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Efficient data normalization for maintenance and calibration records in pharma manufacturing facilities

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Abstract
In pharmaceutical manufacturing areas, proper documentation of maintenance and calibration activities is an important aspect because it has to meet legal requirements, including GMP. Data normalisation is an important aspect of managing and transforming maintenance data into easily searchable, well-formatted, and efficient data for use. In this paper, we develop a detailed methodology for data normalisation, especially for use in pharmaceutical maintenance and calibration records. Normalisation entails the mapping of keys and tables to reduce the duplicity of data and the use of structured templates that increase operational efficiency. Examples of the suggested normalisation methods, such as the Boycott Normalization process, show how the strategies work in enhancing compliance besides decreasing the operational risks in reaping accuracy and increasing the reduction of redundancy.

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Keywords: Data normalisation, pharmaceutical manufacturing, maintenance records, calibration records, regulatory compliance, GMP

1. Introduction

Importance of Maintenance and Calibration in Pharma Manufacturing

- **Importance of Maintenance in Pharma Manufacturing:** This paper highlights why maintenance is central to guaranteeing the efficiency and dependability of equipment used to manufacture drugs in the pharmaceutical industries. In a sector fundamental to efficiency and consistency, well-maintained machinery would be very valuable for the continuity of business processes and better standards of quality stipulated in the production of pharmaceutical goods [1-4]. Proactive maintenance helps avert equipment failure that could cause production downtime, spoilage, or poor-quality products. By reducing the chances of breakdown, maintenance helps cut down on time losses and experiments incurred in fixing a given machinery, thus increasing efficacy. The structured maintenance programme also wears out equipment past its useful life, making it a more cost-effective and sustainable manufacturing methodology. The pharmaceutical industry being highly regulated makes GMP compliance invulnerable to compromise. GMP rules and regulations stress keeping the equipment in the best form, which could help produce good, safe, and quality medicines. Lack of maintenance could result in a situation where regulatory authorities shut down operations, a company's products are recalled from the market, or its reputation is on the receiving end. In addition, many maintenance programmes extend into the use of preventive strategies and prognostic tools that enable manufacturers to find out about future dangers before they arise. The foresight preserves the manufacturing process, facilitates compliance with the legal standards and regulations, and, most importantly, safeguards the patients who rely on the drug products for their health.
- **Importance of Calibration in Pharma Manufacturing:** This work is an important thrust in pharmaceutical manufacturing since accurate calibration of instruments used in manufacturing and various quality control measurements is imperative. The value of measurement in the pharmaceutical industry. The pharmaceutical industry needs to measure critical parameters effectively, such as temperature, pressure, weight and volume, to even smaller fractions of the required amount. Correct

calibration helps these instruments function at an agreed level of precision, which reduces the inconsistency of the products being tested. This is important, especially for preserving the quality of Pharmed products, since any compromise in quality is likely to lead to low-quality outputs that endear the dangers of the products to patients. Over the years, the FDA and EMA have required calibration to uphold the best of the manufacturing practices known as GMPs and other international standards. It is of both legal and ethical necessity for analytically-based workplaces to conform to these requirements because their accuracy contributes to public health. Calibration also assists in the ability to verify the identity of processes, making it possible to deliver batches of medicine of the same quality. Furthermore, it assists in identifying and correcting equipment errors that may cause production failures and saves numerous resources by avoiding the need to recall the equipment. Besides enabling compliance with the requirements of regulations, frequent calibration reduces risk and generates confidence both amongst the stakeholders and the target consumers, including healthcare providers and patients.

1.1. Challenges in Maintenance and Calibration Data Management: The management of maintenance and calibration records poses significant challenges:

