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Scinexis Journal of Medical Devices and Healthcare Innovation
Volume 2 | Issue 1 | Mar-Apr | 2024
https://www.scinexis.org/journals

Research Article

Advanced AI implementation for risk classification in medical device manufacturing: A proof-of-concept methodology using a K-Nearest neighbors algorithm

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ABSTRACT

Companies in regulated industries have more onerous requirements to control their decisions and activities through risk management procedures. Because of FDA regulations, companies can spend dozens of pages writing detailed procedures on how to classify supplier risk levels. However, this can work against the organization by creating an "Audit trap," where a company creates such specific procedures that are nearly impossible to follow. This will create low-hanging fruit for an auditor, and may cause the company to lose its certification—or, in extreme cases, even get shut down by the FDA.

Academia has until now focused on non-transparent Artificial Neural Networks (ANNs) and binary-classifying Support Vector Machines (SVMs), both of which are inappropriate for use in companies with a Quality Management System (QMS); the lack of transparency will be a red flag for auditors, and the binary classification is insufficient for QA departments who need more granularity in their risk classes. This reveals two gaps in the existing literature: A lack of papers on explainable algorithms in regulated manufacturing, as well as a lack of broad-scope treatment of machine learning applications.

The methodology proposed in this paper fills those gaps: It involves training and evaluating a KNN model to classify supplier risk as low, medium, or high, given variables from both quality and supply chain, and ensuring transparency and explainability in anticipation of QMS audits. This model, applied in various synthetic datasets, serves as a proof-of-concept for industry.

Keywords: *Artificial Intelligence, Algorithms, K-Nearest Neighbors, KNN, Medical Devices, Manufacturing, Audits*

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Received on: Mar 01, 2024; Accepted on: Mar 05, 2024; Published on: Apr, 30, 2024

Citation: Plummer, D. (2024), Advanced AI implementation for risk classification in medical device manufacturing: A proof-of-concept methodology using a K-Nearest neighbors algorithm, *SJMDHI 2*(1), 1-14.

Introduction

In regulated industries, such as medical device manufacturing, ensuring product quality and regulatory compliance is paramount. The present study proposes a novel approach to identify the appropriate risk level of suppliers in regulated manufacturing companies through a K-Nearest Neighbors (KNN) machine learning model. The proposed approach involves training and evaluating a KNN model to classify supplier risk as low, medium, and high given variables from both quality and supply chain, and ensuring transparency and explainability in anticipation of QMS audits.

RQ1: How can regulated manufacturing industries utilize machine learning models to classify supplier risk levels?

RQ2: What machine learning models are most appropriate for regulated manufacturing industries?

Background and significance

Background

Regulated industries are generally cautious and slow-moving entities, as they must satisfy standards and compliance regulations [1]. The main way to fulfill these requirements is implementing and maintaining a "Standardized management systems such as QMS, EMS, [and] H&SMS"[2]. These acronyms refer to systems centering around risk management in the areas of quality, environment, and health and safety, respectively. These systems mitigate risk by defining both the probability and severity of the potential risk, as well as defining justifications for how the risk is sufficiently controlled.
Taking as an example the medical device industry, risk management has been increasingly prominent in the guidelines and requirements from the US Food and Drug Administration (FDA), as illustrated in their seminal 2021 flowchart:

