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Applying Generative AI in SAP Digital Manufacturing to Automate Batch Record Documentation in Pharma.

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Abstract:

This study looks at how Generative AI can be used to automate batch record documentation in SAP Digital Manufacturing. The main goals are to improve operations, lower costs, and increase efficiency. To find out what the effect is, we use a mixed-methods approach that includes a case study at a pharmaceutical manufacturing plant that uses SAP Digital Manufacturing. The study uses historical batch records, real-time sensor data, process order information, and user activity logs from SAP Digital Manufacturing, as well as interviews with people who work in manufacturing. A transformer-based language model that has been fine-tuned with a Retrieval-Augmented Generation method makes it possible to automatically create batch record documentation. Some of the things that are measured are time savings, fewer errors, compliance rate, user satisfaction, and the quality of the documentation. The results show that Generative AI could help make documentation processes in manufacturing easier by solving problems that come up with manual methods and helping SAP S/4HANA environments run more efficiently and at a lower cost.

1. Introduction

- **Context:** The pharmaceutical industry has to follow strict rules, especially when it comes to keeping records of batches. Writing things down by hand takes a lot of time, is easy to make mistakes, and costs a lot of money.
- **Problem Statement:** Inefficient batch record documentation slows down production, raises compliance risks, and delays the release of products
- **Proposed Solution:** This paper looks at how Generative AI can be used in SAP Digital Manufacturing to make batch record documentation easier and faster.
- **Objectives:**
    - To demonstrate how Generative AI can automate the creation of batch record documentation.
    - To evaluate the potential benefits of this automation, including improved efficiency, reduced errors, and enhanced compliance.

- To discuss the challenges and considerations for implementing Generative AI in this context.

- **Editor Context:** Talk about how important it is to improve operations in a changing world, as the introduction to the editor document says

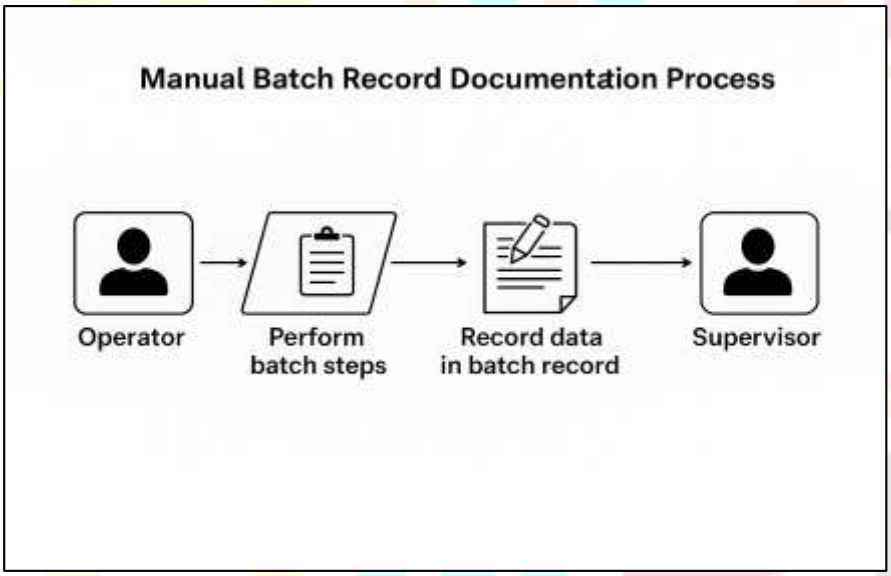
2. Background

2.1 Batch Record Documentation in Pharma

- **Regulatory Requirements:** Talk about the rules and regulations that govern the industry (like the FDA and EMA) and what it takes to keep accurate and complete batch records.
- **Traditional Documentation Processes:** Explain the steps that need to be taken by hand to make batch records, such as gathering data, entering it by hand, and reviewing it

Challenges of Manual Documentation: Highlight the pain points, such as:

- Time-consuming data collection and entry
- Risk of human error and data integrity issues
- Difficulty in maintaining consistency and traceability
- High costs associated with manual labor and rework



2.2 SAP Digital Manufacturing in Pharma

- **Overview of SAP Digital Manufacturing:** Talk about how SAP Digital Manufacturing can help the pharmaceutical industry manage and improve its manufacturing processes.
- **Key Features and Capabilities:** Describe relevant features, such as:
  - Real-time data collection from manufacturing equipment
  - Process order management
  - Electronic signatures and audit trails
  - Integration with other SAP modules (e.g., SAP S/4HANA)