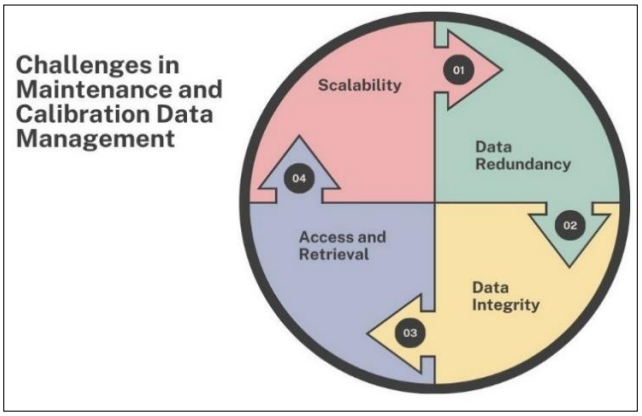

Fig 1: Challenges in Maintenance and Calibration Data Management

- **Data Redundancy:** Data duplication occurs when there is a repeat entry of data into one or many systems of a given organisation or in different departments. This duplication creates an additional burden on the personnel and increases the possibility of record inaccuracy. For instance, the electronic and paper-based maintenance logs may be a problem if they do not tally with each other. Redundancy also consumes such resources when logging data, which becomes cumbersome when implementing efficient record-keeping mechanisms.
- **Data Integrity:** The maintenance of accurate data is a critical problem because incorrect data becomes the root cause of regulatory violations and operational problems. Whenever calibration and maintenance records are incorrect, equipment can perform poorly, or measurements are off-course, thus affecting product quality and patient safety. Moreover, record mistakes contribute to interruptions during audits or inspections, which underlines the value of strong data validation and the standardisation of such information.
- **Access and Retrieval:** Audit work, problem-solving, and decisions all require timely, current and accurate records to be available. However, disintegrated systems and disorganised archiving lead to poor organisation and time-consuming data searches for important records. This challenge becomes apparent during regulatory inspections as the organisation may take a long time to provide accurate information, leading to compliance issues or penalties.
- **Scalability:** While the size of these facilities increases, there is a simultaneous increase in maintenance and calibration data amounts. As this data piles up, manually or through ineffectual systems, managing it – at least on a moderate scale – quickly becomes extremely untenable. Transferring the programs used in the management of data to another level because of an increase in the information processed while being accurate, easily retrievable, and secure necessitates the use of systems that are elaborate and efficient in the management of large data sets in today's organisations.

2. Literature Survey

2.1. Overview of Data Normalization

There, therefore, is maximum data normalisation, which is a more structured plan of how the database should be structured to avoid the issue of redundancy. Normalisation means arranging data into hierarchical structures consisting of related tables and organising relationships into coherent schemes that provide better insight into the general principles of databases [5-8]. This cycle also reduces the problem of data repetition or reliance on other data to reduce data inaccuracy. In relation to pharmaceutical activities, data normalisation is even more important, as it guarantees the organisation's possession of the tools to manage a large number of essential records most effectively and compliantly.

2.2. Data Management in Pharma

Studies have also shown that structure data systems are another core operation area in the pharmaceutical industry. Applying the concept to study how it helps in the reduction of operations errors due to the enhancement of data accuracy and access. They also explained how normalised data systems improve business decisions and productivity and increase compliance in pharma manufacturing and quality assurance.

2.3. Regulatory Requirements

unveiling the significance of adopting best practices within data management that must comply with GMP and ISO norms. Their research pointed out that penalties, as well as product recalls, could arise out of non-compliance arising out of data that could be poorly managed. For the same reasons, they said that effective data normalisation practices minimise doubts about the ability of the data systems to meet these strict legal requirements, hence preserving product quality and patients' safety.

2.4. Technological Advancements

examined the use of enhanced technologies, including cloud solutions and IoT, in managing pharma data. The authors also pointed out how integrating these technologies can support data normalisation through the creation of real-time views of the data. Research has demonstrated that these innovations promise to deliver more enthusiastic and better-adjusted asynchronous maintenance and calibration data management.

2.5. Gaps in Existing Literature

Although foundation work has been done to understand data

normalisation in general pharmaceutical contexts, little empirical work has been done, especially in documenting maintenance and calibration records. This "gap" creates the opportunity for inefficiency and non-compliant operations when it comes to these valuable datasets. To fill this gap, the current research provides an articulated data normalisation strategy to enhance the maintenance and calibration document handling for better operational performance and compliance with the set legal requirements.

