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BUILDING A CULTURE OF CONTINUOUS AUDIT READINESS IN THE INDIAN PHARMACEUTICAL INDUSTRY

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ABSTRACT

In the highly regulated pharmaceutical sector, audit readiness is a critical factor for ensuring compliance, maintaining quality standards and sustaining global competitiveness. This study focuses on building a culture of continuous audit readiness within pharmaceutical companies located in Hyderabad, India. The research investigates the socio-working factors influencing the organizational culture and how these factors promote sustained audit preparedness. Using frequency tables and ANOVA tests, this study analyses the impact of socio-working details on fostering a culture conducive to audit readiness. Findings aim to provide actionable insights to strengthen regulatory compliance and enhance quality-driven operations in the Indian pharmaceutical industry.

Keywords: Audit Readiness, Pharmaceutical Industry, Culture, Socio-Economic Factors, Hyderabad, Continuous Compliance, Regulatory Readiness.

1. INTRODUCTION

In recent years, the Indian pharmaceutical sector has come under heightened regulatory scrutiny from agencies like CDSCO, US FDA and international bodies, pushing companies to move beyond episodic audit preparation toward a state of continuous audit readiness (Paul, Kundu, Patra, & Ray, 2024). India-based facilities are increasingly facing surprise inspections, making prior-only compliance strategies inadequate (Inotek, 2025). The literature points out that audit readiness is no longer just about having SOPs and documentation in place, but about embedding a culture of quality, transparency and regulatory discipline across all levels of the organisation (Pharma GMP, "How to Prepare for GMP Compliance Audits", 2024). Internal audits, CAPA processes, documentation integrity and facility design are now seen as integral components from plant design to daily operations (Inotek "Surprise FDA Inspections", 2025; Paul et al., 2024). However, despite these signals, many firms (especially smaller or older ones) still operate on reactive audit-preparation models, leading to regulatory observations, delays and sometimes severe penalties. It becomes essential, therefore, to understand how socio-economic and cultural factors influence the emergence of an audit-ready culture, particularly in pharmaceutical companies centred in Hyderabad, which is one of the major pharma hubs in India.

2. REVIEW OF LITERATURE

Azzarella (2025) discusses the evolving landscape of validation in the pharmaceutical industry, noting a shift towards prioritizing audit readiness. The article highlights the adoption of digital validation tools and the need for leaner validation teams to meet increasing regulatory demands. It suggests that embedding audit readiness into daily operations and fostering a culture of continuous compliance are essential strategies for navigating the industry's transformation.

Pharmalane UK (2025) identifies several challenges faced by pharmaceutical companies in maintaining Good Manufacturing Practice (GMP) compliance. The article highlights issues such as unannounced inspections, supply chain oversight, and the need for continuous inspection readiness. It emphasizes the importance of fostering a compliance-oriented culture, investing in employee training, and adopting advanced quality systems to navigate these challenges effectively.

Paul, Kundu, Patra, and Ray (2024) emphasize the importance of establishing systematic audit-ready processes within pharmaceutical companies. Their study highlights the need for maintaining comprehensive documentation, adhering to regulatory guidelines, and fostering a culture of continuous compliance. They argue that such processes not only ensure preparedness for audits but also enhance operational efficiency and stakeholder trust. The authors advocate for integrating quality management systems and data integrity frameworks to support sustained audit readiness.

An article by **Pharmuni (2024)** discusses the risks associated with inadequate audit preparation in the pharmaceutical industry. It outlines potential consequences such as regulatory penalties, compromised product quality, and damage to

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company reputation. The piece underscores the necessity of a proactive approach to audit readiness, including regular internal audits, employee training, and robust documentation practices, to mitigate these risks.

3. NEED FOR THE STUDY

Despite the Indian pharmaceutical industry's expanding footprint, many companies' still approach audits as episodic events, preparing reactively rather than fostering a culture of constant readiness. This gap leads to non-compliance risks, quality lapses and potential regulatory actions that can affect business sustainability (Sharma & Gupta, 2020). In Hyderabad a pharma hub with a diverse workforce understanding how socio-working factors influence audit readiness culture is critical. This study addresses this knowledge gap by analysing cultural and socio-working parameters to propose strategies that promote perpetual audit preparedness.

4. OBJECTIVES OF THE STUDY

- To assess the current culture of audit readiness in pharmaceutical companies based in Hyderabad.
- To examine the influence of socio-working factors on promoting continuous audit readiness culture.
- To analyse the impact of socio-working details on fostering audit readiness in the organizational culture.

