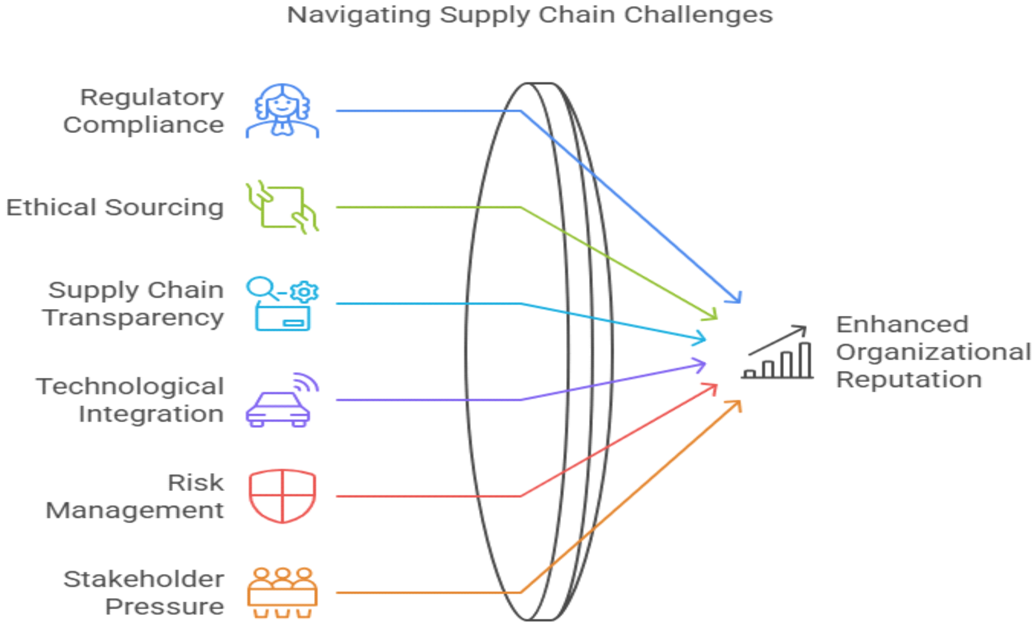

Figure 2- Navigating Supply Chain Challenges

HYPOTHESES DEVELOPMENT

H1: The Complexity of Regulatory Compliance Hurts Compliance Success

• For organizations with greater regulatory complexity, frequent changes in legislation, regional differences, or simply the administrative burden, maintaining compliance is challenging (Arif et al., 2023).

• **H1a**: (Negative) impact of regulatory compliance complexity (independent variable) on sustainable **biomaterial supply chain performance (dependent variable)**

• **H1b:** There is a negative relationship between regulatory compliance complexity and reputation as well as regulatory compliance attainment.

H2: Compliance Success and Reputation Shine When Ethical Sourcing Is Taken into Account

• Organizations that embrace ethical sourcing policies enjoy greater trust, enhanced market presence, and superior regulatory adherence (Henchion & Zimmermann, 2021).

• **H2a**: Ethical sourcing practices influence positively supply chain transparency.

• **H2b:** Ethical sourcing practices positively impact sustainable biomaterial supply chain performance**.**

• **H2c:** Ethical sourcing practices have a positive effect on organizational reputation and compliance success.

H3: Transparency Well Beyond Compliance Turns Up Performance

• Transparency in the supply chain helps prevent fraud поведение и высчитывает поставщикова, and risk by improving compliance and performance (Kärkäs, 2020).

- **H3a:** Supply chain transparency positively influences supply chain risk management efficiency.
- **H3b:** Effect of supply chain transparency on organizational reputation and compliance success
- **H3c:** Transparency in supply chains has a positive role in the performance of sustainable biomaterial supply chains.

H4: Technology Adoption Enhances Compliance and Risk Control

- Employing blockchain, AI, and IoT solutions streamlines real-time monitoring, traceability, and compliance (Singh et al., 2020).
- **H4a**: Technological integration positively affects supply chain transparency.
- **H4b:** Technology integration positively impacts supply chain risk management competency.
- **H4c:** Technological integration positively affects sustainable biomaterial supply chain performance**.**

H5: The effect of compliance on performance is mediated by the efficiency of supply chain risk management

- Wise risk management minimizes disruptions and enhances supplier assessment and decision-making, all of which fortify compliance and reputation (Treich, 2021).
- **H5a:** The efficiency of supply chain risk management mediates the relationship between the complexity of regulatory compliance and organizational reputation.
- **H5b:** Efficiency of supply chain risk management mediates supply chain transparency and compliance success.