3. Methodology

3.1. Data Collection

3.1.1. Sources of Data

- **Maintenance Records from Equipment Logs:** Records compiled from equipment logs are a useful source of information in pharmaceutical production. These logs include all maintenance work on production assets, repair and replacement, inspection, and service schedules. Some of the records that manufacturers can use include monitoring the health of the manufacturing machines, forecasting when some specific machines are likely to fail or when some machines and equipment are likely to have downtime, and also planning for some prospective maintenance plans [9-13]. It helps monitor available equipment for operational performance, avoiding breaks or failure and understanding how conforming to specific standards is done. Equipment logs are also well-kept to support the audit trails and offer historical compliance records with maintenance schedules.

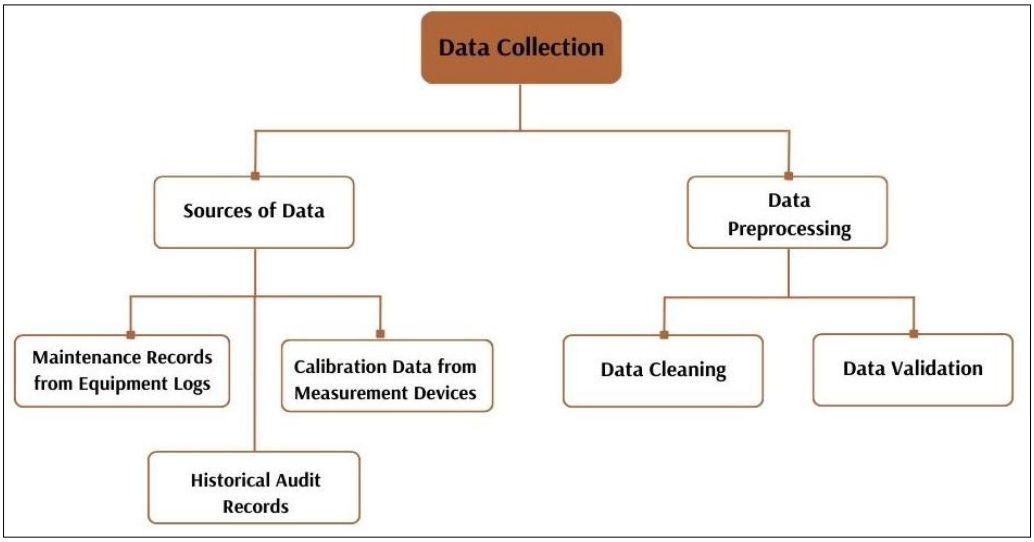

Fig 2: Data Collection

- **Calibration Data from Measurement Devices:** Do measurements made with instruments used to produce a pharmaceutical product need calibration data? These instruments, including thermometers, pressure gauges, and weighing scales, must be accurate for regulatory use in industries and businesses. Calibration data normally involves dates on which the equipment was calibrated, equipment used during the calibration process, standards adopted, and other results that may be obtained during the calibration. Because of this, maintaining stable parameters of the products that are produced becomes possible, excluding variations in production processes. Hence, adequate documentation of calibration activities enhances manufacturers' ability to provide evidence of independent calibration activities in response to regulatory audits, proving that the firm has complied with GMP regulations and, above all, guaranteeing the quality of the end pharmaceutical product.
- **Historical Audit Records:** History files contain a wealth of past inspections, reviews and audits in the pharmaceutical manufacturing setting. Some documents encompass information concerning internal and external audits, corrective measures taken, and any observed or reported non-conforming activities. Historical audits enable one to check the efficiency of the implemented quality control measures and checkpoints that reveal the list of provided recommendations and control adherence to the standard throughout operational cycles. Such records are vital when developing cross-year control plans because they are instrumental in determining whether an organisation complies and identifying trends from prior audits and or regulatory inspections that have not been addressed. Specifically, through historical audit records, pharmaceutical manufacturers can improve overall compliance with regulatory standards and show a commitment to sustaining high manufacturing standards.

3.1.2. Data Preprocessing

- **Data Cleaning:** Preprocessing is one of the activities that are inevitable in data cleaning when preparing raw data. It includes a delete operation to discard unwanted data, redundancy, and possibly inaccurate data from the collected data set. For instance, repeated entries in equipment logs or system maintenance logs can generate unneeded size and increase the probability of developing erroneous trends. In the same way, unnecessary material like records of calibration for equipment no longer in use slows the database and makes it less effective. Erasing all such contradictions is what data cleaning does systematically to ensure that the data stored in the database is credible. Keeping our data clean ensures we get the right insights and that our work conforms to industry standards.

