Critical Success Factors for Operational Excellence in the Pharmaceutical Industry: Insights from a Qualitative Study

Elizabeth O'Callaghan[1,3(✉)], Olivia McDermott[2], Gavin Walker[3], and Mark Southern[1,3]

[1] School of Engineering, University of Limerick, Limerick, Ireland
elizabeth.ocallaghan@ul.ie
[2] College of Science and Engineering, University of Galway, Galway, Ireland
[3] School of Chemical Sciences, Bernal Institute, University of Limerick, Limerick, Ireland

Abstract. The paper aims to investigate the Critical Success Factors that exist for Operational Excellence methodology deployment in the Pharmaceutical industry. The research will seek to establish the levels of current Operational Excellence awareness and integration in the Pharmaceutical industry in terms of the deployment of Continuous Improvement methodology. The study involves the analysis of the pros, cons, strengths, weaknesses, and limitations of management commitment for the application to the deployment of Continuous Improvement methodologies in the Pharmaceutical industry. A qualitative methodology was utilised by interviewing a cohort of 28 Pharmaceutical manufacturing Operational Excellence and Continuous Improvement practitioners. The study found that while participants advocated and supported the requirement and importance of Operational Excellence, a key Critical Success Factor identified was senior management support in fostering Operational Excellence culture. A top challenge highlighted for Operational Excellence and Continuous Improvement success, particularly in regulated industries, was a regulatory compliance culture and regulatory bureaucracy. The paper provides a valuable resource for organisations to obtain insight into Critical Success Factors for Continuous Improvement and Operational Excellence and in particular, in a regulated Pharmaceutical manufacturing industry.

Keywords: Operational Excellence · Manufacturing · Continuous Improvement · Pharmaceutical industry · Lean

1 Introduction

Operational Excellence (OpEx) attainment is a journey of Continuous Improvement (CI). CI is defined as "*a learned and stable pattern of collective activity through which the organisation systematically generates and modifies its operating routines in pursuit of improved effectiveness*" [1, 2]. OpEx is defined as the continuous pursuit of improvement of a production plant in all dimensions [3]. In Ireland, the Pharmaceutical sector

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employs more than 30,000 people, with as many more in spin-off jobs and has grown from a mere 5,200 people in nineteen eighty-eight [4]. The sector has seen continued capital investment averaging €1 billion per annum since 2011 attributed to manufacturing success [4, 5]. Ireland hosts 75 Pharmaceutical companies, comprised of 9 of the world's top 10 Pharmaceuticals, and is currently the largest net exporter (over 50% of Pharmaceuticals in the European Union (EU)) [4].

Integrating OpEx into all policies and procedures gives a company the ability to develop and supply superior products to the customer [6]. Having created an OpEx culture, companies achieve a competitive advantage that they can capitalise on in the market without current or potential competitors [7, 8]. The Food and Drug Administration (FDA) has reported that OpEx still has a long way to go in the Pharmaceutical industry because Quality is still kept separate from OpEx both organisationally and culturally [9, 10]. Lean as an enabler for OpEx has been largely studied [11–13]. Studies on CI in the Pharmaceutical and Medtech sector have acknowledged that the regulated industry can stifle CI [5, 14]. Thus, sustaining CI activities for OpEx has been challenging [2, 15]. Therefore, there is a need for a study analysis of the applicability of CI activities in a regulated industry. This research contributes to a gap in published literature by investigating CSFs for OpEx in the highly regulated Pharmaceutical industry [16, 17].

This research will explore the relationship between workers' perceptions of their manager's commitment to OpEx and CI and the organisation's OpEx culture. The research questions as follows were set by the researchers for this empirical study:

1. What is the current level of awareness and benefits for OpEx and CI within the Pharmaceutical Industry?
2. What are the CSFs and challenges of OpEx and CI deployment?

2 Literature Review – Background and Context

Within the Pharmaceutical industry, OpEx has a long way to go because Quality and Compliance are kept separate from OpEx organisationally and culturally [9]. A survey on CI groups found that, according to 71% of participants, the major issues are around people's engagement in CI methods, e.g. Lean at the shop floor and middle to senior management levels [18]. Other major issues worth noting related to the sustainability of CI and OpEx efforts. One way of looking at OpEx is as an "umbrella concept" [19]. OpEx challenges can be accommodated by values, a shared vision, commitment, and dedication from everyone. Opportunities exist to embrace OpEx culture and CI methodologies which play a key role for OpEx from the manufacturing floor to the customer or patient (as in the case of Pharmaceutical applications). Moreover, culture and CI are paramount for manufacturing the innovative pipeline of complex products to meet unmet medical and Pharmaceutical needs [4].