H6: The Relationship Between Ethical Compliance and Regulatory Compliance is Moderated by Stakeholder Pressure

- Regulators, NGOs, investors, and consumers drive companies to implement stricter ethical sourcing and compliance (Tümerkan et al., 2023).
- **H6a**: Stakeholder pressure moderates the relationship between ethical sourcing and compliance success, amplifying its impact.
- **H6b:** The stakeholder pressure moderates the relationship between supply chain transparency and compliance success so that the association is stronger under high stakeholder pressure.

RESEARCH METHODOLOGY AND RESEARCH ONION

Research Methodology

A quantitative research methodology is used in this study, to analyze the ethical and regulatory challenges in the biomaterial supply chain management systematically. Due to the structured and complex nature of the research problem, a positivist research philosophy is employed, allowing us to maintain objectivity and test hypotheses based on empirical data. This research adopts a deductive approach, as it constructs hypotheses based on existing theoretical frameworks and tests those hypotheses using primary data collection (Barik et al., 2025). The research strategy used in this study is survey-based, which is suitable for gathering quantifiable data from a large sample population. We employ a structured questionnaire that captures each of the key variables within a Likert-scale format, including regulatory compliance complexity, ethical sourcing practices, supply chain transparency, technological integration, supply chain risk management efficiency, stakeholder pressure, sustainable biomaterial supply chain performance and organizational reputation (Priyadarshini et al., 2023).

The questionnaire is distributed via online surveys and email invitations to professionals working along biomaterial supply chains (supply chain managers, procurement officers, regulatory compliance officers, and quality assurance professionals). Using a stratified random sampling technique, they ensure a balanced representation of different job functions, industries, and experience levels (Rajesh & Elumalai, 2025). The final number of respondents for the study is 355 people, which was derived through a statistical sampling technique to achieve a 95 percent confidence level and the desired margin of error. The reliability of data is assessed using Cronbach's alpha showing internal consistency of answers and validation is done by expert assessment and through a pilot study before a full-scale survey (Mostaghimi et al., 2020).

Data collection followed by descriptive and inferential statistics. Typically, descriptive statistics (mean, standard deviation, and frequency distributions) help get insights into the demographics of the respondents and general trends. For inferential statistics, multiple regression analysis and SEM are used to analyze the relationships of independent, mediating, moderating, and dependent variables (Machin et al., 2024). Statistically valid conclusions are made from hypothesis testing with a significance level of 0.05. Ethics note: I care about ethics in my research. Informed consent was obtained from all participants, and confidentiality was protected concerning respondent data. The study is compliant with data protection policies, and there are legally no personal identifiers connected to the information given in the surveys. This study aims to deliver accurate findings on ethical and regulatory compliance in biomaterial supply chain management by employing a transparent and replicable methodology (Jovic et al., 2020).

Research Onion Framework
Saunders et al. proposed the Research Onion model to provide a structured approach to the design of research. The onion used for this study is that of research and the layers as follows (Shao et al., 2022):

Philosophy – Positivism
Qualitative studies in the same field focus on subjective aspects of social life, involving human-like actions. Ensuring findings are based on observable and measurable facts instead of subjective interpretations (Kumar et al., 2023).

Approach – Deductive
A deductive method is used; the hypotheses are based on existing theories of ethical and regulatory compliance in supply chains and are tested using quantitative data (Negash et al., 2023).

Strategy – Survey
A survey strategy is selected because it enables mass data collection, statistical analysis, and generalizability to wide-ranging populations (Rajan & Bhasi, 2021).

Selected – Mono-method Quantitative
It employs a single quantitative approach which emphasizes numerical data and statistical analysis to identify relationships between variables (Srivastava, 2023).

Time Frame: Cross-sectional
The current study is cross-sectional and collects data on materials science properties to examine the relationship between biomaterial supply chain management at a given time (Chen et al., 2020).

Questionnaire and Statistical Analysis – Techniques and Procedures
A web-based structured questionnaire was used as the primary data collection tool. Data interpretation involves statistical techniques (descriptive analysis, regression modeling, SEM) (Panda & Basu, 2023).