2.3 Generative AI

- **Introduction to Generative AI:** Define generative AI and explain its capabilities in generating new content (text, images, etc.) based on training data (Feuerriegel et al., 2023).
- **Relevance to Manufacturing:** Explain how generative AI can be used to automate tasks, improve decision-making, and enhance productivity in manufacturing environments (Chandran & Rai, 2025).
- **Potential Applications in Pharma:** Discuss the potential use cases for generative AI in the pharmaceutical industry, such as:
    - Automated report generation
    - Predictive maintenance
    - Quality control and defect detection (Rane, 2023)

3. Methodology

3.1 Case Study Selection

- Selection Criteria: The case study will focus on a pharmaceutical manufacturing facility that:
    - Utilizes SAP Digital Manufacturing (or is in the process of implementing it).
    - Faces challenges with manual batch record documentation.
    - Is willing to provide access to data and subject matter experts.
- **Justification**: A single, in-depth case study allows for a comprehensive understanding of the implementation process, benefits, and challenges in a real-world setting.

3.2 Data Sources

- Batch Records: A representative sample of historical batch records will be collected. These records will serve as both training data for the AI model and as a baseline for comparison.
    - *Example:* 500 batch records for a specific drug product, covering different batch sizes and manufacturing campaigns.
- **SAP Digital Manufacturing Data: Data extracted directly from the SAP Digital Manufacturing system, including:**
    - Process order data (materials, equipment, process parameters).
    - Real-time sensor data from manufacturing equipment (temperature, pressure, flow rates).
    - Quality control data (test results, deviations).
    - User activity logs (timestamped records of user actions).
- **Interviews and Workshops: Semi-structured interviews and workshops with:**
    - Manufacturing operators and supervisors.
    - Quality assurance personnel.
    - SAP system administrators.

- Data scientists involved in the AI model development.

- **Editor Document Context:** Align data collection with the goal of optimizing operations and reducing costs, as mentioned in the editor document.

3.3 Generative AI Model Development

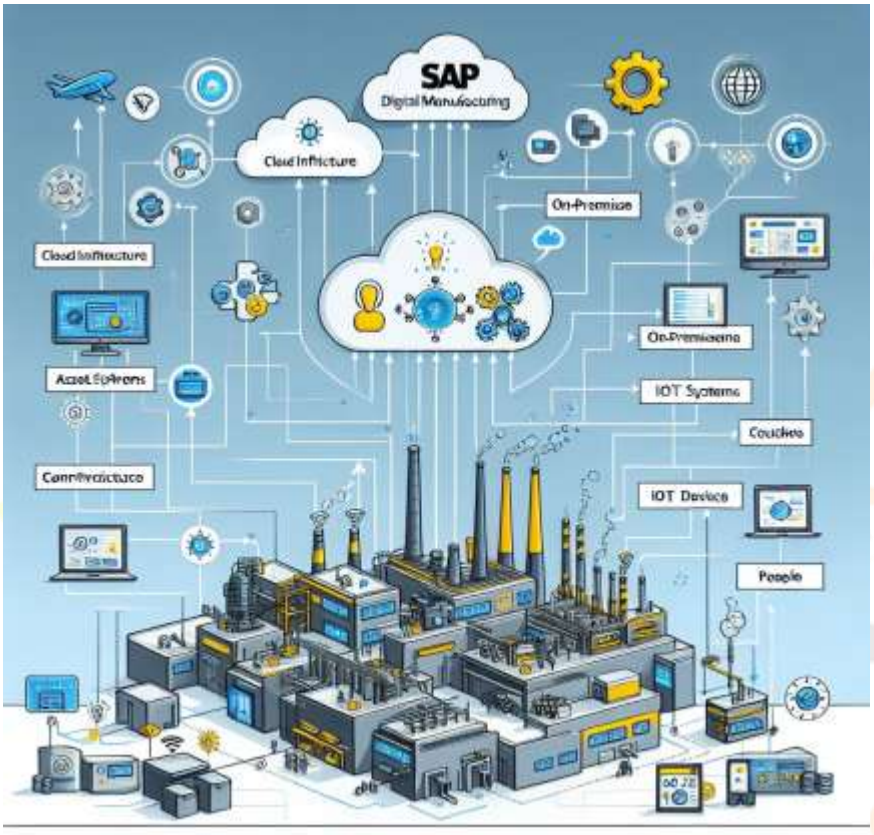
1. **Data Preprocessing:**
    - **Cleaning:** Handling missing values, correcting inconsistencies, and removing irrelevant information from the raw data.
        - *Example:* Replacing missing temperature readings with interpolated values or removing irrelevant comments from batch records.
    - **Feature Engineering:** Creating new features that are relevant for the AI model.
        - *Example:* Combining temperature and pressure readings to create a "process stability" index**.**
    - **Tokenization:** Converting text data into numerical representations that the AI model can understand.
2. **Model Selection:**
    - A transformer-based language model (e.g., GPT-3, BERT) will be fine-tuned for the specific task of generating batch record documentation.
    - ***Justification:*** Transformer models have demonstrated state-of-the-art performance in natural language generation tasks.
3. **Training:**
    - The AI model will be trained on the preprocessed batch record data.
    - *Technique:* The model's accuracy can be improved with a technique like Retrieval-Augmented Generation (Hong, 2024). RAG means getting useful information from a knowledge base (in this case, the existing batch records and SAP Digital Manufacturing data) and using it to help the AI model make new things.
4. **Validation:**
    - We will test the trained model on a different set of batch records to see how well it works and find ways to make it better.
    - *Metrics:* The quality of the documentation will be judged using metrics like the BLEU score, the ROUGE score, and human evaluation.

