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The Role of Internal Initiatives and External Forces for Sustainable Waste Reduction in the Pharmaceutical Industry

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Abstract: The pharmaceutical manufacturer industry is a key player in health care at the global level. The industry is facing growing challenges in achieving sustainable waste management with the speedy rise of regulatory standards, material inefficiency, and environmental impact. The aim of this paper is to study the influence of internal initiatives like Lean Manufacturing, Industry 4.0 and Employee Engagement as well as external forces like Economic and Environmental Impacts and Regulatory Compliance, on sustainable waste reduction. The study used a quantitative survey method targeting pharmaceutical professionals and employed multiple regression analysis to measure those relationships. The results show that Lean Manufacturing and Industry 4.0 technologies significantly improve waste reduction and operational efficiency, while regulatory compliance is an important driver of sustainability. Employee engagement alone may not have as much impact as one might believe, but it does show impact when supported through structured training and digital initiatives. This study offers a framework for drug manufacturing which is strategic, integrative of technology, and regulatory-oriented to achievement lasting environment and economic sustainability.

Keywords: *Lean Manufacturing; Industry 4.0; Sustainable Waste Reduction; Regulatory Compliance; Employee Engagement; Economic Impact; Environmental Sustainability*.

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I. INTRODUCTION

The pharmaceutical manufacturing industry faces mounting pressures to adopt sustainable practices amidst tightening environmental regulations, increasing societal awareness, and evolving technological landscapes. One important aspect of sustainability relates to waste reduction which helps to lessen environmental impact and improve operational efficiency.

Lean Manufacturing (LM) is a technique to prevent waste and increase productivity and efficiency. It has been used by manufacturing industries for a long time. By continuous removal of waste and optimizing processes, Lean has proved effective in various sectors including pharmaceuticals [1]. Industry 4.0 technologies like real-time monitoring, predictive analytics and increased automation can help optimize production processes in a way which Lean cannot do on its own [2]. To obtain the sustainable benefits Lean practices promise, an organization needs to adopt this initiative of engaged and trained employees [3]. The implementation of innovative waste reduction practices is often hampered by stringent regulatory frameworks and adherence to health and safety standards [4]. Finally, economic and environmental forces put serious pressure on pharmaceutical producers to cut costs and improve sustainability[5].

Though most pharmaceutical companies are eager to integrate internal initiatives like Lean Manufacturing, Industry 4.0 technologies and Employee Engagement with external pressures like Regulatory Compliance and Economic-Environmental imperatives, it is not yet happening in a sustainable manner with resultant waste.

Waste reduction is simple as a term but much more complex in practice. To align internal organizational efforts with external regulatory forces is certainly a challenge. In academic literature, however, not much attention has been given to this interaction. This is especially true in a highly regulated industry like pharmaceuticals.

A. Problem Statement

Companies that manufacture pharmaceuticals products are increasingly aware of the need for sustainable waste reduction. Nevertheless, little work has been done on a more comprehensive framework that takes both internal drivers (such as Lean and digitization) and external ones (such as regulatory and environmental-economic, and ultimately, customer pressures) into account.

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Failure to understand the system will hamper sustainability, active engagement and effectiveness of waste reduction efforts.

With that, the pharmaceutical industry must employ internal initiatives and engage with external forces to implement a sustainable waste management practice.

B. Research Questions

To address the identified gap, this study aims to answer the following research questions:

- How do internal initiatives such as Lean Manufacturing Practices, Industry 4.0 Integration, and Employee Engagement impact sustainable waste reduction in pharmaceutical manufacturing?
- How do external forces, specifically Economic and Environmental Impacts and Regulatory Compliance, influence sustainable waste reduction?
- Which factors exert the most significant influence on achieving sustainable waste reduction in pharmaceutical manufacturing?

C. Research Objectives

➢ *Broader Objective:*

To analyze the role of internal operational strategies and external environmental and regulatory forces in promoting sustainable waste reduction within the pharmaceutical industry.

➢ *Specific Objectives:*

- To evaluate the effectiveness of internal initiatives—including Lean Manufacturing, Industry 4.0, and Employee Engagement—in optimizing waste reduction in pharmaceutical manufacturing.
- To assess the impact of external factors, such as regulatory compliance, economic pressures, and environmental considerations, on the success of sustainable waste reduction practices in pharmaceutical manufacturing.
- To design and propose an integrated framework that combines Lean Manufacturing, Industry 4.0, employee engagement, economic & environmental impacts, and regulatory compliance to guide pharmaceutical companies toward sustainable waste reduction.

D. Significance of Study

This research is both theoretical and practical. It adds to theoretical and practical literature of sustainability and operations management by offering an integrated model of both internal as well as external factors affecting sustainable waste reduction. In practical terms, the findings help pharmaceutical manufacturers to synchronize their operational excellence initiatives with regulatory & environmental requirements. By pooling internal and external factors together, organizations can come up with better sustainability strategies. In addition, the results may be used by the policymakers, regulators and industry associations to develop target guidelines and frameworks for sustainability of the sector.

E. Rationale of the Study

The environmental responsibility of the pharma industry is as essential as its role in health care. If not, properly managed pharmaceutical waste could have a serious impact on the environment. At the same time, stricter environmental regulations are being enforced around the world, while technology offers brains for efficiency. It is necessary to look at the internal improvement initiatives and how they work with the external compliance pressure. This research is timely and important. Through this research, it might unfold any theoretical gaps and assist the industry practices with a view to achieving a more sustainable and responsible ecosystem for pharmaceutical manufacturing.

