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Comparison of Manufacturing Processes in the Pharmaceutical Industry

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Abstract:
This research paper compares in-house and contract manufacturing processes in the pharmaceutical industry, focusing on the Indian market. It examines the advantages and challenges associated with each approach by analyzing secondary data from companies like Sun Pharmaceutical Industries and Dr. Reddy's Laboratories, as well as primary data from an interview with Edge Pharma. The study highlights key factors such as quality control, cost efficiency, flexibility, and regulatory compliance. It aims to provide insights into how pharmaceutical companies can optimize their manufacturing strategies to enhance productivity, reduce costs, and maintain high standards of product quality and safety.

Keywords: Pharmaceutical manufacturing; In-house manufacturing; Contract manufacturing; Indian pharmaceutical industry; Manufacturing strategies; Pharmaceutical operations; Quality control; Supply chain management; Generic drugs; Biosimilars; Active pharmaceutical ingredients (API); Research and development (R&D); Sun Pharmaceutical Industries; Dr. Reddy's Laboratories; Cipla Limited; Lupin Limited; Manufacturing process; Drug production; Regulatory compliance; Manufacturing efficiency; Production documentation; Batch records; GMP (Good Manufacturing Practices); Outsourcing; Vendor qualification; Financial ratios; Intellectual property; Market demand; Manufacturing flexibility; Competitive advantage.

Introduction

The Indian Pharma Sector:

The Indian pharmaceutical industry has developed into a robust industry over time, growing at a CAGR of 9.43% over the past nine years, and it is presently ranked third in terms of pharmaceutical output by volume. According to the Indian Economic Survey 2021, the domestic pharmaceutical market stood at $ 42 billion in 2021 and is likely to reach $ 130 billion by 2030.

India, the largest manufacturer of generic pharmaceuticals in the world, is renowned for its inexpensive generic medications and vaccinations. India provides over fifty percent of Africa's demand for generics, forty percent of generic demand in the United States, and twenty-five percent of all medication in the United Kingdom. India also accounts for 60% of global vaccine demand and is a leading supplier of DPT, BCG, and measles vaccines. 70% of the WHO's vaccines (as per the essential immunization schedule) are sourced from India. In addition to over the-counter medications, bulk medications, contract research and manufacturing, biosimilars, and biologics, other key sectors of the Indian pharmaceutical industry include bulk medications, contract research and manufacturing, biosimilars, and biologics.

India is home to the majority of pharmaceutical production facilities that adhere to US Food and Drug Administration (USFDA) regulations. The pharmaceutical industry in the United States consists of 10,000

manufacturing facilities and 3,000 medicinal enterprises. Nearly 80% of the antiretroviral medications currently being used to fight AIDS around the world are provided by Indian pharmaceutical companies.

Manufacturing Strategies:

Manufacturing is a crucial step in the manufacture of goods and is crucial to a company's success. Making the best manufacturing strategy choice is a crucial decision that can have a big effect on a business' performance. In-house and contract manufacturing are the two basic strategies.

In-house Manufacturing:

When a firm chooses to use its own resources, personnel, and facilities to produce goods, it is known as in-house manufacturing. In this approach, an organization owns its manufacturing facilities and equipment, which are operated by workers trained and employed by it.

This enables the business to control every stage of the manufacturing process, from acquiring raw materials to delivering the finished product. It is easier to keep a check on the quality of the product. It also proves to be a more flexible approach to responding quickly to changes needed in the manufacturing process or the product itself.

Keeping the manufacturing in-house also allows the company to control access to sensitive information and proprietary technology, which would not be possible with outsourcing. This approach could also lead to the creation of new processes or product variants and create competitive advantages.

However, in-house production is typically more expensive than outsourcing. This is because funding facilities, equipment, and staff is time-consuming and expensive. Investment in activities that can be outsourced could lead to a distraction from the company’s core activities.

Contract Manufacturing:

In the contract manufacturing approach, a company hires a third party to manufacture its products or components. This method aims to take advantage of the resources of an expert manufacturer, providing a cost-effective way around scaling obstacles.