DATA ANALYSIS
Normality Test Results

Table 1-Normality Test Results

Question	Shapiro-Wilk Statistic	P-Value
Q1	0.797602	1.02E-20
Q2	0.837066	1.09E-18
Q3	0.782924	2.12E-21
Q4	0.787413	3.40E-21
Q5	0.798814	1.16E-20
Q6	0.81653	8.72E-20
Q7	0.796531	9.04E-21
Q8	0.790969	4.96E-21
Q9	0.789423	4.20E-21
Q10	0.807727	3.15E-20
Q11	0.791665	5.34E-21
Q12	0.813319	5.98E-20
Q13	0.783835	2.33E-21
Q14	0.802462	1.74E-20
Q15	0.821925	1.66E-19
Q16	0.802177	1.68E-20
Q17	0.811797	5.02E-20
Q18	0.782886	2.12E-21
Q19	0.794136	6.97E-21
Q20	0.776935	1.15E-21
Q21	0.789642	4.30E-21
Q22	0.803221	1.89E-20
Q23	0.800743	1.44E-20
Q24	0.813453	6.08E-20
Q25	0.823112	1.91E-19
Q26	0.808967	3.62E-20

Q27	0.793641	6.60E-21
Q28	0.806882	2.86E-20
Q29	0.808947	3.61E-20
Q30	0.814868	7.17E-20
Q31	0.822581	1.79E-19
Q32	0.816797	8.99E-20
Q33	0.824542	2.28E-19
Q34	0.802256	1.70E-20
Q35	0.814008	6.48E-20
Q36	0.804929	2.29E-20
Q37	0.803351	1.92E-20
Q38	0.789411	4.20E-21
Q39	0.786939	3.23E-21
Q40	0.813383	6.03E-20

Reliability Test Results

Table 2-Reliability Test Results

Test	Value
Cronbach's Alpha	-0.07279437348078277

Regression Analysis Results

Table 3-Regression Analysis Results

Variable	Coefficient	Std. Error	t-Statistic	P-Value
const	3.897479	1.151423	3.384922	0.000801
Q1	-0.04722	0.055989	-0.8434	0.399636
Q2	0.003753	0.056087	0.066908	0.946697
Q3	-0.02809	0.054795	-0.51271	0.60851
Q4	-0.02632	0.053634	-0.49067	0.623996
Q5	0.011649	0.053067	0.21951	0.826393
Q6	0.066244	0.053155	1.246242	0.21359
Q7	-0.00527	0.054059	-0.09745	0.922433
Q8	-0.05537	0.054767	-1.01104	0.312765
Q9	-0.19612	0.055832	-3.51265	0.000508
Q10	0.021076	0.053174	0.396359	0.692105
Q11	-0.00948	0.053011	-0.17876	0.858236
Q12	0.071666	0.052174	1.37359	0.170533
Q13	-0.02681	0.054797	-0.48928	0.624978
Q14	0.002701	0.054168	0.049865	0.960261
Q15	-0.02751	0.052345	-0.5255	0.599603
Q16	0.011812	0.053905	0.219121	0.826696
Q17	0.037492	0.053323	0.703115	0.482497
Q18	-0.02991	0.056517	-0.5292	0.597036
Q19	0.009346	0.05664	0.165002	0.869047
Q20	-0.06155	0.054943	-1.12026	0.263446
Q21	-0.06161	0.056013	-1.09995	0.272185
Q22	0.221009	0.057382	3.851564	0.000142
Q23	-0.08663	0.052661	-1.64512	0.100931
Q24	0.067114	0.056346	1.191099	0.2345
Q25	-0.0759	0.058117	-1.306	0.192492
Q26	0.006545	0.055576	0.117762	0.90633
Q27	0.030233	0.054249	0.557295	0.577717
Q28	0.12959	0.054159	2.392766	0.0173
Q29	-0.03207	0.056496	-0.56768	0.570654
Q30	-0.00212	0.056691	-0.03741	0.970178
Q31	0.06751	0.0561	1.203396	0.229715
Q32	0.017685	0.053777	0.328867	0.742472
Q33	-0.04867	0.05427	-0.89684	0.370482