II. LITERATURE REVIEW

➢ *Lean Manufacturing in Pharmaceutical Industry*

Lean Manufacturing (LM) aims to systematically eliminate waste and streamline the production process in the manufacturing industry without compromising on quality. The article examines literature relevant to the application of Lean practices in pharmaceutical manufacturing. In the pharmaceutical manufacturing environment where regulatory requirements are stringent, Lean practices have proved to be useful in improving operational efficiencies reducing material wastage, and enhancing [6]. Techniques like Just-in-Time (JIT), 5S, Kaizen have been successful in curtailing production waste.

➢ *Industry 4.0 Technologies and Sustainable Operations*

Industry 4.0 is where the Internet of Things, Big Data, AI, and automated machines transform production and manufacturing operations in smart factories. Using these technologies together will ensure real-time monitoring, predictive maintenance, and data-driven decision-making that support Lean initiatives [2]. Although Industry 4.0 can help firms be sustainable, its adoption in pharmaceutical settings remains hampered by high adoption costs as well as regulatory adaptation [7].

➢ *Employee Engagement and Training*

Employee engagement and structured training are critical to the successful deployment of Lean and Industry 4.0 initiatives. Engaged employees contribute proactively to continuous improvement and sustainable practices [3]. Studies indicate that organizations investing in employee empowerment and technical training witness higher rates of successful digital transformation and waste reduction [8].

➢ *Economic and Environmental Sustainability*

Economic viability and environmental stewardship are increasingly recognized as complementary goals in pharmaceutical manufacturing. Waste reduction projects are not only very economical, but they also reduce carbon emissions and chemical pollution [9]. Adopting Lean 4.0 practices improves economic and environmental performance, achieving the Triple Bottom Line goals.

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➢ *Regulatory Compliance as an External Driver*

Regulatory compliance, particularly adherence to Good Manufacturing Practices (GMP) and environmental regulations, is a crucial external force influencing sustainability strategies. Compliance requirements compel pharmaceutical manufacturers to innovate waste reduction methods while maintaining product safety and quality [4]. Institutional Theory suggests that regulatory pressures legitimize and drive organizational transformation toward sustainable practices [10].

➢ *Theoretical Foundations*

This study is anchored in multiple theoretical frameworks:

- **Resource-Based View (RBV)**: Firms can leverage internal resources, such as Lean capabilities and digital infrastructure, to gain sustainable advantages [11].
- **Dynamic Capabilities Theory**: Firms must continuously adapt and reconfigure their resources to respond to environmental and technological shifts [12].
- **Technology Acceptance Model (TAM)**: Successful adoption of Industry 4.0 technologies depends on perceived usefulness and ease of use [13].
- **Institutional Theory**: Regulatory and societal pressures shape organizational practices toward sustainability [14].
- **Stakeholder Theory**: Engaging multiple stakeholders, including employees and regulatory bodies, enhances sustainable waste management [15].
- **Triple Bottom Line (TBL)** and **Environmental Kuznets Curve (EKC)** models underscore the necessity of balancing economic, environmental, and social goals during growth phases.

➢ *Research Gap*

While a good deal of research has explored separate aspects of reducing waste sustainably, great gaps still exist. Earlier studies concentrated on internal operational initiatives like Lean Manufacturing and Industry 4.0 adoption or external forces like regulatory compliance. Very rarely did they study the combined effect of internal and external drivers driving global operations. This piecemeal approach restricts an integrated understanding of waste management.

In addition, aside from waste reduction, despite Lean Manufacturing's vast academic literature, there is limited empirical evidence of the integration of the emerging Industry 4.0 technologies with Lean Manufacturing in pharmaceutical manufacturing, a highly regulated and quality-oriented sector [16].

Third, while Employee Engagement is regarded highly for sustainability initiatives, there is little empirical evidence regarding its impact on measurable waste reduction results, especially in more highly regulated areas [3].

The research on sustainability points a lot of parameters towards environmental performance in general. However, most of that research overlooks one aspect. That is the distinct operational mechanism. That mechanism is through which regulatory and economic pressures affect waste reduction practices [17].

A handful of studies have constructed integrated models to simultaneously test the internal initiatives (process innovations) and external forces (regulatory, environmental, economic pressures) to predict sustainable waste reduction outcomes.

This study proposes an integrated model of Lean Manufacturing Practices, Industry 4.0 Integration, Employee Engagement, Economic and Environmental Impacts, and Regulatory Compliance to assess the collective and individual impacts of this model on Sustainable Waste Reduction in the pharmaceutical manufacturing industry to fill these gaps. By addressing the identified gaps, the current study intends to provide both theoretical and practical insights to achieve sustainability for heavily regulated sectors.

III. DEVELOPMENT OF HYPOTHESES

The conceptual framework of this study integrates both internal initiatives and external forces to explore their impact on sustainable waste reduction in the pharmaceutical manufacturing sector. Guided by prior research and theoretical models, the following hypotheses are developed:

➢ *Lean Manufacturing and Sustainable Waste Reduction*

Lean Manufacturing removes waste from the system to increase efficiency and utilization of resources [1]. Lean practices help in waste generation and improving the processes in the pharma sector to make production more sustainable. Whenever organizations adopt Lean Manufacturing principles, they are expected to see a significant improvement in waste reduction outcomes.

