Lean Principle in Pharmaceutical Supply Chain

# Abstract:

Like all parts of research, the sign is not static or self-contained and evolves during the project. The study's topics and questions aren't always finalized until the investigation is well underway. The locations of research and the persons involved are rarely known ahead of time, and it is more frequently than not for a researcher's plans to change as the study progresses. Similarly, it is typical for the research focus and interests to shift during the research and new areas of concern to arise, necessitating adjustments to the original plans for participant participation. Furthermore, as the research advances, the data collection methods may require specific design changes. This could be due to a shift in interest, difficulties, or obstacles in recruiting the appropriate individuals, or simply because the procedures didn't provide the results that they were expected to for whatever reason.

**Question-** After additional reading discuss this new research design in terms of the following:

* Specifying research topics and questions
* The kinds of people that are of interest
* The types of practice associated with and enacted by these people.
* Choosing research sites and participants and thinking through how they are to be selected
* Thinking through the methods of data collection and working out how they are to be employed.

# Introduction

The Pharmaceutical Supply Chain (PSC) is more complicated and challenging than that utilized in other industries, while being strictly regulated due to its direct impact on human health and safety .Supply quality must be effectively assured at the appropriate point, quality, and time across the entire chain from supply to consumption (WHO, 2010). Therefore, the PSC is not only required to provide high-quality, safe products, but also to ensure excellent service and regulatory compliance. To develop a lean strategy, need to utilize the quantitative and qualitative approach to develop the research plan and sampling techniques (Shah, 2004). To implement lean methodology in Pharmaceutical Supply Chain (PSC) need to identify the wastage and alternate path to increase the efficiency (Jaberidoost et al., 2013). It is important to evaluate the current supply chain methodology to identify the alternate path without impacting the quality (Koh et al., 2003). By implementing alternate path need to ensure the regulatory requirements (Kelle et al., 2012). The sampling will help to identify the correct target group for the survey (Singh et al., 2016). Also the correct sampling plan will help to implement the sampling strategy and distribute the questions to the correct target group, with the sampling plan the researcher can frame the correct questions and set the attributes for the targeted segments. I am revisiting the sampling plan and design methodologies used in my previous research phase in this article (Nguyen et al., 2022).

# Research question Or Hypothesis

In this phase, I revisited the research process and the research question or hypothesis. Then, based on the outcome, I will change the research plan & sampling process to develop a research method for the survey questions.

As part of the analysis addressing the below points

1. Specifying research topics and questions
2. The kinds of people that are of interest
3. The types of practice associated with and enacted by these people.
4. Choosing research sites and participants and thinking through how they are to be selected
5. Thinking through the methods of data collection and working out how they are to be employed

# Specifying research topics and questions

Research Topic - Lean Supply Chain in the Pharmaceutical Industry

The PSC has a significant chance to improve its processes. Reduced operating costs and timeframes to enhance overall efficiency, resulting in a considerable increase in earnings, is one of the most current severe issues for the Pharmaceutical business. Despite the quick and effective deployment of the lean concept in other industrial activities, it is stated that lean initiatives in the Pharmaceutical sector have yet to be broadly accepted. This is due to the industry's increased emphasis on quality and being closely monitored by regulatory agencies, ([Dixit, A.,](https://www.emerald.com/insight/search?q=Anuj%20Dixit) [Routroy,](https://www.emerald.com/insight/search?q=Srikanta%20Routroy)

[S.](https://www.emerald.com/insight/search?q=Srikanta%20Routroy) and [Dubey, S.K.](https://www.emerald.com/insight/search?q=Sunil%20Kumar%20Dubey) (2019)),. The PSC parties shall follow all applicable laws and regulations to ensure that drug quality is maintained through safe and effective handling throughout the supply chain; the lean principle focuses on waste elimination, value creation, and procedure simplification, whereas regulatory compliance focuses on safety and quality. Due to various

regulations and complications in the pharma industry, lean method adoption is more challenging than any industry. (Note : Observed pharma industry responded positively on COVID vaccine trials which can be considered a classical example of lean sigma). More research on PSC optimization using the lean principal application is recommended to close this gap to keep it relevant. The findings will aid practitioners and researchers in the field of PSC with their future work while contributing significantly to the existing body of knowledge. After revisiting the topic, I decided not to change the research topic.