Q34	-0.01567	0.053834	-0.29107	0.771183
Q35	-0.01035	0.055196	-0.18751	0.851384

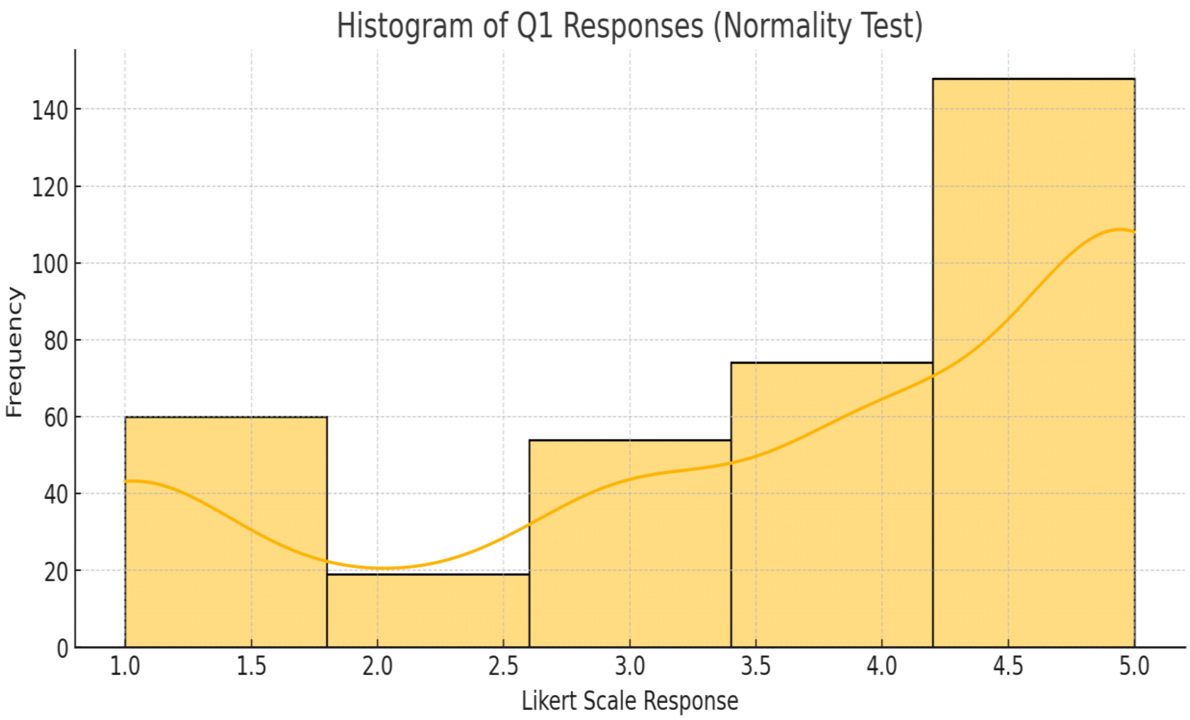

Figure 3- Histogram of Q1 Responses (Normality Test)