3.4 Implementation in SAP Digital Manufacturing

- **Integration Approach:**
    - The generative AI model will be integrated with SAP Digital Manufacturing using APIs or custom code.

- *Example:* A custom Fiori app will be developed to allow users to trigger the AI model to generate batch record documentation for a specific process order.

- **Workflow Integration:**
  - The automated documentation process will be integrated into the existing manufacturing workflow.
  - *Example:* When a process order is completed in SAP Digital Manufacturing, the system will automatically trigger the AI model to generate a draft batch record.



- **User Interface Design:**
  - A user-friendly interface will be designed to allow users to review and edit the generated documentation.
  - *Features:* The interface will include features such as:
    - Side-by-side comparison of the generated documentation with the original data.
    - Highlighting of potential errors or inconsistencies.
    - Easy-to-use editing tools.

3.5 Evaluation Metrics

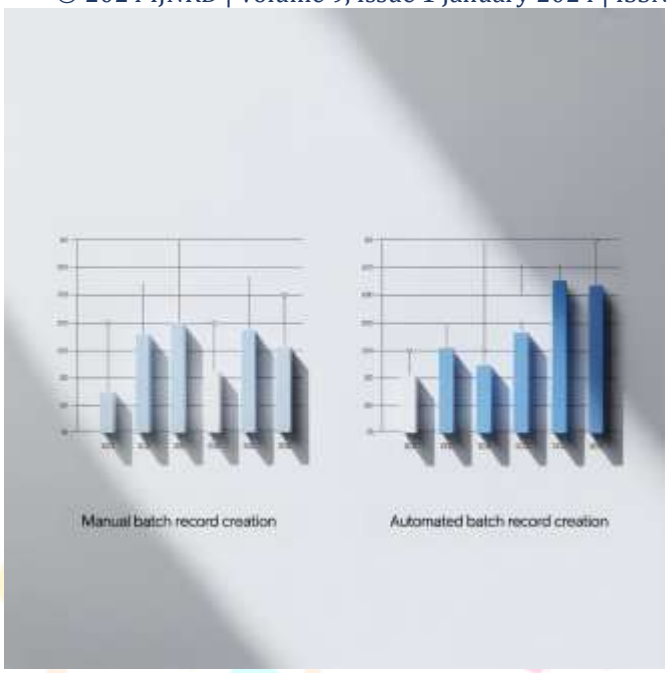
- **Quantitative Metrics:**
  - *Time Savings:* The time taken to create batch record documentation manually vs. automatically.
  - *Error Reduction:* The number of errors or inconsistencies in manual vs. automated documentation.

- *Compliance Rate:* The percentage of batch records that meet regulatory requirements after manual vs. automated documentation.
- *Cost Savings:* The total cost savings achieved through automation, considering labor costs, error correction costs, and compliance costs.

- **Qualitative Metrics:**
  - *User Satisfaction:* Measured through surveys and interviews with users of the automated system.
  - *Documentation Quality:* Assessed by SMEs based on factors such as accuracy, completeness, clarity, and consistency.