The benefit of using the contract manufacturing approach is that it gives a company access to the knowledge of a highly skilled and effective manufacturer while saving resources and increasing earnings. This may result in more effective manufacturing techniques and, ultimately, higher quality goods. Furthermore, a company can benefit from advancements in manufacturing processes while maintaining competitive advantages by outsourcing to a contract manufacturer that has invested in cutting-edge technology and equipment.

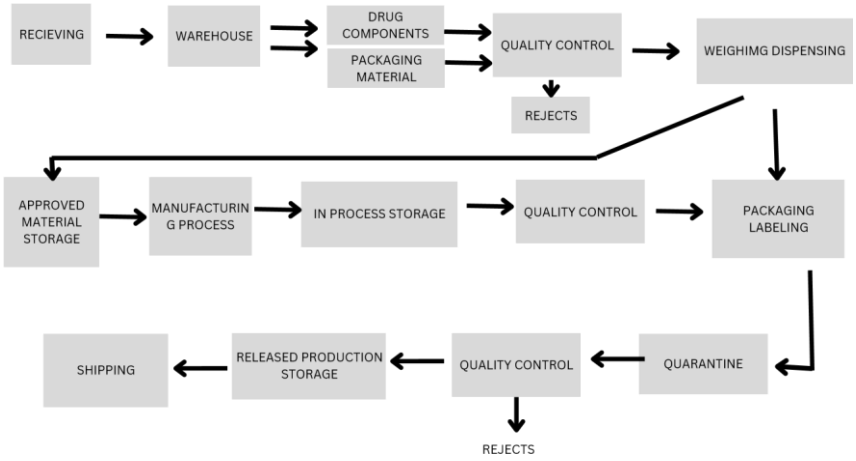
Contract manufacturers will benefit more as they work with more clients and produce more goods. When a business raises its level of output, it benefits from economies of scale in terms of production costs. By distributing their fixed costs, such as overhead and capital investments, over a larger production volume, manufacturers can reduce their unit costs. They also developed relationships with their suppliers, allowing them to negotiate for lower component and material costs.

But outsourcing leads to a loss of control over the production process and quality control. In sectors that require a high degree of adaptability and flexibility, the inability to modify production procedures or respond to changes in product design can be a significant disadvantage. In addition to intellectual property and trade secrets, a third-party manufacturer can gain access to sensitive data. Logistics and supply chain

management can also be challenging because businesses must ensure that third-party suppliers are reliable and able to make on-time and effective deliveries.

Pharmaceutical Operations

The pharmaceutical industry plays a vital role in ensuring the health and well-being of people around the world. To meet the high demand for various medicines, pharmaceutical companies must follow strict and highly regulated manufacturing processes. The manufacturing process involves several critical steps, each of which plays an important role in producing safe, effective and high-quality medicines.



Here is a more detailed overview of the pharmaceutical manufacturing process:

Receiving: In the inbound process, pharmaceutical companies receive raw materials, pharmaceutical ingredients, and packaging materials from suppliers. These materials are checked for quality and quantity and any discrepancies are reported to the supplier. Goods receipt is a critical step in the pharmaceutical manufacturing process, as quality issues at this stage can affect the quality of the final product.

Warehousing: A warehouse is a designated area that stores acquired materials. Warehouses require proper storage conditions, such as temperature and humidity control, and proper lighting. To avoid cross-contamination, it is important to separate storage areas for raw materials, pharmaceutical ingredients, and packaging materials.

Drug Components and Packaging Materials: After storing the received materials in the warehouse, we sort out the active pharmaceutical ingredients and packaging materials according to the manufacturing order. A production order specifies the exact materials required for the manufacturing process. Pharmaceutical companies must ensure that they have sufficient quantities of items to meet the requirements of their manufacturing orders.

Quality Control: We perform quality control of drug substances and packaging materials before entering the manufacturing process. These controls are performed by our quality control department to ensure that the materials meet the required specifications. Quality control ensures that the final product is safe, effective and of consistent quality.

Weighing and Dispensing: The weigh and dispense process accurately weighs and dispenses the materials required for the manufacturing process. The weighing and dispensing process should be performed in a controlled environment to ensure accuracy and avoid contamination. This step is critical to ensure that the final product meets the required specifications.

Approved Material Storage: Dispensed materials are stored in approved material storage areas until required in the manufacturing process. The storage area is temperature and humidity controlled to keep

materials stable and safe. Proper storage conditions are important for materials to maintain their quality and potency.

