BARRIERS IN ADOPTION OF PHARMA 4.0: AN AHP AND FUZZY AHP APPROACH FOR IDENTIFICATION OF CRITICAL BARRIERS

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CANDIDATE'S DECLARATION

I Aman Maan (2K22/IEM/02) hereby certify that the work which is being presented in the thesis entitled "**Barriers in adoption of Pharma 4.0 : An AHP and Fuzzy AHP approach for identification of critical Barriers**" in partial fulfilment of the requirements for the award of the Degree of Master of Technology, submitted in the Department of Mechanical Engineering , Delhi Technological University is an authentic record of my own work carried out during the period from January, 2024 to May 2024 under the supervision of Dr. N. Yuvaraj & Dr. Mohd. Suhaib.

The matter presented in the thesis has not been submitted by me for the award of any other degree of this or any other Institute.

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Certified that Aman Maan (2K22/IEM/02) has carried out his search work presented in this thesis entitled "**Barriers in adoption of Pharma 4.0: An AHP and Fuzzy AHP approach for identification of critical Barriers**" for the award of Master of Technology from Department of Mechanical Engineering, Delhi Technological University, Delhi, under our supervision. The thesis embodies results of original work, and studies are carried out by the student himself and the contents of the thesis do not form the basis for the award of any other degree to the candidate or to anybody else from this or any other University/Institution.

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Barriers in adoption of Pharma 4.0: An Analytic Hierarchy Process approach for identification of critical Barriers

Aman Maan

ABSTRACT

The pharmaceutical industry is under major transformation driven by the Industry4.0 technologies. This concept of adoption tools and technologies is known as Pharma 4.0. It aims in the revolution of development of medicines, manufacturing of drugs and distribution. It is achieved with the implementation of sensors, data analytic landscape, Robotics, Blockchain and many other Ind 4.0 technologies. This adoption provides a lot of benefits like reducing costs, quality improvement of medicines, rapid research on new chemical combination and quick responsive supply chain. But this adoption also offers barriers like high initial investments, security of digital data, workforce talent gaps and organizational and managerial regulatory adaptations. Therefore, the pharmaceutical landscape is filled with lot of barriers which needs to be addressed because the traditional methods lack real-time tracking of processes and faced supply chain disruptions. So, identification of critical barriers is necessary because there is ever evolving regulatory landscape of any industry which demands data privacy, efficient processes and security concerns. Thus, identifying critical barriers among various barriers which an industry faces facilitates making adequate strategies for adoption of this concept.

Keywords- Pharma4.0, Industry4.0, Barriers Exploration, MCDM Technique, AHP, FAHP

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List of Abbreviations

Abbreviation	Meaning
AHP	Analytic Hierarchy Process
CI	Consistency Index
CR	Consistency Ratio
FAHP	Fuzzy Analytic Hierarchy Process
GM	Geometric Mean
I4.0	Industry 4.0
MCDM	Multi Criteria Decision Making
P4.0	Pharmaceutical 4.0
RI	Random Index
ROI	Return on Investment

CHAPTER - 1

INTRODUCTION

The pharmaceutical sector is poised of significant transformation because of the unique requirement of the pharmaceutical industries operations. The concept of convergence is known as Pharma 4.0. It aims to revolutionize pharmaceutical processes and supply chain through advanced technologies like AI, ML, Robotics, IoT and blockchain Ingrid et al. (2020). The pharmaceutical industry constantly seeking innovation and efficiency as most of its operations are performed in complex and dynamic environment. They constantly seek innovation and efficiency Khan M et al. (2020).

I4.0 marks a radical shift in manufacturing driven by the merge of physical world with digital universe. This revolution hinges on a set of core technologies, revolutionizing production and logistics within the pharmaceutical industry N. Sarah Arden et al. (2021). A transformative wave surges through the pharmaceutical industry, propelled by the potent fusion of Industry 4.0 and its pharma-centric extension. This revolution reimagines the entire drug journey, from the lab bench to the bedside Bharti et al. (2021).

Pharma 4.0 isn't just a passing trend; it's a reorchestration of the pharmaceutical landscape. It's about harnessing the power of technology to revolutionize the way we discover, develop, and deliver life-saving medications Shah P et al. (2019). It's about putting patients at the heart of every note, ensuring a harmonious healthcare future. And in this exciting transformation, the melody of a healthier world echoes ever stronger Wachter & Yu, (2018).

Within the industry, a cultural transformation is at the forefront because data now become the new language for free flow of information Kwon et al. (2019). Replacing rigid hierarchies with agile decision-making, talent undergoes a rebirth because of acquiring skills to gain the ability to use the data. A strong technological infrastructure serves as the platform for pharma4.0 adoption Glaser (2020). That is why, addressing barriers in its adoption is critical to study. The outside world has its own tune as regulations require strict considerations of data security and privacy which offers a complicated move in adoption. An adaptability to rotate the conditions so as to meet the unforeseen obstacles is required Langer & Bolon (2021). Now, the orchestra of technology enters the scene:

- **AI:** The virtuoso, streamlining drug discovery, optimizing clinical trials, and composing personalized melodies of medicine for each patient Char et al. (2019).
- **IoT:** The conductor's assistant, weaving a web of interconnected devices that gather real-time data, allowing for process optimization and remote monitoring Bhattacharya & Sahu (2018).
- **Blockchain:** The security maestro, building trust and combating counterfeiting through complete supply chain transparency Yu J et al. (2020).
- **Big data and analytics:** The data whisperers, unlocking hidden insights to guide smarter decisions and mitigate risks before they crescendo Tang P et al. (2017).
- **Digital twins:** The virtual understudies, mimicking physical systems to allow for risk-free simulations and optimization, maximizing efficiency without a single false note Qi et al. (2018).

The pharmaceutical industry in human capital generally faces major competencies in digital skills of the work force, research skills on new product development, organization regulatory compliance and data ethics Fakhreddin et al. (2022). This work aims to delve into these influencing factors which acts as barriers in adoption within the pharmaceutical realm.

In a study by Frank et al. (2019), the adoption of Ind 4.0 technologies was explored across 92 manufacturing facilities to gain insights. This research introduced a conceptual framework categorizing technologies into front and base technologies. The front-end technologies are Smart development of products while base technologies comprise of big data and analytics.

The findings reveal that base technologies pose barriers with limited adoption of big data and analytics in the examined sample**.** The industry has a keen eagle eye focus on Research & Development because the time it takes to get a drug from lab to market is crucial for success. This lengthy process, encompassing clinical trials and regulatory hurdles, clashes with the limited patent lifespan (20-25 years) that companies hope to maximize.

For instance, in Japan, drug development takes 9-16 years, leaving a tight window for profit within patent protection. The hefty price tag – an average of 1-1.2 billion USD amount of money. This amount includes failed projects as well. This further amplifies the pressure on this race against time JPM Association (2017).