- ***H1:*** *Lean Manufacturing positively influences Sustainable Waste Reduction.*

➢ *Industry 4.0 and Sustainable Waste Reduction*

Industry 4.0 technologies, such as the Internet of Things (IoT), Big Data analytics, and automation, enable real-time monitoring, predictive maintenance, and optimized decision-making [18]. These technologies enhance operational transparency, improve process efficiencies, and minimize waste throughout the production cycle. Hence, the adoption of Industry 4.0 technologies is anticipated to positively influence sustainable waste reduction initiatives.

- ***H2:*** *Industry 4.0 positively influences Sustainable Waste Reduction.*

➢ *Employee Engagement and Sustainable Waste Reduction*

Employee Engagement plays a pivotal role in achieving Sustainable Waste Reduction within manufacturing organizations. Engaged employees are more likely to be proactive in identifying opportunities for minimizing waste, implementing best practices, and promoting a culture of sustainability [3]. When employees at all organizational levels are trained, motivated, and empowered, they contribute

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actively to environmental initiatives, such as efficient resource utilization, waste segregation, and recycling programs. Employee-led continuous improvement activities, such as Kaizen events and suggestion systems, often lead to innovative solutions for waste reduction that management alone might overlook. Furthermore, fostering a sense of ownership and responsibility among employees encourages consistent adherence to sustainability goals. In the pharmaceutical industry, where precision and regulatory compliance are critical, well-engaged employees can bridge the gap between operational excellence and environmental stewardship. Therefore, strong Employee Engagement mechanisms are vital for embedding sustainable waste management practices into daily operations and long-term strategic planning [8].

- ***H3:*** *Employee Engagement and Training positively influence Sustainable Waste Reduction.*

➢ *Regulatory Compliance and Sustainable Waste Reduction*

Due to regulatory compliance, pharmaceutical manufacturers face stringent environmental and operational requirements [4]. Following these rules will help companies adopt best waste management practices, resource optimizing strategies and pollution controlling techniques. As a result, regulatory pressure is a big incentive for sustainable waste reduction.

- ***H4:*** *Regulatory Compliance positively influences Sustainable Waste Reduction.*

➢ *Economic and Environmental Impact and Sustainable Waste Reduction*

The alignment of incentives and sustainability motivated the firms to invest in waste reduction practices. Improving process efficiencies and reducing material waste helps bring down the cost and boost the reputation of the business [5]. Companies that see the long financial benefits and the environmental benefits are more likely to committed to initiatives for sustainability.

- ***H5:*** *Economic and Environmental Impact positively influence Sustainable Waste Reduction.*

➢ *Conceptual Framework*

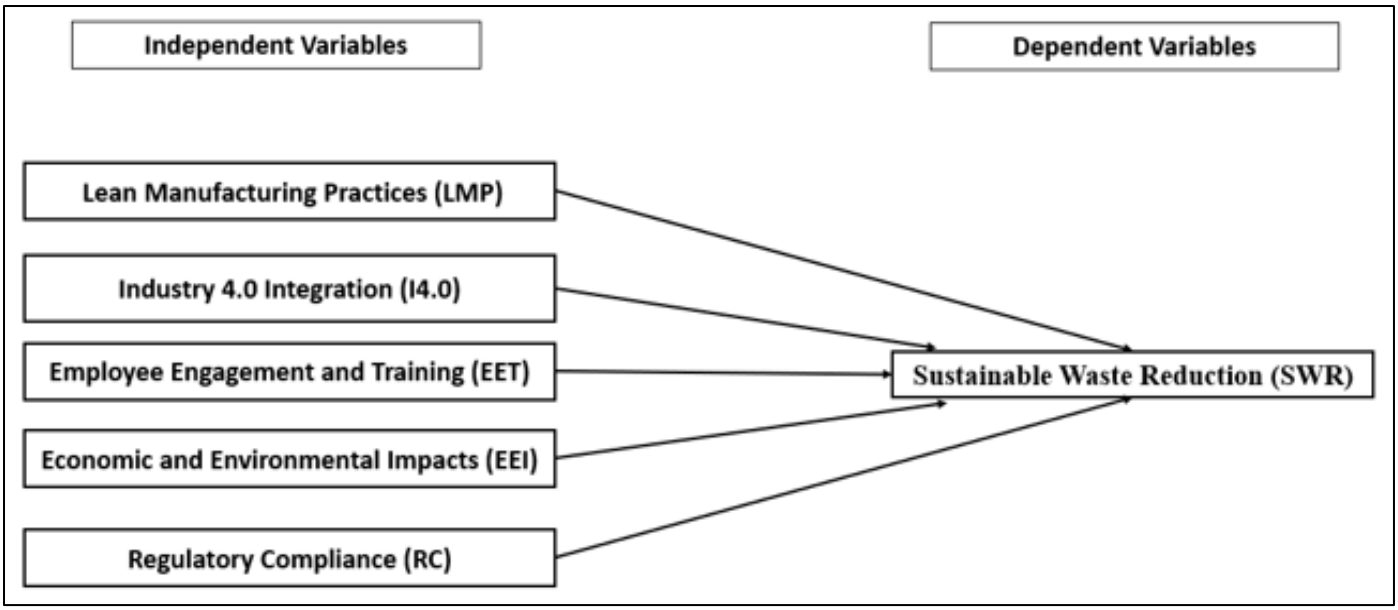

Fig 1 Conceptual Framework

IV. METHODOLOGY

This study aims to investigate the relationships between Lean Manufacturing (LM), Industry 4.0 (I4.0) technologies, Employee Engagement (EE), Regulatory Compliance (RC), and Economic and Environmental Impacts (EEI) toward Sustainable Waste Reduction (SWR) in pharmaceutical manufacturing. A quantitative research approach was employed, utilizing a structured survey to assess the influence of these internal and external factors.