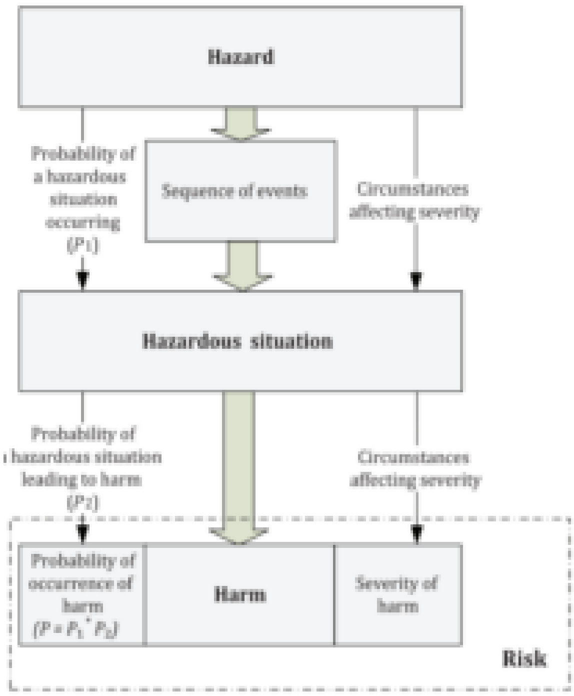

Fig. 1: The risk evaluation process. Image source: U.S. FDA Center for Devices and Radiological Health, 2021

One way that medical device companies prove risk mitigation is through risk management documents. The most common document is a Failure Mode and Effect Analysis (FMEA). The Institute for Healthcare Improvement clarifies the purpose of an FMEA: “Failure Modes and Effects Analysis (FMEA) is a tool for conducting a systematic, proactive analysis of a process in which harm may occur. In an FMEA, a team representing all areas of the process under review convenes to predict and record where, how, and to what extent the system might fail” [3]. FMEAs usually list components or functional elements of a device, what could go wrong with each, what the effects would be, and how the risk of that outcome is mitigated.

Significance

This, however, is insufficient for supplier evaluation. Basing supplier risk exclusively on the components that they manufacture or provide is only one piece of the puzzle. There is a myriad of factors at play, and any risk management solution must take into account as many of these factors as possible: Financial stability, quality of the products, on-time deliveries, and response time all matter. To put forth a hypothesis that if a company’s part is determined in the engineers’ FMEA documents to be a low risk, that an unprofitable supplier who consistently ships nonconforming parts late and doesn’t respond to meeting requests is also subsequently “proven” to be a low risk is simply untenable. Taking into account the considerable risks to patient safety, there is a need for a much more rigorous risk classification method.

Where FMEAs fall short, algorithmic supplier analysis can supplement and fill the gaps in risk management. This benefits both academia and industry. Creating and evaluating a machine learning model is a typical exercise in the scholarly conversation, as evidenced in the Literature Review section below. The figure above demonstrates that risk management is fundamental to business success in medical device manufacturing, so taking advantage of that need is paramount. Sometimes, however, a gap in the academic landscape simultaneously presents a somewhat-rare opportunity to satisfy an industry need as well. In service of this goal, this paper presents a novel methodology to train a machine learning model for the regulated manufacturing industries—robust enough for engineering use in actual departments, but transparent enough to pass QMS audits.

Literature review

Academia has until now focused on non-transparent neural networks and binary-classifying Support Vector Machines (SVMs), both of which are inappropriate for use in companies with a Quality Management System (QMS); the lack of transparency will be a red flag for auditors, and the binary classification is insufficient for QA departments who need more granularity in their risk classes. This reveals two gaps in the existing literature: A lack of papers on explainable algorithms in regulated manufacturing, as well as a lack of broad-scope treatment of machine learning applications.

Machine learning algorithms for risk mitigation

The first goal is to place machine learning algorithms in a manufacturing context. A survey article by Ademujimi *et al.*,[4] describes various machine learning algorithms used in manufacturing from 2007 to 2017. This 10-year overview paints a broad picture, as the authors explain: "The methodology used in the study involves a review of papers published from 2007 to 2017 that utilized machine learning techniques for manufacturing fault diagnosis, focusing on artificial neural networks (ANN), Bayesian networks (BN), support vector machine (SVM), and Hidden Markov model (HMM) techniques"[4]. This 10-year analysis covers neural networks (ANN, BNs, and HMMs) as well as SVMs, with an emphasis on summarizing the similarities and differences in a retrospective context.

