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RESEARCH PAPER

Application of Parameters and Requirements for the Expert Systems Assessment in Nano Fiber Based Pharmaceutical Technology

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ABSTRACT

This study explores the unique characteristics and parameters used in intellectual systems for drug delivery. Todays, the most widely used category of intelligent systems are expert systems that are computer systems capable of partially replacing a highly trained professional in his/her area of expertise by means of information previously gained by the experts. That is why expert systems are agreed to be viewed along with information bases, which are models of the actions of experts in a particular area, and logical assumptions are extended to decision-making procedures. The application field of expert systems is absolutely unlimited. A vivid example is their use in diagnostic tasks of modern medicine. Following a brief discussion of the basic mechanics underlying electrospinning, a thorough discussion of the parameters that can impact the mechanism and the nature of their effect was given. Data revealed that SPC Methodology was an efficient and effective mean to automate the monitoring of expert system rule behavior and other process measures that were important for expert system performance.

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INTRODUCTION

The pharmaceutical studies are changing industry and technological developments to improve product quality and manufacturing capacities. In medical services, two energizing employment of man-made brainpower in the facility for patient consideration and in the lab for drug disclosure are amazingly various applications. That maybe clarifies why it's still early days for both, they are creating at various rates. About half of late-stage clinical preliminaries flop because of ineffectual medication targets, bringing about just 15% of medications progressing from phase 2 to endorsement. What's more, analysts will in general mix around similar sickness zones and targets. The food, drug and cosmetic act characterizes drugs, partially, by their planned use, as "articles proposed for use in the analysis, fix, moderation, treatment, or avoidance of infection" and "articles (other than food) expected to effect on the design or any capacity of the collection of man or different creatures [1]. The drug development has the reputation of being attentive to implementing new technology and slow to make changes. This caution is attributed, at least in part, to the legal obligation to prove that any improvement to the procedure would not have an adverse influence on the value of

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the item. Regulatory authorities and the industry have, nevertheless, made a concerted push during the last couple of decades to implement practices and innovations that can enhance quality and production performance. There is also recognition that more improvements will be required to further respond to modern production methods, such as product development, industry and customized medicine, as well as technological services such as process analytics and automated process management. Pharmaceutical research is a critical aspect in the project lifecycle of medicinal products. There are several methods and models for assessing information systems, including expert systems based on databases. The disadvantages of the assessment methods described earlier are their lack of systematization and complexity of application, lack of uniform terminology and insignificant practical application. One solution to this problem is to use statistical process control (SPC) to automate monitoring of expert system performance. By using statistical analyses to monitor rules, attention can be focused on only those rules that exhibit significant changes in performance over time. Originally developed for use in the manufacturing industry, the principles and techniques of SPC can easily be applied to expert systems. SPC methods have also been advocated in healthcare for quality improvement [2] and for healthcare epidemiology [3,4]. After addressing an alert, the pharmacist uses a dynamic web interface to enter response information into a database, including whether or not the pharmacist and physician agreed with the alert. This information is necessary to effectively monitor DoseChecker since there are valid clinical reasons why a patient can be given a drug dose that is outside of the recommended ranges.

In evaluating strategies for automating DoseChecker monitoring, our team chose SPC methods as the most efficient and effective solution. The principle tool of SPC is the control chart, which plots performance data over time along with calculated upper and lower control limits. The control limits define the variation that can be attributed to common causes, and in our case are set at three standard deviations above and below the process average. If a point falls outside the control limits or if other unexpected patterns occur in the data, a change is occurred that cannot be attributed to random fluctuations. This is called special cause variation, and may indicate that a significant change or event has occurred in either the expert system or the clinical environment.

For this application, we employed a p-chart using three rules for signaling special cause variation [5,6] including a point above or below the calculated control limits, eight points in a row above or below the process average, any ten out of eleven points above or below the process average. The methodological guidelines for the pharmaceutical industry include a document adopted by the international conference on harmonization of technical criteria for the registration of human medicines-ICH Q, representing steps, material, logic and requirements [7,8]. According to this document planned quality, or quality by development, provides “a systematic approach to development based on sound scientific evidence and product quality risk management that begins with the definition of objectives and focuses on understanding the product and process and controlling the latter”. Only from the point of view, the planned quality FD will be a kind of guarantee for the production of quality, efficient and safe medicines [9]. Today, one of the least standardized and formalized stages of development of the finished dosage form is the stage of pharmaceutical development [10].