Manufacturing Process: The manufacturing process includes various steps such as mixing, granulation, drying and compression. Each step is carefully monitored and controlled to ensure the final product meets the required specifications. Manufacturing processes are critical to ensuring that the final product is safe, effective and of consistent quality.

In-Process Storage: Products are stored in the in-process storage area until they pass the required quality control. Storage conditions are closely monitored to avoid adverse effects on the product. Proper storage conditions are important to ensure that the product remains stable and safe throughout the manufacturing process.

Quality Control: Quality controls are performed at various stages of the manufacturing process to ensure that the final product meets the required quality specifications. Our quality control department conducts tests such as physical, chemical and microbiological tests to ensure that our products are safe and effective. Quality control is important to ensure that the final product is safe, effective and of consistent quality.

Packing and Labeling: The packaging and labeling process includes the packaging of the final product and its labeling in accordance with relevant regulatory requirements. The packaging process is performed in a controlled environment to prevent contamination and ensure product stability. Proper packaging and labeling are important to ensure that the product remains safe and effective throughout its shelf life.

Quarantine: After packaging and labeling, products are quarantined to ensure they are safe to use and meet all regulatory requirements. The quarantine period may vary depending on the product and regulatory requirements. Proper quarantine is important to ensure that products are thoroughly inspected and tested to ensure they meet the required quality standards. If quality issues are found during quarantine, the product will be rejected or sent for rework.

Quality Control: After the quarantine period, the products undergo another quality check to ensure they meet the required quality specifications. Our quality control department conducts tests such as physical, chemical and microbiological tests to ensure that our products are safe and effective. This final quality control is critical to ensure that the final product is safe, effective and of consistent quality.

Released Production Storage: After the product has passed all the required quality controls, it is released from quarantine and stored in the released production storage area. Released production storage areas must be condition controlled to ensure that the product remains stable and safe until it is shipped to the customer.

Shipping: The final step in the pharmaceutical manufacturing process is shipping the product to the customer. Products are carefully packed and shipped to different destinations according to customer requirements. The shipping process must be performed in accordance with relevant regulatory requirements to ensure safe and timely delivery of products.

In summary, the pharmaceutical manufacturing process is a complex and highly regulated process. Each step is critical to ensuring the final product is safe, effective and of consistent quality. Proper control, monitoring and testing of materials and products at every stage of the process is necessary to ensure the success of the manufacturing process.

In-house Manufacturing Process of Pharmaceutical Companies in India

Sun Pharmaceutical Industries

Sun Pharmaceutical Industries is the largest pharmaceutical company in India, and one of the top 10 generic drug manufacturers in the world. The company has a strong focus on in-house manufacturing, and invests heavily in research and development to create new drugs.

Research and Development: Sun Pharmaceutical Industries has a dedicated research and development (R&D) department, which focuses on developing new drugs and improving existing ones. The company has R&D centres located in India, the United States, and Israel, and employs over 5,000 scientists and researchers worldwide. Sun Pharmaceutical Industries invests around 8% of its revenue into R&D, which is one of the highest percentages in the industry.

Manufacturing: Sun Pharmaceutical Industries has 25 manufacturing facilities across the globe, with 16 located in India. The company's manufacturing facilities are certified by regulatory bodies such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Sun Pharmaceutical Industries' manufacturing process is highly automated and uses cutting-edge technology to ensure consistent product quality and reduce waste.

Financial Ratios: Sun Pharmaceutical Industries' financial ratios as of 2023 are as follows:

Return on Equity (ROE): 14.0%

Debt-to-Equity (D/E) Ratio: 0.08

Price-to-Earnings (P/E) Ratio: 30.1

Current Ratio: 2.34

Inventory turnover: 1.23

Dr. Reddy's Laboratories

Dr. Reddy's Laboratories is another major pharmaceutical company in India, with a strong focus on in-house manufacturing. The company develops and manufactures a wide range of drugs, including generic and biosimilar drugs.

Research and Development: Dr. Reddy's Laboratories has several research and development centers located in India, the United States, and Europe. The company invests heavily in R&D to develop new drugs and improve existing ones. Dr. Reddy's Laboratories has a team of over 1,200 scientists and researchers working on various R&D projects.