A wave of environmental and ecological discussions has swept across the globe, leaving managers in businesses, governments, and society at large grappling with the uncertainties looming over industries and companies Pourmehdi et al. (2022). Companies are increasingly recognizing the value of product recovery, driven by both cost-efficiency and environmental concerns. This pursuit of supply chain improvement aligns with the United Nations' ambitious goals, further fuelling the drive for innovative solutions Park and Li (2021).

The pharma supply chain is quite complex as drugs moving from raw materials to patients through multiple stages. While this complexity ensures vital medications reach those who need them, it also presents a multitude of challenges Petrillo et al. (2018). Fragmented systems and manual processes hinder real-time tracking of drugs, making it difficult to identify counterfeits, recalls, and potential disruptions. Information is often isolated in individual databases, hindering collaboration and efficient data exchange Glaser (2020).

Globalized supply chains are susceptible to political unrest, trade wars, and natural disasters, leading to shortages and delays. Extreme weather events threaten cold chain integrity and temperature-sensitive drug stability Shah & Singh (2016). The opportunities that are opened on adoption of Pharma 4.0 are secure and transparent data sharing can enhance traceability and combat counterfeiting Kiel et al. (2019).

Thus, it is not about deploying fancy new technology but it is about reshaping the entire operations from conception to delivery of lifesaving medications Khan S. et al. (2020). The regulatory landscape needs careful consideration of data privacy and security by building robust and adaptable supply chains Dolinskaya et al. (2017).

The rewards of Pharma4.0 are bountiful. It unlocks significant cost savings benefiting bottom line and real-time monitoring helps ensuring consistent product quality. The drug discovery in today's world paves the way for personalized medicine and predictive analytics supports supply chains becoming agile and resilient Kannan et al. (2012).

- AI takes centre stage, from streamlining drug discovery and clinical trials to tailoring treatments to individual patients Wachter et al. (2018).
- Blockchain builds trust and battles counterfeiting by ensuring complete transparency and traceability throughout the supply chain Yu et al. (2020).
- Big data and analytics unleash hidden insights, empowering smarter decisions and risk mitigation Kim et al. (2017).
- Finally, digital twins, virtual replicas of physical systems, allow for simulation and optimization, minimizing real-world risks and maximizing efficiency Qi et al. (2018).

But challenges lurk on this path. Significant amount of upfront investment is a barrier for smaller companies and protecting sensitive data becomes paramount in this hyper-connected environment.

- Bridging talent gap through upskilling and reskilling requires resources.

- Understanding new technologies are complex and time-consuming process.
- Navigating this terrain demands a spirit of collaboration.
- Shared vision for more efficient and patient-centric pharmaceutical ecosystem.
- Understanding the intricate link between internal and external factors.

1.1 Research Gap

As Pharmaceutical industry is facing numerous barriers in adoption of Ind4.0 technologies. Therefore,

- Identifying barriers in adoption of the technologies
- Ranking of barriers so as to find the critical one among all described barriers.

CHAPTER - 2

LITERATURE REVIEW

2.1 Navigating Pharma 4.0 Barriers

The path towards a smarter Pharma is not without its challenges. Significant upfront investment can be a hurdle for smaller companies. Protecting sensitive data and ensuring cyber-secure systems becomes paramount in this hyper-connected environment. Bridging the talent gap through upskilling and reskilling requires commitment and resources and much more. Let's delve into the potential barriers associated with adopting this paradigm shift:

Table 2.1 Barrier identification and references

S. No.	Barrier	Reference
1.	Deficiency of High Investment	A.B. Bhuiyan et al. (2020)
2.	Increment in unit cost of medicines	K. Zhou et al. (2015)
3.	Malpractice & Lack of Transparency	J.C. Kohler et al. (2016)
4.	Underdeveloped technological infrastructure & Lack of Expertise	S. Akter et al. (2022)
5.	Mismatch between prevailing and required skills	S.N. Sirimanne (2021)
6.	Insufficient mass knowledge about Industry 4.0	S. Akter et al. (2022)
7.	Lack of motivation towards new system adoption	M. Anesary et al. (2014)
8.	Fragile government regulations and legal rigidity	G. Orzes et al. (2018)
9.	Deficiency of raw material sources	W. Rahman (2016)
10.	Lack of value chain integration	A.K. Shilesh, B. Senthilkumar (2019)
11.	Disruption to existing employment ecosystem	S.K. Kundu et al. (2015)

12.	Probability of fatal technological failure	H. Birkel et al. (2019)
13.	Initial investment level for setup	M.A. Islam et al. (2018)
14.	Organizational resistance	A.B. Bhuiyan et al. (2020)
15.	Absence of qualified professionals	Vrchota et al. (2020)
16.	Threat to information security	G. Orzes et al. (2018)
17.	Equipment and technology integration	Markarian (2018)
18.	Low IT Structure	A.G. Frank et al. (2019)
19.	Less management engagement in I4.0	Ghobakhloo (2019)
20.	High degree of regulatory requirements	Romero-Torres et al. (2018)
21.	Unemployment Social bubble	Stock et al. (2018)
22.	Lack of Strategies and Maturity for implantation	Glaser (2020)
23.	Complexity of biological processes	M. Azam (2016)
24.	High risks-Medical area	Stentoft et al. (2020)
25.	Lack of detailed published information	Ingrid et al. (2020)
26.	Difficult characteristics of pharmaceutical processes	Romero-Torres et al. (2018)
27.	Knowledge Security	A.K. Shilesh, B. Senthilkumar (2019)
28.	Financial Return on Investment	S.N. Sirimanne (2021)

Now, these barriers are need to be clustered under one single dimension of barrier under which these barriers will act as sub-barriers to that dimension.

2.2 Clustering of Barriers

This clustering of barrier provides an ease to identify the number of varied barriers but comprising of one particular sector which offers resistance in adoption of concept of Pharma4.0. Among a lot of barriers these barriers are clustered under one major dimension of barriers and creating sub barriers to these dimensions. This helps in analysing the barriers in more lenient way. A broad picture of barrier dimension will be understood by clustering Felipe et al. (2020).

Barriers like complexity of biological processes, difficult characteristics of pharmaceutical processes, lack of detailed published information, high degree of regulatory requirements, high risks-Medical area, deficiency of raw material sources gives the sense of inherent barriers. These barriers are inherently associated with the complex processes of pharmaceutical industry Horváth et al. (2019).

2.2.1 Inherent Barriers

The inherent barrier which pharmaceutical sector carries include huge twists of biological processes which needs to be met with scientific studies. These hinderances of the pharmaceutical industry slows down the action to implement the I4.0 concept.

- **Complexity of biological processes**
  The biological systems are inherently variable in nature. Thus, this nature gets affected under the influence of factors like genetics and environmental conditions. So, it makes it difficult to standardize processes.
- **Characteristics of pharmaceutical processes**
  Many biological processes involved in development of drug and manufacturing is still incomplete. It makes difficult to create perfect digital models and simulations for automation and optimization Gernaey et al. (2012).
- **Lack of scientific materials/cases**
  As proper scientific researches had not been made in order to develop the all possible combination for drug development due to its complex nature.
- **Regulatory landscape**
  Regulating the complex processes of pharmaceutical industries and building a proper landscape for its functioning offers endogenous barrier in itself.
- **Pharma prospects**
  Medical area is not free from risks. As a little technological fault can be fatal to life. This area brings this high risk thus offering a resistance in adoption.

