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QUALITY AND OPERATIONAL METRICS

PREPARED FOR: DR. MARLA PHILLIPS, DIRECTOR, XAVIER HEALTH

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I. Introduction and Background

The purpose of this paper is to provide data and analysis for the Chief Quality Officer Forum (CQO Forum). This analysis will provide insight into the impacts of key metrics of cross-functional departments within the pharmaceutical and medical device industries. Quality can better determine how their actions can support the goals of the overall business. A comparison of the metrics Quality tracks versus those of their peers will identify opportunities for Quality to address synergies and conflicts to improve overall understanding of the business and the ability to drive that business.

The CQO forum was created to advance the role of Quality for the 21st century in a way that enables speed of innovation to address unmet patient needs.. The need for Quality to shift how it operates has been highlighted by the Food and Drug Administration's (FDA) progressing focus on safety and quality measures, along with industry initiatives related to quantifying product quality, safety and efficacy (including FDA/industry teams led by Xavier University). The CQO Forum has recognized that pharmaceutical and medical device companies are rapidly advancing to address the complexities of patients around the globe, but the systems supporting this innovation are antiquated – often due to perceived and real regulatory restrictions and expectations. However, it is time to resolve the barriers to advancing product quality across the total enterprise, as evidenced by:

- *Historically-repeated product and process failures that continue to compromise the assurance of product quality in a way that impacts patients and the business.*
- *The tools available to assure product quality are not sufficient to enable the organization to predict circumstances that lead to failure, and therefore prescribe the processes, criteria, and specifications needed to avoid failure.*

- *Industry and regulators operate as though bound by the regulations, instead of evolving to meet the demands of the 21st century.*

In order to address the need brought forth by the FDA, industry itself, and Xavier Health, the goals of the CQO Forum are twofold:

1. To improve the effectiveness and efficiency of Quality (i.e. the Department itself) for all stakeholders
2. To improve the assurance of product quality for all stakeholders

The scope of these issues cannot be fully realized without analyzing the metrics that cross-functional peers within the organization utilize. Knowing the metrics Quality Departments should use is vital to operational success, however, finding conflicts and synergies between Quality Departments and cross-functional teams promotes business cohesion. In order to foster impactful change, this paper will highlight the role of Quality, their cross-functional peers across the total product lifecycle, and report themes, synergies, and conflicts that will support impactful and sustainable change.

The CQO Forum Charter, with a list of participating organizations and members, can be found in *Appendix 1*.

II. Project Request and Scope

Quality is an important factor when it comes to any control and is vital to building a successful business that delivers products that meet or exceed customer's expectations. The primary focus of a Quality Department within an organization is to ensure the product safety and quality meets the intended use, and the risk to the patient is minimized and understood. The Quality Department also serves as a conduit for the organization to the regulations and expectations of global regulatory authorities. A difficulty that often exists between other cross-

functional departments within an organization and Quality includes disconnects between metrics measured and overall initiatives. This misalignment can lead to inefficiencies within organizations as well as an increase to patient safety risk. Prior research conducted by the Chief Quality Officer Forum identified the need to identify the metrics that cross-functional teams utilize. Unfortunately, no formal process was in place to obtain this information.

Dr. Marla Phillips, Director of Xavier Health, requested support from the Xavier University Master of Health Services Administration Consulting Group (XCG) to identify metrics that are critical to cross-functional teams throughout the pharmaceutical and medical device industries. Understanding what metrics are critical to these cross-functional teams helps Quality Departments better understand the business case for quality and to enable the success of the entire enterprise for the benefit of the patients they serve.

The overall scope of the project is outlined below:

- *Develop a questionnaire for cross-functional leaders to provide insight on how their specific department measures quality within the total product life-cycle.*
- *Obtain data from pharmaceutical and medical device companies regarding operational metrics addressed by cross-functional departments.*
- *Analyze various operational metrics from departments such as R&D, procurement, regulatory, supply chain, and operations to identify areas of opportunity for synergy and elimination of waste.*

The XCG charter outlining the full project request and scope can be found in *Appendix 2.*

III. Method and Materials

With the guidance of Dr. Phillips, the XCG developed a survey through Qualtrics to identify metrics from cross-functional departments, such as research and development,

procurement, operations, supply chain, and regulatory affairs. The survey was sent via email on February 13, 2019 to 17 industry professionals from the CQO forum companies - Abbott, AstraZeneca, Elanco, Gilead, Novo Nordisk, Fisher Paykel, CSL Behring, GlaxoSmithKline, Proctor & Gamble, and Eli Lilly. After 19 responses were received, a reminder email was sent on March 1, 2019 encouraging CQO forum members to push for additional survey responses, which resulted an additional 11 responses for a total of 30 responses.