A. Research Philosophy

The study adopts a positivist philosophy, emphasizing objective, quantifiable data collection and analysis. This approach aligns with the hypothesis-testing nature of the research and supports empirical validation through structured surveys and statistical methods.

B. Research Paradigm

A quantitative research paradigm was adopted, focusing on the collection of numerical data to test hypotheses. Statistical methods were employed to analyze the relationships among internal initiatives and external forces influencing sustainable waste reduction.

C. Research Approach

A deductive research approach guided the study. Hypotheses were developed based on existing theories, such as Lean Manufacturing and Industry 4.0 frameworks, and

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were empirically tested using survey data collected from pharmaceutical industry professionals.

D. Research Strategy

The research employed a survey-based strategy, targeting professionals involved in pharmaceutical manufacturing operations. Surveys were chosen for their efficiency in gathering large-scale data necessary for hypothesis testing and generalizability.

E. Research Choice

A mono-method quantitative design was used. A structured questionnaire served as the primary data collection instrument, facilitating systematic measurement of the study variables derived from the literature.

F. Time Horizon

A cross-sectional time horizon was adopted. Data were collected at a single point in time to provide a snapshot of sustainable waste reduction practices and the roles of internal and external factors influencing them.

G. Research Techniques and Procedures

Structured questionnaires were distributed online to professionals in the pharmaceutical industry. The survey measured the study constructs using established scales adapted from validated studies, with responses captured using a five-point Likert scale (1 = Strongly Disagree to 5 = Strongly Agree).

H. Data Collection Method

➢ *Measurement Instrument*

The questionnaire was structured into two sections:

- **Section 1:** Demographic information (role, experience, company size).
- **Section 2:** Measurement of variables, with five items each for:

✓ Lean Manufacturing Practices (LMP)
✓ Industry 4.0 Integration (I4.0)
✓ Employee Engagement and Training (EET)
✓ Economic and Environmental Impact (EEI)
✓ Regulatory Compliance (RC)
✓ Sustainable Waste Reduction (SWR)

Table 1 Variables with Items

Variable	Items
Lean Manufacturing Practices (LMP)	5
Industry 4.0 Integration (I4.0)	5
Employee Engagement (EET)	5
Economic and Environmental Impacts (EEI)	5
Regulatory Compliance (RC)	5
Sustainable Waste Reduction (SWR)	5

➢ *Data Collection Process*

Out of 500 distributed questionnaires, 350 valid responses were collected, yielding a strong response rate consistent with prior research standards. Snowball sampling was used, leveraging professional networks to reach specialized participants.

I. Population, Sampling Design, and Unit of Analysis

The study population consisted of pharmaceutical professionals engaged in waste reduction, regulatory compliance, and sustainability initiatives. A **snowball sampling technique** was utilized, and the **unit of analysis** was the individual respondent.

J. Demographic Information

Demographic data collected included respondent roles, years of experience, and organization type and size. This allowed for assessment of sample representativeness and further analysis of subgroup trends.

K. Pretest Study

A pretest was conducted with 20 participants to ensure clarity, relevance, and reliability of the questionnaire. Feedback from the pretest led to minor refinements, ensuring the final instrument was appropriate for full-scale deployment.

L. Data Analysis

Descriptive statistics summarized the sample characteristics. Inferential statistics, particularly regression analysis using SPSS and SmartPLS 4, were used to test the hypotheses and determine the relationships among Lean Manufacturing, Industry 4.0, Employee Engagement, Regulatory Compliance, Economic and Environmental Impacts, and Sustainable Waste Reduction.

M. Ethical Considerations

Ethical principles guided all stages of the research. Participants were informed about the study's objectives and participated voluntarily. Anonymity and confidentiality of responses were strictly maintained in compliance with academic research ethics standards.

V. RESULTS

A. Demographic Analysis of Survey Respondents

Table 1 summarizes the demographic data of the 350 respondents. Most of the respondents fell in the age group of 25–30 years (65.4%). Thus, the pharmaceutical industry workforce participating in sustainability initiatives is relatively young. A total of 61.1% of the respondents were female while 38.9% was male. Most participants have postgraduate qualifications (47.1%) and graduates (45.7%) according to educational qualifications. Almost half of the

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respondents were operational level (46.9%) and mid-level (45.1%) managers with a small section (8%) having top management. The vital section having 10–12 years' work experience (41.4%) shows there is a group of matured professionals engaged in waste management.

Table 2 Demographic Profile of Respondents

Demographic Variable	Categories	Frequency (N)	Percentage (%)
Age	25-30 Years	229	65.4
	31-35 Years	46	13.1
	36-40 Years	31	8.9
	41-45 Years	12	3.4
	46-50 Years	12	3.4
	Above 50 Years	20	5.7
Gender	Male	136	38.9
	Female	214	61.1
Educational Level	Graduation	160	45.7
	Post-Graduation	165	47.1
	Post-Graduation with other degrees	25	7.1
Job Title/Position	Mid-Level	158	45.1
	Operational Level	164	46.9
	Top Level	28	8.0
Years of Experience	1-3 Years	59	16.9
	4-6 Years	36	10.3
	7-9 Years	110	31.4
	10-12 Years	145	41.4
	12 Years and Above	59	16.9

B. Measurement Model

A measurement model is a conceptual and statistical abstraction which describes the relationship between a latent construct and its measured variables [1]. The measurement model aims to quantify and validate the measurement of a concept or attribute that cannot be directly observed. The model's analysis was undertaken using two essential items; that is convergent validity and discriminant validity.