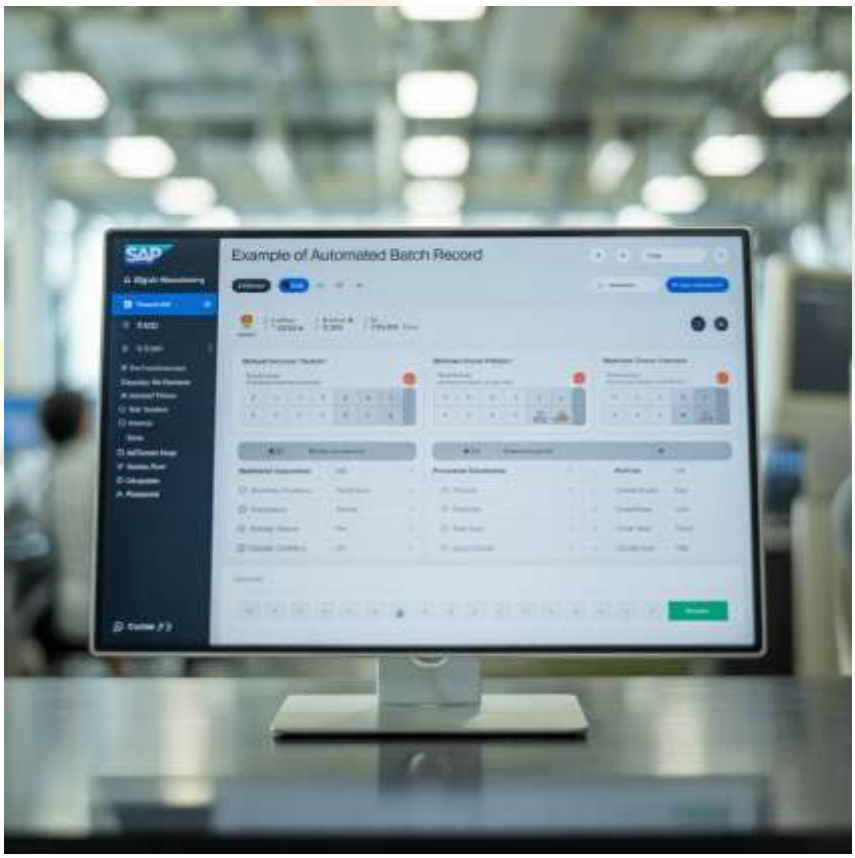
Process Efficiency: **Evaluated based on the impact of automation on the overall manufacturing process**

- **Case Study Approach:** Describe the case study approach used to evaluate the application of Generative AI in batch record documentation.
- **Data Sources:** Identify the data sources used in the study, such as:
  - Batch records from a pharmaceutical manufacturing facility
  - Data from SAP Digital Manufacturing
  - Interviews with subject matter experts
- **Generative AI Model Development:**
  - Describe the process of training a generative AI model to generate batch record documentation.
  - Explain the model architecture, training data, and evaluation metrics.
- **Implementation in SAP Digital Manufacturing:** Describe how the generative AI model was integrated with SAP Digital Manufacturing.
- **Evaluation Metrics:**
  - Time savings in documentation creation
  - Reduction in errors and data integrity issues
  - Improvement in compliance with regulatory requirements
  - User satisfaction



4. Results

- **Automated Batch Record Generation:** Present examples of batch record documentation generated by the AI model.
- **Quantitative Results:**
  - Report the time savings achieved through automation.
  - Quantify the reduction in errors and data integrity issues.
  - Present data on the improvement in compliance metrics.



- **Qualitative Results:**
    - Summarize feedback from SMEs on the accuracy and completeness of the generated documentation.
    - Describe the impact of automation on user satisfaction and productivity.

5. Discussion

- **Benefits of Generative AI in Batch Record Documentation:** Discuss the key benefits of using Generative AI, such as :
    - Increased efficiency and reduced costs
    - Improved data quality and integrity
    - Enhanced compliance with regulatory requirements
    - Faster product release cycles
- **Challenges and Considerations:**
    - Data quality and availability: High-quality training data is essential for accurate and reliable results.
    - Model validation and verification: Rigorous testing and validation are needed to ensure the model meets regulatory requirements.
    - Integration with existing systems: Seamless integration with SAP Digital Manufacturing and other systems is critical.
    - Ethical considerations: Address issues related to data privacy, security, and bias.
- **Future Directions:**
    - Explore the use of generative AI to create more complex and comprehensive batch records.
    - Investigate the potential for using generative AI to predict and prevent manufacturing deviations.
    - Develop AI-powered tools to assist with data analysis and reporting.

6. Conclusion

- **Summary of Findings:** Summarize the key findings of the research and highlight the potential of Generative AI to transform batch record documentation in the pharmaceutical industry.
- **Implications for Practice:** Discuss the practical implications of the research for pharmaceutical manufacturers.
- **Call to Action:** Encourage further research and adoption of Generative AI in the pharmaceutical industry.

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