5. SCOPE OF THE STUDY

This study is confined to pharmaceutical companies operating in Hyderabad, known as India's 'Pharma City' for its dense pharmaceutical ecosystem. The research focuses on understanding cultural aspects related to continuous audit readiness, specifically analysing socio-work-related factors influencing this culture. Data analysis will be performed using frequency tables and ANOVA tests to identify significant relationships. The study excludes pharmaceutical companies outside Hyderabad and does not cover other industry sectors.

UNIVERSE AND SAMPLE

As this work relates to the pharma industry in Andhra Pradesh and Telangana States, different pharma companies that were existed in both states were identified initially. Out of all companies most important and large industries were considered for this study. They are Dr. Reddy's Laboratories (DRL), Granules India, Hetero Drugs and Lupin Pharmaceuticals Here the executives existing in those four companies are 675, 887, 618 and 405 respectively. The total population size of all pharma companies considered is 2585. The Krejcie and Morgan table gives the sample size as 334. To take the same proportion of sub samples from each company the proportion of sample size in population was identified in the first step. That is (335 / 2585) X 100 = 12.95 % ≈ 13%. Therefore, 13 % of the sub population sizes of Dr. Reddy's Laboratories (DRL), Granules India, Hetero Drugs and Lupin Pharmaceuticals are 675, 887, 618 and 405 are 87, 115, 80 and 53. These are taken as sub sample sizes and whose sum is 335. This is the sample size. The developed structured questionnaire was then used to collect data, was pretested, and was finally made ready for use. The researcher was able to obtain only 311 completed questionnaires despite repeated requests from the identified sampling units. The remaining 24 were non-responses, either incomplete or incorrectly completed. Those 311 completed questionnaires were considered finally and used for analysis.

DISTRIBUTION OF RESPONDENTS BASED ON DIFFERENT SOCIO-WORKING INFORMATION UNDER CONSIDERATION

The respondents are distributed based on the different demographic variables namely Company, Gender, Age, Educational Qualifications, Experience and Department.

The distribution of respondents based on Socio-Working details was presented in table 1.

Table 1: Response based distribution of respondents on their Socio-Working Details

Company	No. of Respondents	Percent
DRL	83	26.7
Granules	107	34.4
Hetero	74	23.8
Lupin	47	15.1
Gender		
Male	234	75.2
Female	77	24.8
Age		

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18-25	75	24.1
25-35	83	26.7
35-45	103	33.1
>45	50	16.1
Education		
Bachelor's Degree	125	40.2
Master's Degree	150	48.2
PhD/Doctorate	18	5.8
Other	18	5.8
Experience		
0-5 years	98	31.5
5-10 years	56	18.0
10-15 years	57	18.3
> 15 years	100	32.2
Department		
Operations	133	42.8
Quality	103	33.1
Others	75	24.1
Total	**311**	**100.0**

Table 1 shows that, 26.7 percent of the respondents are from DRL, 34.4 percent of them are from Granules, 23.8 percent of them are from Hetero and 15.1 percent of them are from Lupin. From the total respondents, 75.2 percent are Male and 24.8 percent of them are female.

Out of the total respondents, 24.1 percent of the respondents are in the age group of 18-25 years, 26.7 percent of them are in the age group of 25-35 years, 33.1 percent of them are in the age group of 35-45 years and 16.1 percent of them are from in the age group of 45 years and above. From the total respondents, 40.2 percent of the respondents are having bachelor's degree, nearly half of the respondents having Master's Degree, 5.8 percent of them are having Ph.D/Doctoral Degree and 5.8 percent of them are having other educational qualifications.

Out of the total respondents, 31.5 percent of the respondents are having 0-5 years of work experience, 18.0 percent of them are having 5-10 years of Work experience, 18.3 percent are having 10-15 years and 32.2 percent are having 15 and above years of Work experience. From the total respondents, 42.8 percent of the respondents from Operations department including Production, Packing, Engineering and Warehouse, 33.1 percent of them are from Quality department including Quality Control, Quality assurance and Regulatory affairs and 24.1 percent are from other departments.

DISTRIBUTION OF RESPONDENTS BASING ON THEIR RESPONSES ON DIFFERENT STATEMENTS UNDER THE CULTURAL TRANSFORMATION PARAMETER – CULTURE PROMOTING ALL TIME AUDIT READINESS

Basing on the responses given by the respondents on different statements under the parameter Culture promoting all time Audit Readiness, the respondents were distributed and presented in Table 2.

SA=Strongly Agree, A=Agree, N=Neutral, D=Disagree and SD=Strongly Disagree.