The first type of machine learning technique they describe is an artificial neural network (ANN): "[An] artificial neural network is a non-parametric machine learning algorithm inspired by the functioning of the human central nervous system"[4]. According to a paper by Lau *et al.*,[5] the main advantages of ANNs are that they can be used for various applications, such as "Pattern recognitions [sic], classifications, forecasting, and prediction," as well as "Extend [ing], the capability of analyzing complicated amount of data that are not easily to be simplified through the conventional statistical techniques, [and] implicitly detect [ing], non-linear relationships between dependent and independent variables [5]. Lau's team here emphasizes that predictive models that rely on neural networks excel at pattern recognition and identifying relationships that would not otherwise be accessible through the Bayesian Networks and Hidden Markov models that Ademujimi and his team mention in the same 2017 paper.

Filling the first literature gap: Unexplainable algorithms

These neural networks all fall short, however, in one significant way: "Most of the neural networks remain black-box models, where the inner decision-making processes cannot be easily understood by human beings. Without sufficient interpretability, their applications in specialized domain areas such as medicine and finance can be largely limited"[6]. There is little explainability as to what each node in the network is doing or deciding, especially if there are multiple layers of nodes. It’s very likely that multiple layers would be required to address something as rigorous and complex as a risk classification for regulated industries, which causes them to be “largely limited,” as Yang’s team mentions. This "Black-box" aspect of neural networks all but excludes them from use in regulated industries, due to their process obfuscation and most importantly the subsequent problems they would cause during audits.

The final algorithm type listed in the 10-year retrospective is a Support Vector Machine, or SVM [4]. Similar to a K-Nearest Neighbor algorithm, SVMs can be used for classification and don't suffer from the same explainability pitfall as neural networks. The main divergence in methodology between SVMs and KNN algorithms comes in the granularity of classifications: Whereas KNN algorithms can, by definition, identify k number of classes, SVMs can separate only two binary classes. While it is possible to train multiple SVMs and achieve multiclass classification results, this would decrease the level of explainability required for QMS audits.

It can be seen, then, that neural networks, while cutting-edge and effective for both pattern recognition and classification, are essentially inaccessible for regulated industries. This is the first way in which the present study fills a gap in the literature: KNN algorithms have not yet been identified as a preferred method for regulated-industry use.

Filling the second literature gap: Myopic scope

There is significant literature regarding the application of machine learning algorithms to specific manufacturing processes, such as the injection molding shots covered in Mueller et al. in 2018. The team built a Linear Regression algorithm, and validated it through predictive validation, event validation testing, and a two-sided t-test [7]. The study's methodology centered around monitoring sensors within a particular mold and analyzing the subsequent SPC control charts. Mueller and his team applied machine learning principles to a real-life manufacturing problem, and were successful in anticipating SPC measurements accurately using their Linear Regression algorithm. Similar papers can be found using machine learning to predict roughness quality [8], predict CNC efficiency [9-10], select and maintain tooling [11-13], monitor machine health [12,14], improve productivity rates [10,12,14], implement novel approaches in additive manufacturing [15], and even classify dielectric fluids in electron discharge machining (EDM) operations [11]. There are also several forward-looking papers regarding future developments in machine learning applications for machine shops, such as Das (2021) and Rajesh *et al.*, (2022) [16-17], who discuss algorithmic implementations of developing and controlling non-traditional machining processes.

This plethora of papers on specific processes stands in stark contrast to the dearth of research taking a gestalt view of manufacturing writ large, such as a company's supplier risk classification.

Filling the third literature gap: Proof-of-concept Studies

Looking at a final machine learning study, from Baryannis *et al.*, (2019) [18] it can be seen that academia is analyzing SVMs vs. Decision Tree algorithms to classify risk—however, the part of the team's analysis most relevant to the present paper doesn't come from the study's methodology or their research question: It is the study's significance. "The novelty of the presented research lies not in the employed algorithms which are well-established and whose choice is indicative, but rather in the manner in which such technologies are to be integrated in an SCRM process" [18]. In much the same way, the point of this present paper is not an explanation of the algorithm used, but draws its novelty from the particular application in combining quality and supply chain metrics.