➢ *Convergent Validity*

Convergent validity shows how well something is measured by different indicators. Convergent validity is determined by the item loadings, the Cronbach's Alpha (CA), the Composite Reliability (CR) and the Average Variance Extracted (AVE) in PLS-SEM [19]. As can be seen in Table 3, the item loadings of the current study were between 0.599 and 0.881 as all of them were greater than the threshold of 0.60 which shows a high correlation between the item indicators and their respective construct. For example, Lean manufacturing practices 1 (LMP1) had the highest loading i.e. 0.855 and LMP5 had the lowest i.e. 0.599, however, it was still acceptable. The internal consistency was measured using Cronbach's Alpha and were found in the range of 0.702 to 0.853. And all the constructs have a value that is greater than the benchmark of 0.70.

The composite reliability values are apparently sound as they were well above the 0.70 thresholds. Regulatory Compliance (RC) has the highest CR value (0.889), followed closely by Sustainable Waste Reduction (SWR) at 0.888. Further, all constructs satisfied the AVE criterion. The AVE value of all constructs ranged from 0.519 to 0.638 confirming adequate variance of the indicators of the construct [20]. The findings show a strong convergent validity and indicate that the measurement model validates the link between lean manufacturing with industry 4.0, employee engagement, economic & environmental impact, regulatory compliance, and waste reduction sustainability.

Table 3 Convergent Validity and Reliability

Construct	Items	Loading Value	Cronbach's Alpha	Composite Reliability (RHO_A)	Composite Reliability (RHO_C)	Average Variance Extracted (Ave)
Lean Manufacturing Practices (LMP)	LMP1	0.855	0.766	0.776	0.842	0.519
	LMP2	0.749				
	LMP3	0.707				
	LMP4	0.668				
	LMP5	0.599				
Industry 4.0 Integration (I4.0)	I4.0_1	0.881	0.853	0.861	0.898	0.638
	I4.0_2	0.858				
	I4.0_3	0.796				
	I4.0_4	0.774				

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	I4.0_5	0.682				
Employee Engagement & Training (EET)	EET1	0.832	0.829	0.835	0.879	0.593
	EET2	0.772				
	EET3	0.765				
	EET4	0.752				
	EET5	0.729				
Economic & Environmental Impacts (EEI)	EEI1	0.808	0.799	0.822	0.861	0.555
	EEI2	0.777				
	EEI3	0.775				
	EEI4	0.745				
	EEI5	0.609				
Regulatory Compliance (RC)	RC1	0.844	0.843	0.857	0.889	0.618
	RC2	0.830				
	RC3	0.795				
	RC4	0.766				
	RC5	0.687				
Sustainable Waste Reduction (SWR)	SWR1	0.860	0.840	0.844	0.888	0.615
	SWR2	0.835				
	SWR3	0.810				
	SWR4	0.710				
	SWR5	0.696				

➢ *Discriminant Validity*

Ensuring that a model's constructs are distinct from each other is known as discriminant validity. Discriminant validity yield results that do not correlate with other constructs [19]. This study used the Fornell-Larcker Criterion and Heterotrait-Monotrait Ratio (HTMT) to achieve discriminant validity.

- *Fornell-Larcker Criterion*

According to the Fornell-Larcker Criterion [20], the square root of a construct's Average Variance Extracted (AVE) should be greater than its correlation with any other construct. This means a construct shares more variance with its indicators than with other constructs.

Table 4 Fornell-Larcker Criterion

	EEI	**EET**	**I4.0**	**LMP**	**RC**	**SWR**
EEI	0.745					
EET	0.766	0.77				
I4.0	0.67	0.767	0.799			
LMP	0.674	0.63	0.712	0.721		
RC	0.766	0.731	0.716	0.677	0.786	
SWR	0.758	0.722	0.673	0.678	0.778	0.784

As demonstrated in Table 4, for each construct, the square root of the AVE is higher than their correlation with other variables. This shows that the constructs are different from one another. The AVE for Sustainable Waste Reduction (SWR) is 0.784, which is greater than the correlation with Lean Manufacturing Practices (LMP) is 0.678. Similarly, the correlation with Industry 4.0 Integration (I4.0) is 0.673. This demonstrates an acceptable discriminant validity.

- *Heterotrait-Monotrait (HTMT) Ratio*

A method to evaluate discriminant validity is the HTMT ratio. It examines the correlation between different constructs. The presence of HTMT value less than .85 is strong evidence of distinctness of constructs [21].

Table 5 HTMT (Heterotrait-Monotrait Ratio)

	EEI	**EET**	**I4.0**	**LMP**	**RC**	**SWR**
EEI						
EET	0.854					
I4.0	0.806	0.823				
LMP	0.838	0.801	0.843			
RC	0.861	0.836	0.824	0.837		
SWR	0.806	0.756	0.715	0.846	0.863	

The HTMT results (Table 5) confirm that all constructs meet this criterion, with values ranging from 0.720 to 0.863. The highest HTMT value was found between Regulatory Compliance (RC) and Sustainable Waste Reduction (SWR) (0.863), though still within the acceptable threshold. Other values, such as Lean Manufacturing Practices (LMP) and

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Employee Engagement & Training (EET) (0.801), also demonstrate that the constructs are not excessively correlated, affirming discriminant validity.