Evidence-based body of knowledge reveals that OpEx philosophy is based on 'research [11, 18, 20–23] and based on 'learning by doing" [20]. This demonstrates that the winners of tomorrow's *'Big Pharma'* landscape will emphasise an integrated approach from an overall system perspective for enhanced overall OpEx performance. According to Antony et al. [24], many OpEx initiatives fail to sustain in organisations for

7 key reasons including; lack of awareness and importance of a structured CI program; no belief in OpEx; lack of leadership for OpEx, not sure of the benefits of OpEx; implementing OpEx without a strategy in place; senior management not convinced of OpEx benefits; and a perception that OpEx is time-consuming and costly. The implementation of CI and culture is driven directly by business strategy and led by management [8, 25].

Research shows that successful OpEx implementation is closely related to organisational and culture change [26]. CI practices help to install organisational habits and mindsets that favour systematic process improvements [27]. Trust and openness with praise for all workers is an integral part of the management process while shaping the vision for a sustainable healthy OpEx workplace environment [9, 17, 27].

Studies have investigated the transformation of OpEx across multiple industries, including the Pharmaceutical industry, about CI [11, 33]. Sustainability is an important factor in OpEx CI and culture. The CSFs of engaging people in Lean efforts at the shop floor including middle to senior management levels were identified as 'mindset', 'language', 'confidence', and 'passion for excellence'. Moreover, it is not about people using the tools, systems, or indeed what people see [18].

Case studies by OpEx experts [20, 22, 23] discuss the key learnings and CSFs of the CI journey using Lean and Six Sigma as well as Agile [28, 29]. Benefits of OpEx CI include: increasing levels of overall equipment efficiency; increasing positive OpEx culture across all teams; increasing productivity; zero accidents; zero complaints; zero recalls; zero stoppages; zero downtime; reduced inventory; and reduced operational costs [20].

However, to implement sustainable Lean manufacturing, the top three most crucial CSFs are 'top-management commitment', 'internal expertise' and 'employee involvement. Top management's involvement directly impacted the working culture [30].

Lastly, studies have discussed how OpEx and CI projects do not thrive in regulated environments, with various studies highlighting heavily regulated environments as difficult to maintain a CI culture [31]. The Pharmaceutical industry is one of the most regulated industries in the world, and thus, any improvements or changes that may affect the product's compliance with regulations or perhaps have a patient safety impact requires regulatory submissions [14, 32, 33]. This regulatory submission takes time to submit to regulatory authorities. It can require a lot of data, justification, and resources to follow through to gain, for example, FDA approval, thus deterring many CI solutions from being implemented or even submitted for approval in the first place [14]. The requirement for revalidation and requalification of processes after an improvement action or change is suggested also takes a lot of time, paperwork and resources [31].

3 Research Methodology

The primary instrument chosen was semi-structured, in-depth and face-to-face interviews, utilising purposive sampling [34–37]. The interview questions were outlined in Table 1 and consisted of two sections: the first aimed to obtain respondents' general information and the second aimed at their organisational knowledge.

Table 1. Interview questions and themes

SECTION A
Department
Q1 Role in your Company
Q2 What is your belt qualification -yellow/green/black?
Q3 No of years experience in your present company
Q4 No of employees in your company globally
SECTION B
Q1 What is your opinion/awareness of OpEx?
Q2 Which departments in your company is OpEx implemented in?
Q3 What OpEx tools do you use daily at work?
Q4 What are the challenges of the pursuit of OpEx and CI implementation in your organisation?
Q5 What are the CSFs for OpEx implementation in Pharmaceutical organisations?

