To: Dr. Erika Paterson
From: Elton Kok
Date: October 12, 2020
Subject: Proposal for improving the QC inspection process for consumables at Sanofi Pasteur

Introduction

Sanofi Pasteur is the vaccine division of the global healthcare company Sanofi. Sanofi Pasteur has multiple vaccine portfolios that are currently on the market or in the process of making it to the market. Currently sold vaccine products of this company includes but is not limited to: Acadel, Quadracel, and Fluzone vaccines. The company manufactures more than a billion vaccine doses a year which helps people around the world become immunized to common infectious diseases. The Sanofi Pasteur Toronto site is one of the major vaccine manufacturing plants that has significant contribution to the number of vaccines sold yearly by the company.

Since this company is involved in manufacturing life-saving products, the quality control (QC) inspection process must be built in throughout their entire manufacturing process. From the moment the raw materials arrive on site, to the finished product being injected into the patient, quality inspection must occur to ensure the safety of these products. The company also has a strong mindset on efficient manufacturing methodology that minimizes waste and maximizes productivity. Due to the large scale of manufacturing that occurs at the company, even small inefficiencies can be amplified. Therefore, the company must also focus on eliminating the waste in their quality inspection process while also adhering to the guidelines set forth by regulatory bodies to ensure their products are safe to inject into patients.

Statement of Problem

Currently at the Sanofi Pasteur Toronto site, the QC inspection process of incoming raw materials uses paper to document quality data. Hundreds of raw materials are received weekly, all which have quality documents associated with them. Having worked in the QC Raw Materials department for a year, I have seen thousands of paper sheets used solely for quality documentation. We currently live in a world driven by new and innovative technology. This technology as the potential to store enormous amounts of data while minimizing the environmental impact through eliminating the use of paper. Paper documentation process is also much slower than electronic as redundant data such as batch numbers, and dates must be copied onto different pages of the quality documentation.

Proposed Solution

My proposed solution to the quality inspection process of the raw materials at the Sanofi Pasteur Toronto site is to move towards a digital documentation system. Currently, the company is prioritizing new vaccine projects and manufacturing departments. A move towards a digital documentation system would eliminate the copious amount of paper waste generated by the QC inspection process and improve documentation efficiency as redundant data (batch numbers, lot numbers, dates) would not have to be manually copied over onto several other forms. This solution would help the company reduce

its environmental impact and decrease the time it takes to release raw material for use, adhering to the efficient manufacturing principles the company follows by.

Scope

To determine the effectiveness of my solution, I propose to explore the following questions:

- How much paper on average is used per batch of raw material and how much does this cost the company?
- Is there an existing digital system in or outside the company that could be used to capture the quality documentation for raw materials?
- What would be a good estimate for the time saved using digital documentation?
- Do current employees and managers of this department prefer digital or paper documentation and why?
- What are the reasons sticking to the current practice of paper documentation?
- What are the negative consequences as a result of switching to digital documentation?
- What are the environmental and financial costs of digital compared to paper?
- What effects, if any, would switching to digital documentation have on the effectiveness of the QC process?

These inquiries will help guide me on the best solution to implement digital documentation in the QC Raw Materials department at Sanofi Pasteur.

Methods

My primary data sources will be anonymous surveys and interviews with my previous coworkers in the department, the manager, and possibly the deputy director.

My Qualifications

I am a Bachelor of Science graduate from the University of Toronto and have worked for Sanofi Pasteur in two different departments for a cumulative total of two years at the company. My first position there was as a Co-Op Student in the Research and Development Department, and my second position was an Advanced Technician in the QC Raw Materials department. I have a solid firsthand understanding of the systems and processes used by the company and my connection with people from various departments should allow me to explore the issue I proposed.

Intended Audience

This report will be intended for the Deputy Director of QC Raw Materials at the Sanofi Pasteur Toronto Site who should have the authority to decide whether this solution should be implemented or not.

Conclusion

Sanofi Pasteur is one of the world's largest vaccine manufacturers that strives to create safe and efficacious vaccines for people around the world. Sanofi Pasteur has the responsibility and a mission to manufacture as many vaccine doses as possible so that no human alive suffers from a vaccine preventable disease. To achieve this, the onus is on the company to eliminate waste and improve efficiency in their manufacturing process. The QC raw material inspection process is a pain point of the manufacturing process that should be looked at for improvement. Ultimately, this should help the company achieve their mission to produce vaccines for everyone around the world.

MEMORANDUM

To: Erika Paterson, ENGL 301 instructor
From: Elton Kok, ENGL 301 student
Date: November 13th, 2020
Subject: Progress Report

I have written below my progress report for the formal report assignment about improving the QC inspection process for the QC raw materials department at Sanofi Pasteur Toronto site. This progress report outlines important information pertaining to the report such as audience and purpose.

Audience of the report

This report is intended for management and directors of the raw materials quality control department at Sanofi Pasteur Toronto. The current manager of the raw materials department is Anh Nguyen and the deputy director of the raw materials department is Bo Li. These two individuals have extensive knowledge of the processes in this department, how the work done at this department impacts the company as a whole, and the power to implement change in the department.