Both Fornell-Larcker Criterion and HTMT analysis confirm that the constructs in this study are distinct from one another. The findings indicate that Lean Manufacturing Practices, Industry 4.0 Integration, Employee Engagement & Training, Economic & Environmental Impacts, Regulatory Compliance, and Sustainable Waste Reduction measure unique and independent aspects of the research model. Thus, discriminant validity is established, supporting the robustness of the measurement model.

C. Structural Model

Structural models show how to relate to other constructs that have been derived from estimating a series of regression equations [2]. The purpose of this structural model is to provide an estimation of the relationship between the independent variables (Lean Manufacturing Practices, Industry 4.0 Integration, Employee Engagement & Training, Economic & Environmental Impacts & Regulatory Compliance) on dependent variable Sustainable Waste Reduction. The analysis was conducted using Partial Least Squares Structural Equation Modeling (PLS-SEM) to estimate the direct relationship between these variables and the model's predictive power.

The model was assessed using the path coefficients (β), standard deviation, t-values, p-values, and the R^2 value. The path coefficients show how strong the hypothesized relationships are and whether they go in the right or wrong direction. The t-values and p-values show how reliable the paths are, which means at what level we need to reject the effect. A level of $p < 0.05$ is usually considered to be significant. R^2 value showed how well independent variables explained the dependent variable while f^2 values highlighted effect values of independent variables on the dependent variable in the study model.

➢ *Path Analysis*

The researchers tested the proposed relationships using path coefficients, t-values, and p-values for significance. As shown in Table 6, the most important predictor is Regulatory Compliance (RC) which is significantly connected to SWR ($\beta = 0.483$, $p < 0.01$). It was found that Lean Manufacturing Practices (LMP) and SWR are statistically significant ($\beta = 0.189$, $p = 0.007$) showing Lean practices contribute towards sustainable waste reduction.

The study results showed that Industry 4.0 Integration (I4.0) impacts SWR significantly ($\beta = 0.132$, $p = 0.01$). Likewise, Economic & Environmental Impacts (EEI) ($\beta = 0.141$, $p = 0.005$) also impacts SWR positively and significantly. On the other hand, Employee Engagement & Training (EET) has an insignificant effect on SWR ($\beta = -0.002$, $p = 0.969$). Hence, only employee engagement would not bring sustainable waste reduction – there should be a more comprehensive framework.

Table 6 Path Analysis

Hypothesis	*Path*	*β*	*Standard Deviation*	*t-value*	*p-value*	*Decision*
H1	LMP → SWR	0.189	0.069	2.695	0.007	Significant ($p < 0.05$)
H2	I4.0 → SWR	0.132	0.051	2.593	0.01	Significant ($p < 0.05$)
H3	EET → SWR	-0.002	0.053	0.039	0.969	Not Significant ($p > 0.05$)
H4	EEI → SWR	0.141	0.051	2.783	0.005	Significant ($p < 0.05$)
H5	RC → SWR	0.483	0.067	7.229	0.0002	Highly Significant ($p < 0.01$)