Twenty-eight purposively selected Pharmaceutical professionals were interviewed over eight weeks from seven Pharmaceutical companies, and all wished to remain anonymous while the researchers assured confidentiality [38]. Participant details were obtained using LinkedIn as a professional networking site [39]. Each interview was carried out on the MS Teams platform and audio-taped, lasted 25 minutes and covered all open-ended questions in one sitting for speed of data collection from participants expediently [40]. For consistency, the same questions were asked to all respondents. The interviews and quotes are verbatim and indicate participant number (P number), as pseudo names are given for anonymity. Qualitative studies help to investigate participants' opinions regarding issues, events, or incidents [45]. The authors adopted a qualitative phenomenological approach using a method by Colaizzi [41]. This research approach aims to acquire knowledge by considering the world from other viewpoints [42]. This allows the behaviour and reactions of others to be anticipated, as our perceptions may be largely influenced by social observations and interactions [43]. Finally, it enabled the researcher to listen to employees 'hidden voices' about management commitment and OpEx culture and these impacts within a manufacturing context [44]. Significant statements were highlighted, clustered into dimensions [45] and sorted into several thematic areas, which helped answer the research questions.

4 Results

The authors interviewed professionals from functions such as Production, Quality and R&D. The interviewees had experience in various OpEx and CI methodologies such as Lean and Six Sigma and were selected from several Pharmaceutical companies.

In terms of the interviewees, they represented the following functions: Production Operator (53%), Line Manager (32%); Global OpEx Lead (7%); Supervisor (4%); and Site Lead (4%) positions. In addition, 15 out of 28 interviewees (i.e., nearly 54%) had an OpEx/CI training or belt qualification, with 13 interviewees (i.e., nearly 46%) stating they were trained but had no belt qualification. All interviewees had over 2 years of experience within their Pharmaceutical organisations and were from large Pharmaceutical companies based in Ireland with over 1500 employees.

4.1 Opinion and Awareness of OpEx and CI

In section B, the first question was: **"***What is your opinion/awareness of OpEx?***".** This question relates to participants' beliefs and feelings on the culture of OpEx in their work environment and whether they use CI tools daily. The selected quotes from the interviews are outlined in Table 2. Generally, there was a positive consensus around having an OpEx and CI program with employee involvement and training in CI projects. Concerning OpEx organisations, typical benefits of having Lean tools implemented can include a "more innovative and embedded culture at work", "a CI mindset", and "driving efficiencies for improvements on the shop floor with buy-in from management". Some respondents spoke about the pros of having management styles that demonstrated leadership in driving OpEx. They also reiterated the need for "transparency" and "consistency" around OpEx integration and alignment of OpEx and CI with strategy. Lean tools, in particular, were highlighted as a good foundation to enable a smooth integration of OpEx as part of the company culture.

Table 2. The opinions and awareness of OpEx and CI

"I have done much internal training here on the job over the years… people can do green and black belt through projects…the consultants said you will need to give autonomy to the people on the floor…you will need to become leaders, not managers. I use all Lean tools". P4
"I like the concept of CI and reducing the standard deviations and putting ownership and responsibilities to the people at the front line. I do not use Lean tools". P6
"For three years now, we have been rolling out OpEx across our global functions… So when they have questions on OpEx, we can help them.". P1
"It has been a good experience (with OpEx) because when I started with the company, they had already started the Lean journey for two years previously…so there was a good foundation…I tried to bring my experience to improve what they had done, and this is my focus and trying to move onto the next step ..people were friendly and open…so I had a good opening for new ideas and new proposals …I led the governance, but my main responsibility is to integrate OpEx as part of the culture of the company. I use mainly Lean tools". P19
"So, I have a multi-site position, so I see some with a variety of OpEx systems…some very mature and embedded into their organisations…while others have very little OpEx. It is a broad range of integration. I use all Lean tools". P3
"12 months into my job from starting here…the OpEx department was known as CI department...I did a six-sigma course which was the start of my OpEx experience here. I use all Lean tools". P4
"In my view, OpEx is an extremely important sector in process improvement…process times are reviewed and analysed, improvement is continuous.". P27
"They give us training and let us attend conferences and webinars and internal training assisting us…so these activities help us know about OpEx…if they notice any problems, we are facing…everyone discusses issue together and give suggestions too". P21
"I have support from my team and my boss, who is senior management, but I need to go to him always…in all areas, we have an escalation system where they fill in a card on maintenance, CI and engineering, and it is put up on the system and dealt with". P4
"Good support…CI has much focus now". P7
"Full support from management…each person gets trained equally…no one is left out". P1"

4.2 Integration of OpEx and Tools Utilised

A question related to **"***Which departments is OpEx implemented in?"* was asked to understand the levels of integration throughout the participant's organisations. The quotes are outlined in Table 3. The next question asked was *"What OpEx tools do you use daily?*". Again, there was an emphasis on all types of Lean tools used. Almost all interviewees cited Lean as the CI methodology of choice within their Pharmaceutical organisations. Only 3 interviewees stated they *"did not know"* or *"we are not sure"*. A theme amongst

the questions as to where OpEx was integrated led to comments about the lack of integration due to the *"regulatory standards", "bureaucratic*" processes and *"time"* consuming processes.