Methodology

Methodology 1: Synthetic data generation

To achieve a well-rounded risk management system, the variables chosen must support the targeted metrics that are targeted within the study, as well as aligning with the industry’s department needs. Within the scope of this study, the metrics are supplier performance in the areas of quality and supply chain. These will not only provide a strong significance in the academic aspect of the proposed algorithm, but also satisfy industry needs in both areas.
The starting point for variable selection was Urbaniak *et al.*, who review the literature in their 2022 paper and gather relevant variables from past and current scholarship. Part of their table is reproduced below, in a more concise format:

Table 1: Combined variable list from Urbaniak *et al.*, 2022 and this author’s edits for the present study. Table by author.

Variable List from Urbaniak et al., 2022	New Variable from Author	Dept.
Quality defects of products	% of NCMRs per total lots	QA
Assortment mistakes in deliveries	Delivery inaccuracy	Supply Chain
Low level of environmental performance of products	-	-
Threats to timely deliveries	Failed OTD	Supply Chain
Low level of employee qualifications	Audit findings	QA
Supplier's financial standing	Financial obstacles	Supply Chain
Low level of after-sales service	Response delay (docs)	QA
Low level of after-sales service	-	-
Limited production capacity	Capacity limit	Supply Chain
Low level of product innovation	-	-

Problem with product identification	Lack of documentation (CoC, etc)	QA
Errors in the delivery documentation	-	-
Long order processing time	-	-
No emergency delivery plans	-	-
Technological problems	-	-
Unjustified raising prices for products	Unjustified price increase	Supply Chain
Low level of supplier involvement in joint research and development	-	-
Maladjustment of information systems in communication	-	-
Low level of supplier involvement to reducing operating costs	No cost reduction participation	Supply Chain
Communication problems (SC)	-	-
Low level of delivery flexibility	-	-
Long response time to complaints	-	-
Number of employees	-	-
Implementation of QMS (yes/no)	-	-
Implementation of EMS (yes/no)	-	-
Implementation of H&SMS (yes/no)	-	-
Implementation of Toyota Production System (Kaizen, 5S, TPM) (yes/no)	-	-
Capital (domestic/foreign)	-	-
Sector	-	-

For the present study, several variables were renamed, and others cut from the table to constrain the scope to match this paper, focusing only on quality and supply chain metrics:

Table 2: Renamed and filtered variable list. Table by author

Variable List from Urbaniak et al., 2022	New Variable from Author	Dept.
Quality defects of products	% of NCMRs per total lots	QA
Assortment mistakes in deliveries	Delivery inaccuracy	Supply Chain

Threats to timely deliveries	Failed OTD	Supply Chain
Low level of employee qualifications	Audit findings	QA
Supplier's financial standing	Financial obstacles	Supply Chain
Low level of after-sales service	Response delay (docs)	QA
Limited production capacity	Capacity limit	Supply Chain
Problem with product identification	Lack of documentation (CoC, etc.)	QA
Unjustified raising prices for products	Unjustified price increase	Supply Chain
Low level of involvement to reduce op. costs	No cost reduction participation	Supply Chain

Data for each variable was created and placed into a DataFrame using Python's Pandas library, creating 350 rows. Synthetic data was used in the absence of confidential company data, which was unavailable at the time of writing, due to NDAs and proprietary policies. Due to this, the present study is a proof-of-concept rather than a real-world analysis.

This decision to use synthetic data conforms to academic best practices, as the data is acknowledged to be synthetic and not collected in a statistical state of nature. For example, a skew is intentionally introduced using the increase percentage variable as a multiplier to artificially modify the significance of the various metrics as needed, such as increasing the risk weight for failed supply chain metrics, including Shipment Inaccuracy, and Failed OTD.