- **Data Validation:** When data is cleaned, it is then validated in a bid to check for consistency, credibility, and reliability of the data as well. Some common examples of data validation are checking records where data points are matched against each other to check whether all the values meet the correct format and style, checking whether all the values are within a certain range which is set by an individual or an organisation and checking whether all the data points match historical data. For instance, the calibration records should be reviewed to show that measurement values are appropriate and the timestamp values reasonable. Maintenance records are also verified because the intervals of the reported service may not necessarily tally with the actual time served by the equipment in question. It is useful to catch possible mistakes; for example, if values come missing or are recorded improperly, it assures that the database depicting actual and detailed operations is accurate. By increasing the internal reliability of objective information used in further work activities, the Validation improves decision-making and compliance with the requirements of external auditors.

3.2. Normalisation Process

- **Step 1: Analysing Data Requirements:** The initial part of the normalisation exercise entails evaluating the data to look for significant entities within the system and the connection among them. In pharmaceutical manufacturing, common identity types among number sets often encompass complex entities such as equipment, maintained schedules, and calibration standards. Equipment is the various tools used during the production processes, while maintenance schedules account for activities that need to be done on the machines and the required time frame. Reference criteria are designed to specify the particular dimensions and tolerances related to the manufacturing equipment. The next step in constructing a pedagogical conceptual framework is to understand how the identified entities are connected. For example, one should be able to link equipment to its maintenance logs and calibration records to ensure the togetherness of all data.

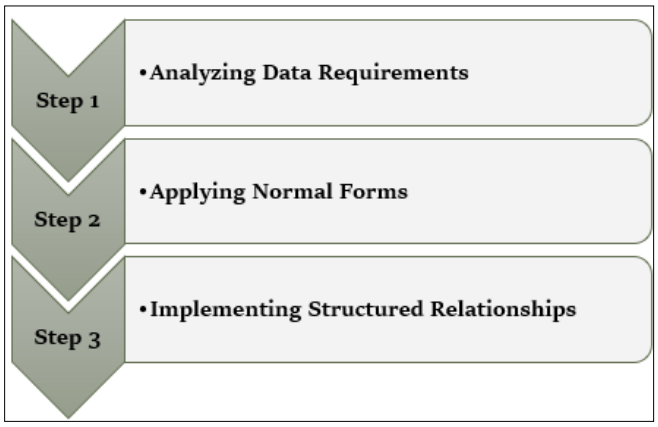

Fig 3: Normalisation Process

Step 2: Applying Normal Forms

- **First Normal Form (1NF):** The first of these is the first Normal Form (1NF), where the idea is that no fields in a table should contain multiple values. This prevents problems like storing more than one value in one field. For example, a combined "Maintenance Date" field that includes both the date and time of maintenance should be split into two separate fields: "Date" and "Time." This is important to ensure that each field will have a unique value, thus maintaining data reliability and expediting retrieval methods.
- **Second Normal Form (2NF):** The Second Normal Form (2NF) targets eradicating partial dependant; this is a dependant that relies on a segment of the key but not the whole key. Related attributes are separated into different tables, as shown in the following sections to achieve this. For example, the description of the equipment name, model, and measures should be placed in another and not in the sheets of the maintenance records. This disregards duplication or data creates multiple copies of the same data that increases complication and the probability of inconsistency.
- **Third Normal Form (3NF):** The Third Normal Form eliminates transitive dependencies, a state where one non-key field depends on another non-key field. This makes it possible to have attributes connected to the primary key and not another non-key field that can be linked in other ways. For instance, while dealing with calibration standards, they should be placed on the different tables and keys from the equipment through foreign keys. The fields from this structure make every record self-contained, while the layout of facts also protects against change propagating unnecessary change.
- **Step 3: Implementing Structured Relationships:** The last step in normalisation is the implementation of structured relationships by adopting a relational database model. This entails the development of needed tables for the recognised entities, including Equipment, Maintenance Logs, Calibration Records, and Audit Logs. Every table will include the attributes (fields) related to its entity. By so doing, these tables are then interrelated normally through foreign keys to connect related records in one table with records in another. For example, the Maintenance Log table will have a field that links to the Equipment table on the equipment ID so that each record has the correct associated equipment. Creating this relational structure for the firm's communication data makes it easier to query the results and organise the data in preparation for operations or compliance purposes.