In the present study, the key stage in the implementation of any expert system is a clear understanding and adherence to the principles of information support for process control systems. Our group used control charts and other SPC tools for manually monitoring expert system performance and impact. We selected our DoseChecker application to test whether SPC could be used to automate expert system monitoring. DoseChecker was designed to screen drug orders for dosing errors that result from failing to adjust for renal function [11]. Using patient-specific information from pharmacy and laboratory systems, a creatinine clearance estimate is calculated and the ordered dose is compared to a set of allowable dose ranges.

MATERIALS AND METHODS

Electronic data sets (EMBASE and PubMed) were looked to distinguish papers distributed between 1985 and 2020. No restrictions were applied for the language of distribution or nation of cause. Studies were incorporated in the event that they detailed experimental information with respect to the turn of events or assessment of value

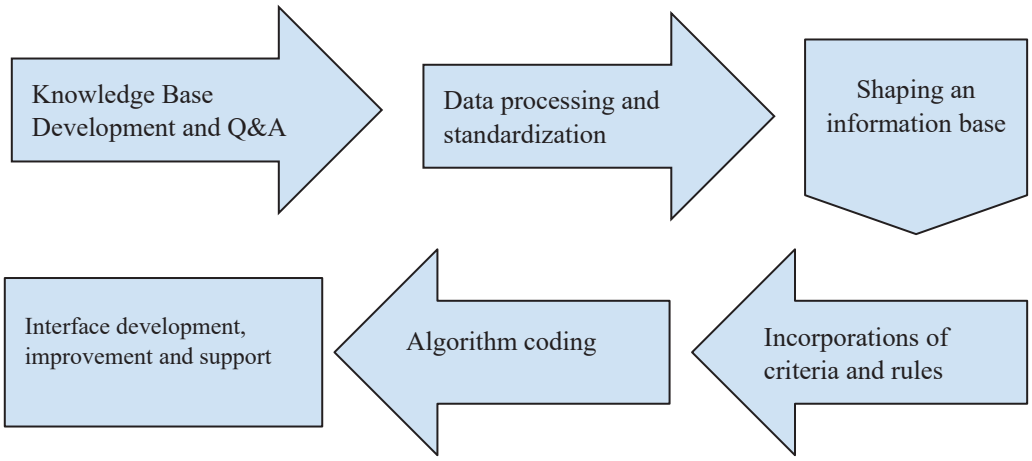

Fig. 1. Development of the expert system.

pointers. All investigation plans were qualified for incorporation. The copy free screening was embraced by the list items.

The essential thought and improvement steps of the master framework are introduced in Fig. 1. On account of distinguished bugs and insufficiency, past advances ought to be rehashed. As can be seen from scheme 1, the initial four stages are identifying with information base shaping and information designing. Fundamental presumptions utilized for this stage will be clarified in the accompanying content.

As a first step, the importance of each criteria for every spinning characteristic has to be determined and stored in the knowledge base of the expert system. At this point, there is a limited number of spinning characteristics to use the approach that will be presented here, modular knowledge for others can easily be added to the knowledge base. Determination of the criteria importance was based on the literature overview. Importance of each criteria has to be entered (0 - no importance, 10 - max. importance). Criteria: A-Working distance (needle to collector distance) [12]; B-Needle gauge (inner diameter of the needle) [12]; C-Electrospinning time [12]; D-Counter materials [12]; E-Molecular weight [13]; F-Solution viscosity [14,15]; G-Dielectric effect of the solvent [16]; H-Flow rate [16]; I-Temperature [16]; J-Humidity [17]; K-Pressure [17].

RESULTS AND DISCUSSIONS

Currently, information in this field needs to be categorized and systematized in order to build efficient resources to minimize development time, which is a restricting stage when a new drug enters the market. In accordance with the above, the role of designing and establishing an intellectual framework for the selection of pharmaceutical formulations, supplementary substances, which will be based on an expert system and knowledge base in the field of drug discovery, should be of current science and practical significance. A strong definition and commitment to the concepts of knowledge management for process management systems is a crucial step in the implementation of any professional framework.