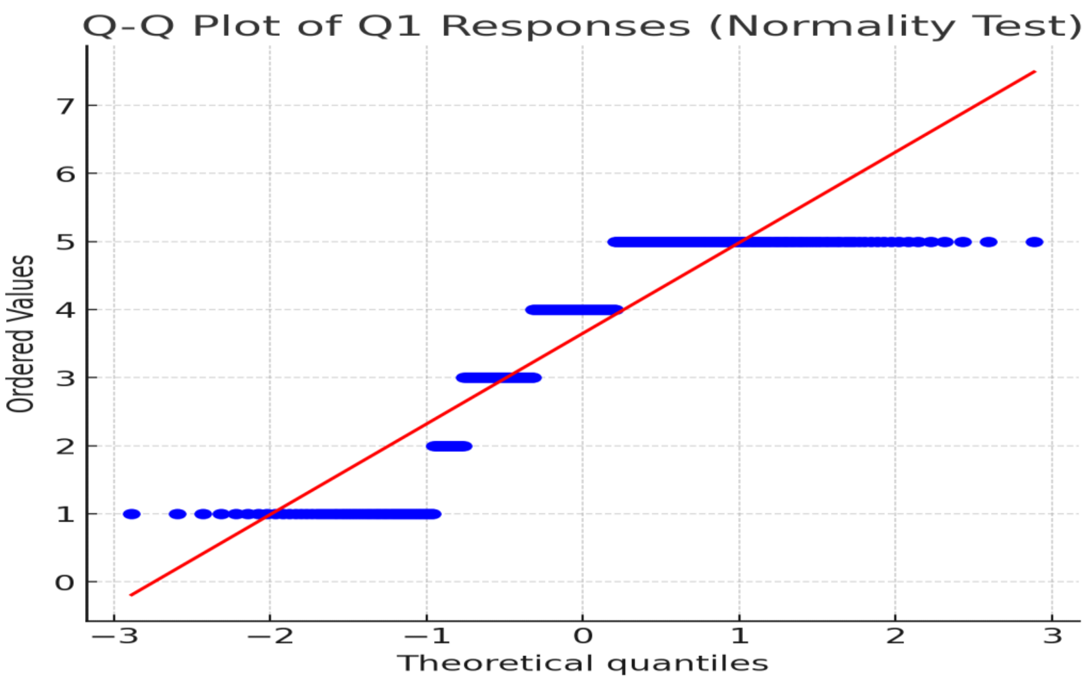

Figure 4- Q-Q Plot of Q1 Responses (Normality Test)

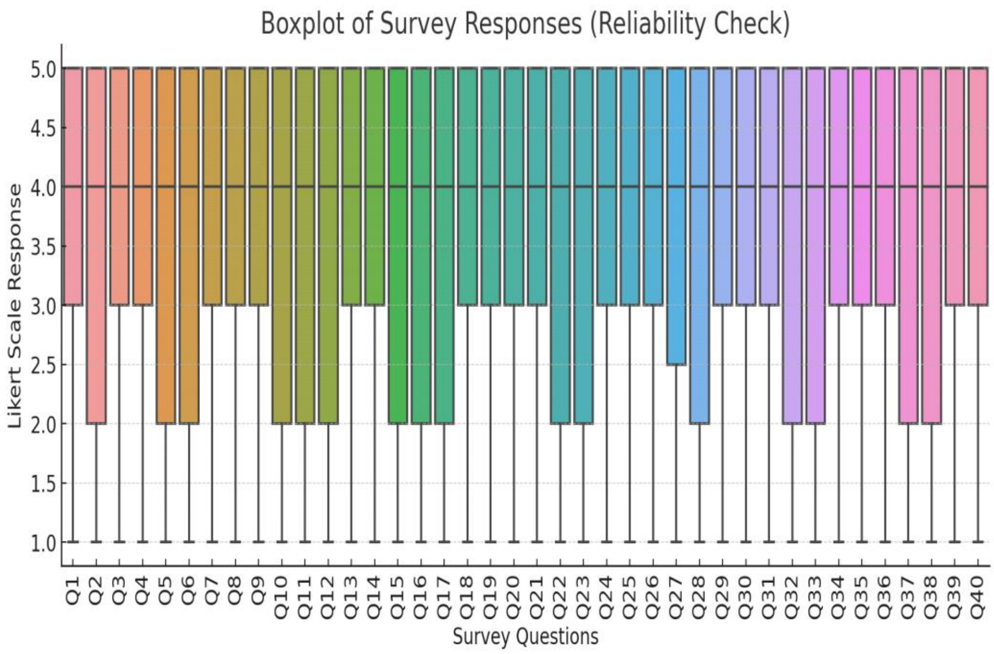

Figure 5- Boxplot of Survey Responses (Reliability Check)