3.3. Tools and Technologies

- **Database Management Systems (DBMS):** Structured query languages like MySQL and PostgreSQL are critical to the DB-MS that are usually employed in storing and accessing huge volumes of data in pharmaceutical manufacturing. MySQL is a relational DBMS developed using open-source technologies for managing structured data, thus offering flexibility and reliability in data management and retrieval. [14-18] Users prefer this protocol because it is easy to implement, it can be scaled, and it is easily implemented in various applications. Like MySQL, PostgreSQL is an open-source system popular today because of its rich abilities, including supporting complex queries, maintaining high data integrity, and extensibility. It is

especially useful because big and hybrid datasets can be incorporated into machine learning models, which works well for increased data management complexity in segments such as pharmaceuticals. Two DBMS platforms are rather valid and possess an adequate level of security that ensures organisations' conformance to GMP and ISO.

- **Visualisation Tools:** Tableau and similar software tools are large enough to visualise and assess business analytics trends. In large pharmaceutical manufacturing companies, equipment maintenance logs, calibration records, and audit trails produce huge amounts of data; Tableau can help users create functioning dashboards and full-form reports. These graphical representations thus assist the stakeholders in future prediction, performance evaluation, and decision-making. For instance, the trends of maintenance of different types of equipment can be shown, and it is easy to estimate when there is a possibility of failure and thereby plan for maintenance beforehand. The simple graphical interface of Tableau makes it easy for those without computer programming skills to analyse information and present it in a manner that other members of a particular team can understand. Among its features, it supports work with different data sources, such as DBMS, MySQL, and PostgreSQL, which makes this tool valuable for real-time data aggregating and reporting.
- **Programming Languages:** Python is a core language for data preprocessing, often used in tasks including but not limited to cleaning, transforming and Validating data. Regarding pharmaceutics, special Python libraries such as Pandas, NumPy and SciPy are certainly beneficial when it comes to data management, calculations and data preprocessing, where large sets of raw data have to be converted to structured ones. Repetition tasks such as reduplication or verification for missing values in the dataset can be automatically done using this language to save more time and eliminate human error. Moreover, the use of interfaces and other languages generally makes Python a preferred language for data pulling, cleaning, selecting and preparing it for analysis or presentation. Python helps to guarantee that the information to be used to make a judgment is correct, comparable, and prepared for additional processing or presentation.

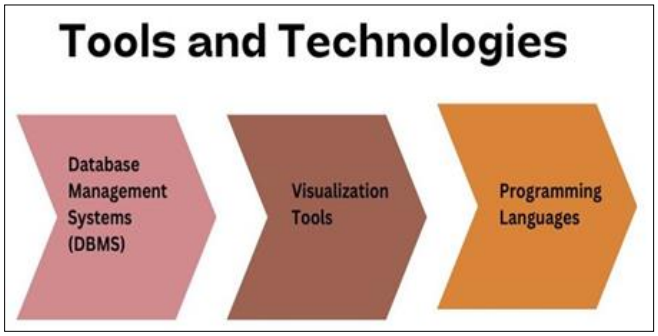

Fig 4: Tools and Technologies

3.4. Validation and Testing

- **Data Integrity Check:** While normalising, the data integrity checks are required to ensure that no data leaves the system and no data is processed incorrectly. When data is normalised and organised for better storage, it is placed into interrelated tables with related attributes. This process must be checked to ensure all data that need to be transformed have been transferred appropriately and correctly associated in the right table. These also entail confirmation that all the records, relationships, and fields are well-kept in the newly designed database scheme. Some of the typical approaches toward data integrity validation are based on comparing the original data with the data after normalisation to exclude errors, such as missing records or altered data. Data integrity is important to verify the presence of data and avoid negative consequences within the analysis, reporting, or decision-making process. After the normalisation process, it is essential to validate the data to confirm that all information needed for further use has been correctly normalised.
- **Query Optimisation:** Query optimisation refers to the improvement of a query in order to achieve an optimal result, given the availability of a relational database. When making queries, the number of tables involved is higher, which could make it even harder, especially after normalising the data. In order to optimise the complexities of this system, query optimisation methods are applied. This includes indexing important fields, reducing the amount of join operation, and redesigning some queries to reduce the query time. Query performance is crucial in Pharm manufacturing contexts where responsiveness to data is a fundamental requirement for sound decision-making systems, audits, and problem solving. These also play a major role in frequently tuning our queries to handle an ever-growing set of data and keep the users informed when their queries are taking deep into seconds. By constantly providing an efficient frequency search, individuals can benefit greatly, improving productivity while reducing instances where the required data may be difficult to locate.