Manufacturing: Dr. Reddy's Laboratories has 7 manufacturing facilities located in India, which are certified by regulatory bodies such as the US FDA and the EMA. The company's manufacturing process is highly automated and uses advanced technology to ensure consistent product quality and reduce waste. Dr. Reddy's Laboratories also has a dedicated biosimilars manufacturing facility located in Hyderabad, India.

Financial Ratios: Dr. Reddy's Laboratories' financial ratios as of 2023 are as follows:

Return on Equity (ROE): 11.5%

Debt-to-Equity (D/E) Ratio: 0.08

Price-to-Earnings (P/E) Ratio: 21.8

Current Ratio: 2.16

Inventory turnover: 1.63

Advantages of in-house manufacturing process:

Control over quality: By manufacturing drugs in-house, Companies havegreater control over the quality of its products. This allows the company to ensure that its drugs are of high quality, which can improve

patient outcomes and increase customer satisfaction.

Cost savings: In-house manufacturing can be more cost-effective for companies, as they can avoid the markups and fees charged by third-party manufacturers. Companies can also optimize its production processes and reduce waste, leading to potential cost savings.

Innovation: By having an in-house research and development team, Companies can develop new and innovative drugs that can set the company apart from its competitors. This can help the company maintain its market position and grow its market share.

Challenges process of in-house manufacturing

Investment cost: In-house manufacturing requires significant investment in research and development, manufacturing equipment, and employee training. This can be a significant financial burden for companies, particularly in the early stages of development.

Flexibility: The company needs to have a flexible manufacturing system that can adapt to changing market demands. Companies need to be able to produce different types of drugs in different quantities to meet changing customer demand.

Regulatory compliance: The company must ensure that its in-house manufacturing process complies with local and international regulations. Failure to comply with these regulations can result in fines and legal consequences.

Conclusion:

In terms of financial ratios, both companies have strong return on equity ratios, indicating that they are generating solid returns for their shareholders. Additionally, both companies have relatively low debt-to-equity ratios, indicating that they have a strong financial position.

Overall, in-house manufacturing has provided Sun Pharmaceutical Industries and Dr. Reddy's Laboratories with a competitive advantage in the pharmaceutical industry in India. While there are challenges associated with this approach, both companies have successfully navigated these challenges and have achieved success in the market. By continuing to invest in research and development and optimizing their manufacturing processes, these companies are well-positioned to maintain their market positions and continue to grow in the future.

Contract Manufacturing Process of Pharmaceutical Companies in India

Cipla Limited

Cipla Limited is a leading Indian multinational pharmaceutical company that was founded in 1935. It is headquartered in Mumbai, India and has a presence in more than 80 countries. Cipla is known for its expertise in respiratory, anti-retroviral, and anti-malarial therapies, and has a portfolio of more than 1,500 products.

Financial Ratios: Lupin Limited's financial ratios as of 2023 are as follows:

- Current ratio: 4.41
- Quick ratio: 3.23
- Inventory Turnover ratio: 0.88
- Dividend Payout ratio: 13.63
- Retention ratio: 86.36

Lupin Limited

Lupin Limited is a leading Indian multinational pharmaceutical company, founded in 1968 and headquartered in Mumbai, India. The company has a strong presence in over 100 countries and is a major player in the global pharmaceutical industry, with a focus on developing and manufacturing generic and branded pharmaceuticals, as well as specialty products.

Financial Ratios: Lupin Limited's financial ratios as of 2023 are as follows:

- Current ratio: 2.38
- Quick ratio: 1.49
- Inventory Turnover ratio: 0.96
- Dividend Payout ratio: 90.65
- Retention ratio: 256.37

Advantages of Contract Manufacturing process:

Access to expertise and resources: Contract manufacturers typically have specialized knowledge and expertise in a particular area, such as pharmaceuticals or electronics. By working with a contract manufacturer, companies can access this expertise and benefit from the latest technologies and best practices.

Flexibility: Contract manufacturing allows companies to be more flexible and responsive to changes in demand. If demand for a particular product increases, for example, a contract manufacturer can quickly ramp up production to meet that demand.

