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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. 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, there is no urgency to change the process as the company prioritizes other projects over improving internal processes. 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 as to why my proposed solution has not yet been implemented, and its benefits.

**Methods**

My primary data sources will be 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 Manager and 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.