Barriers like mismatch between prevailing and required skills, absence of qualified professionals, underdeveloped technological infrastructure & lack of expertise, low IT structure, equipment and technology integration, probability of fatal technological failure, lack of value chain integration, knowledge security forms a base for the dimension of workforce and infrastructure. Similar barrier can be merged and remaining barriers forms sub-barriers under the workforce and infrastructure dimension.

2.2.2 Workforce and Infrastructure Barriers

These barriers indicate towards difficulties of attracting qualified human resources, trained and prepared to work with certain technological elements recommended by I4.0, especially when applied to the pharmaceutical industry. Also, it direct barriers towards significant deficit in relation to the training of professionals and lack of infrastructure in organizations or the condition in which the human resource operate to receive or integrate the technological elements.

- **Under supply of trained personnel**
  Pharma 4.0 requires expertise in areas like data science, artificial intelligence and process engineering. Having knowledge of these skillsets differ from the traditional skillsets found in the pharmaceutical workforce.
- **Out dated architecture of equipment**
  Pharma 4.0 generates huge data for which huge data base storage system is required. But deficient infrastructure in this regard of pharmaceutical industries offers barrier in adoption.
- **Systems Unification**
  Integration of old machines with new digital technologies for seamless data exchange is quite difficult.
- **Knowledge security infrastructure**
  Current infrastructure of pharma industries is uncapable to secure the information. Thus, with this infrastructure and human capital skillset it makes it difficult to adopt new advanced technologies.

Barriers like Initial investment level for setup, Deficiency of High Investment, Financial Return on Investment, increase in unit cost of medicines, Fragile government regulations and legal rigidity falls under the umbrella of Expenditure barriers.

2.2.3 Expenditure Barriers

This aspect is related to the high investment required and the uncertainty of return. This is in picture because many projects and initiatives have a significant financial contribution but are unsuccessful. This barrier directs towards government support regarding adoption but complex regulatory norms and standards for functioning.

- **High Initial financial requirement**
  Sensors, data analytic platform, IT infrastructure and automation equipment demands huge initial investment.
- **Difficulty in quantifying financial return**
  Improved product quality and faster development times are difficult to translate into concrete financial metrics. It offers challenges in calculation of return on investment (ROI) for these technologies.
- **Government Support**
  Complex landscape, Strict guidelines of government funding and insufficient funding can pause the development of industry in between.

Barriers such as organizational resistance, lack of value chain integration, insufficient mass knowledge about Industry 4.0, lack of strategies and maturity for implantation, less management engagement in I4.0, disruption to existing employment ecosystem, malpractice & lack of transparency forms basis for the dimension Management planning and strategy barriers.

2.2.4 Management planning and strategy Barriers

This barrier aspect is related to the resistance for traditional organizational culture to disseminate the I4.0 culture in the industry. The reason behind this is the perceived risks in traditional management due to data inclusion and fear of its breach. Also, the business maturity in digital landscape offers barriers in the industry for the adoption. Accurate planning and strategy is required for efficient execution of the processes which sometime management lacks. This aspect of barrier also offers resistance because of the time required in implantation of technology in organization management structure.

- **<u>Organization culture</u>**
  It refers to the shared values, beliefs and attitudes that tells how employees behave within an industry. It offers resistance due to lack of trust in management's ability to effectively implement change.
- **<u>Circulation of technological culture</u>**
  An unfamiliar public lacking I4.0 knowledge creates society with skillset gaps in area of Pharma 4.0 is critical. Thus, retaining people with such skillsets is difficult.
- **<u>Deficiency of appropriate strategy</u>**
  Identifying specific areas for implementation, allocating sufficient resources including budget and personnel to support the process is crucial for successful implementation.
- **<u>Business understanding</u>**
  Lack of clear and well-defined vision of technology integration suffers the business goals to justify investments. So, management capabilities and employee resistance hinder successful adoption.
- **<u>Conceptual standardization</u>**
  It refers on everyone agreement on the definition of terms, data formats, and processes with the new language having absence of that creates confusion and impact standardization.
- **<u>Malpractice elimination and maintaining transparency in processes</u>**
  It refers that ensuring practices done in the pharmaceutical industry should be free from any malpractice. Ensuring this management requires more effort. This leads for the management to resist the adoption of the pharma 4.0 concept. The maintenance of transparency of processes across different levels so as to ensure security of the manufacturing process involved in drug formation is also critical for the management to maintain.

Barriers like unemployment-social bubble, lack of motivation towards new system adoption, lack of value chain integration means linkage between different hierarchical system in the industry like retailers in pharmaceutical industry of developing countries does not have technical knowledge. Thus they have fear of job replacement. This creates hinderance in adoption of pharma 4.0 and can be put in the category of Social impact barrier as a bigger dimension to these barrier.