Purpose of the report

The purpose of this report is to explore the implementation of a digital documentation system in contrast to the paper-based documentation system currently in place in the QC raw materials department at Sanofi Pasteur Toronto. Other companies and departments within Sanofi Pasteur have been moving from paper documentation to a digital documentation system over the past years as technology has advanced. Digital documentation has advantages over paper as it greatly reduces the company's carbon footprint and does not require physical storage.

Significance of the report

The investigation into implementing a digital documentation system has significant advantages. Sanofi Pasteur relies on LEAN manufacturing principles which strives to eliminate waste in the manufacturing process. Paper documentation generates significantly more waste and can often have duplicated information across several pages. A digital documentation system can significantly reduce paper waste generated in the department reduce the redundant information that propagates through various forms. Ultimately, a digital documentation system can serve to increase efficiency and minimize the chance of human error.

Research plan

This report attempts to investigate the following:

- Understanding why paper documentation is still being used

- Gather statistics of how much paper is used per release batch
- Cost analysis of paper usage
- Interviews with the managers and directors
- Interviews with current employees
- Opinions on the current paper documentation
- Opinions on replacing paper with digital documentation
- Analyze survey questions

Writing schedule

November 15 – Contact and inform managers, directors, and employees of the QC raw material department of this report.

November 16 to 22 – Send surveys to managers, directors, and employees. Schedule times for interviews.

November 27 – Finish conducting interviews and data analysis.

December 1 – Create initial draft of the report and post on team forum

December 12 to 13 – Revise draft based off peer review

December 15 to 16 – Finishing touches and re-reading report

December 17 – Deadline of Formal Report posted on team forum

Thank you for taking the time to read this progress report. Any insights and suggestions are welcomed.

Enclosures:

Survey Questions

Question 1: Rate your paper usage on a scale from 1 to 5 with 1 being lowest paper usage and 5 being highest paper usage.

- ☐ 1 – Lowest usage
- ☐ 2
- ☐ 3

☐ 4

☐ 5 – Highest usage

Question 2: How do you feel about how data is currently documented?

☐ Unsatisfied

☐ Somewhat unsatisfied

☐ Neutral

☐ Somewhat satisfied

☐ Satisfied

Question 3: How would you feel about a digital documentation system (typing data into a program on a laptop)?

☐ Unsatisfied

☐ Somewhat unsatisfied

☐ Neutral

☐ Somewhat satisfied

☐ Satisfied

Question 4: How comfortable are you with computers on a scale of 1-5?

☐ 1 – Not comfortable at all

☐ 2

☐ 3

☐ 4

☐ 5 – Very comfortable

Question 5: If you had a choice, what documentation system would you choose to use/prefer to use?

☐ Paper

☐ Digital

Question 6: For the above question, select the reasons for your choice. You can also add a reason by specifying in the other option.

☐ More comfortable for me

☐ Faster for me

☐ More convenient/easier to use

☐ Environmental reasons

☐ I like writing things as opposed to typing

☐ I like typing things as opposed to writing

Question 7: In your opinion, what are the top ADVANTAGES of paper documentation? You can list 1 to 3 of them.

Question 8: In your opinion, what are the top ADVANTAGES of digital documentation? You can list 1 to 3 of them.

Question 9: In your opinion, what are the top DISADVANTAGES of paper documentation? You can list 1 to 3 of them.

Question 10: In your opinion, what are the top DISADVANTAGES of digital documentation? You can list 1 to 3 of them.

Question 11: Rate on a scale of 1 to 5 how much priority should be placed on moving towards a digital documentation system.

☐ 1 – No priority at all

☐ 2

☐ 3

☐ 4

☐ 5 – Top priority

Question 12: How much do you agree with the following statement?

The department's current documentation practices are up to date.

☐ Strongly disagree

☐ Disagree

☐ Neutral

☐ Agree

☐ Strongly agree

Interview Questions

Questions for Manager

Why has the department kept with the current paper documentation so far?

If there are plans to move towards digital documentation, how long have there been plans for?

If there have been plans for that long, why hasn't digital documentation been implemented yet?

On average, how much paper is used per material inspected?

Given how much paper is used per material inspected, and the price of paper, can you provide an estimate on how much this costs the company annually?

What are all the requirements and steps necessary to successfully approve and implement a digital documentation system?

Can you provide an estimate on the cost to implement a digital documentation system?

Is there a digital system that is currently used in other departments/companies that you know of which can be modelled after/reused?

Do you think it would result in time saved if digital documentation replaced paper? If so, where do you think time could be saved and how much time?

What challenges do you think there would be implementing a digital documentation system in the department?

Overall, what documentation system do you think would be better for the department and why?

Questions for employees

Do you think all areas of your work could be simplified by digital documentation?

If not, what are the areas of your work where paper would be more efficient/simple?

In your opinion, has the company pushed for digital documentation?

What documentation system do you prefer and why?

How do you think technology could be implemented in your workflow to improve efficiency (does not have to be specifically for documentation)?

What challenges do you think digital documentation could face if it were implemented in your work?

In your opinion, should the department keep current documentation practices or push for digital and why?