Table 2

Statement	SA	A	N	D	SD
Effective documentation practices contribute to audit readiness in Indian pharmaceutical companies	164 (52.7)	85 (27.3)	24 (7.7)	31 (10.0)	7 (2.3)
Adequacy of training programs provided to employees ensures they are well-prepared for audits in Indian pharmaceutical	151 (48.6)	37 (11.9)	97 (31.2)	26 (8.4)	0 (0.0)

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companies					
Internal audit processes are not effective in preparing Indian pharmaceutical companies for external regulatory audits	53 (17)	7 (2.3)	24 (7.7)	177 (56.9)	50 (16.1)
Lack of seriousness from internal auditors is leading to lacunas in preparing Indian pharmaceutical companies for external regulatory audits	118 (37.9)	18 (5.8)	6 (1.9)	156 (50.2)	13 (4.2)
Ineffective findings in internal audits is a leading cause in many observations during external regulatory audits	85 (27.3)	13 (4.2)	5 (1.6)	185 (59.5)	23 (7.4)
Indian pharmaceutical companies communicate audit requirements and expectations to their employees very effectively	84 (27.0)	138 (44.4)	47 (15.1)	42 (13.5)	0 (0.0)
Insufficient awareness programmes is the primary reason for the moderate audit readiness in Indian pharmaceutical companies	33 (10.6)	19 (6.1)	31 (10.0)	204 (65.6)	24 (7.7)
Lack of dedicated resources for audits impacting the audit readiness in Indian pharmaceutical companies	65 (20.9)	14 (4.5)	8 (2.6)	188 (60.5)	36 (11.6)
Inadequate documentation practices are impacting the audit readiness in Indian pharmaceutical companies	66 (21.2)	11 (3.5)	24 (7.7)	184 (59.2)	26 (8.4)
Limited access to up-to-date regulatory information is impacting the audit readiness in Indian pharmaceutical companies	77 (24.8)	12 (3.9)	8 (2.6)	197 (63.3)	17 (5.5)
Lack of standardized internal processes hinders the audit readiness in Indian pharmaceutical companies	103 (33.1)	177 (56.9)	15 (4.8)	12 (3.9)	4 (1.3)

Table 2 shows that, out of the responses, 52.7 percent strongly agree, 27.3 percent agree, 7.7 percent Neutral, 10 percent disagree and 2.3 percent strongly disagree with the statement "Effective documentation practices contribute to audit readiness in Indian pharmaceutical companies". Out of the responses, 48.6 percent strongly agree, 11.9 percent agree, 31.2 percent Neutral and8.4 percent disagree with the statement "Adequacy of training programs provided to employees ensures they are well-prepared for audits in Indian pharmaceutical companies". Out of the responses, 17 percent strongly agree, 2.3 percent agree, 7.7 percent Neutral, 56.9 percent disagree and 16.1 percent strongly disagree with the statement "Internal audit processes are not effective in preparing Indian pharmaceutical companies for external regulatory audits". Out of the responses, 37.9 percent strongly agree, 5.8 percent agree, 1.9 percent Neutral, 50.2 percent disagree and 4.2 percent strongly disagree with the statement "Lack of seriousness from internal auditors is leading to lacunas in preparing Indian pharmaceutical companies for external regulatory audits".

Out of the responses, 27.3 percent strongly agree, 4.2 percent agree, 1.6 percent Neutral, 59.5 percent disagree and 7.4 percent strongly disagree with the statement "Ineffective findings in internal audits is a leading cause in many observations during external regulatory audits". Out of the responses, 27 percent strongly agree, 44.4 percent agree, 15.1 percent Neutral and13.5 percent disagree with the statement "Indian pharmaceutical companies communicate audit requirements and expectations to their employees very effectively". Out of the responses, 10.6 percent strongly agree, 6.1 percent agree, 10 percent Neutral, 65.6 percent disagree and 7.7 percent strongly disagree with the statement "Insufficient awareness programmes is the primary reason for the moderate audit readiness in Indian pharmaceutical companies". Out of the responses, 20.9 percent strongly agree, 4.5 percent agree, 2.6 percent Neutral, 60.5 percent disagree and 11.6 percent strongly disagree with the statement "Lack of dedicated resources for audits impacting the audit readiness in Indian pharmaceutical companies".