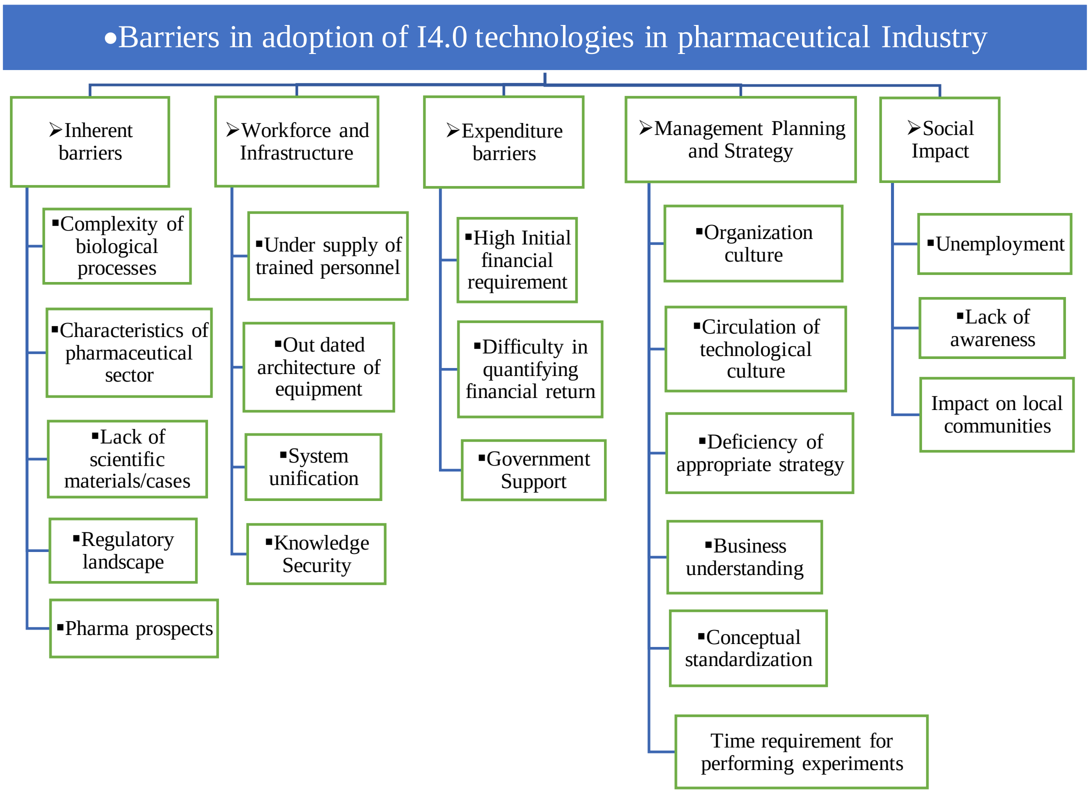
2.2.5 Social Impact Barriers

This aspect talks about the barrier related to the fear in employees of job loss due to technology inclusion. Therefore, unemployment creates a bubble, lack of technology knowledge creates social bubble of getting behind from the others. Thus, local communities have an image of inefficient strength of themselves to compete against others. This barrier creates inferiority in the work force resulting in the hinderance in adoption of I4.0.

- **Unemployment**
  The industry processes are carried out by traditional workers and they are not compatible with the new technology operations. This inhibits a sense of fear of job replacement in them Vatovec et al. (2013).
- **Lack of awareness**
  Limited understanding of pharma processes and with deficient communication among stakeholders and employees creates lack of awareness which hinders adoption.
- **Impact on local communities**

  It refers to the employment dynamics, economic effects and environmental impact because communities thought introduction of technology increases more amount of hazardous waste from pharma companies. Thus, it hinders adoption of I4.0 concept.

Fig 2.1 Major dimension of barriers and their Sub - Barriers



This flowchart represents different sub barriers to the major dimension of barriers. Like the inherent barriers constitute complexity of biological processes, characteristics of pharmaceutical sector and so on. Similarly for the workforce and infrastructure, expenditure barriers, Management Planning and Strategy and Social Impact.

Table 2.2 Barriers dimensions with sub-barrier and their notation

Dimensions	Barriers and risks	Notation
Inherent Barriers (B1)	1. Complexity of biological processes	B11
	2. Characteristics of the pharmaceutical sector	B12
	3. Lack of scientific materials/cases	B13
	4. Regulatory landscape	B14
	5. Pharma prospects	B15
Workforce & Infrastructure (B2)	1. Under supply of trained personnel	B21
	2. Outdated architecture of equipment	B22
	3. Systems Unification	B23
	4. Knowledge security	B24
Expenditure Barriers (B3)	1. High initial financial requirement	B31
	2. Difficulty in quantifying financial return	B32
	3. Government Support	B33
Management planning and strategy (B4)	1. Organization culture	B41
	2. Circulation of technological culture	B42
	3. Deficiency of appropriate strategy	B43
	4. Business Understanding	B44
	5. Conceptual Standardization	B45
	6. Malpractice elimination and maintaining transparency in processes	B46
Social impact (B5)	1. Unemployment	B51
	2. Lack of awareness and motivation	B52
	3. Impact on local communities	B53

Now, barriers can be written with notations for ease of understanding in further study.

CHAPTER - 3

METHOD SELECTION AND MODEL FORMATION

3.1 Method Selection

The Analytic Hierarchy Process methodology is opted as to analyse barriers and get a view of the critical ones. Ranking barriers is crucial because through the ranking framework we can strategically take decisions. In this application of AHP the hierarchy structure is formed by making cluster factors under major dimension. After this, pairwise comparison is applied by industry experts to compare the factors. As we obtain the factors comparison, we calculate the weightage and then check consistency of results. If in acceptance region then and global rankings of factors are calculated. As we get the global weightage and ranking, we are able to rank the barriers in a hierarchical order of their criticality.

3.2 The Analytic Hierarchy Process

Thomas L. Saaty created the AHP, a structured methodology, in the 1970s. This method is applied to the organization and analysis of intricate judgments. The idea of hierarchies, which are frameworks that can be utilized to depict a problem in terms of its constituent parts and subcomponents, serves as the foundation for this. It breaks down a difficult decision problem into its constituent pieces, assesses each one using a mix of psychology and mathematics, and then determines the best course of action. The user assesses each component based on its relative importance in the pairwise comparison phase by comparing it to every other component.

The relative significance scores from the pairwise comparison stage is added and then we obtain a relative importance score. After that, this answer can be utilized to choose the finest course of action and make an informed choice.

3.2.1 AHP Mathematical Framework

The Analytic Hierarchy Process is a quantitative approach that relies on the subjective relative significance that individuals assign to different elements Saaty (1990). Responding to pairwise comparison questions with the following format is necessary for this process:

Step 1: A Matrix will be made of the responses filled for the dimensions for which analytic hierarchy process is used. This matrix can be filled in the following manner

- Importance of A w.r.t B or,
- Importance of B w.r.t A

This importance is given based on the AHP scale of relative importance which is discussed ahead.

Step 2: The geometric mean of the responses of the experts are taken and form new matrix with these geometric values. For example, if a survey consists of 3 expert then the weight is computed as

$$V_1 = 3\sqrt{}(X_{11} * X_{12} * X_{13})$$

where, X_{11} depicts

$X_{1\_}$ = first criteria of the survey matrix &

$X_{\_1}$ = first expert filled criteria matrix

this is the geometric mean (criterion 1) of the question's scores.

Similarly, geometric mean for rest of the experts is taken.

Step 3: The weights are then calculated by dividing each geometric average for the sum of all the other criteria:

$$W_{11} = V_1 / (V_1 + V_2 + V_3)$$

It forms a pairwise comparison matrix.

Step 4: Now, in this step from the pairwise comparison matrix criteria weight is calculated for each dimension. It can be calculated by taking the average of weights.

$$CW = (W_{11} + W_{12} + W_{13})/3$$

Step 5: Weighted sum value is calculated for the pairwise comparison matrix. It can be calculated as

$$WSM_1 = W_{11} + W_{12} + W_{13}$$

Step 6: Now, ratio of Weighted sum value and Criteria Weight is calculated.

$$Ratio = (WSM/CW)$$

Step 7: Now, maximum principal eigen value i.e. λ_{max} is calculated. It is calculated as

$$\lambda_{max} = \text{Maximum of ratio } WSM/CW$$

Step 8: In this step Consistency Index i.e. CI is calculated. It is calculated as

$$CI = (\lambda_{max} - n)/(n - 1)$$

where, n = number of attributes

Step 9: In the last step Consistency ratio is calculated i.e. CR is calculated. It is calculated as

$$CR = CI/RI$$

where, RI is Random Index

Random Index calculates the mean consistency indices of a specific numbers of random number pairwise comparison matrices. The RI table is as follows

Table 3.1 Random Index values with size of comparison matrices

n	1	2	3	4	5	6	7	8	9	10
RI	0.00	0.00	0.58	0.90	1.12	1.24	1.32	1.41	1.45	1.49

Step 10: Now check for the value of Consistency Ratio. For consistent solution the CR value should be less than 0.1. If the CR value is less than 0.1 then the solution is acceptable, otherwise rejected.

