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Fuzzy-set qualitative comparative analysis: A tool to evaluate the impact of training on human factors in Ayurvedic drug manufacturing

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Abstract
A pharmaceutical manufacturing process involves many variables that affect the product quality *viz.* sensory variables, process variables as well as human factors. Humans are involved at each and every step of the process and play a significant role in improving the product quality. One way to control human factors is training. In the present study, the impact of training was evaluated using fuzzy-set qualitative comparative analysis (fsQCA). The data was collected from the subjects exposed to training in various segments of Ayurvedic drug manufacturing through a multiple-choice questionnaire. The data-set was constructed by taking into consideration the process variables as conditions and successful training as the outcome and fsQCA was applied. The results obtained from fsQCA revealed that training plays a significant role in controlling the human factor thereby affecting product quality. Hence, among the various factors considered for poor quality, human factors should also be taken into consideration.

Keywords: Human factors, pharmaceutical manufacturing, qualitative comparative analysis, fsQCA

1. Introduction

Drug manufacturing is a complex process and many variables are involved in the process which has an impact on the product quality. Methods for determining the identity and purity of a product are well established. However, to ensure quality, consideration should be given to the qualitative attributes used to qualify the product during the process. These mainly include sensory and process variables as well as the human factors. Humans are considered an important part of a system and contribute largely to the manufacturing process.

Human factors can be defined as the involvement of human in the process or the interaction of humans with the system. According to the definition given by the International Ergonomics Association, 'Human factor is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance [1].' In case of pharmaceutical manufacturing, humans are involved at each and every step of the process. The cost of ignoring human factors is poor quality as it leads to increased chances of error, lower productive output and low-quality work [2]. Hence for improving quality, focus on human factors is important rather than merely focusing on the process variables. Thus, human factor is an inevitable part of the manufacturing process and it cannot be ignored.

One way out to control human factor is Training. Guidelines given by the regulatory bodies around the world highlight the importance of training. Training is an investment in people that pays its dividends in a more skilled workforce, improved productivity and service quality [3]. Providing proper training will develop a better understanding of the process leading to improved performance, reducing the probability of batch failure, reduction in re-work and improving cost thereby developing a better-quality product. Hence, in the present study the impact of training is evaluated using a technique called Fuzzy set Qualitative Comparative Analysis (fsQCA).

1.1 Qualitative Comparative Analysis (QCA)

Qualitative comparative analysis (QCA) was developed by the social scientist Charles Ragin [4]. It is a configurational, case oriented method that allows for the analysis of different cases as a complex combination of properties [5]. QCA analyses causal complexity in terms of conjunctural causation or equifinality and identifies necessary and sufficient conditions for an outcome [6]. Conjunctural causation conveys that a combination of different conditions may be necessary or sufficient for an outcome while equifinality explains the different paths that lead to the same outcome [7]. There are three main techniques: Crisp-set QCA (csQCA), multi-value QCA (mvQCA) and fuzzy-set QCA (fsQCA). Among these techniques, fsQCA allows for partial set-membership using varying degree of membership between 0 and 1 unlike crisp sets that depend only on binary data i.e., either 0 or 1. Thus, fsQCA combines the advantage of both qualitative and quantitative assessment [8]. Therefore, fsQCA utilized in the current study serves as a suitable technique that identifies the different combination of conditions leading to successful training.

2. Materials and Method

2.1 Data Collection

The data was collected by taking feed-back from the subjects exposed to training in various segments of Ayurvedic drug manufacturing at in-house pharmacy through a multiple-choice questionnaire which is shown in Table 1. The questionnaire was designed by taking into consideration the critical process parameters which can be affected by human factors and thereby have a direct impact on critical quality attributes.

2.2 Construction of data-set

Step 1: Assigning membership values

In the present study, for fuzzy-set four value scheme was adopted namely,"0", "0.33", "0.66", "1". The multiple-choice preferences were given membership values in descending order as follows:

- Optimum – 1
- Average – 0.66
- Below average – 0.33
- Inappropriate – 0

The membership values thus assigned to the preferences are as shown in Table 2.

Step 2: Selection of conditions

For the construction of data-set the process parameters mentioned in the questionnaire were taken as conditions for successful training as the outcome. If optimal condition is perceived by the subject then the outcome is 1 otherwise 0 and the overall outcome was measured as shown in Table 3.

On the basis of step 1 and step 2, the data-set was constructed which is shown in Table 4.