The disadvantages of the assessment methods described earlier are their lack of systematization and complexity of application, lack of uniform terminology and insignificant practical application. However, most authors identify their efficiency and effectiveness as the most important indicators of expert systems. Efficiency is understood as a level of achievement of the purpose in the set conditions, connected with results of decision-making, received on an output, that is efficiency of correlation of inputs (resources) and outputs. Efficiency means the use of the smallest number of resources, however, on the other hand, efficiency can be verified by feedback from users of the expert system. This method of evaluating the efficiency of an expert system allows to make sure that it meets the interests of users and meets their needs [18]. Evaluation can be presented as a process that allows increasing the use, quality and usefulness of the expert system.

An important point in the evaluation of expert systems is the necessity to consider the expert system not as an isolated object, but as a working

tool used to achieve certain goals. The review of literature has revealed some parameters for the evaluation of expert systems. These parameters clearly show that the productivity of expert systems should be evaluated from the point of view of influence of users, system and organization, where the expert system is implemented, on each other. Expert systems generate profits for the organizations in which they are implemented, for example, by leading to more accurate and informed decision-making and by reducing time spent on tasks [18]. Users, with the proper use of expert systems, increase productivity in the organization. As mentioned above, the majority of approaches for estimating expert systems on literary data do not have formal criteria for estimating expert systems. The criteria which can be used for estimating the productivity of the expert systems have been pooled together for further identification and standardization according to the position of the subjects involved in the expert system estimation: the user, expert system and the organization [19,20]. Computerized master frameworks give a dependable and successful approach to improve patient wellbeing in an emergency clinic climate. Their capacity to dissect a lot of information without exhaustion is a settled benefit over clinicians who play out similar assignments. As reliance on master frameworks increment and the frameworks become more unpredictable, it is essential to intently screen their exhibition. Inability to produce cautions can risk the wellbeing and security of patients while creating extreme bogus positives can make substantial alarms be excused as clamor [21]. In any case, quick improvement of new data advances just as the presentation of new strategies and information give a novel, efficient and experimentally based methodology in choosing the fitting game for a person.

In the acknowledgment cycle, two fundamental issues were distinguished. In the first place, the assignment of finding a specialist in this field is very troublesome because of the way that the space of explicit information is isolated. Additionally, as a rule, specialists have top to bottom information on the applicable elements for a particular field of Drug store and are shallower for different innovations. The subsequent issue is truth be told like the first and it identifies with the accessibility of the information (master) regardless of whether we have the perfect individual. To keep away from these issues, the choice of building up a PC based master framework was brought [21]. By and large, information securing procedures that are most habitually utilized today, require a gigantic measure of time and exertion with respect to both the information engineer and the area master. They additionally require the information designer to have an uncommonly wide assortment of meeting and information portrayal abilities to be fruitful [22]. A specialist framework ought to be versatile to steady changes of new standard qualities and quantifies just as open to addition of new information.

Fig. 2 presents FESEM images of the nanofiber at two magnifications. The images show that

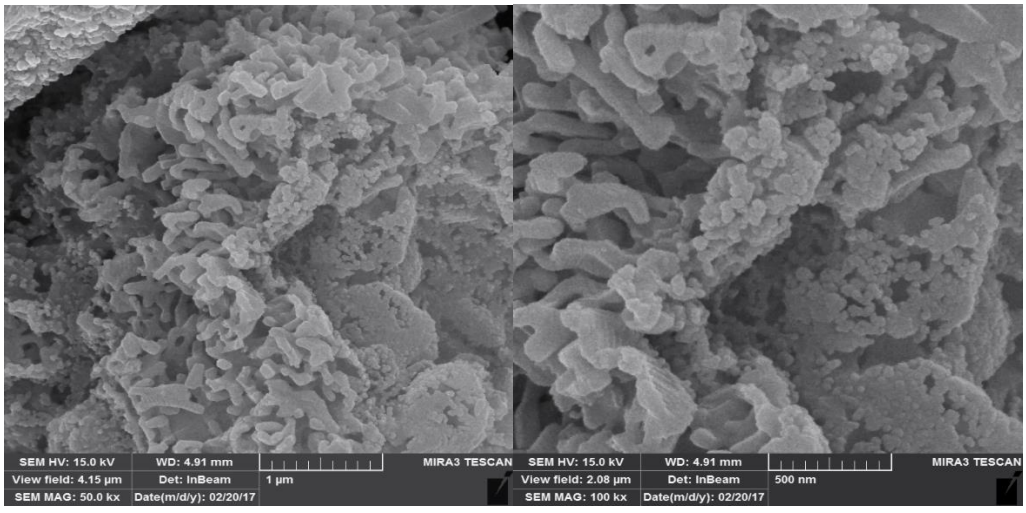

Fig. 2. FESEM images of nanofibers.