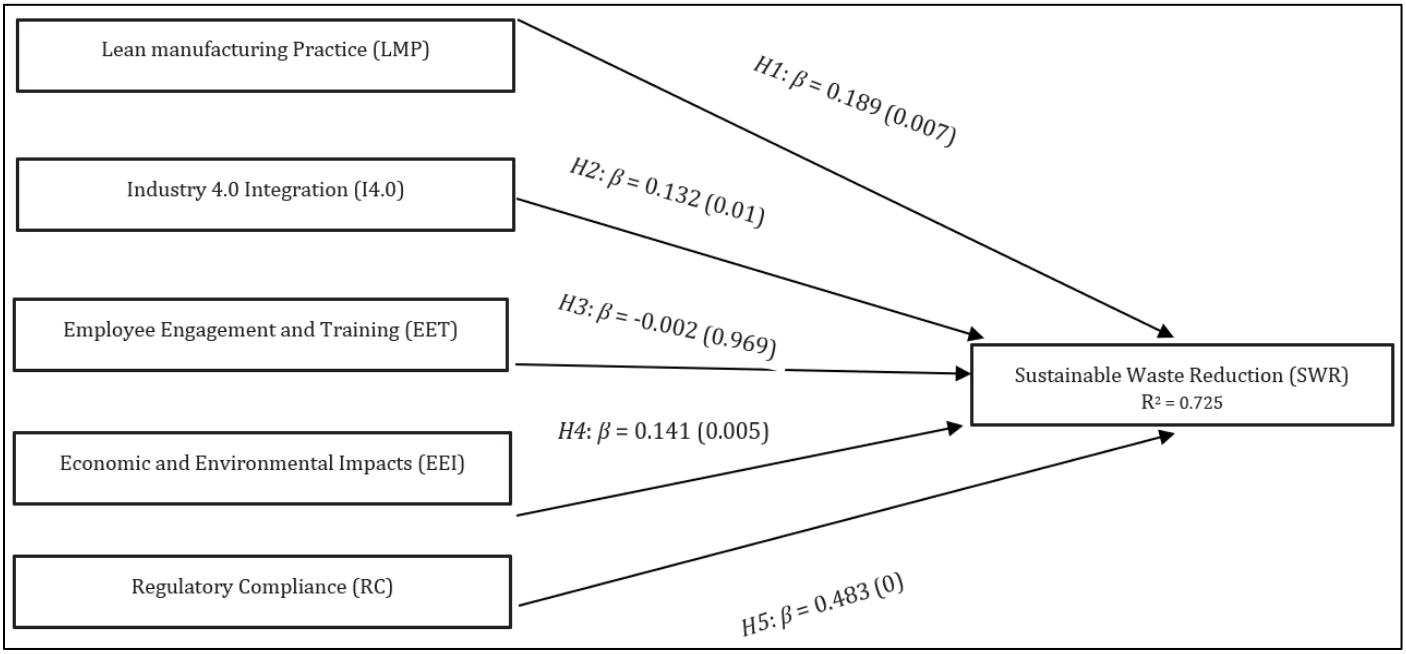

Fig 2 Result of Path Coefficient with p-value

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➢ *Model Fit and Predictive Power*

The R^2 value estimates the amount of variance in the SWR explained by independent variables. From Table 7 we can see R^2 for SWR is 0.725 which further means that 72.5 % variance in sustainable waste reduction is explained by LMP, I4.0, EET, EEI, and RC. This indicates that the model can explain the sustainable waste reduction in the pharmaceutical sector quite well.

The impact of different predictors was examined through effect size (f^2) values. The effect size (f^2) of Regulatory Compliance (RC) was found to be largest (0.277, moderate effect), while Economic & Environmental Impacts (EEI) (0.038) and Lean Manufacturing Practices (LMP) (0.03) had small effects on SWR. Employee Engagement & Training (EET) had no effect (0.00) on SWR and I4.0 had a very small effect (0.018) which means no direct influence**.**

Table 7 r^2 and f^2 Value

	R^2	F^2	DECISION
SWR	0.725		
EEI		0.038	Small effect
EET		0	No effect
I4.0		0.018	Very small effect
LMP		0.03	Small effect
RC		0.277	Moderate effect

VI. DISCUSSION

This study explored the impact of Lean Manufacturing Practices, Industry 4.0 Integration, Employee Engagement and Training, Economic and Environmental Impacts, and Regulatory Compliance on Sustainable Waste Reduction within the pharmaceutical manufacturing sector.

The findings provide critical insights into how internal process optimization and external regulatory pressures shape waste management and sustainability practices.

➢ *Influence of Lean Manufacturing Practices on Sustainable Waste Reduction*

The findings revealed that Lean manufacturing practices have a positive and significant effect on Sustainable waste reduction ($\beta = 0.189$, $p < 0.01$).

This indicates the importance of the lean philosophy of manufacturing where waste is minimized, improvement takes place constantly and customer value is created through systems that remove waste.

- **Discussion:** In the field of pharmaceutical manufacturing, waste reduction can take place using some very important lean tools like value stream mapping, just-in-time, process standardization, etc to reduce material waste, reduce defect rates, and optimize inventory levels. This finding shows that Lean practices can result in environmental and operational efficiencies, as previous research found.
- **Implication:** To enhance sustainability, organizations must significantly incorporate Lean into their manufacturing and operational processes.

➢ *Influence of Industry 4.0 Integration on Sustainable Waste Reduction*

Lean manufacturing practices positively and significantly influence sustainable waste reduction ($\beta = 0.197$, $p < 0.01$). This means that the application of lean manufacturing practices in an industry will have a positive effect on sustainable waste reduction.

- **Discussion:** According to the Discussion, the application of Industry 4.0 technologies such as IoT, Big Data analytics, automation and smart manufacturing for real-time monitoring, predictive analysis and automation of corrective measures creates less waste. The effect size was "very small" ($f^2 = 0.018$), but significant, indicating that emerging digital technologies may be starting to play a role in promoting environmental sustainability.
- **Implication:** But for the advantages of Industry 4.0 to be realized fully and more broadly, a wider adoption and integration across various manufacturing processes would be required. Of sorts, pharmaceutical companies are at an earlier stage of their digital transformation for sustainability purposes.

➢ *Influence of Employee Engagement and Training on Sustainable Waste Reduction*

Contrary to expectations, Employee Engagement and Training was found to have no significant influence on Sustainable Waste Reduction ($\beta = -0.002$, $p > 0.05$).

- **Discussion:** This unexpected finding indicates that although employees may be aware of sustainability initiatives, their individual engagement alone may not directly translate into measurable waste reduction outcomes without structural, system-wide interventions. It suggests that unless employee initiatives are linked with strategic operational goals, employee-driven efforts may lack the power to drive tangible environmental improvements.
- **Comparison to Literature:** While earlier studies have emphasized employee empowerment and participation as essential for sustainable outcomes, this study suggests that in highly regulated sectors like pharmaceuticals, top-down process controls and regulatory compliance may overshadow the impact of bottom-up initiatives.
- **Implication:** Organizations may need to integrate employee engagement with formal process innovations and compliance systems rather than relying solely on motivational efforts.

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➢ *Influence of Economic and Environmental Impacts on Sustainable Waste Reduction*

Economic and Environmental Impacts were found to have a significant positive effect on Sustainable Waste Reduction ($\beta = 0.141$, $p < 0.01$).

- **Discussion:** This finding supports the premise that economic incentives and environmental responsibility are not mutually exclusive. Cost savings achieved through efficient waste management, energy reduction, and resource optimization align closely with corporate environmental stewardship goals, leading firms to adopt sustainable practices not just as a compliance requirement but as a strategic advantage.
- **Implication:** The dual pursuit of financial and environmental performance enhances the likelihood that firms will actively engage in waste reduction practices, aligning business competitiveness with sustainability.