First, a DataFrame was created using the filtered and renamed variables, based on Urbaniak *et al.*, 2022[2]. The DataFrame's distribution can be seen in the histogram below. Note that the population mean of several of the variables, such as Failed OTD, are shifted up to ~100 instances, and are normally distributed around this new mean, within 1 standard deviation:

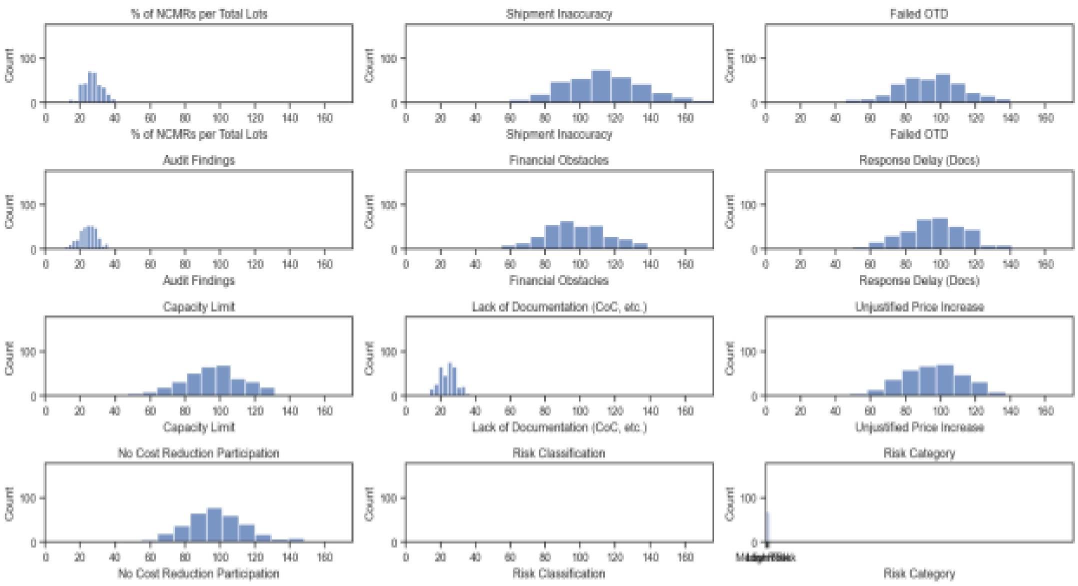

Fig. 2: Histograms showing the distribution of total instances for each variable

Programmatically, this difference is introduced intentionally by using these parameters:

```
SC_increase_percentage = 4
QA_increase_percentage = 1

### DataFrame Structure ###
df = pd.DataFrame({
    "% of NCMRs per Total Lots": [round(27 * QA_increase_percentage)] * 350,
    "Shipment Inaccuracy": [round(28 * SC_increase_percentage)] * 350,
    "Failed OTD": [round(24 * SC_increase_percentage)] * 350,
    "Audit Findings": [round(24 * QA_increase_percentage)] * 350,
    "Financial Obstacles": [round(24 * SC_increase_percentage)] * 350,
    "Response Delay (Docs)": [round(24 * SC_increase_percentage)] * 350,
    "Capacity Limit": [round(24 * SC_increase_percentage)] * 350,
    "Lack of Documentation (CoC, etc.)": [round(24 * QA_increase_percentage)] * 350,
    "Unjustified Price Increase": [round(24 * SC_increase_percentage)] * 350,
    "No Cost Reduction Participation": [round(24 * SC_increase_percentage)] * 350,
    "Risk Classification": [2] * 350
})

# Generate random values for columns within 1 standard deviation
for col in df.columns:
    base_value = df[col].mean()
    std = base_value * 0.1
    df[col] = [round(random.normalvariate(base_value, std)) for _ in range(350)]
```