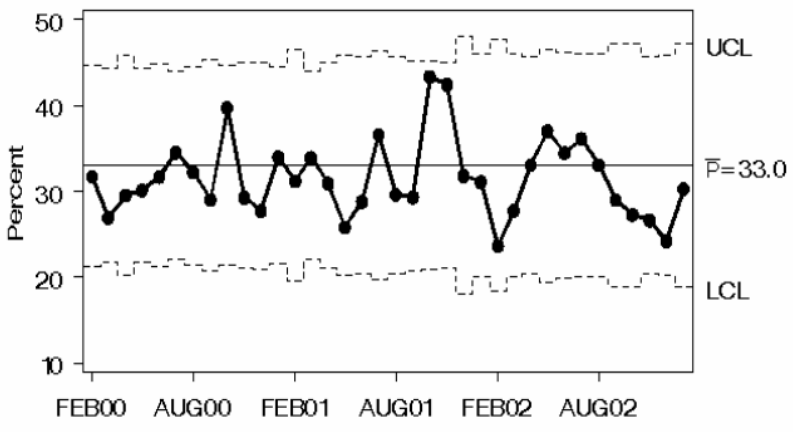

Fig. 3. Sample alert rate chart without special cause variation.

porosity structure of the material. It is found that the size of the nanomaterial is in the range of 50 – 100 nm.

Any single data point can satisfy the first rule. The second and third rules both require a series of data points, which indicate a sustained change in the process. When this occurs, the process average may be recalculated in order to evaluate future performance. Fig. 3 is a sample control chart for a process that shows no special cause variation. The centerline is the process average, while the dotted lines above and below are the control limits. The control limits vary with each point on the chart, because they are dependent on the sample size used to calculate the individual monthly rates. The points connected by the solid black line represent the actual data used to calculate the other aspects of the control chart. Each point represents a single month.

For the initial trial, the following DoseChecker performance attributes were selected the following items for monitoring such as alert rate, pharmacist agree rate, physician agree rate, missing outcome response rate.

The Alert Rate is the number of alerts divided by the number of orders screened. The Pharmacist Agree Rate is a subset of the alert rate and is calculated by dividing the number of alerts with which the pharmacist agreed by the number of alerts for which an outcome was entered. The Physician Agree Rate is a smaller subset and is calculated by dividing the number of alerts with which the physician agreed by the number of alerts with which the pharmacist agreed. If the pharmacist does not agree with an alert, a physician is not contacted. Finally, the Missing Outcome Response Rate is the number of alerts for which no outcome was entered divided by the total number of alerts.

To create the control charts, a monthly procedure was put in place to analyze the necessary information, using a standard statistical

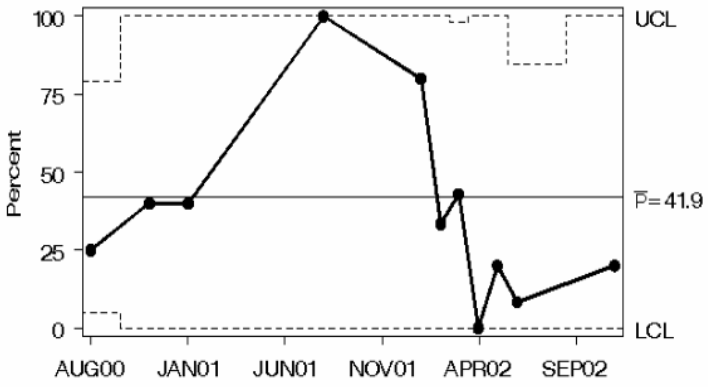

Fig. 4. Ticarcillin/clavulanate alert rate.