Reduced risk: Outsourcing manufacturing to a contract manufacturer can help reduce risk for companies. Contract manufacturers assume responsibility for the quality and safety of the products they produce, which can help reduce liability for the company that has outsourced the manufacturing.

Challenges of Contract Manufacturing process:

Quality control: When outsourcing manufacturing processes to a contract manufacturer, companies need to rely on the manufacturer to maintain high quality standards. This can be a challenge, especially if the manufacturer is located in a different country or region with different regulations and standards.

Communication and coordination: Effective communication and coordination between the company and the contract manufacturer are crucial for success. However, language barriers, cultural differences, and time zone differences can make it challenging to maintain effective communication and coordination.

Dependency: By outsourcing manufacturing processes, companies become dependent on the contract manufacturer for the production of their products. This can create a risk of supply chain disruptions or quality issues.

EDGE PHARMA- PRIMARY DATA

Edge Pharma is a budding Indian pharmaceutical company with a truly global mindset.

International marketing is their mainstay, and their foremost objective is to establish brands in the CIS countries. Their head office is located at Mumbai and representative office is at Moscow, Russia.

They have partnered with global packaging solution providers to study sensitivity profiling of their brands. This patented technology facilitates development of formulation-specific packaging to guarantee optimum protection throughout product shelf-life. Utmost care is taken even during storage, transportation, and distribution to further uphold brand quality till it reaches their patrons. Edge Pharma is ready to transform

and grow to a creditable position in the pharmaceutical industry but is also conscious of its societal commitments. As part of their corporate responsibility, they will be promoting the importance of "adherence to therapy" by means of their campaign Medication Adherence Program. They want to create an edge by moving ahead to enhance life.

ANALYSIS OF THE INTERVIEW

The interview with Edge Pharma covers a range of topics related to the company's approach to ensuring the accuracy and completeness of their production documentation, managing the storage and distribution of controlled substances, handling product recalls and supply chain impacts, and efforts to reduce waste and increase efficiency in their operations and supply chain.

Regarding the accuracy and completeness of production documentation, the interviewee emphasized the importance of clearly written procedures to prevent errors resulting from spoken communication or other factors. They also highlighted the need for documents to be designed, prepared, reviewed, and distributed with care and responsibility, and done only by competent and authorized persons. To ensure completeness, they described a "doer-checker" method, where one person carries out a task while another checks it simultaneously. They also mentioned the importance of following good manufacturing practices (GMP) to ensure quality control.

The interviewee also discussed the company's approach to keeping batch records and quality control. They explained that batch records are the most essential part of the manufacturing and packing process and that reviewing them is one of the most important jobs in ensuring that documentation is not only recorded but also that it actually happened. The interviewee emphasized the importance of reviewing batch records by both the quality assurance and operations teams to minimize errors.

The interviewee then discussed how the company manages the storage and distribution of highlypriced materials, though they clarified that they do not deal with controlled substances. They explained that they have specific arrangements for storing these materials based on their requirements, such as whether they need to be kept at room temperature or under lock and key. They also mentioned that only authorized and authenticated persons are supposed to handle such materials, and there is a doer-checker system in place to ensure their proper handling.

The interview then turned to the topic of product recalls and associated supply chain impacts. The interviewee stated that, fortunately, the company has not had to deal with a recall yet, but they have documented procedures in place in case of such an event. They explained that a recall requires a lot of documentation, including the reason for the recall, associated organizations, QA documents, manufacturing analysis, and more. The interviewee emphasized the need for proper documentation and careful analysis to make decisions about recalls.

Finally, the interviewee discussed the company's efforts to reduce waste and increase efficiency in their operations and supply chain. They mentioned that the supply chain is an essential part of the entire procedure, and the company is trying to speed up decision-making processes and improve product tracking to prevent counterfeits and competitors from copying their products. They also mentioned that they are updating their procedures and continuously evaluating and qualifying their vendors to ensure quality assurance. The interviewee highlighted that the company has a standardized checklist for vendor qualification, and they visit vendors' facilities to check GMP documentation and ensure that they can supply the appropriate materials for a goodquality product.

WHAT DID EDGEPHARMA SAY ABOUT CONTRACT MANUFACTURING?