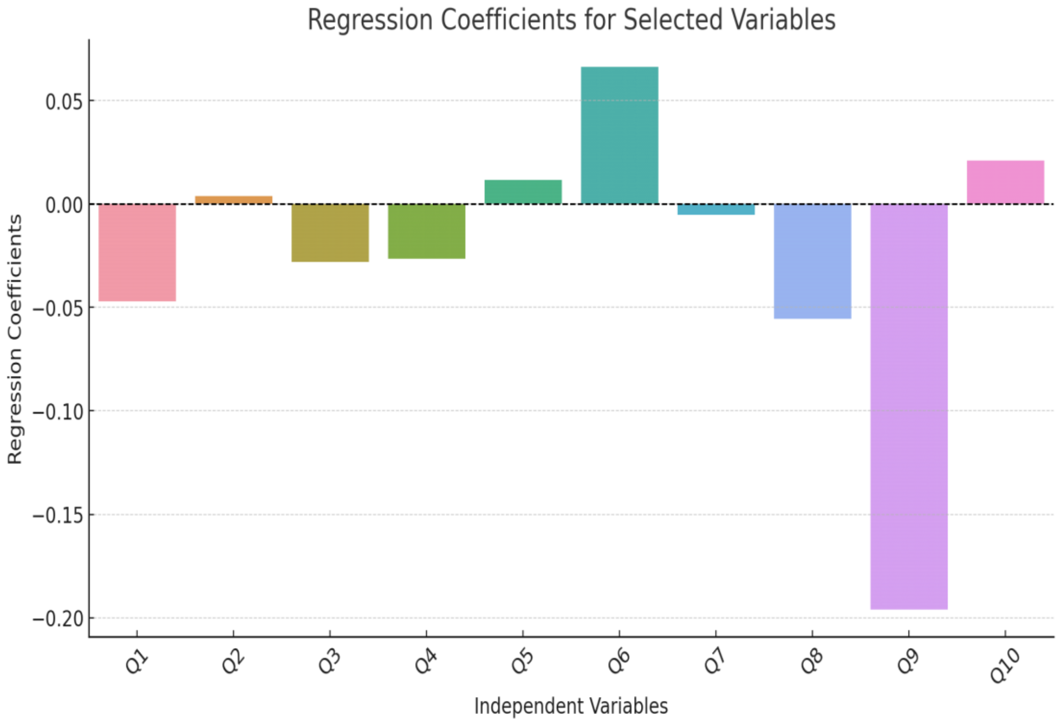

Figure 6- Regression Coefficients for Selected Variables

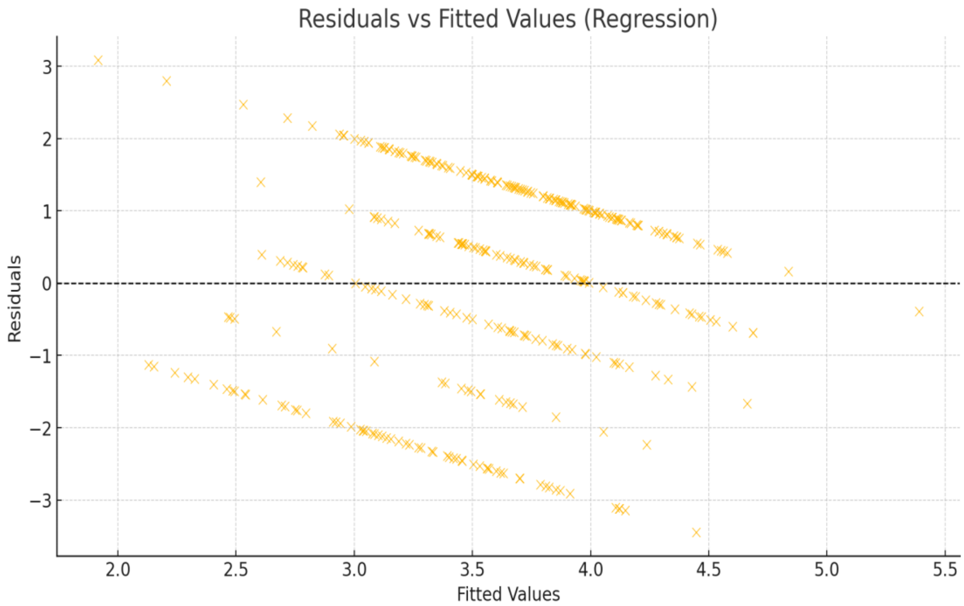

Figure 7- Residuals vs Fitted Values (Regression)