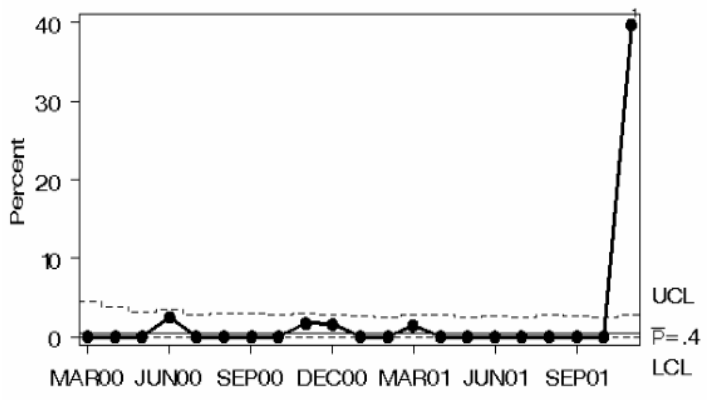

Fig. 5. Missing outcome response rate.

software package (SAS, Cary, NC). The same process performs the calculations and generates the control charts, which are displayed via an existing intranet web application. To make problems easier to detect, control charts that show special cause variation trigger an SPC flag to appear on the website. This flag is a small icon that appears next to the drug name and lets the user know when any of the three special cause rules have been satisfied. The flags were the basis for our analysis, since they could be used to notify our maintenance team that a specific drug or drug rule should be investigated.

Because of the statistical calculations involved in generating SPC charts, only drug rules with an average of twenty-five or more orders screened each month were evaluated. Rules with very small sample sizes tend to have highly variable data, which makes the control limits on the SPC charts much less useful. Fig. 4 shows a control chart for the Ticarcillin/Clavulanate Alert Rate at one BJC HealthCare facility. With a twelve-month average of fewer than four orders per month, the result is a chart with control limits that range from zero to one hundred percent.

Fig. 5 is one example of how SPC methods can be used to detect a process that is out of statistical control. In this case, a staffing change at one BJC facility in November 2001 prevented their pharmacy from effectively addressing DoseChecker alerts and entering response information. This control chart for intravenous vancomycin was generated the month following the staffing change. The Missing Outcome Response Rate increased to forty percent, which is nearly ten times the value of the upper control limit. This triggered an SPC flag that could have been used to alert the maintenance team o f a potential problem.

Another example that illustrates how SPC can be used for monitoring an expert system occurred early in 2002, when policy changes at a BJC facility gave the pharmacists the authority to change certain drug orders in response to DoseChecker

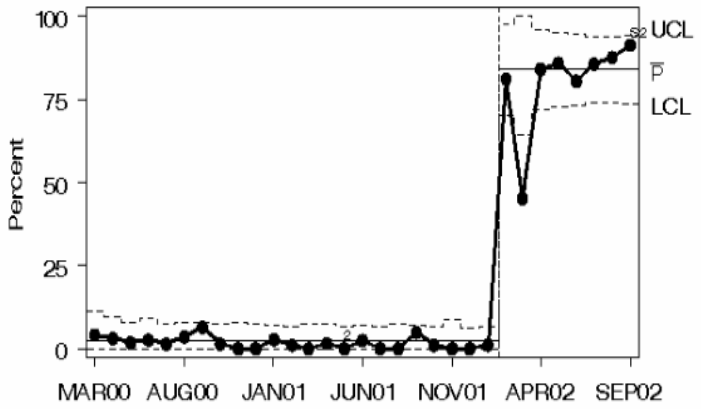

Fig. 6. Increase in pharmacist agree rate as a result of a policy change.

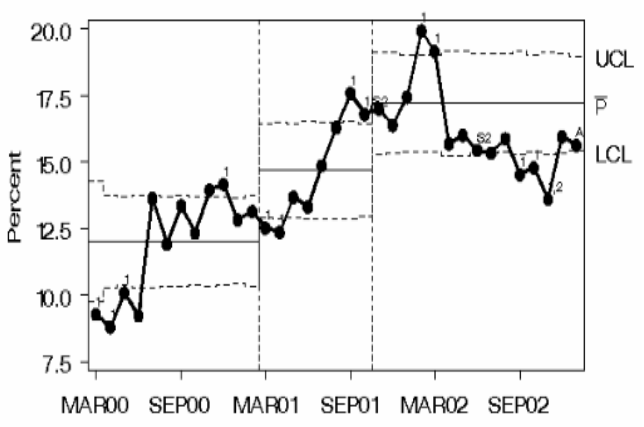

Fig. 7. change in overall alert rate.