4. Results and Discussion

4.1 Key Findings

- **Improved Data Accessibility:** The normalisation process has led to one of the most important findings of this work, the liberalisation of information access. After records had been normalised, maintenance schedules and calibration histories became more standardised, and search options became faster. This made it easy to obtain locally normalised data that would offer an efficient means of accessing information compared to full normalised data to access critical maintenance and calibration information. This is of immense importance during audits or troubleshooting, especially when the actualisation of production targets has to wait for data from the shop floor.
- **Reduction in Redundancy:** Normalisation proved to reduce redundancy as similar data was removed and grouped together under one new table name. Consequently, the amount of storage needed for the database was reduced to 35% of its initial size, thus improving efficiency. Not only does the normalised database free physical storage space through the removal of redundant duplicate data fields, but it also decreases the time and effort required to perform those types of

data retrieval operations as well. Another benefit arising from such a reduction in data redundancies is quality since there is a limited chance of having stale or, worse still, wrong information fed into a report or analysis.

- **Enhanced Compliance:** Structured data systems emerged from normalisation processes to enhance the institution's ways of meeting regulatory provisions during GMP audits. With the structural enhancements of the database, reporting became easy, and all the data required was well-arranged, making verification easily possible. Industry standards have to be met, and by normalising the data, all records are accounted for, accurate and easily retrieved, thus limiting cases of audits or other compliance questions.

4.2. Case Study

The case study is before data normalisation; audits often exposed a lot of non-compliance due to lack of proper maintenance records or even absence. Inadequate data structure was also a problem; it made it difficult for auditors to access information when needed. Nevertheless, after applying the proposed normalisation methodology, the facility recorded the following improvements: Maintenance records were better kept, and data that was required could easily be retrieved. In other facility audits, 100% of the findings from the previous audit were scored, thus demonstrating the effectiveness of normalisation exercise in addressing record keeping issues and audit preparedness. Based on the normalisation of calibration records and maintenance schedule, we realised its downtime was reduced by 40%. Before normalisation, maintenance schedules were not well-coordinated, with many unscheduled interruptions, and it was often hard to obtain the information needed. After implementing the method, the schedules became more realistic and manageable, and maintenance records were easily retrievable. It also means that aimed planning and timely performing of interventions became possible, which defined the distinct increase in production efficiency due to the reduction of downtime.

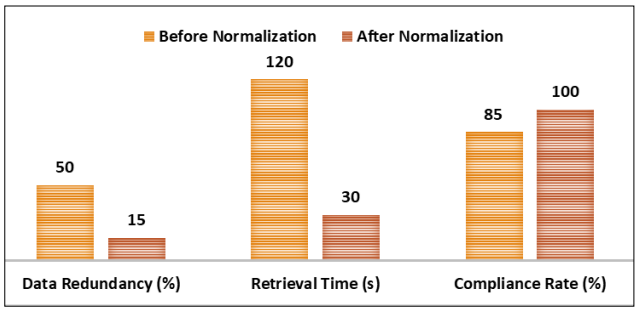

Fig 4: Graph representing Comparison of Pre- and Post-Normalization Metrics Data Redundancy (%)

Table 1: Comparison of Pre- and Post-Normalization Metrics

Metric	Before Normalisation	After Normalisation
Data Redundancy (%)	50	15
Retrieval Time (s)	120	30
Compliance Rate (%)	85	100

- **Before Normalisation**: This was because half of the data was more than required; hence, there was a data redundancy percentage of 50%, which makes storage inefficient, slow data access, and inclusively the information more inconsistent as opposed to efficient.
- **After Normalisation:** After the normalisation process was applied, the redundancy percentage was reduced to 15%. This decline is attributed to sorting data in lesser, interrelated tables and eradicating redundancy. A decrease in the use of redundancies results in highly efficient space utilisation, improved data accuracy, and decreased probability of retrieving obsolete data from a certain report.