➢ *Influence of Regulatory Compliance on Sustainable Waste Reduction*

Regulatory Compliance emerged as the most influential predictor of Sustainable Waste Reduction ($\beta = 0.483$, $p < 0.001$), with a moderate effect size ($f^2 = 0.277$).

- **Discussion:** In producing medicine, there are so many regulations in place that they must meet the environmental regulations.
- The powerful impact of Regulatory Compliance indicates how much organizations are forced to adopt and maintain sustainable practices owing to external institutional pressures. This relates especially to waste management and the environment.
- **Comparison to Literature:** This finding conforms with the theory of 'institutional isomorphism' in which firms engage in compliance towards rules and regulations not just for achieving efficiency but for the sake of legitimacy and survival in an industry that is regulated.
- **Implication:** Firms must maintain proactive regulatory monitoring systems, foster internal audit mechanisms, and embed regulatory standards deeply into their operational frameworks to drive sustainable waste management outcomes.

➢ *Model Strength and Predictive Power*

The overall model explained 72.5% ($R^2 = 0.725$) of the variance in Sustainable Waste Reduction, indicating strong predictive ability.

- **Discussion:** This high R^2 value suggests that the selected constructs collectively provide a comprehensive framework for understanding sustainable waste reduction practices in pharmaceutical manufacturing. Among all variables, Regulatory Compliance had the most substantial individual effect, while Lean Manufacturing Practices and Economic and Environmental Impacts also contributed meaningfully. Industry 4.0 showed a positive but relatively smaller impact, highlighting an area for future enhancement as digital transformation matures.

VII. CONCLUSION

The study examined the relationship between Lean Manufacturing Practices, Industry 4.0 Integration, Employee Engagement and Training and Impact on Environment and Regulation to Sustainable Waste Reduction in the pharmaceutical manufacturing industry. The results provide valuable information on the strategic and operational factors affecting sustainability actions within a highly regulated context.

Study findings show that Lean manufacturing practices, integration of industries 4.0, economic and environmental impact and regulation compliance positively and significantly impact sustainable waste reduction. Of these, Regulatory Compliance was the most important driver. This indicates that external regulatory pressure has a large influence on sustainable pharmaceutical operations.

Lean Manufacturing Practices along with Economic and Environmental Impact considerations have also proven to be important enablers of sustainability initiatives, as they improve process efficiency and are aligned to economic and environmental goals. On the other hand, Employee Engagement and Training did not have a major impact on waste reduction.

The unforeseen outcome indicates that employee engagement should be integrated more strategically with management systems for sustainability, rather than being seen as stand-alone initiatives.

The independent variables explained 72.5% of the Sustainable Waste Reduction model, according to the strength of the research model. This strong model shows that internal operational strategies with external compliance imperatives can help ensure sustainable manufacturing processes.

➢ *Theoretical Contributions*

This study enriches the body of knowledge on sustainable manufacturing by integrating operational excellence practices (Lean Manufacturing, Industry 4.0) and regulatory compliance factors into a unified model.

The findings affirm institutional and resource-based theories suggest that both internal capabilities and external pressures shape sustainable organizational outcomes.

Moreover, by revealing the non-significant effect of Employee Engagement when disconnected from structured systems, this research contributes a nuanced perspective that challenges simplistic assumptions regarding workforce involvement in sustainability.

➢ *Practical Implications*

For practitioners and policymakers, the findings suggest that successful waste reduction strategies must prioritize:

- Strong adherence to environmental regulations,
- Systematic adoption of Lean practices,

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- Integration of emerging digital technologies (Industry 4.0),
- Alignment of sustainability initiatives with economic benefits.
- Organizations should ensure that employee engagement efforts are supported by clear operational goals and tangible process changes to maximize their impact on sustainability outcomes.

VIII. LIMITATIONS AND FUTURE RESEARCH DIRECTIONS

➢ *While the Study Offers valuable insights, certain Limitations should be Acknowledged:*

- *Cross-Sectional Design:*

The research was conducted at a single point in time, limiting the ability to assess long-term sustainability outcomes.

- *Geographical Scope:*

The sample was limited to professionals within a specific region or sector, which may affect the generalizability of the findings to broader contexts.

- *Measurement of Employee Engagement:*

Employee Engagement was treated as a broad construct. Future research could refine the measurement by distinguishing between different types of engagement (e.g., behavioral vs emotional).

- *Dynamic Technology Adoption:*

Given the fast evolution of Industry 4.0 technologies, longitudinal studies are recommended to capture the gradual impact of digital transformation on sustainable manufacturing.

Further research can find moderating factors that influence the relation such as organizational culture, leadership support or technical readiness.

To sum up, sustainable waste reduction in pharmaceutical manufacturing can get achieved through harmonized internal improvements and external compliance efforts.

Companies are likely to achieve better sustainability outcomes by aligning their waste management programs with lean, technology, environmental and compliance programs.

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The research “The Role of Internal Initiatives and External Forces for Sustainable Waste Reduction in the Pharmaceutical Industry” study Lean Manufacturing Industry 4.0 Employee Engagement Economic and Environmental Implications Regulatory Compliance to save the manufacturing of Pharmaceutical waste on sustainability. This study aims to enrich academia and industry with additional literature on prevention science.

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