alerts. Prior to this, the Pharmacist Agree Rate for intravenous vancomycin alerts was nearly zero. Afterwards, the Agree Rate increased dramatically, as seen in Fig. 5. This increase generated another SPC flag that would have notified the maintenance team. This control chart also shows the benefit of recalculating a shift in the process average. After eight points were plotted that were above the previous average, a new average was calculated using the same eight points. If the new process average was not calculated, the automated monitoring system would continue to generate SPC flags until the agree rate fell to its previous rate. In this case, the policy change resulted in an improved process because pharmacists were agreeing with the alerts, so expecting the process to return to the previous state would not make sense. Furthermore, by redefining the process average, an SPC flag would be generated if the agree rate decreased below its newly established baseline.

Finally, we saw that control charts can draw attention to overall trends at a facility. Fig. 7 shows the overall Alert Rate at a BJC facility as of January 2003. From March 2000 to March 2002, three different process average shifts occurred. Each shift resulted in an SPC flag that could have called attention to the change in the alert rate. After the facility implemented a policy change early in 2002, three points have been below the lower control limit, and eight in a row and ten out eleven have been below the mean. All of these events result in SPC flags that indicate a statistically significant trend in Fig. 6: Missing Outcome Response Rate Fig. 7: Increase in Pharmacist Agree Rate as a Result of a Policy Change.

Table 1 presents the parameters and criteria for evaluation of expert systems. From the point of view of the user of the expert system, three parameters can be distinguished, according to which the system can be evaluated: usability, utility, quality. The parameter “usability” is described by foreign authors as ease of use of the system.

The parameter “usability” is described by foreign authors as ease of use of the system. One more parameter, considered from the user’s point of view, for estimation of productivity of an expert system is “utility”. The “utility” is understood as what benefit the user of the expert system gets. Performance of the system should be estimated according to its usefulness. In order to determine whether the expert system meets expectations, it is necessary to understand whether the expert system will be used to solve the user’s tasks despite the existing difficulties or inconveniences. The technical definition established by the international organization for standardization (ISO) describes the term “quality” as usability [23]. This suitability needs to be confirmed [24].

Table 2 presents the criteria that are related to the criterion of “quality”: reliability, quality of the obtained solution of the problem, consistency, update time, coherence, response time.

From the system point of view, two parameters have been defined for the evaluation of expert systems: interface and structure. The interface and structure parameters allow the criteria to be identified according to the software and hardware aspects. The “interface” parameter corresponds to the system design and should provide access to information. The interface in the expert system

Table 1. The parameters and criteria for evaluation of expert systems.

Subjects	Parameters	Criteria	
User	Usability	Study	Efficiency
		Allowable error	Satisfaction
		Performance	Expediency
	Utility	Scale	Expediency
	Quality	Credibility	The quality of the obtained solution to the problem
		Coherence	Update time
		Coherence	Response time
Expert system	Interface	Ease of use	Quality of proposed solutions
		Appearance	Search simplicity
		Quality of data input and display	
	Structure	Stability	Number of mistakes
		Processing operations	History
		Operations Processing Time	
Organization	Productivity	Motivation	Task optimization
		Profit	Reports
		Performance	Cost
		Efficiency	
	Profit	Competitiveness	Return on investment
		Cost reduction	

is a set of characteristics that users apply when interacting with the system. Thus, the interface is all that is available to the user to control the system and how the system should react to the user's actions. To evaluate the "interface" parameter five criteria are defined: ease of use, quality of proposed solutions, appearance, ease of search, quality of data input and display. The next parameter related to the system is structure. Criteria for evaluation of this parameter are stability, number of errors, processing of operations, history, processing time of operations [25].

From the point of view of the organization that implements expert systems, there are two parameters that have been defined to evaluate expert systems: productivity and profit. Criteria for evaluation of the parameter "productivity": motivation, task optimization, profit, reports, efficiency, cost and efficiency. These criteria evaluate aspects related to financial turnover and economic activities, which are mentioned in the studies. The parameter "profit" emphasizes the connection between the expectations associated with investments in the development of expert systems and the expected income. The main criteria of this parameter are competitiveness, cost minimization and return on investment.