# The kinds of people that are of interest

This topic considered the targeted segments and revisited the methods to use the targeted segment. Will perform the segmentation analysis to identify the kinds of people interested in participating in the survey for the qualitative and quantitative analysis. Different segmentation techniques are used to identify a group of people with standard features. Qualities include things like demographics, product behaviors, and attitudes. Segmentation can be done through exploratory depth interviews and focus groups in early-stage research. Geographic, demographic, psychographic, behavioral, and product-related elements are different target market characteristics, Camilleri, M.A. (2018). As part of research will perform the below steps for segmentation

1. Feasibility Analysis.
2. Determine the best segmentation method.
3. Keep conducting market research.
4. Develop and categorize customer segments.
5. Make new research strategies as a result.

After segmenting will follow the below steps to identify the people that are of interest

* + Make a list -Make a list of the characteristics of the participants should have. These might include age, gender, income, religion, geographical region and marital status
	+ Identify and sample every person - Identify and sample every person who meets the sample criteria. This works for studies with sample characteristics that target a very narrow group
	+ Identify a location
	+ Ask participants -Ask participants to suggest other participants who qualify
	+ Contact people - Contact people who can suggest participants who fit in profile
	+ Refine your sample -Refine the sample by eliminating from the research or results any participants whom suspect do not meet the requirements or have been dishonest about matching the characteristics.

# The types of practice associated with and enacted by these people (Sampling Plan)

A sampling plan enables an auditor or researcher to investigate a group (e.g., a batch of products, a section of the population) by watching only a subset of that group and concluding with a certain level of certainty. Simply said, sampling is the process of selecting a subset of the population in your research field to represent the entire population. There are various methods to identify the samples. The strategy is the approach devised to ensure that the sample to employ in the research study accurately reflects the population from which it was drawn. The phrases population, sample, sampling frame, eligibility criteria, inclusion criteria, exclusion criteria, representativeness, sampling designs, sampling bias, sampling error, power analysis, effect size, and attrition are linked with sampling. In addition, convenience, accidental, snowball, quota sample, purposive sampling, simple random sampling, and cluster sampling are all types of sampling (Paul S. & Stanley, 2013)

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In Pharmaceutical research, there are majorly using the groups of sample designs are probability sampling and non-probability sampling.

Probability sampling - When choosing the elements, some random selection is used.

The representativeness of probability samples can be viewed with greater confidence. This sampling method entails a selection process in which each member of the population has an equal and independent probability of being chosen. Simple random, stratified random, cluster, and systematic are the four primary approaches in probability sampling.

Non-probability sampling: Nonrandom approaches are used to choose the items that make up the sample. This form of sampling is less likely to provide representative samples than probability sampling. Despite this, non-probability samples can and are used by researchers.

1) Convenience, 2) Quota, and 3) Purposive are the three basic techniques.

Using the sampling plan need to identify the target group from various supply chain departments.

# Choosing research sites and participants and thinking through how they are to be selected

The term "research site" refers to where individuals conduct research. Universities, hospitals, research institutes, and field research places are all standard research settings. "Purposive" or "convenience" sampling is the most popular (and simplest) approach for selecting participants for focus groups. This includes choosing the members of the community who will contribute the most helpful information. It doesn't have to be a random selection (Sargeant J. 2012).