Survey

Outside of basic demographic questions, the survey (*Appendix 3*) was comprised of six open-ended questions, which allowed the respondents to give detailed answers.

- Demographic questions included organization name, first/last name, work email, industry, current department, and years of experience in the industry.
- Question one: determination of the metrics typically tracked by the respondent's area in the total product lifecycle - pre-production, production, or post production.
- Question two: identification of the top three metrics that are critical for the respondent's area of operation, including the equation, reason for measurement, and relevance to organizational goals.
- Question three: identification by the respondents of any Quality Department metrics that are in conflict with the goals their department is attempting to achieve.
- Question four: identification by the respondents of any Quality Department metrics that are supportive of the goals their department is attempting to achieve.
- Question five: suggested actions by the respondents that the Quality Department could take to better support their own functional department goals.

- Question six: determination of the respondent's awareness of any Quality Department metrics that are in conflict with the goals their own functional department is attempting to achieve.

Analysis Method of Survey Results

Question two: Metric categories

Responses from survey question two provided numerous metrics respondents found critical to their area of operation. Through these responses, the XCG was able to identify commonalities within the metrics that translated into themes:

- Audit
    - Key words include: Audit
- Financial
    - Key words include: Cost, savings, and $
- On Time
    - Key words include: On time, times, date, and schedule
- Other
    - Key words include: n/a, nil, and any other singular category
- Productivity
    - Key words include: forecast, volume, and speed
- Right First Time
    - Key words include: right first time, compliance, reject rate, deviations, and accuracy

Questions three-six: Response analysis

Analysis of responses from questions three through six provided additional insights into synergies and conflicts of metrics between Quality Departments and cross-functional teams. Due to the nature of responses, a basic summarization is provided in the results section.

Analytical methods

Results were extracted from Qualtrics and analyzed in Excel. Comparison of metric category by industry, position in the total product lifecycle, and department were analyzed.

Exposure of XCG to Industry Facility

XCG members attended an on-site tour of a local AstraZeneca plant site to gain a greater understanding of the operations being measured by Quality and cross-functional departments. During the tour, industry members explained the manufacturing process, new advances in training methodologies (including augmented reality), and critical metrics. Through the facility walkthrough and engaging discussion with leaders, the XCG learned how various departments across a plant site work to improve quality.

IV. Results

Survey Response

In order to determine the survey response rate, the XCG assumed that the 17 professionals from the CQO companies sent the survey to five people across various functional areas within their organizations. However, the actual number of people the survey was sent to is not known. Based on the assumption made by the XCG, the total possible responses that could be received would be 85. The total number of survey responses received was 30, resulting in a response rate of 35%. Responses were received from 9 of the 12 CQO companies, resulting in a participation rate of 75%. Raw data tables are available in *Appendix 4.*

Demographics

Industry

Of the 30 respondents that completed the survey, 22 (73.3%) indicated they were in the pharmaceutical industry, three (10%) indicated they were in the medical device industry, and five (16.7%) indicated they were in a different industry (e.g. consumer product goods, molecular diagnostics, animal health). This is depicted in *Figure 1*.

Department

Of the 30 respondents who completed the survey, six (20%) indicated they were in operations, two (6.7%) in procurement, seven (23.3%) in Quality, three (10%) in research and development, five (16.7%) in regulatory, and seven (23.3%) in supply chain. Departmental breakdown is depicted in *Figure 2.*

Position in Total Product Lifecycle

Of the 30 respondents who completed the survey, six (20%) respondents indicated they were in the pre-production, 13 (43.3%) in production, and 11 (36.7%) in post-production. This is depicted in *Figure 3*.

Years of Experience

Of the 30 respondents who completed the survey, the average years of experience was calculated to be 21.54 years. However, two respondents did not provide an answer, and four respondents chose a “more than” or “over” selection for years of experience (e.g. more than 25 years, or over 15 years). Using the lowest number these four respondents provided, their average years of experience was 22.5 years.