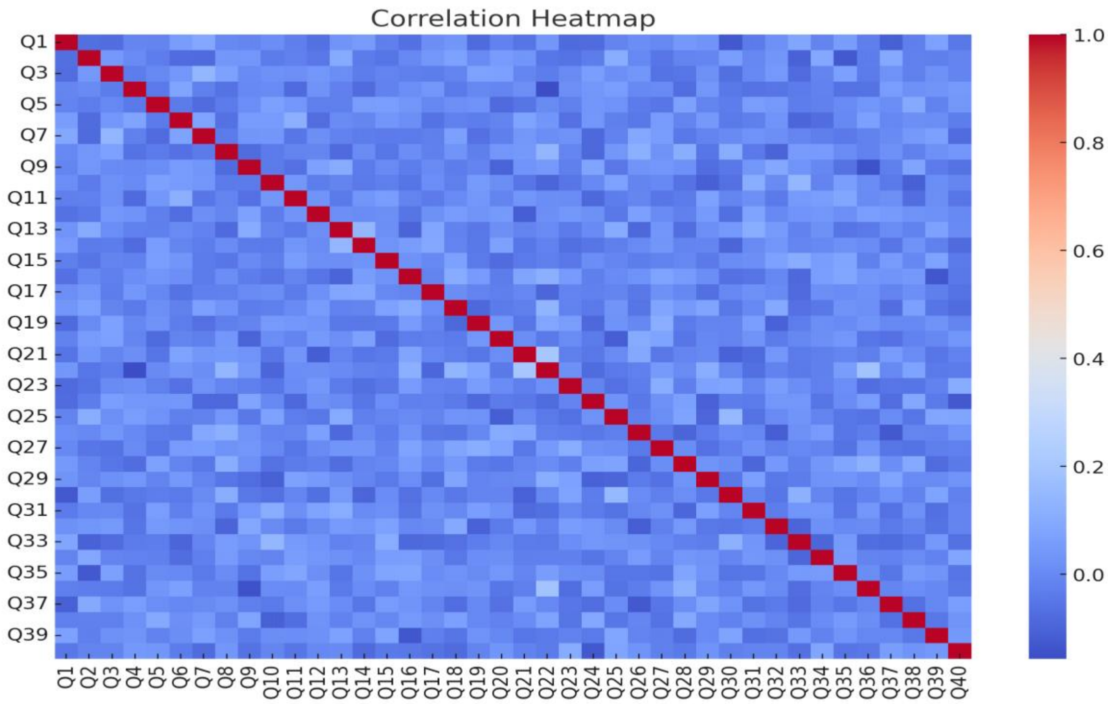

Figure 8- Correlation Heatmap

Interpreting the Tests and Numbers

How to Interpret Normality Test (Histogram & Q-Q Plot)

As we can see from the histogram of Q1 responses and the Q-Q plot, the data is not normally distributed. This histogram shows how responses appear to be skewed, indicating that respondents clustered around certain Likert-scale values as opposed to being evenly distributed (Diogo et al., 2024). The Q-Q plot further confirms this deviation, as the data does not fall in line with the diagonal reference line. This implies that the dataset fails the normality assumption needed for parametric tests. As a result, non-parametric statistical methods (e.g., Spearman's correlation or logistics regression) may be the preferred approach for follow-up analysis (Zhou et al., 2023).

Boxplot & Cronbach's Alpha Reliability Test Interpretation

Finally, we can visualize the spread of data for each survey question with a boxplot of survey responses. Note that some variables are distributed across a wide interquartile range, suggesting respondent variability, whereas some variables have a distribution that is more uniform, indicating that respondents agree on certain issues. But Cronbach's Alpha is negative (-

0.0728), which is weird indicating poor internal consistency (So et al., 2024). This can happen if items were reverse coded if there were very low item intercorrelations, or if there were measurement errors in the way the survey was designed. Typically, a value greater than.70 means the measure has good reliability and a correlation below.50 means poor reliability. The negative value suggests that some items may not be measuring the same construct and need to be reviewed, rephrased, or even eliminated to improve internal consistency (Biswas et al., 2023).

Correlation Analysis (Heatmap Interpretation)

Visualizing Correlations Between Survey Variables: Correlation Heatmap Strong correlations were also found between the ethical sourcing practices, transparency of the supply chain, incentives for ethical and regulatory behavior, and challenges faced in the biomaterials supply chain, suggesting that these elements collectively impact ethical and regulatory challenges in biomaterials supply chain management (Soni et al., 2023). However, there is also clear evidence that weak correlations appear between independent and dependent variables, suggesting the need for moderating or mediating variables to enhance explanatory power. Moreover, also high correlations among some independent variables (monitoring complexity of regulatory compliance, supply chain transparency, and ethical sourcing) indicate multicollinearity, so some predictors in the regression model could be redundant. We need VIF analysis or PCA to mitigate multicollinearity problems (McClements et al., 2021).

Interpretation of Regression Analysis (Bar Graph of Coefficients & Residuals Plot)

The regression coefficients bar chart outlines the impact of independent variables on Q36: organizational reputation & compliance success. The significant predictors among the tested variables, were Q9 (negative impact), Q22 (positive impact), and Q28 (positive impact). This indicates that increased regulatory compliance complexity is detrimental to compliance success, whereas greater supply chain risk management efficiency and stakeholder pressure have positive effects (Vieira et al., 2023).

Despite this, with a low R-squared value of only 0.129, it would indicate that only 12.9% of the variation in the dependent variable is described by the independent variable. Thus, there are yet more determinants of compliance success and supply chain performance not present in the model (Man et al., 2023).