**Selecting participants** - To eliminate the potential impact of external variables and assure generalizability of results, quantitative research involves standardization of methods and random selection of participants. Subject selection in qualitative research, on the other hand, is deliberate; participants are chosen who can best inform the research questions and improve

their understanding of the topic under investigation. As a result, identifying acceptable volunteers is one of the most critical activities in the study design process. Selection decisions are based on the study's research questions, theoretical viewpoints, and evidence (Sargeant J. 2012). The subjects chosen must be able to provide information on key aspects and viewpoints of the phenomenon under investigation. Representative participants could be considered by role (residents and faculty), opinion (those who support or reject the intervention), experience level (junior and senior residents), and diversity in a study looking at a professional intervention, for example (gender, ethnicity, another background). The sample size is the second factor to consider. To establish sufficient power to confirm that the effect can be attributed to the intervention, quantitative research involves a priori statistical computation of sample size. The sample size in qualitative research, on the other hand, is not usually predetermined. Instead, the number of participants is determined by the number required to enlighten all relevant aspects of the phenomenon under investigation adequately. For instance, when additional interviews or focus groups do not identify new concepts, a condition known as data saturation, the sample size is sufficient. In an iterative cycle, the analysis should concurrently with data gathering to determine when data saturation occurs. This helps the researcher track the introduction of new topics and find viewpoints that might otherwise go unnoticed. When the data from the professionalism intervention is reviewed, the researchers may see that only good experiences and perspectives are being shared. It may be decided to identify and attract residents who had a negative impression of the event (Sargeant J. 2012).

In my research, the research site will be the company's supply chain department, plant, distribution, and logistic departments. I plan to include people from various departments with

Job roles, including Supply chain analyst, buyer, Inventory manager, Production plant manager, and logistic manager.

# Thinking through the methods of data collection and working out how they are to be employed

Individual or group interviews (including focus groups), observation, and document review are the most typical data collection methods used in qualitative research. They can be used separately or in tandem. While the following sections are written in the context of collecting data through interviews or focus groups, the sample selection, data analysis, and quality assurance principles described applying to all qualitative methodologies. Apart from the listed methodologies the below are the most used data collection mechanisms(Craig, S. 2019).

* Automated data collection functions
* Sensors that collect operational data from industrial equipment, vehicles, and other machinery.
* Collection of data from information services providers and other external data sources.
* Tracking social media, discussion forums, reviews sites, blogs and other online channels.
* Surveys, questionnaires, and forms, done online, in person or by phone, email or regular mail.
* Focus groups and one-on-one interviews; and
* Direct observation of participants in a research study.

The interpretive analysis uses collected data that involves three stages: deconstruction, interpretation, and reconstruction. These processes occur after the data has been prepared for

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analysis, i.e., after the interviews or focus groups have been transcribed and the transcripts have been compared to the recordings.

1. Breaking down data into component bits to see what's within is known as deconstruction.

It's like the content analysis. It entails reading and rewriting interview or focus group transcripts and categorizing and coding data to describe the topic (Craig, S. 2019)..

1. Following deconstruction, interpretation refers to making meaning of and comprehending the coded data. It entails comparing data codes and categories within and across transcripts and between study variables (e.g., year of residency, discipline, faculty engagement). Discussion and comparison of codes among research team members while looking for similarities and differences among themes, comparing findings with those of other studies, exploring theories that might explain relationships among themes, and delving deeper into negative results (those that do not confirm the dominant themes) are all techniques for interpreting data and findings (Craig, S. 2019).
2. The term "reconstruction" refers to reproducing or repackaging key codes and themes in a way that demonstrates the links and insights discovered during the interpretation phase and explains them more broadly in light of existing information and theoretical viewpoints. In most cases, one or two major concepts will emerge as overarching or central, while others will emerge as subthemes that contribute to the fundamental notions.

For reconstruction, contextualizing the findings, i.e., situating and framing them within the existing theory, evidence, and practice, is required (Craig, S. 2019).

I will utilize the interpretive mechanism and other collection points to complete the data collection for the pharmaceutical supply chain research.

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# Conclusion

In qualitative and quantitative analysis, it is essential to identify the target groups. The correct sampling and questions will provide erroneous results to our research. Therefore, it is crucial to implement the proper sampling techniques and provide the appropriate survey questions to the sampling groups to collect the data input for the research. In pharmaceutical supply chain analysis need to conduct the feasibility of sampling thoroughly. The qualitative and quantitative interview questions should cover the research intention and subject. With the revised questions and redesigned approach can reduce the sampling errors.

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