Metric categorization

Using the metric categorization key words provided in the methods and materials section, analysis and categorization was completed on the 90 recorded metrics. The two most prevalent data categories include: 36 (40.0%) metrics associated with delivering a product *Right First Time* and 30 (33.3%) metrics associated with completing a task *On Time*. These two categories represent nearly two-thirds of the total metrics (73.3%). Other metric responses include: 9 (10.0%) categorized uniquely as *Other*, 6 (6.7%) associated with *Finances*, 6 (6.7%) metrics were *Productivity* driven, and 3 (3.3%) of the metrics were associated with *Audits. Table 1* illustrates this distribution. *Note: RFT is Right First Time and not all totals add to 100% due to rounding.*

Table 1

Total Responses Distribution (90)		
RFT	36	40.0%
On Time	30	33.3%
Other	9	10.0%
Financial	6	6.7%
Productivity	6	6.7%
Audit	3	3.3%
Total	90	100.0%

Table 2 provides a breakdown of metric categorization and industry respondents. Results show the top two departments to respond were *Quality* 21 (23%) and *Supply Chain* (23.3%) followed by *Operation* 18 (20.0%), *Regulatory* 15 (16.7%), *Research & Development* 9 (10.0%), and lastly *Procurement* 6 (6.7%). The respondents represent a balanced distribution with all departments surveyed contributing metrics for consideration.

Table 2

Total Responses Industry Distribution (90)		
Quality	21	23.3%
Supply Chain	21	23.3%
Operations	18	20.0%
Regulatory	15	16.7%
R&D	9	10.0%
Procurement	6	6.7%
Total	90	100.0%

The distribution of the number of metrics provided by the various Positions in Total Product Lifecycle is provided in *Table 3.* Distribution across the position in total product lifecycle is: *Pre-Production (R & D, Tech Transfer)* 18 (20.0%) metrics, *Production (Post-Tech Transfer, Commercial Operations)* 39 (43.3%) metrics, and *Post-Production (Product on the Market)* 33 (36.7%) metrics.

Table 3

Position in Total Product Lifecycle Distribution		
Pre-Production	18	20.0%
Production	39	43.3%
Post-Production	33	36.7%
Total	90	100.0%

Further analysis for Position in Total Product Lifecycle distribution can be found in *Table 4* with each position's responses broken down into the six specific metric categories. Those respondents in Pre-Production indicated metrics mostly in *Right First Time* 13 (72.2%). Respondents in Production indicated a majority of *On Time* 14 (35.9%) and *Right First Time* 13 (33.3%) metrics. Post-Production respondents also indicated a majority of metrics in *On Time* 13 (39.4%) and *Right First Time* 10 (30.3%) with 6 (18.2%) of metrics in other categories.

Table 4

Pre-Production Distribution (18)			Production Distribution (39)			Post-Production Distribution (33)		
RFT	13	72.2%	On Time	14	35.9%	On Time	13	39.4%
On Time	3	16.7%	RFT	13	33.3%	RFT	10	30.3%
Audit	1	5.6%	Financial	4	10.3%	Other	6	18.2%
Productivity	1	5.6%	Productivity	4	10.3%	Financial	2	6.1%
Financial	0	0.0%	Other	3	7.7%	Audit	1	3.0%
Other	0	0.0%	Audit	1	2.6%	Productivity	1	3.0%
Total	18	100.0%	Total	39	100.0%	Total	33	100.0%

To gain a further understanding of which categories of metrics are important to each department, it was necessary to create *Table 5* (Operations), *Table 6* (Procurement), *Table 7* (Quality), *Table 8* (Regulatory), *Table 9* (Research & Development), *and Table 10* (Supply

Chain). Distribution of metric categories for each Department are illustrated in the following tables.

Table 5

Operations (18)		
RFT	7	38.9%
On Time	4	22.2%
Financial	2	11.1%
Other	2	11.1%
Productivity	2	11.1%
Audit	1	5.6%
Total	18	100.0%

Table 6

Procurement (6)		
On Time	4	66.7%
Financial	1	16.7%
RFT	1	16.7%
Audit	0	0.0%
Other	0	0.0%
Productivity	0	0.0%
Total	6	100.0%

Table 7

Quality (21)		
RFT	13	61.9%
On Time	5	23.8%
Audit	2	9.5%
Productivity	1	4.8%
Financial	0	0.0%
Other	0	0.0%
Total	21	100.0%