Table 1: Training evaluation questionnaire

S. No.	Questions	Options
1	When making powder what should be the particle size of the Raw materials?	a. Coarse b. Moderately coarse c. Fine d. Very fine
2	How should mixing of ingredients be carried out to obtain uniform mixture?	a. One by one b. Two at a time c. Mixed altogether d. Mix and then size reduce
3	How does mixing affect the product quality?	a. Dose uniformity b. Appearance c. Stability d. All of the above
4	During *Mardana*, how much liquid should be added to obtain desired consistency?	a. More b. Quantity sufficient c. Less d. Equal
5	During *Mardana*, if liquid is added in more amount then how is it corrected?	a. Increase duration of *Mardana* b. Adding extra quantity of ingredients c. Adding starch d. All of the above
6	How does the duration of *Mardana* affect the product characteristics?	a. Gives uniform size reduction b. Uniform texture and consistency c. Uniform mixing d. All of the above
7	During drying the material in the tray dryer	a. Spreaded as thin layer b. Placed as it is c. Thick layer d. As small lumps
8	How does high temperature and increase time duration affect the product quality?	a. Burnt and degradation of thermostable material b. Stable c. Moist d. Improved appearance

Table 2: Assigning of membership values

S. No	Preferences	Membership value
1	Very fine	1
	Fine	0.66
	Moderately coarse	0.33
	Coarse	0
2	One by one	1
	Two at a time	0.66
	Mixed altogether	0.33
	Mix and then size reduce	0
3	All	1
	Dose uniformity	0.66
	Stability	0.33
	Appearance	0
4	Quantity sufficient	1
	Equal	0.66
	More	0.33
	Less	0
5	Increase duration of *Mardana*	1
	Adding starch	0.66
	Adding extra quantity of ingredients	0.33
	All of the above	0
6	All	1
	Uniform size reduction	0.66
	Uniform mixing	0.33
	Uniform texture and consistency	0
7	Spreaded as thin layer	1
	Thick layer	0.66
	As Small lumps	0.33
	As it is	0
8	Burnt and degradation of thermo-stable material	1
	Improved appearance	0.66
	Stable	0.33
	Moist	0

Table 3: Measuring outcome

Total score	Score obtained	Percentage	Remarks
8	8	100%	Excellent
	5.6-8	≥70%	Good
	0-5.5	≤70%	Below average

Table 4: Constructed data-set

Case	SR (Size reduction)	MT (Mixing technique)	EM (Effect of mixing)	BD (*Bhavna dravya*)	QB (Quantity of *Bhavna dravya*)	DM (Duration of *Mardana*)	DR (Drying)	DRT (Drying time)	Outcome
s1	0.33	1	1	1	1	1	1	1	1
s2	0.66	1	1	1	0.33	0	1	1	1
s3	0.66	1	1	1	0.33	0	1	1	1
s4	0.33	1	1	1	0.33	0	1	1	1
s5	0.33	1	1	1	1	1	1	1	0
s6	0.66	0.33	1	1	0.33	0.33	0.66	1	1
s7	0.66	0.33	1	1	1	1	1	1	0
s8	0.66	1	0.66	1	1	1	0.33	1	1
s9	0.33	1	1	1	0	0	1	1	1
s10	0.66	1	0.66	1	1	1	1	1	0
s11	0.66	1	0.66	1	1	1	1	1	1
s12	0	1	1	1	0	1	0.33	1	1
s13	0.33	1	1	1	0	1	1	1	0
s14	1	1	1	0.33	1	1	1	1	1
s15	1	1	1	1	1	0.33	0.33	1	1
s16	0.66	1	1	1	1	1	0.33	1	1
s17	0	0.33	1	1	1	1	1	1	1
s18	0.66	1	1	1	1	1	1	1	1
s19	1	1	1	1	0	1	1	1	1
s20	0	1	1	1	0	1	1	1	1

2.3 Fuzzy-set QCA
The analysis was carried out using the package QCA in the software R studio version 1.1.383 [8].

2.3.1 Calibration
Calibration is the first step for carrying out the fsQCA, to convert raw data into fuzzy-set scores based on thresholds. In the study the direct method of calibration was used which uses a logistic function to transform raw data into fuzzy set values based on three qualitative thresholds such as exclusion, cross over and inclusion. The calibration threshold for exclusion was set to 0.3, cross over was set to 0.6 and inclusion threshold was set to 1.

2.3.2 Analysis of Necessity and Sufficiency
After calibration the analysis of necessary and sufficient conditions accountable for the outcome was done.
A condition is considered necessary if it is always present when the outcome occurs, i.e., the outcome cannot occur in the absence of the condition whereas a condition is sufficient if the outcome always occurs when it is present but other conditions can also be responsible for the outcome [10]. The assessment of necessary and sufficient conditions is done on the basis of consistency and coverage. Consistency may be defined as the degree to which a relation between a condition and outcome is met while coverage is the degree to which a condition is relevant to the outcome. For a condition to be necessary the consistency threshold should be more than 0.75 [11].

2.3.3 Construction of Truth table
The truth table identifies different causal combination of conditions associated with the outcome. It is a step to convert fuzzy sets into crisp set truth table. However, while constructing the truth table the key determination to be made is the consistency threshold which is used as a cut-off value for determining which causal combinations pass fuzzy set theoretic consistency and which do not.
In this study, the consistency threshold value was set to 0.8 which is more than 0.75. The causal combinations with consistency scores at or above the cut-off value are designated as fuzzy subsets of the outcome and are coded as 1 while those below the cut-off value are not fuzzy subsets and are coded as 0 [12].