In the interview, Edge Pharma talked about outsourcing/contract manufacturing as a way to scale up their production without investing in expensive equipment and facilities. They mentioned that outsourcing allows them to leverage the expertise of their contract manufacturers, who specialize in specific areas of production, to produce high-quality products efficiently. They spoke about how they analyze the vendor, go and visit them whether they are in the position to supply the appropriate material that they need to make a good quality product. Say for example they are qualifying an API, which is the active ingredient that they use in manufacturing, they ask them for samples from 3 different batches and we analyze it at our end, check if the quality if compliant to any pharmacopeial references or our in-house standards. Our specialized team goes and visits their facility, checks all the GMP documentation and they have a standardized checklist that needs to be followed which is followed.

On asking is it that the vendors approach them or is it that they go to the market to look for them. They replied saying It totally depends. There are people who approach them also, but they have their own sourcing and purchasing team so whenever a product is identified in terms of the API they find the appropriate source through our teams, test their quality, and keep at least three sources ready with them and then they qualify two of them so that they do not face supply chain issues in case one has an issue. Every company has their own system, but the qualification is dependent on how stringent they need to be. They also noted that outsourcing helps them to reduce their overhead costs and increase their flexibility in responding to changes in market demand. However, they acknowledged that outsourcing also has its challenges, including managing quality control, maintaining intellectual property, and ensuring regulatory compliance. Overall, the organization emphasized the importance of building strong relationships with their contract manufacturers and having clear communication to ensure successful outsourcing.

TRANSCRIPT OF THE INTERVIEW WITH EDGE PHARMA

Q. How do you ensure the accuracy and completeness of your production documentation?

Interviewee: See in the pharmaceutical companies, a good documentation is a very essential part of your system, okay, so there should be clearly written procedures to prevent errors resulting from spoken communication or the other things and documents might be designed, prepared, reviewed and distributed with a lot of care and responsibility and it must be done only with competent and authorized persons. It shouldn't have any ambiguous contents. The title, the nature, the purpose must be clearly stated. To ensure completeness there are 2 people involved "A doer-checker method" - a person who keeps on doing it and there's a person who checks it simultaneously. So that is the whole system. All the procedures what you have to follow this process GMP (good manufacturing practices)

Q. Can you describe your company's approach keeping in batch record?

Interviewee: Okay, batch record is the most essential part. It it's the manufacturing record and the packing record. So the review of the batch record is one of the most important job. This basically shows that it's not only documented, you know, but it also happened so here we have a review process and we review the batch records. The QA team reviews it, the operations team reviews it so that there are no errors, and the executed batch record is a documentation which shows any atypical events that may have occurred. So this is how we keep it.

Q. How do you manage the storage and distribution of control substance is another highly regulated pharmaceuticals?

Interviewee: as an organization we do not have regulated substances in our portfolio. But what we have is very highly priced materials which comes in very low quanity.This, again, the storage we have to check whether it has to be stored at room temperature or whether it's supposed to be under lock and key, depending upon the type of product what we're using. So that arrangement is already there in the facility. So as and when the material comes its handled according from the first phase of its receipt. From the offset and we also have to be very careful in dispensing such material and only authorized and authenticated persons are supposed to handle such type of materials. And in every stage there is a doer checker. So there's one person who's doing and one person from quality assurance is checking it.

Q. How do you handle product recalls and any associated supply chain impacts?

Interviewee: So far we've been fortunate that there have been no recalls. But also the procedures are documented if incase there is a recall you have to know the reason of the recall. Because it's not a small event, recall is a very big event so for a recall there are different protocols that a company follows and I can tell you with my experience that recall for a recall you need to have a lot of documentation in firstly in place the reason of the recall then the associated organizations with it the QA documents and apart from recall the manufacturing the analysis everything is rechecked and then a decision is arrived for a recall.

Q. Can you discuss any efforts Edgepharma is making to reduce waste and increase efficiency in the operations and supply chain?

Interviewee: Supply chain is the most essential part of the entire procedure. So with respect to supply chain, we try to speed up the decision-making procedure. And for improvements in tracking the product, this is the second part what we're doing, so there's be no counter feats and competitors copying our products. We're trying to improve the technology of our product at each stage so that it will give us a cost benefit, so this is what we're doing also to have a competitive edge like the name of the company suggests. We're timely updating our procedures we're timely upgrading with all the contract manufacturers. Outsourcing is the new win, right? We have our vendor qualifications. Every time we meet and decide on a new vendor, we evaluate them on different aspects of quality assurance. And for the supply chain we're also checking the impact of various factors which impact the supply chain which can be weather, rise in the fuel prices and we keep a tract of that.