Table 8

Regulatory (15)		
RFT	7	46.7%
On Time	4	26.7%
Other	4	26.7%
Audit	0	0.0%
Financial	0	0.0%
Productivity	0	0.0%
Total	15	100.0%

Table 9

Research & Development (9)		
On Time	3	33.3%
RFT	3	33.3%
Other	2	22.2%
Productivity	1	11.1%
Audit	0	0.0%
Financial	0	0.0%
Total	9	100.0%

Table 10

Supply Chain (21)		
On Time	10	47.6%
RFT	5	23.8%
Financial	3	14.3%
Productivity	2	9.5%
Other	1	4.8%
Audit	0	0.0%
Total	21	100.0%

To help determine the differences in metrics being recorded when comparing the Quality Department to cross-functional teams, *Table 11* was constructed. As previously noted, right first time and on time metrics are prevalent throughout Quality and non-Quality Departments.

Table 11

Total Responses Non-Quality (69)			Quality (21)		
On Time	25	36.2%	RFT	13	61.9%
RFT	23	33.3%	On Time	5	23.8%
Other	9	13.0%	Audit	2	9.5%
Financial	6	8.7%	Productivity	1	4.8%
Productivity	5	7.3%	Financial	0	0.0%
Audit	1	1.5%	Other	0	0.0%
Total	69	100.0%	Total	21	100.0%

To help determine the differences in metrics being recorded when comparing the metrics by industry, *Table 12* was constructed.

Table 12

Medical Device (9)			Other (15)			Pharmaceutical (66)		
Financial	2	22.2%	RFT	7	46.7%	RFT	29	43.9%
On Time	2	22.2%	On Time	6	40.0%	On Time	22	33.3%
Other	2	22.2%	Audit	1	6.7%	Other	7	10.6%
Productivity	2	22.2%	Financial	1	6.7%	Productivity	4	6.1%
Audit	1	11.1%	Other	0	0.0%	Financial	3	4.5%
RFT	0	0.0%	Productivity	0	0.0%	Audit	1	1.5%
Total	9	100.0%	Total	15	100.0%	Total	66	100.0%

Conflicts

Based on question three of the survey: *Are you aware of any Quality Department metrics that conflict with the goals that you are trying to achieve?*, 27 (90%) respondents answered in some form of no. No common themes were identified outside of the "no" respondents. Of the remaining five respondents, one respondent answered yes, one answered not applicable, one respondent commented "*I am not actually aware of any of the metrics that the Quality*

Department measures so I can't comment if they conflict with the goals of my Department", one commented about processes, not metrics, and one respondent commented "*Deviation on-time closure can conflict and delay release and introduction into the marketplace. Deviation closure is required for disposition by Quality.*" The lack of awareness of Quality metrics presents an opportunity for Quality to drive synergies. Additionally, the vast number of "no" responses related to existing conflicts contradicts the feedback received by cross-functional members of the CQO companies through a previous survey on "What Quality Should Stop Doing". The responses included: "Quality does not understand the business", "Quality impedes my operations", and "Quality is a roadblock". Three explanations can be given for the differences in responses between the previous survey and the metrics survey discussed herein: (1) different members of the organization may be responding to the metrics survey versus those who provided input during the "What Quality should Stop Doing" survey, (2) it may be harder for cross-functional peers to actually identify "evidence" when asked for this level of detail, and (3) the conflicts might not be metrics related, but "how" each functional area works to achieve their goals, which may result in tension.

Synergies

Question four of the survey gauged the awareness of the respondent regarding Quality Department metrics that support the goals they are trying to achieve. Multiple respondents listed individual metrics that were in support of their department's goals. However, no common themes were identified. 23 (76.7%) of respondents either replied with a simple "yes" or some form of specific metrics, indicating synergy between Quality Departments and their respective cross-functional team. Specific metrics include *major and critical deviation rate, first class batch,*

right first time, on time inspection, and supplier audit/nonconformance tracking. The full list can be found on pages 40-43 in *Appendix 4*.

One respondent noted that their organization used dashboards to help all sector teams track metrics; the dashboard is cloud-based and real time, which allows Quality Departments to act on data rather than assemble the data. Five (16.7%) respondents answered no or not applicable, one respondent indicated they were in a Quality Department, and one respondent answered they were unaware of the metrics Quality Departments measure.