After generating 350 rows of synthetic data (within 1 standard deviation), all risk classification values here are set at a default of 2 (Medium Risk), and will be modified with the following code, in order to generate risk classifications for this "Existing" dataset. This code supplements the existing data by assigning values in the Risk Classification column based on thresholds. This is a continuation of the synthetic data generation process:

```
# Set thresholds for "existing" risk assessment data #
high_threshold_NCMR = 40
high_threshold_shipment = 85
high_threshold_OTD = 85
high_threshold_audit = 50
high_threshold_finance = 85
high_threshold_response_delay = 105
high_threshold_capacity = 105
high_threshold_CoCs = 45
high_threshold_price_increase = 100
high_threshold_cost_reduction = 100

# Risk Assignment #
for index, row in df.iterrows():
    high_count = 0
```

```
    # Check each column and increment counter
    for col in df.columns:
        if row[col] >= high_threshold_NCMR and col == "% of NCMRs per Total
Lots":
            high_count += 1
          elif  row[col]  >=  high_threshold_shipment  and  col  ==  "Shipment
Inaccuracy":
            high_count += 1
        elif row[col] >= high_threshold_OTD and col == "Failed OTD":
            high_count += 1
        elif row[col] >= high_threshold_audit and col == "Audit Findings":
            high_count += 1
          elif  row[col]  >=  high_threshold_finance  and  col  ==  "Financial
Obstacles":
            high_count += 1
        elif row[col] >= high_threshold_response_delay and col == "Response
Delay (Docs)":
            high_count += 1
          elif  row[col]  >=  high_threshold_capacity  and  col  ==  "Capacity
Limit":
            high_count += 1
            elif  row[col]  >=  high_threshold_CoCs  and  col  ==  "Lack  of
Documentation (CoC, etc.)":
            high_count += 1
elif  row[col]  >=  high_threshold_price_increase  and  col  ==  "Unjustified
Price Increase":
            high_count += 1
        elif row[col] >= high_threshold_cost_reduction and col == "No Cost
Reduction Participation":
            high_count += 1

# Assign risk based on counter value
    if high_count >= 8:
        df.loc[index, "Risk Classification"] = 1 # 8 or more exceed
    elif high_count < 8 and high_count >= 6:
        df.loc[index, "Risk Classification"] = 1
    elif high_count < 6 and high_count >= 4:
        df.loc[index, "Risk Classification"] = 2
    elif high_count < 4 and high_count >= 1:
        df.loc[index, "Risk Classification"] = 3
    else:
        df.loc[index, "Risk Classification"] = 3  # None exceed
```

This code creates a small histogram showing the distribution of risk classes, where 1 is Low, 2 is Medium, and 3 is High:

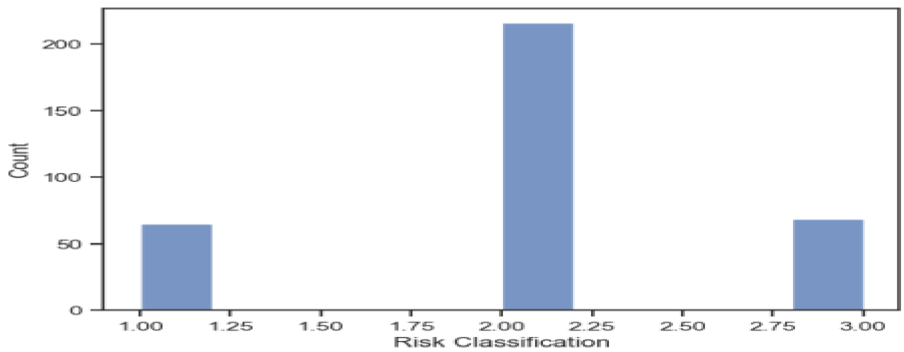

Fig. 3: Histogram showing the distribution of risk classifications: Low (1), Medium (2), and High (3).

Methodology 2: Training a KNN model for risk classification

In order to classify the risk level of nonconforming materials, a KNN model was trained using the prepared data. This model was trained using the scikit-learn Python library:

```
# Split the data into training and testing sets, 75/25, respectively
X_train, X_test, y_train, y_test = train_test_split(X, y, test_size=0.25, random_state=42)

# Scale features using StandardScaler (on training set only)
scaler = StandardScaler()
X_train_scaled = scaler.fit_transform(X_train)
X_test_scaled = scaler.transform(X_test)

# KNN model with prediction and evaluation (using test set labels)
knn = KNeighborsClassifier(n_neighbors=3)
knn.fit(X_train_scaled, y_train)
y_pred = knn.predict(X_test_scaled)
risk_mapping = {3: "Low Risk", 2: "Medium Risk", 1: "High Risk"}
X["Risk Category"] = X["Risk Classification"].map(risk_mapping)
```