Q. How do you collaborate with external partners such as contract manufacturers to ensure seamless integration in your supply chain?

Interviewee: So we have a system which is integrated by our quality team and we do the vendor qualification so this is with the help of vendor qualification. It is actually a part of our quality assurance system. We analyze the vendor; we go and visit them whether they are in the position to supply the appropriate material that we need to make a good quality product. Say for example we're qualifying an API, which is the active ingredient that we use in manufacturing, we ask them for samples from 3 different batches and we analyse it at our end, we check if the quality if compliant to any pharmacopoeia references or our in house standards. Our specialized team goes and visits their facility, checks all the GMP documentation and we have a standardized checklist that needs to be followed which is followed.

Q. Can I ask a follow up from my side? Is it that the vendors approach you or is it that you go to the market to look for them?

Interviewee: It totally depends. There are people approaching us also, but we have our own sourcing and purchasing team so whenever a product is identified in terms of the API we find the appropriate source through our teams, test their quality and keep at least three sources ready with us and then we qualify two of them so that we do not fail supply chain issues in case one has an issue. This system is devised at our

end. Every company has their own system, but the qualification is depending upon how stringent we need to be.

Q. How do ensure that your company complies with all regulations regarding quality control and safety?

Interviewee: Ya see safety and quality are the most essential aspects in pharma. We have our own quality assurance team. So, all the documentation that comes from the factory or from the unit the first person to check this is the QA team. They check right from the input of the API to the exit of the formulation which is the finished formulation. And whether its following the entire flow of the product in a particular manner

Q. Okay, there must be regulations the state also provides right?

Interviewee: Yes yes, so generally all the manufacturing is done in the GMP approved plans so that is the extra precaution we take. And if it is for an export, then we see to it that our plant complies to the international regulation.

Q. Can you discuss any step you're taking to increase transparency in the supply chain?

Interviewee: If an auditor comes, we give him access to any documentation he asks. If not the public eye, the regulators yes.

Q. How do you assess and manage the various risks all the way from sourcing your raw materials to the ultimate stage of the consumer?

Interviewee: The risks are mainly of competition, quality of the product, tech, and uncertainty like COVID. At every stage we have mitigated the risks right from the beginning by having redundant alternatives at our disposal in case of a default of our primary one. We do a dual check in terms of quality, it is checked at the site of manufacturing and also checked by other agencies before exporting it. Certain companies have the requirement of checking the product in their country before allowing the trade which also we facilitate.

CONCLUSION

On what basis should firms choose a manufacturing technique?

Budget: The first criteria to consider would be the financial resources and budget of the organization. In-house manufacturing requires a larger initial investment, whereas contract manufacturing requires less investment but recurring costs.

Control: Companies who require a high level of control over the manufacturing process and are interested in customizing the products should opt for in-house manufacturing. On the other hand, contract manufacturing should be preferred in case a company wants to focus on core competencies and let someone else handle the manufacturing process.

Capacity: Companies should consider their production capacity when deciding between inhouse manufacturing and contract manufacturing. If there is not enough capacity in-house, the company might need to outsource production.

Expertise: Companies should evaluate their expertise in manufacturing. If they have skilled personnel to handle the manufacturing process, they can go for in-house manufacturing. Conversely, if they lack in-house expertise, they should work with a contract manufacturer with exceptional manufacturing knowledge.

Time: The time taken to complete the manufacturing process is also an important consideration. In-house manufacturing may take longer than contract manufacturing since it requires building and maintaining infrastructure. Contract manufacturing, on the other hand, may have more efficient processes in place reducing the time required to manufacture products.

Risks: If the company is using sophisticated manufacturing equipment and/or handling hazardous materials, it's essential to weigh the risks associated with in-house manufacturing vs contract manufacturing. Contract manufacturing might prove to be a safer and more convenient option.
Therefore, companies should evaluate the above factors and decide which manufacturing method will be most suitable as per their needs.

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