Table 3. The Integration of OpEx by function/department

"We do not have OpEx specifically in each department, but in this fiscal year we have OpEx team projects in quality, supply chain, and production areas guided by our KPIs… the directors set the targets". P18
"Focused on Manufacturing, Product Supply including Quality only…not in Human Resources, Finance, Commercial... in my current Pharma company. "But in my last pharma company, OpEx was in every department because they planned to train people in OpEx from every department...". P6
"The mindset of our people working on the shop floor, I say if you do this, your department will receive this or that…it is a motivating factor honestly, very hard to keep people motivated to keep going". P15
"With much demand for production and with reduced staff…it has been very difficult to maintain OpEx integration across the company and be able to participate in CI implementations and actions". P24
"What usually makes progress in an improvement project difficult is the Pharma regulatory standards…so when improvement is proposed…it often comes up against Regulatory standards and getting Regulatory approvals…". P27

A common theme around the integration of OpEx was the difficulty of people's behaviours and engagement. To effectively implement changes at work, an organisation must be aware of strategically aligning the business model with the organisational system. The focus is on creating the best environment to get its people to work together to carry out the business [8] to improve the process by degrees every day [18, 46].

4.3 Challenges of the Pursuit of OpEx and CI in Your Pharmaceutical Organisation

There was an emphasis that management commitment was a challenge in deploying CI in all Pharmaceutical organisational functions, not just in Production and Engineering. A high level of openness and trust was needed for a truly effective relationship between management and non-management at work. One respondent stated that *"Over 10 years of using our original OpEx model…it had done well…I noticed over the next three years that it started to plateau…it was hard to keep people motivated…when the new Director came…we rebranded a new OpEx model and redesigned it" P2.* OpEx can be seen by some corporate management as just "a passing management fad" [47] which is due to poor leadership and lack of commitment.

A comprehensive list of responses is outlined in Table 4. Several respondents commented on the difficulties in implementing and closing out the CI cycle. Many interviewees mentioned that while there are plenty of resources, there were incomplete OpEx open actions as "*management do not latch on to the fact that OpEx also applies to other departments apart from Manufacturing*". One respondent maintained that "*the Regulatory authorities do not reward the continuous improvement side of Pharmaceutical processing and that the FDA think and act differently to their FDA field inspectors*". A respondent questioned, "*how do you energise the organisation to take on OpEx CI cycles when there is such a focus on Regulatory compliance and not rocking the boat with regulatory submissions?*"

Table 4. Challenges to OpEx and CI

"For the implementation of OpEx projects…there are plenty of resources but not so many to complete actions or improvement". P9
"Poor support". P10
"There is a difficulty in the dynamics to resolve or implement improvements such as budget, approvals and implementations". P24
"They praise me for achieving the financial performance, but they do not realise that I am doing fundamental OpEx…they do not latch on to the source that OpEx also applies in Engineering. They only see it as in manufacturing". P6
"If people are not following the OpEx tools procedures, then this is a management and cultural issue". P3
"Certainly, no one from senior management ever appears". P4
"I often wanted to visit other sites to learn about OpEx which the local Skillnet used to email us about. Unfortunately, we never visited any, which I felt we could have brought back good ideas for our company…also, the OpEx team on site never got us trained on 5S or yellow belt". P12
"Over 10 years of using our original OpEx model…it had done well…I noticed over the next three years that it started to plateau…it was hard to keep people motivated…when the new Director came…we rebranded a new OpEx model and redesigned it". P2
"*The Regulatory authorities do not reward the continuous improvement side of Pharmaceutical processing and that the FDA think and act differently to their FDA field inspectors*". *P6.*
"*How do you energise the organisation to take on OpEx CI cycles when there is such a focus on Regulatory compliance and not rocking the boat with regulatory submissions?*" *P5.*

The "*lack of senior management visibility*" and "*interaction with people on the shop floor*" was referenced by many interviewees as outlined in the following Table 5.