3.2.2 AHP Scale of Relative Importance

In 1980, Saaty recommended the use of a nine-point scale for assessing the relative importance or 'intensity' of each pair of criteria, where '1' implies equal importance between two criteria and '9' indicates the absolute importance of one criterion over another.

Table 3.2 AHP Scale of Relative Importance

Score	**Significance**
1	Equal Importance
3	Moderate Importance
5	Strong Importance
7	Very Strong Importance
9	Extremely Strong Importance
2, 4, 6, 8	Intermediate Values
1/3, 1/5, 1/7, 1/9	Values for Inverse Comparison

3.2.3 Application of AHP on Barriers Weightage Calculation

Now, apply the AHP Methodology on the barriers.

Initially, AHP is applied on major dimension of the barrier. This will provide the initial weightage of the barriers and forms a picture of the criticality of the various major dimensions. Notation is given to these barriers for easy understanding in the results.

Assigning Notations to the Major dimensions of the barriers

Table 3.3 Major Dimension and their Notation

Major Dimension of Barriers	**Notation**
Inherent barriers	B1
Workforce & Infrastructure	B2
Expenditure barriers	B3
Management planning and strategy	B4
Social impact	B5

Table 3.4 Initial pairwise comparison matrix

Barriers	**B1**	**B2**	**B3**	**B4**	**B5**
B1	1	1.473	2.908	2.019	4.196
B2	0.679	1	1.966	1.512	2.889
B3	0.344	0.509	1	0.999	2.308
B4	0.495	0.660	1.001	1	2.948
B5	0.255	0.361	0.4334	0.339	1

This is the initial pairwise comparison matrix formed from the responses of the experts by applying the geometric mean methodology.

Table 3.5 Criteria Weights calculation for Major dimension Sub - barriers

Barriers	**B1**	**B2**	**B3**	**B4**	**B5**	**Criteria Weights**	**Rank**
B1	0.357	0.365	0.425	0.352	0.314	0.357	1
B2	0.242	0.248	0.288	0.264	0.216	0.248	2
B3	0.123	0.126	0.146	0.174	0.173	0.146	4
B4	0.177	0.163	0.146	0.174	0.221	0.174	3
B5	0.091	0.089	0.063	0.059	0.075	0.075	5

$\lambda_{max} = 5.079$

CR = 0.018 which is < 0.1. Therefore, this result is acceptable.

The ranking for major dimension of barriers is

1. Inherent barriers
2. Workforce and infrastructure
3. Management planning and strategy
4. Expenditure barriers
5. Social Impact

This ranking shows which factor is most important to consider initially in order to reduce resistance in adoption.

Inherent barriers need utmost consideration in order to adopt I4.0 concept. Whereas Social Impact has a least influence but it doesn't mean that it does not require attention to solve issues related to it.

Workforce and infrastructure, Management planning and strategy also holds immense significance in creating hinderance to the adoption. Expenditure Barriers also needs a lot of effort to reduce the resistance associated in it and thus supports in facilitation of adoption.

Table 3.6 Pairwise Comparison Matrix for B1 Sub - barriers

Barriers	**B11**	**B12**	**B13**	**B14**	**B15**
B11	1	0.848	3.220	2.032	5.985
B12	1.179	1	1.331	0.644	2.063
B13	0.311	0.751	1	1.360	3.121
B14	0.492	1.552	0.735	1	4.547
B15	0.167	0.485	0.320	0.220	1

Table 3.7 Criteria Weights calculation for B1 Sub - barriers

Barriers	**B11**	**B12**	**B13**	**B14**	**B15**	**Criteria Weight**	**Rank**
B11	0.347	0.176	0.552	0.433	0.368	0.347	1
B12	0.408	0.207	0.228	0.137	0.127	0.207	3
B13	0.108	0.156	0.171	0.290	0.192	0.171	4
B14	0.171	0.322	0.126	0.213	0.280	0.213	2
B15	0.058	0.101	0.055	0.047	0.062	0.062	5

$\lambda_{max} = 5.414$

CR = 0.092 which is < 0.1. Therefore, this result is acceptable.

The ranking for inherent barriers is as follows

1. Complexity of biological processes
2. Regulatory landscape
3. Characteristics of the pharmaceutical sector
4. Lack of scientific materials/cases
5. Pharma prospects

Table 3.8 Pairwise Comparison Matrix for B2 Sub - barriers

Barriers	**B21**	**B22**	**B23**	**B24**
B21	1	1.048	1.420	1.975
B22	0.954	1	1.756	2.858
B23	0.704	0.569	1	2.784
B24	0.506	0.350	0.359	1

Table 3.9 Criteria Weights calculation for B2 Sub - barriers

Barriers	**B21**	**B22**	**B23**	**B24**	**Criteria Weight**	**Rank**
B21	0.303	0.356	0.340	0.234	0.303	2
B22	0.289	0.339	0.421	0.338	0.339	1
B23	0.213	0.193	0.239	0.329	0.239	3
B24	0.153	0.119	0.086	0.118	0.118	4

$\lambda_{max} = 4.087$

CR = 0.032 which is < 0.1. Therefore, this result is acceptable.

The ranking for workforce and infrastructure barriers is as follows

1. Outdated architecture of equipment
2. Under supply of trained personnel
3. Systems Unification
4. Knowledge security

Table 3.10 Pairwise Comparison Matrix for B3 Sub - barriers

Barriers	B31	B32	B33
B31	1	3.108	3.580
B32	0.322	1	2.188
B33	0.279	0.457	1

Table 3.11 Criteria Weights calculation for B3 Sub - barriers

Barriers	B31	B32	B33	Criteria Weight	Rank
B31	0.611	0.770	0.504	0.611	1
B32	0.197	0.248	0.308	0.248	2
B33	0.171	0.113	0.141	0.141	3

$\lambda_{max} = 3.084$

CR = 0.072 which is < 0.1. Therefore, this result is acceptable.