Out of the responses, 21.2 percent strongly agree, 3.5 percent agree, 7.7 percent Neutral, 59.2 percent disagree and 8.4 percent strongly disagree with the statement "Inadequate documentation practices is impacting the audit readiness in Indian pharmaceutical companies". Out of the responses, 24.8 percent strongly agree, 3.9 percent agree, 2.6 percent Neutral, 63.3 percent disagree and 5.5 percent strongly disagree with the statement "Limited access to up-to-date regulatory information is impacting the audit readiness in Indian pharmaceutical companies". Out of the responses, 33.1 percent strongly agree, 56.9 percent agree, 4.8 percent Neutral, 3.9 percent disagree and 1.3 percent strongly disagree with the statement "Lack of standardized internal processes hinder the audit readiness in Indian pharmaceutical companies" regarding the parameter "Culture promoting all time Audit Readiness".

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IMPACT OF DIFFERENT CLASSIFICATION OF SOCIO-WORK RELATED VARIABLES OVER THE AVERAGE SCORE OF CULTURE OF ALL TIME AUDIT READINESS FACTORS / PARAMETER:

The ANOVA table obtained for average score of Culture of all time Audit readiness against Socio-Work related variables is presented in table 3.

The null hypothesis here is that there is no significant variation of different Socio-Work related variables on Culture of All Time Audit Readiness Parameter and the alternative hypothesis is that there is a significant variation over the Socio-Work related variables on Culture of All Time Audit Readiness Parameter.

Table 3: Table showing ANOVA values for testing the variation of Culture of All Time Audit Readiness parameter against classification of different Socio-Work related variables

	Source of variation	Sum of Squares	df	Mean Square	F	Sig.
Avg. Score of Culture of all time Audit readiness against Company	Between Groups	.891	3	.297	2.650	**.049**
	Within Groups	34.422	307	.112		
	Total	35.313	310			
Avg. Score of Culture of all time Audit readiness against Gender	Between Groups	.246	1	.246	2.165	.142
	Within Groups	35.067	309	.113		
	Total	35.313	310			
Avg. Score of Culture of all time Audit readiness against age	Between Groups	.612	3	.204	1.806	.146
	Within Groups	34.701	307	.113		
	Total	35.313	310			
Avg. Score of Culture of all time Audit readiness Educational Qualification	Between Groups	.178	3	.059	.520	.669
	Within Groups	35.135	307	.114		
	Total	35.313	310			
Avg. Score of Culture of all time Audit readiness against Experience	Between Groups	1.144	3	.381	3.427	**.018**
	Within Groups	34.169	307	.111		
	Total	35.313	310			
Avg. Score of Culture of all time Audit readiness against Department	Between Groups	.065	2	.032	.284	.753
	Within Groups	35.248	308	.114		
	Total	35.313	310			

From the table 3, it can be inferred that among the various socio-work related variables, Company and Experience show a statistically significant impact on the Culture of All Time Audit Readiness Parameter, with p-values of 0.049 and 0.018 respectively. This indicates that audit readiness culture significantly varies across different companies and levels of experience among employees. In contrast, variables such as Gender, Age, Educational Qualification and Department do not show any significant influence on audit readiness culture. Therefore, it can be concluded that organizational environment and work experience play a more pivotal role in shaping audit readiness culture, whereas personal demographic factors have comparatively less influence. This insight is particularly relevant in the context of Hyderabad-based pharma companies, where aligning experience-based training and company-wide cultural policies may yield better compliance outcomes.

6. FINDINGS

The study involved 311 respondents from four major pharmaceutical companies in Hyderabad, Granules, Dr. Reddy's, Hetero and Lupin. Most participants were male and belonged to the 35-45 years age group. Nearly half had a master's degree and experience was fairly distributed, with 32.2% having over 15 years. Operations and quality departments represented the majority of respondents. The ANOVA results showed that the company and employee experience significantly influence the culture of continuous audit readiness, with p-values of 0.049 and 0.018 respectively. Other factors like gender, age, education and department showed no significant impact. Further, the responses revealed that effective documentation and training are strongly linked to audit readiness, while issues like lack of dedicated

resources, inadequate awareness programs and ineffective internal audits hinder continuous audit preparedness in Indian pharmaceutical companies.

7. CONCLUSION

This study clearly shows that in Indian pharmaceutical companies, especially those in Hyderabad, building a strong culture of continuous audit readiness depends largely on the company itself and the experience level of employees. While personal factors like age, gender, and education do not significantly affect audit readiness culture, the role of proper training, effective documentation and committed leadership cannot be overstated. Challenges such as insufficient resources and lack of awareness programs still persist, which need urgent attention. It is therefore essential for pharma companies to focus on nurturing a proactive mind-set, investing in skill development and fostering transparency at all levels to meet both national and international regulatory standards consistently. Only through such cultural transformation can Indian pharma maintain its reputation as a reliable and quality-driven industry on the global stage.

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