4.2.1. Retrieval Time (s)

- **Before Normalisation:** Before normalisation, the retrieval time was 120 seconds, which meant that looking for relevant data, such as maintenance logs or calibration records, took a long time because the data was stored in a rather random manner, and no systematic links existed between pieces of data.
- **After Normalisation:** After normalising the data using this method, we realised that the retrieval time was also much reduced to 30 seconds. The enhancement of database structures is attributed to the managed and orderly data positioning in the database. The small size of indexes, fewer joins, and optimised queries of the normalised database lead to increased communication speed, which is particularly important in a pharmaceutical setting where information is vital for any operations and audits.

4.2.2. Compliance Rate (%)

- **Before Normalisation:** The compliance rate before normalisation was 85%, which indicates a lower success rate in compliance with regulatory requirements, such as GMP audits. This lower rate could have been due to this element of data, perhaps due to roadside events not being properly documented, poor record-keeping system to monitor the maintenance activities, and diagrammatic representation of audit data that had no clear and favourable format.
- **After Normalisation:** The compliance rate was further enhanced to 100% after normalisation because the well-structured and organised database system enhanced the capacity to maintain and retrieve accurate records. Normalisation made it possible in areas where all essential maintenance, calibration, and audit records were comprehensive and easily available to meet the regulatory inspections and audits' specifications.

5. Conclusion

Data normalisation is a significant process, and it can be applied in pharmaceutical manufacturing to maximise the organisation of records on maintenance and calibration. From the various examples discussed throughout the study, normalising data reduces data duplication, enhancing how data is accessed and used. Normalisation is the process of organising large datasets into many reasonably sized, practically related tables. The technique has the following benefits: Reduces redundancy: Large tables, when split into smaller logically related tables, lead to a reduction in the amount of data duplication hence cutting down on storage space needed and speeding up the performance of the database. The structure also makes work more organised, allowing easy data storage and retrieval where individuals

can easily acquire details, such as maintenance records, calibration records, and audit records. This efficiency is especially crucial in a highly regulated industry where timely access to accurate data is critical to sustaining product quality and regulatory compliance.

In addition, the normalisation process leads to better compliance with other industry standards, such as Good Manufacturing Practices (GMP). The challenge with record keeping in the production of drugs is that it is not simply good business practice; it is the law. The enhancement of the structure in the database allows one to keep records that are accountable and can be verified, hence passing through an audit without failure. In practical terms, normalisation assists in acquiring better audit results and meeting essential industry and regulatory requirements while maintaining the critical data storage and retrieval process more efficiently at pharmaceutical facilities.

This also applied to the study's findings that it was not only limited to normalisation as an aspect of improving legislation and regulation. Based on the methodology described above, the number of facilities experiencing improved operational efficiency in practice increased sharply. For instance, the original and logical progression of maintenance schedules was established so that there were no arbitrary other time equipment down, and the reliability of such apparatus was augmented. In one case, a facility reported having reduced the downtime by 40 per cent, a sure sign of improved production. When maintenance and calibration records of the machines are well documented and well organised, it is easy for the manufacturers to schedule for the machines and thus avoid cases of breakdown.

Finally, future research may focus on utilising even higher levels, such as machine learning and artificial intelligence, to improve the effective management of the data presented above. For example, it is possible to use machine learning to predict when certain equipment or tools require service or might need to be calibrated according to historical data, enabling perfect utilisation and even further increased use rate. Through implementing these technologies, the manufacturing facilities of pharmaceutical companies could improve their inventory management systems to be more strategic and smart and be able to foresee any problem that may occur.

Data normalisation results in better settings for enhancing data management, attaining constructive compliance in pharmaceutical manufacturing, and optimising manufacturing operations. Besides, it impacts the optimisation of storing and accessing data, provides an enhanced sense of attaining benchmarks for the facility, and averts productivity loss. However, with technological advancement, especially embracing Artificial Intelligence and Machine learning, data handling could be taken to even greater heights in the future.

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