Support from Quality Departments

Question five of the survey asked respondents about actions Quality Departments could take to better support their departmental goals. Four common themes were found and responses were categorized. Nine (30%) respondents felt their goals were already aligned well with Quality Departments. Seven (23.3%) respondents commented that better visibility, access, and/or involvement from Quality Departments and the metrics they track would be beneficial to their department. Five (16.7%) respondents noted that Quality Departments should be better aligned with company goals. Nine (30%) respondents' answers did not fit within one of the aforementioned categories and thus were labeled "other".

Other aspects

Question six of the survey asked respondents to provide any additional aspects that should be considered when addressing synergies and conflicts between functional areas and Quality Departments. 14 (46.7%) respondents had no additional comments while 9 (30%) indicated that Quality Departments should be better aligned with cross-functional teams. The remaining 7 (23.3%) responses held no theme.

V. Discussion

Metric Categorization, Conflicts, and Synergies

Quality Departments and cross-functional peers both find right first time and on time to be important metrics to track as witnessed in *Table 11.* Communicating these shared goals throughout the business not only shows the value of Quality but also provides opportunities for synergy. Using *Tables 5-10,* Quality Departments can help align metrics throughout each individual cross-functional department. For instance, knowing over 60% of the metrics that operations departments track are right first time or on time, Quality Departments can then build their metrics to fit within the department, if necessary. Additionally, Quality Departments already track right first time metrics, providing increased synergy.

However, there are inherent conflicts with Quality Departments and cross-functional teams. Cross-functional teams concerned with speed to market and financial measures could see Quality as a hindrance to their goals. Cross-functional teams reported that Quality can slow down operations and thus it is imperative to keep the agreed delivery times. Knowing that on time metrics are critical to these cross-functional teams, Quality can develop strategies to keep their processes timely and ensure they do not impose undue burden.

Future research opportunities

Although a variety pharmaceutical and medical device organizations were surveyed, it would be insightful to research specific global organizations. Since the scope would be narrowed, it may be easier to decipher common trends and themes that exist providing additional clarity on the existence of synergies and conflicts within a company. The gained results from this study could help create a standardized process across the board for a specific entity.

Many organizations have manufacturing sites worldwide. Since a variety of products are often being manufactured the techniques and procedures can vary immensely. Due to various governmental regulations, certain regions of the world may have to follow higher quality standards thus increasing alignment or clearer communication between cross-functional teams. Like Pharmaceuticals, the Medical Device industry has its own regulatory systems. Medical devices have shorter product life cycles, since technical improvements are typically available within two years, whereas improvements in drugs are more likely to take decades. Therefore, creating a stronger focus may find synergies to strengthen quality. compliance, and safety.

This paper highlights synergies, conflicts, and common metrics measured by cross-functional peers. While this research is expansive, there are still other avenues it does not address. Therefore, a detailed report of all areas in which Quality impacts overall business operations could yield more areas for future research and improved relationships between cross-functional departments and Quality.

Limitations

While the survey design was robust, there are inherent limitations analyzing only qualitative datasets. Utilizing quantitative data would have provided statistical analysis methods, however, there was no plausible way to obtain the necessary data in a quantitative manner. Additionally, more pharmaceutical industry professionals completed the survey compared to medical device and other industries. Lastly, while we believe the response rate was sufficient (30 respondents), a larger sample size would have garnered better industry specific insights.

Recommendations

Question five of the survey prompted respondents to provide actions in which Quality Departments could help to support their department's goals. Interestingly, outside of the 30% of

respondents who indicated that they already feel supported, 33% stated they wanted increased visibility, involvement, and access to Quality Departments and their metrics. One solution to improve the disconnect and silos between cross-functional teams is through the use of dashboards, which allow all team members throughout the total product lifecycle to quickly see relevant data and react appropriately. A member of the digital systems support team that works in coordination with the Quality Department at one of the CQO companies stated:

> *Dashboards can be setup using Power BI (previously we used Tableau, but Power BI is more cost effective now). Dashboards pull data automatically from the company data lake or SAP data systems. This allows the QA professional to spend more time acting on the data rather than assembling the data. This looks to be a progressive way to manage quality data in the future. The data is real time and cloud based. We are also on the journey to display more quality data on-line with our production facilities. By displaying the data on a dashboard directly on-line the operator can immediately act and correct anything that is starting to trend out of spec. There are several systems such as Proficy or Maple that allow on line quality control.*

Dashboards have the potential to improve quality and break barriers in communication across cross-functional team members, providing the synergy needed to improve quality across cross-functional teams.