This code splits and scales training and testing data, preparing it as input for the KNN algorithm. The KNeighborsClassifier and KNN fit functions are called to create and train the model. The final step is to evaluate the model's performance by determining the precision, recall, and the F1 scores:

```
accuracy = accuracy_score(y_test, y_pred)

# Precision, Recall, F1-score (macro and micro)
precision_macro = precision_score(y_test, y_pred, average='macro')
recall_macro = recall_score(y_test, y_pred, average='macro')
f1_macro = f1_score(y_test, y_pred, average='macro')

# Classification report
report = classification_report(y_test, y_pred, output_dict=True)

# Convert the classification report to a dataframe
evaluation_df = pd.DataFrame(report).transpose()
```

```
color_palette = ['orange', 'green', 'red']
g   =   sns.pairplot(X,   hue="Risk   Category",   palette=color_palette,
plot_kws={"alpha": 0.95})
for ax in g.axes.flat:
    ax.set_ylim(0, max_value)
plt.show()
```

Results

The following code creates a scatterplot graph for each possible variable interaction, outputting the subsequent pairplot:

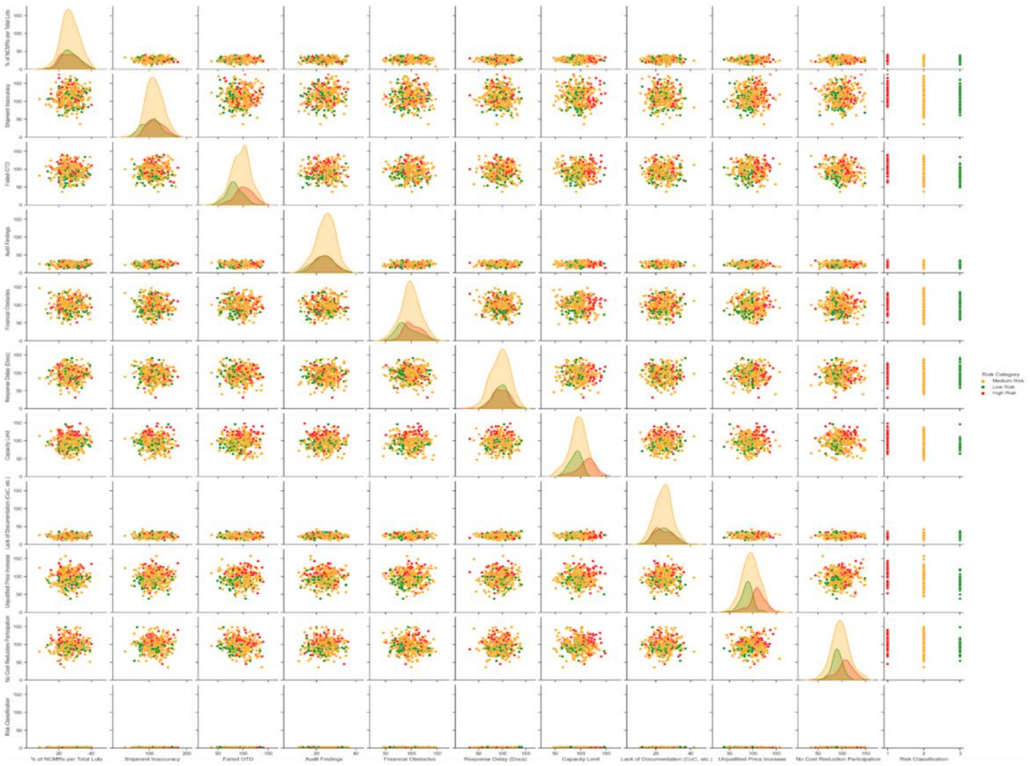

Fig 4: A pairplot showing scatterplot interactions of each unique variable

Discussion

The pairplot reveals several main threads that can be analyzed to both provide insight to academia and support the needs of industry. This KNN model has two main goals: Specificity and transparency.