Table 5. CSFs for OpEx and CI

"The biggest barrier to OpEx is people not buying into it and not understanding that the reason for the change has a long-term benefit. Sometimes the barriers presented are short-term in nature, e.g., resources… all different departments do not want to see OpEx coming in because they are too busy doing their work their way and they do not want to change the way they are doing their work, and they cannot see the benefit as a result because OpEx will change their systems". P3
"The difficulty is motivating them. It comes down to the type of management to push it actively forward over several years. People need to be encouraged with good clear examples ...our focus now is working on our third OpEx programme called 'health check', where an audit is done daily on team tasks,..but it is such hard work for our department at the senior level where management is pushing it so that we improve the topics and it shows you can change the mindset of people. It starts with many baby steps for this great outcome: it is a long continuous journey". P1

4.4 CSFs for OpEx and CI in Pharmaceutical industries

The interviewee's opinions on the CSFs were broad. However, most interviewees suggested a key CSF to implement OpEx as a phased approach across all departments.

Management's support and buy-in were highlighted as a critical CSF and an opportunity to foster a positive OpEx culture. Emphasis needs to be on changing and moving the industry from being primarily '*compliance and bureaucratic centric*' to '*people and process and purpose centric*' by engaging all people from the shop floor to senior management levels and deploying behaviour for CI "*through involvement and learning*". The participants suggested that change is challenging, but clear commitment from management is essential. This is very much in line with the body of literature [20], [48–50] regarding the success of OpEx initiatives. A shared vision of the importance of OpEx is created with management's leadership - "*This has 2 different perspectives…one is it has to be implemented as routine because people will say we do not have the time to do*

each tool, I am being overloaded and we do not have the training, there is more room to apply OpEx intensively. OpEx is the responsibility of every line manager...it must be in their DNA" P5.

Companies that enjoy enduring success have core values and a fixed purpose while their strategies and practices continuously adapt to changes in the ecosystem [51]. Core ideology is the main component of a company's envisioned future, where ideology is understood as culture.

To improve engagement between management and employees, the line managers bring human resources to life at the Gemba [34]. "*Yes, management talked about doing a weekly Gemba walk which was announced, and we took different employees… we got their ideas and their information and what they would like to change...it was great to hear the shop floor employees' impressions because they are with the hands-on process 100% of the time...this is great, this is fantastic to gather information from shopfloor*" P17. The literature agrees that employees are the company's most underutilised resource [22, 48, 49, 52]. Change in an organisation can be met with resistance and grinds to a halt if it does not have the support of corporate management [26].

A final CSF theme highlighted was to try and counteract the "regulatory culture" and "fear of regulatory burden" at the site level. Many CI initiatives that were seen as larger process changes did not go ahead according to the interviewees as they required complicated, bureaucratic time consuming regulatory submissions, revalidation and requalification of processes as highlighted in similar studies [5, 31, 33, 52].

5 Conclusion, Limitations, and Future Research Direction

OpEx is gaining momentum globally and has room for improvement, as evidenced by the limited studies related to its applicability, level of integration and deployment within the Pharmaceutical industry. According to this research study, there is a lack of buy-in from senior and middle management and a lack of visibility supporting and utilising all people on the shop floor. As there is a lack of real case examples demonstrating OpEx and CI deployment within the Pharmaceutical industry, this gap can motivate researchers to carry out further research in the Pharmaceutical industry. Future research could look at how some OpEx and Lean models, such as implementing the Shingo Model, will facilitate OpEx deployment further.

The main limitation of this research study is that all the Pharmaceutical companies were from large Pharmaceutical enterprises and did not include Pharmaceutical enterprises of a small and medium size. However, building on previous research, this study provides a more concrete understanding of OpEx and CI within regulated Pharmaceutical industries. The authors would like to conduct a more longitudinal case study on one Pharmaceutical organisation starting with an OpEx journey and study its deployment over time while measuring its impact on organisational performance. The findings from this research are a valuable source for Lean and OpEx practitioners currently deploying these CI methodologies and for anyone considering undertaking training in Lean settings. In summary, in this article, an attempt has been made to provide a general overview of CSFs for OpEx in the Pharmaceutical industry.

Conflict of Interest. The authors declare no conflict of interest.

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