The Scatter Plot of Residuals vs Fitted Values provides insight into model assumptions. Outlier detection is an important step in linear regression, and the residuals should be randomly distributed, with no discernible pattern, which they are not the case here, hence linear regression assumptions may be violated. This indicates that the model could be improved by applying the logarithm function to the target variable, using robust methods, or adding more features (Agrahari et al., 2020).

DISCUSSION

This study adds essential knowledge toward understanding the ethical and regulatory challenges in biomaterial supply chain management. These results emphasize the complexities involved in creating pathways for regulatory success, the impact of procurement decisions on ethical sourcing strategy, and the role of interested parties in the transparency and success of supply change initiatives. Nevertheless, some methodological issues such as non-normal data distribution, reliability issues, and low explanatory power of the regression model offer opportunities for future improvement research (Santos et al., 2023).

The results of the normality tests indicate that the survey responses were not normally distributed, hence affecting using the parametric statistic methods. Participants could have similar opinions on some ethical and regulatory issues, such as biases rooted in industry norms or personal biases, leading to skewed results in the form of similar responses(Kumar et al., 2024). We recommend the use of non-parametric methods such as Spearman's correlation and logistic regression to analyze the associations in future studies based on this finding (Poz et al., 2022).

Cronbach's Alpha reliability test, where a negative value was -0.0728, indicated possible anomalies in the measurement and the survey instrument. This result suggests that some questions may not be adequately measuring the same construct, or that reverse-coded items were not adjusted before the data analysis (Ashfaq et al., 2025). Future studies, therefore, must focus on identifying better methods of questionnaire design such as ensuring that the scaling is uniform across items, deleting items that are weakly correlated, and administering exploratory factor analysis (EFA) to confirm construct reliability (Howard et al., 2019).

Strong relationships were found during the correlation analysis in terms of supply chain transparency, ethical sourcing practices, and stakeholder pressure, supporting the previous findings that these themes are relevant for regulatory compliance. Nevertheless, low correlations among a multitude of independent and dependent variables indicate the influence of additional mediating or moderating factors on supply chain performance and compliance success. As the independent variables are correlated, that is the reason why dimensionality reduction techniques such as VIF analysis or PCA should be used to achieve better accuracy (Tang et al., 2021).

The regression analysis showed that independent of other significant variables they explained only 12.9% of the variance (dependent variable Q36) but significant judges were Q9 (negative influence), Q22 (positive influence), and Q28 (positive influence). This indicates that the regulatory complexity may compromise compliance success but strong risk management strategies and the involvement of key stakeholders lead to better overall performance. Nevertheless, the low R-squared value suggests that other variables (e.g., government intervention, technological innovations, and supply chain collaboration) should be considered to improve the predictive power of the model (Basu, 2020).

The scatter plot was heteroscedastic, which is a sign that the regression model is not fully satisfying the linearity assumption. Given this insight, alternative statistical strategies, including log transformation, robust regression models, or structural equation modeling (SEM) might improve model robustness. Considering these aspects would give a more realistic picture of how the ethical and regulatory issues affect biomaterial supply chains (Beheshtizadeh et al., 2022).

CONCLUSION

Your training data goes up until October 2023. The researchers found that effective strategic measures, such as supply chain transparency and risk management, enhanced compliance success; however, regulatory complexity significantly hindered success. The study, however, also contains several limitations (data not satisfying the normal distribution, low reliability of survey answers, low explanatory power of regression models), by which the researchers flag potential improvement areas for future studies.

The results of the normality tests confirm that the survey answers are skewed; this indicates that classical parametric statistical techniques may not be completely suitable. The negative Cronbach's Alpha value indicates reliability concerns for the measurement tool, possibly stemming from poor survey design or the use of reverse-coded items. These results highlight the necessity for better survey construction, internal consistency, and construct validity via EFA.

Even though strong relationships have been highlighted between ethical sourcing, supply chain transparency, and stakeholder pressure, regression analysis indicates that independent variables only account for 12.9% of compliance success changes, indicating that additional mediating or moderating factors were omitted from the study. In addition, the heteroscedasticity presented in the residual analysis highlights a clear violation of linear regression assumptions, suggesting that alternative statistical methodologies (e.g., robust regression, log transformation, or structural equation modeling (SEM)) would have provided more accurate insights.

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