The first goal is to provide information that is sufficiently specific to address the needs of the quality and supply chain departments ’risk management initiatives. Company stakeholders can examine the pairplot for an overview of what variable interactions cause a given risk level. For example, the algorithm has classified higher values of some of the variables to be higher risk, as can be seen from the Capacity Limit row: Values above ~110 (y-axis) are classified as high risk, even when accounting for every other variable combination this suggests that the other variables in the horizontal row of squares have little to no mitigating effect on how risky threats to

Capacity Limit are. Another example can be seen in No Cost Reduction Participation: Values above ~100 (x-axis) are classified as high risk, regardless of most other variables, evidenced by that threshold's relative stability across each square.

Finally, the KNN model built in this paper favors the big picture: It tilts toward simplicity and utilizes straightforward mathematics as its mode of execution. This creates a clean, clear algorithm that's readily explainable during QMS audits. The algorithm is choosing the shortest distance between two points at a time to evaluate which should be grouped together. The key here is for the model to produce data and data visualizations, such as this pairplot, that are at the same time actionable and general. For example, the information contained in the histograms in Fig. 2 is re-presented here, where the plots for % NCMRs per Total Lots, Audit Findings, and Lack of Documentation (CoCs, etc.) all have a squashed data band, due to their preset means, distributions, and weights. This is just one way that the KNN output can be used as a helpful visual for human decision-making.

Limitations

It is important to acknowledge the limitations of the proposed approach. Overall, it is important to note that the purpose and scope of this paper is to create a proof-of-concept methodology and algorithm, and further research is needed to validate its effectiveness in real-world manufacturing settings.

Favoring the development of a broad proof-of-concept, the methodological approach does not cover certain edge cases, such as suppliers that deliver only twice per year; in this case, a single error affects half of their total performance for the entire year. These suppliers, as well as others outside the scope of the paper, will need a specially-adapted process and analysis in order to avoid positive or negative algorithmic bias. In addition to evaluating the supplier too charitably or too harshly, the algorithm may risk overfitting due to the small sample size. Furthermore, the present study does not address first-time supplier qualification, only requalification/re-evaluation. Finally, the use of synthetic data rather than collected data poses certain limitations, which need to be carefully considered when applying the approach to real-world data.

Nonetheless, this study's innovative approach and novel methodology offer significant benefits for supplier risk management. This proof-of-concept points to significant avenues for future research, especially in regulated manufacturing industries.

Future research opportunities

Oftentimes, one of the common ways that a study can be expanded upon for future research involves increasing an algorithm's complexity, or replacing it with a neural network. Due to the auditing restrictions detailed above, however, future research will involve testing different datasets, evaluating its performance, and fine-tuning its performance to new business and manufacturing contexts. An additional broad avenue for a future study would be using this KNN model for risk prediction in nonconforming materials or production processes.

Conclusion

The use of explainable AI models in the medical device manufacturing industry is a topic that's relevant to everyone, since humanity depends on medical devices for longevity and quality of life. Although poorly covered in the current academic landscape, further research can yield results that will push other, more well-covered, machine learning fields forward. For example, the present study identified the limitations of the scholarly conversation around machine learning algorithms, such as lack of explainability and myopic scope. This opened the door to a discussion of algorithmic appropriateness and selection, which was found to be a missing piece of that conversation.

In addition, ensuring algorithmic explainability will push all technology and all research forward, as both academia and industry and, in fact, humanity as a whole would benefit from more transparent AI models. These innovations will shape our future and our relationship with technology in some of our most vulnerable and human moments, such as on the operating table. Academia in particular would benefit from a research context from a field with more restrictions: Adding an additional layer of requirements will elicit innovation from both fields, as Necessity is the mother of Invention.

Acknowledgments

First, I would like to thank my wonderful wife Nika, without whom none of this scholarship would be possible. She is a tireless supporter of my research, and I am eternally grateful. To my daughter Charlotte, I would like to extend my heartfelt gratitude for sitting in on every research session during the first year of her life and maintaining morale. Finally, I would like to thank my advisor, Dr. Jamie Teeple, for his guidance, patience, and late nights discussing this research.

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