The ranking for expenditure barriers is as follows

1. High initial financial requirement
2. Difficulty in quantifying financial return
3. Government support

Table 3.12 Pairwise Comparison Matrix for B4 Sub - barriers

Barriers	B41	B42	B43	B44	B45	B46
B41	1	1.384	1.344	1.314	3.373	5.455
B42	0.723	1	2.751	2.043	3.043	7.456
B43	0.744	0.363	1	1.888	1.479	4.378
B44	0.761	0.490	0.530	1	6.980	4.735
B45	0.296	0.329	0.676	0.143	1	5.553
B46	0.183	0.134	0.228	0.211	0.180	1

Table 3.13 Criteria Weights calculation for B4 Sub - barriers

Barriers	B41	B42	B43	B44	B45	B46	Criteria Weight	Rank
B41	0.252	0.383	0.223	0.264	0.240	0.181	0.252	2
B42	0.182	0.277	0.457	0.411	0.217	0.247	0.277	1
B43	0.187	0.101	0.166	0.380	0.105	0.145	0.166	4
B44	0.192	0.136	0.088	0.201	0.497	0.157	0.201	3
B45	0.075	0.091	0.112	0.029	0.071	0.184	0.071	5
B46	0.046	0.037	0.038	0.042	0.013	0.033	0.033	6

$\lambda_{max} = 6.609$

CR = 0.098 which is < 0.1. Therefore, this result is acceptable.

The ranking for management planning and strategy barriers is as follows

1. Circulation of technological culture
2. Organization culture
3. Business Understanding
4. Deficiency of appropriate strategy
5. Conceptual Standardization
6. Time requirement for performing experiments

Table 3.14 Pairwise Comparison Matrix for B5 Sub - barriers

Barriers	B51	B52	B53
B51	1	3.108	3.580
B52	0.322	1	2.188
B53	0.279	0.457	1

Table 3.15 Criteria Weights calculation for B5 Sub - barriers

Barriers	**B51**	**B52**	**B53**	**Criteria Weight**	**Rank**
B51	0.611	0.770	0.504	0.611	1
B52	0.197	0.248	0.308	0.248	2
B53	0.171	0.113	0.141	0.141	3

$\lambda_{max} = 3.084$

CR = 0.072 which is < 0.1. Therefore, this result is acceptable.

The ranking for management planning and strategy barriers is as follows

1. Unemployment
2. Lack of awareness
3. Impact on local communities

Table 3.16 Global Weight and Global Rank Calculation of Barriers

Barriers	Relative Weight	Sub Barriers	Local Weight	Local Rank	Global Weight	Global Rank
Inherent Barriers (B1)	0.357	1. Complexity of biological processes	0.347	1	0.124	1
		2. Characteristics of the pharmaceutical sector	0.207	3	0.074	6
		3. Lack of scientific materials/cases	0.171	4	0.061	7
		4. Regulatory landscape	0.213	2	0.076	4
		5. Pharma prospects	0.062	5	0.022	16
Workforce & Infrastructure (B2)	0.248	1. Under supply of trained personnel	0.303	2	0.075	5
		2. Outdated architecture of equipment	0.339	1	0.084	3
		3. Systems Unification	0.239	3	0.059	8
		4. Knowledge security	0.118	4	0.029	14
Expenditure Barriers (B3)	0.146	1. High initial financial requirement	0.611	1	0.089	2
		2. Difficulty in quantifying financial return	0.248	2	0.036	12
		3. Government Support	0.141	3	0.021	17
Management planning and strategy (B4)	0.174	1. Organization culture	0.252	2	0.044	11
		2. Circulation of technological culture	0.277	1	0.048	9
		3. Deficiency of appropriate strategy	0.166	4	0.029	15
		4. Business Understanding	0.201	3	0.035	13
		5. Conceptual Standardization	0.071	5	0.012	19
		6. Time requirement for performing experiments	0.033	6	0.006	21
Social impact (B5)	0.075	1. Unemployment	0.611	1	0.046	10
		2. Lack of awareness	0.248	2	0.019	18
		3. Impact on local communities	0.141	3	0.011	20

Now, we get the global rank for all the barriers. The barriers now can rank in an order of their criticality to the industry.

1. Complexity of biological processes
2. High initial financial requirement
3. Outdated architecture of equipment
4. Regulatory landscape
5. Under supply of trained personnel
6. Characteristics of the pharmaceutical sector
7. Lack of scientific materials/cases
8. Systems Unification
9. Circulation of technological culture
10. Unemployment
11. Organization culture
12. Difficulty in quantifying financial return
13. Business Understanding
14. Knowledge security
15. Deficiency of appropriate strategy
16. Pharma prospects
17. Government Support
18. Lack of awareness
19. Conceptual Standardization
20. Impact on local communities
21. Time requirement for performing experiments

Now these results are based on AHP Model but AHP has its own limitations. AHP is unable to capture the subjectivity of human judgements as the verbal values are converted into crisp values. It produces vagueness in results. Thus to overcome this Fuzzy AHP method can be applied. Also this will compare the results of AHP and Fuzzy AHP.

3.3 Fuzzy AHP

Fuzzy Analytic Hierarchy Process (Fuzzy AHP) is an extension of the traditional Analytic Hierarchy Process (AHP) that deals with uncertainty and vagueness in decision-making processes. AHP is a widely used multi-criteria decision-making method developed by Thomas L. Saaty in the 1970s. It helps decision-makers systematically analyse complex decision problems by structuring them into a hierarchy of criteria and alternatives and then synthesizing judgments to determine the relative importance of criteria and the best alternative.

Fuzzy AHP incorporates fuzzy set theory into the AHP framework to handle imprecise or ambiguous information that arises when dealing with subjective judgments, linguistic expressions, or vague preferences. Here's a detailed overview of the components and steps involved in Fuzzy AHP:

3.3.1 Components of Fuzzy AHP:

- **Criteria Hierarchy:** Like in traditional AHP, decision problems in Fuzzy AHP are structured hierarchically, consisting of multiple levels of criteria, sub-criteria, and alternatives. The hierarchy represents the decision context and captures the relationships between elements.
- **Fuzzy Numbers:** Fuzzy AHP utilizes fuzzy numbers to represent the uncertainty associated with judgments. A fuzzy number is characterized by a membership function that assigns degrees of membership to values within a certain range. It allows decision-makers to express their preferences in a fuzzy or vague manner.
- **Pairwise Comparison Matrices:** Decision-makers provide pairwise comparisons of criteria and alternatives based on their relative importance or performance with respect to each criterion. These comparisons are typically represented in matrices.
- **Aggregation of Judgments:** Fuzzy AHP aggregates the fuzzy pairwise comparison judgments to derive the overall priority weights for criteria and alternatives. This aggregation process involves mathematical operations on fuzzy numbers to calculate crisp priorities.

- **Consistency Assessment**: Similar to AHP, Fuzzy AHP includes consistency checks to ensure the reliability of judgments. Inconsistencies in pairwise comparisons can lead to unreliable results, so consistency ratios are calculated and compared against predefined thresholds.

3.3.2 Steps in Fuzzy AHP:

- **Problem Formulation:** Define the decision problem and structure it hierarchically, identifying the criteria, sub-criteria, and alternatives involved.
- **Pairwise Comparison:** Obtain judgments from decision-makers regarding the relative importance or performance of criteria and alternatives. These judgments are expressed using fuzzy numbers and captured in pairwise comparison matrices.
- **Fuzzy Number Operations:** Perform mathematical operations on fuzzy numbers to aggregate the pairwise comparison judgments and calculate the priority weights for criteria and alternatives.
- **Consistency Assessment:** Evaluate the consistency of the pairwise comparisons by calculating consistency ratios and comparing them to acceptable thresholds. If necessary, revise judgments to improve consistency.
- **Ranking and Selection:** Use the aggregated priority weights to rank the alternatives and select the best option according to the decision criteria.
- **Sensitivity Analysis**: Conduct sensitivity analysis to assess the robustness of the results to changes in judgments or parameters and identify influential factors.