Shing Jang et al explored the impacts of different boundaries on the electrical execution of nanofiber-based electrospun [6]. They chose four creation boundaries, in particular: working distance, needle measure, electrospinning time, and contact material. A blended symmetrical cluster of analyses was planned concerning one factor having two-level qualities and three variables having three-level qualities. All boundaries were genuinely critical (P-value < 0.05) in light of the fundamental impact plot and ANOVA test. Among the three electrospinning boundaries, working distance and electrospinning time showed more critical effects on the presentation. A more drawn-out working distance would expand the charge thickness of the nanofiber tangle because of its slim nanofibers and smaller constructions, bringing about improved electrical execution. Didem Rodoplu et al describes the effect of vertical - horizontal electrospinning setups and electrospinning parameters on fiber morphology [11]. The stream rate is diminished with different boundaries kept consistent; it is seen that there is a decline in the globule size though there is an expansion in nanofiber breadth. When contrasting the two methods of stream rate, it is deduced that with the reduction in stream rate, globule size could get more modest until the non-beaded construction is obtained. Further lessening in stream rate encourages the need of an increment in voltage all together for the electrospinning to occur. At the point when a non-beaded design still the lessening of the stream rate expanded the fiber distance across [26]. At the point when different boundaries are kept consistent and

Table 2. The related criteria to the "quality" parameter.

Criteria	Description
Credibility	User confidence in system solutions
Coherence	Integrity of the presentation of information in the system
Coherence	Ability of the system to correspond to reality (relevance of decisions)
Quality of the solution	Quality of problem solving
Update time	Ability of system to decide in a short time, and be updated in the decision process
Response time	Time during which the user expects a response from the system, from the time of the request to the decision

voltage is expanded, nanofiber distance across diminishes, anyway the dab sizes increment. The beaded design shows that a steady Taylor cone couldn't be acquired [27]. With the increment of voltage, more prominent measures of charge arise, making the drops and the stream quicken toward the gatherer quicker, in this way bigger dots are framed. It is anticipated that to acquire a Taylor cone and non-beaded fiber morphology, stream rate and voltage ought to be changed together. In the event that the stream rate is changed voltage ought to be changed to another basic voltage esteem. Likewise, for a given voltage, there ought to be a sure stream rate to gather non-beaded nanofibers. On the off chance that one of these two boundaries is changed alone, the beaded construction of filaments, which have bigger breadths, are noticed. At the point when the stream rate is expanded, the basic voltage esteem is likewise expanded for non-beaded fiber morphology. Fiber diameter is increased with increased polymer concentration. Also, the critical voltage value for electrospinning is increased when the concentration of the solution is increased [11]. Fiber distance across is expanded with expanded polymer focus. Additionally, the basic voltage esteem for electrospinning is expanded when the centralization of the arrangement is expanded. The explanation, why they are trapped, is that the dissolvable couldn't completely vanish prior to arriving at the authority. Gravitational power influencing the polymer is insignificant regarding the electric field powers making the polymer turn while electrospinning [25]. Be that as it may, gravity affects the state of the polymer bead and the Taylor cone. This causes a distinction in electrospinning boundaries seen in level and vertical frameworks, the state of the bead shaping on the needle tip relies upon the evenness of the needle tip. This is the reason the needle tip is straightened. It is anticipated that with the control of encompassing boundaries, these interaction boundaries are appropriate for better and non-beaded fiber morphology. It is very notable that, by expanding temperature, consistency is diminished and the versatility of polymer atoms is expanded, along these lines the basic voltage needed for the electrospinning is diminished by utilizing the higher temperature of polymer arrangement. These parameters govern the whole process of electrospinning and on manipulation, effect the morphology and orientation of fibers. The findings demonstrate that the form of solvent used and the voltage applied have a substantial effect on the fiber diameter distribution of electrospun micro/nanofibers.

CONCLUSION

As a result, the provided criteria for the estimation of expert systems will be used for their implementation and for the integration into the manufacturing cycle of companies engaged in the production of medical goods, which would enable sales growth and a reduction in decision-making costs for ordinary employees to improve their competitiveness and minimize labor inputs. The primary processing parameters that micro/nanofiber distribution have been established. This gives important benefits in terms of accurately tailoring the diameters and morphologies of electrospun fibers. Following a brief discussion of the basic mechanics underlying electrospinning,

a thorough discussion of the parameters that can impact the mechanism and the nature of their effect has been given. SPC Methodology is an efficient and effective means to automate the monitoring of expert system rule behavior and other process measures that are important for expert system performance.

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this manuscript.

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