2.3.4 Minimization
The truth table thus constructed was minimized using Quine-McCluskey algorithm to form a shorter, more parsimonious expression from a complex expression. Thus, if two expressions differ only by one condition then that condition can be considered irrelevant and can be removed to form a simpler, combined expression [13].

3. Results and Discussion
3.1 Analysis of necessity and sufficiency
The results obtained from the analysis of necessary conditions are shown in Table 5.
On the basis of results of necessity, the conditions EM*DRT along with MT*DRT reveal that understanding of EM, MT and DRT reflect the success of training. But simultaneously the condition DRT though having a significant inclusion score but has low relevance of necessity. Hence, the understanding of DRT alone cannot be the decisive factor behind the success of training. While, conditions SR+qb+dr, SR+mt+dm+dr, SR+em+qb+dm and SR+mt+qb portray that perception of SR is essential as it is the prime unit operation which can influence the outcome of the subsequent operations namely mixing.
The results obtained from the analysis of sufficient conditions are shown in Table 6.
The results of sufficiency lucidly depict that the perception of conditions MT, EM and SR turn out to be the prime decisive factors for the evaluation of training. A sound understanding of MT, EM and SR ultimately leads towards manufacturing of a quality product. Though DRT turns out to be a sufficient condition but along with the results of necessity it can be said that it may not be the evaluative parameter for training. However, drying time does play a significant role in product quality.

3.3 Truth table and Minimization
The truth table constructed is as shown in Table 7 which was further minimized using Quine-McCluskey algorithm.
On minimization, the configuration obtained is:

~DM + ~DR + SR*MT*EM => OUTCOME

The details of the configuration of conditions obtained are shown in Table 8.

The results obtained from minimization reveal that the perception of Duration of *Mardana* and Drying does not highlight the impact of training.

Table 5: Analysis of Necessary conditions

S. No.	Condition	InclN/Consistency	RoN	CovN
1	DRT	0.950	0.208	0.800
2	qb+DM	0.903	0.300	0.790
3	sr+QB+dm	0.912	0.311	0.796
4	SR+DR	0.831	0.434	0.778
5	MT*DRT	0.835	0.566	0.823
6	EM*DRT	0.845	0.542	0.820
7	SR+qb+dr	0.805	0.672	0.847
8	SR+mt+dm+dr	0.810	0.741	0.877
9	SR+em+qb+dm	0.811	0.628	0.832
10	SR+mt+qb	0.824	0.604	0.830

InclN – Inclusion score for necessity; RoN – Relevance of necessity; CovN – Coverage
+ signifies logical OR; * signifies logical AND

Table 6: Analysis of sufficiency

S. No.	Conditions	InclS/Consistency	CovS
1	MT	0.823	0.835
2	EM	0.820	0.845
3	SR	0.837	0.469
4	DRT	0.800	0.950

Table 7: Truth table

S. No.	SR	MT	EM	BD	QB	DM	DR	DRT	Outcome	incl
1	0	0	1	1	1	1	1	1	0	0.737
2	0	1	1	1	0	0	1	1	1	0.945
3	0	1	1	1	0	1	0	1	1	0.890
4	0	1	1	1	0	1	1	1	0	0.596
5	0	1	1	1	1	1	1	1	0	0.623
6	1	0	1	1	0	0	1	1	1	0.862
7	1	0	1	1	1	1	1	1	1	0.386
8	1	1	0	1	1	1	0	1	1	0.879
9	1	1	0	1	1	1	1	1	0	0.588
10	1	1	1	0	1	1	1	1	1	0.907
11	1	1	1	1	0	0	1	1	1	0.914
12	1	1	1	1	0	1	1	1	1	0.846
13	1	1	1	1	1	0	0	1	1	0.915
14	1	1	1	1	1	1	0	1	1	0.887
15	1	1	1	1	1	1	1	1	1	0.814

Table 8: Result obtained from minimization

S. No.	Conditions	InclS/Consistency	CovS	CovU
1	~DM	0.969	0.397	0.192
2	~DR	0.959	0.292	0.127
3	SR*MT*EM	0.939	0.371	0.157

As a unit operation, the understanding of the purpose of *mardana*, i.e. size reduction clearly indicates the completion of training. Moreover, the comprehension of the effects of *mardana* and mixing which leads to homogeneous mixture thereby dose uniformity, hence coherently indicates the success of training.

4. Conclusion

To conclude, the results of fsQCA give a clear picture that training plays a fundamental role in controlling the Human factors. Among the various factors considered for poor quality, Human factor must also be taken into consideration. Thus, training in juxtaposition with quality management can help deliver better quality product.

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