3.3.3 Fuzzy AHP Algorithm

Step 1: Check the consistency ratio for each individual expert opinion.

Step 2: Now the responses from each individual are undergone fuzzification in which linguistic terms of response are converted into triangular membership function.

The fuzzified pairwise comparison matrix can be formed from the fuzzy scale of relative importance.

For ex. If one expert give one attribute a score of 5 then, according to fuzzy scale of relative importance this 5 can be written as

$$(4\ ,\ 5\ ,\ 6)$$

Step 3: Now a fuzzified pairwise comparison matrix is formed for each individual response.

Step 4: After forming the fuzzified pairwise matrix Fuzzy Geometric mean is calculated.

The geometric mean is calculated as

$$A_1 * A_2 = (l_1, m_1, u_1) * (l_2, m_2, u_2)$$

$$A_1 * A_2 = (l_1 * l_2, m_1 * m_2, u_1 * u_2)$$

where, A_1 and A_2 are two attributes whose triangular membership function is l_1, m_1, u_1 and l_2, m_2, u_2 respectively and

l_1 = lower bound value of 1st attribute

m_1 = middle bound value of 1st attribute

u_1 = upper bound value of 1st attribute

Similarly, for 2nd attribute.

Now the geometric mean is calculated as

For ex. for 3 attributes the geometric mean

- for lower bound will be $GM(r_i) = 3\sqrt{}(l_1 * l_2 * l_3)$
- for middle bound will be $GM(r_i) = 3\sqrt{}(m_1 * m_2 * m_3)$
- for upper bound will be $GM(r_i) = 3\sqrt{}(u_1 * u_2 * u_3)$

Step 5: Now we calculate the sum of fuzzy geometric mean. It is calculated as

$$A_1 + A_2 = (l_1, m_1, u_1) + (l_2, m_2, u_2)$$

$$A_1 + A_2 = (l_1 + l_2, m_1 + m_2, u_1 + u_2)$$

Step 6: In this step, fuzzy weight is calculated. The calculation will be done as follow

$$W_i = r_i * (r_1 + r_2 + \ldots\ldots\ldots + r_n)^{-1}$$

Now, we get the triangular fuzzy weights.

Step 7: Now, we convert these fuzzy triangular values into single crisp value. This value can be calculated as

$$W_i = (l + m + u) / 3$$

Step 8: Now the weights obtained can be used for ranking the barriers. If the sum of weights are greater than 1 then, divide each single weight by the sum of total weights.

3.3.4 Fuzzy Scale of Relative Importance

Table 3.17 Fuzzy Scale of Relative Importance

Importance	Score	Fuzzification
Equal	1	(1, 1, 1)
Moderate	3	(2, 3, 4)
Strong	5	(4, 5, 6)
Very Strong	7	(6, 7, 8)
Extremely Strong	9	(9, 9, 9)
	2	(1, 2, 3)
Intermediate	4	(3, 4, 5)
Values	6	(5, 6, 7)
	8	(7, 8, 9)

3.3.5 Fuzzy AHP application on barriers

As we start applying Fuzzy methodology, in initial stage out of 10 experts only 9 experts initial comparison matrix is found to be consistent. As Expert 9 initial comparison matrix consistency value ratio is more than 0.1.

Table 3.18 Weightage and Rank calculation for expert 1

Fuzzy Weights			**De Fuzzification**	**Normalized Weight**	**Rank**
0.398	0.543	0.734	0.558	0.538	1
0.166	0.240	0.343	0.250	0.240	2
0.081	0.119	0.176	0.125	0.120	3
0.044	0.063	0.093	0.067	0.064	4
0.026	0.036	0.053	0.038	0.037	5

Table 3.19 Weightage and Rank calculation for expert 2

Fuzzy Weights			**De Fuzzification**	**Normalized Weight**	**Rank**
0.249	0.422	0.669	0.446	0.412	1
0.182	0.296	0.504	0.327	0.302	2
0.055	0.084	0.137	0.092	0.085	4
0.100	0.160	0.269	0.176	0.163	3
0.026	0.038	0.058	0.040	0.037	5

Table 3.20 Weightage and Rank calculation for expert 3

Fuzzy Weights			**De Fuzzification**	**Normalized Weight**	**Rank**
0.172	0.421	0.402	0.331	0.314	1
0.075	0.126	0.194	0.131	0.124	3
0.050	0.078	0.124	0.084	0.079	4
0.340	0.333	0.722	0.465	0.440	2
0.029	0.043	0.063	0.045	0.042	5

Table 3.21 Weightage and Rank calculation for expert 4

Fuzzy Weights			**De Fuzzification**	**Normalized Weight**	**Rank**
0.075	0.122	0.196	0.131	0.124	3
0.342	0.504	0.729	0.525	0.496	1
0.163	0.253	0.392	0.269	0.254	2
0.052	0.080	0.133	0.088	0.083	4
0.029	0.041	0.064	0.045	0.042	5

Table 3.22 Weightage and Rank calculation for expert 5

Fuzzy Weights			**De Fuzzification**	**Normalized Weight**	**Rank**
0.324	0.493	0.735	0.517	0.483	1
0.143	0.238	0.386	0.256	0.239	2
0.095	0.154	0.264	0.171	0.160	3
0.043	0.069	0.114	0.075	0.070	4
0.031	0.046	0.077	0.051	0.048	5

Table 3.23 Weightage and Rank calculation for expert 6

Fuzzy Weights			**De Fuzzification**	**Normalized Weight**	**Rank**
0.153	0.265	0.470	0.296	0.271	2
0.031	0.046	0.077	0.051	0.047	5
0.080	0.137	0.235	0.151	0.138	3
0.274	0.459	0.730	0.487	0.446	1
0.057	0.094	0.170	0.107	0.098	4

Table 3.24 Weightage and Rank calculation for expert 7

Fuzzy Weights			**De Fuzzification**	**Normalized Weight**	**Rank**
0.264	0.443	0.704	0.470	0.432	1
0.054	0.088	0.156	0.099	0.091	4
0.176	0.292	0.505	0.325	0.298	2
0.073	0.129	0.223	0.142	0.130	3
0.032	0.048	0.081	0.054	0.049	5

Table 3.25 Weightage and Rank calculation for expert 8

Fuzzy Weights			**De Fuzzification**	**Normalized Weight**	**Rank**
0.102	0.163	0.278	0.181	0.169	3
0.326	0.499	0.747	0.524	0.488	1
0.045	0.074	0.126	0.082	0.076	4
0.031	0.047	0.078	0.052	0.048	5
0.125	0.218	0.362	0.235	0.219	2

Table 3.26 Weightage and Rank calculation for expert 10

Fuzzy Weights			**De Fuzzification**	**Normalized Weight**	**Rank**
0.146	0.239	0.380	0.255	0.240	2
0.338	0.504	0.737	0.526	0.495	1
0.093	0.149	0.251	0.164	0.155	3
0.047	0.070	0.111	0.076	0.071	4
0.027	0.038	0.059	0.041	0.039	5

Table 3.27 Average of Experts result for attributes for rank calculation

Expert	IB	W & I	EB	MP & S	SI
1	0.538	0.240	0.120	0.064	0.037
2	0.412	0.302	0.085	0.163	0.037
3	0.314	0.124	0.079	0.440	0.042
4	0.124	0.496	0.254	0.083	0.042
5	0.483	0.239	0.160	0.070	0.048
6	0.271	0.047	0.138	0.446	0.098
7	0.432	0.091	0.298	0.130	0.049
8	0.169	0.488	0.076	0.048	0.219
10	0.240	0.495	0.155	0.071	0.039
Average	**0.331**	**0.280**	**0.152**	**0.168**	**0.068**

The Rank for the Major dimension of barriers came out to be

1. Inherent Barriers
2. Workforce and Infrastructure
3. Expenditure Barrier
4. Management Planning and Strategy
5. Social Impact

CHAPTER 4

RESULTS AND DISCUSSION

According to the analysis, every interviewee cited the necessity of altering corporate cultures, creating a systematic plan for implementing technological advancements in pharmaceutical companies, and carrying out the digital transformation as major obstacles. This is a basic requirement for any digital transformation project to succeed, according to some respondents. A further aspect that warrants attention is the unique features of the pharmaceutical industry. These features include the intricacy of biological processes, the stringent local regulations that must be followed, and the dearth of solid research on the use of I4.0 principles and aspects in this sector.

As per AHP the ranking for Major dimension is came out as

Inherent Barriers are the most critical one with a weightage of 0.357 means out of other barriers it accounts 35.7% criticality out of the remaining barriers. It signifies that how much it is important to look solutions for it. This barrier came out as most significant barrier which act as major hinderance in adoption of the 4.0 concept in pharmaceutical industry. Whereas, Social Impact results in weightage of 0.075 which means it accounts for 7.5% criticality over other barriers. This does not mean that its solution need not to be addressed but in comparison to other barriers we can look for its solution after other barrier solutions once addressed. Similarly, Workforce and infrastructural barrier results in weightage of 24.8%, Management planning and strategy results in 17.4% weightage and expenditure barrier results in 14.6% weightage. Therefore, addressing issues in order of their criticality helps efficient and quick adoption of I4.0 concept in the pharmaceutical industry.

As per Fuzzy AHP, the result came out to be critical one for Inherent barrier as well. According to this, the criticality weightage for this is 33.1% again which is significant value which needs to be addressed. Again, this methodology generates 0.068

weightage for the Social Impact which shows its action in acting as hinderance in adoption of I4.0 concept. Similarly, Workforce and infrastructure results in 0.280 weightage, Expenditure barrier came out forward with a weightage value of 0.152 and Management planning and strategy with 0.168 weightage. The Expenditure sector and Management planning and strategy sector in an industry hold almost equal weightage.

Discussing about the Sub- Barriers of Inherent characteristics of pharma industry complexity of biological processes came out as the most critical one with a global weightage of 12.4% and High initial financial requirement from expenditure barrier ranks 2nd in the list. Discussing about workforce and infrastructural barriers, outdated architecture of equipment which are not compatible with the introduction of new technology is its significant barrier and holds 3rd rank globally.

The Regulatory landscape of inherent barrier ranks 4th globally in the list while under supply of trained personnel to the pharma industries from workforce and infrastructure point of view stands at 5th position. The most significant sub barrier of Management planning and strategy is circulation of technological culture stands 9th in the rank fear of getting unemployed from social impact stands 10th in the rank.

Therefore, an appropriate strategy to mitigate these barriers should be adopted based on this mathematically oriented result to facilitate the adoption of the technologies.

CHAPTER 5

CONCLUSION, LIMITATION AND FUTURE SCOPE

5.1 Conclusion

The adoption of the advanced technologies of Industry 4.0 may pose challenges to the current regulatory framework, because most of the currently were developed in an Industry 2.0 paradigm of traditional batch manufacturing. In addition to the regulatory, technical, and logistical challenges in new pharmaceutical manufacturing revolution, financial investment is also required. The initial investments direct towards capital and operating expenses to convert facilities. The long-term value of new manufacturing paradigm makes businesses case for adopting new technologies - more control, fewer errors, more responsiveness, and fewer drug shortages. In future, real-time product quality information will be generated, which is more transparent to purchasers, payors, healthcare providers, and patients - impacting demand. Such transparency would further incentivize investment in technologies that can consistently manufacture high quality products. The ultimate winner of Industry 4.0 in pharmaceutical manufacturing, though, should not be drug manufacturers or regulators, but rather the patients who will benefit from higher quality drugs with more reliable supply chains less prone to shortage. In what concerns the main barriers and risks, special notice goes for the rigidity of the organizations' culture and the absence of previous strategies for the orderly implementation of the technological elements of I4.0. The difficulty in identifying qualified professionals to work in the I4.0 era and the need for high investment without the certainty of return were also frequently reported.

While the initial costs might seem daunting, the long-term benefits of Pharma 4.0 go beyond financial gains. Increased productivity, improved patient outcomes, and a more sustainable industry represent a compelling return on investment, not just for individual companies, but for society as a whole. Workforce transformation in Pharma 4.0 goes beyond acquiring new skills. It requires a shift in mindset, embracing a willingness to learn, adapt, and collaborate with technology. Fostering a culture of innovation, open communication, and risk-taking is essential for employees to thrive in this dynamic environment.

5.2 Limitation

This study is restricted to involve more participants and higher authority strategic managers who can give more detailed viewpoint on the existing barriers in pharma industries. As addressing these barriers are intellectual property for the industries which if addressed in detail will bring more transparent outcome on these barriers.

5.3 Future Scope

The future of Pharma 4.0 is brimming with possibilities, promising a transformative landscape focused on efficiency, precision, and patient-centricity.

- Develop hyper connected infrastructure among pharmaceutical tools helps in real-time visibility and traceability.
- Adaptable systems that will adjust to real-time demand fluctuations, reducing waste and ensuring timely delivery of needed medications. Also, the integration with personalized medicine platforms which helps in analyzing patient data and will inform personalized treatment plans, leading to more effective therapies.
- Predictive analytics and AI-powered decision making that helps to analyze vast data so as to optimize logistics, and automate tasks, boosting agility and resilience.
- Digital platforms for data exchange and collaboration which will facilitate data sharing between stakeholders, fostering innovation and accelerating drug development.

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