VI. Conclusions

Common themes throughout the survey data indicate there are more areas for synergy throughout the total product lifecycle than previously believed. 90% of respondents noted that Quality Department metrics did not conflict with their Departmental metrics. Likewise, 80% of respondents indicated that they are aware of metrics that are directly supporting their departmental goals. Being that Quality Departments and cross-functional teams both track right first time metrics extensively throughout the total product lifecycle, more areas for synergy exist but must be communicated properly. However, with many cross-functional teams indicating that on time metrics were critical to their success, Quality Departments unfortunately may be seen as

a hindrance to getting products to market. Despite these perceptions, Quality Departments are dedicated to ensuring patient safety through producing products properly the first time.

VII. References

Chief Quality Officer forum: Creating Quality for the 21st century. (2019). Retrieved April 24, 2019 from https://www.pathway4ph.org/cqo-forum

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Medical Device Innovation Consortium. (2016). Xavier Health MDIC Case for Quality Programs: Medical Device Quality Metrics. Retrieved January 18, 2019 from http://mdic.org/wp-content/uploads/2016/08/MDIC-Medical-Device-Quality-Metrics-Best-Practices.August-01-2016.pdf

Pricewaterhouse Coopers Advisory Services LLC. (2016). Xavier Health and PwC: Pharmaceutical Quality Metrics white paper.

The 2015 FDA "Request for Metrics" draft guidance and the intent of its use are described on the following FDA Voice Blog page FDA/Xavier University PharmaLink Conference, March 14, 2014 presentation by Russ Wesdyk

VIII. Tables and Figures

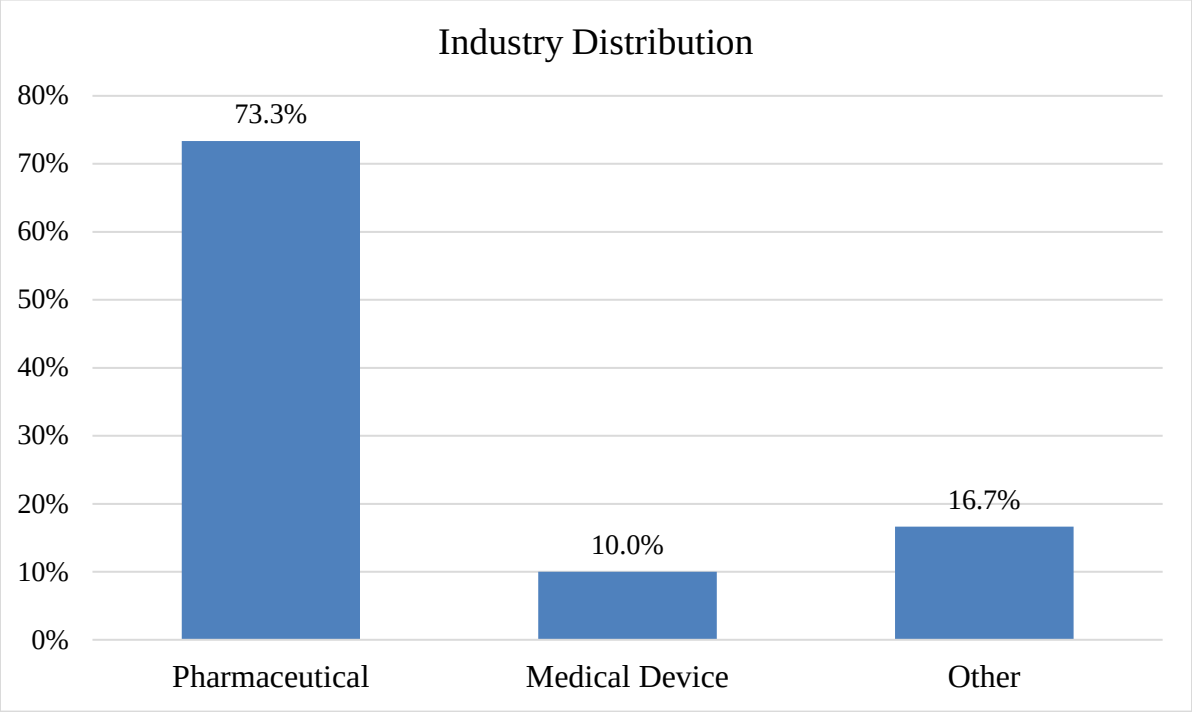

Figure 1

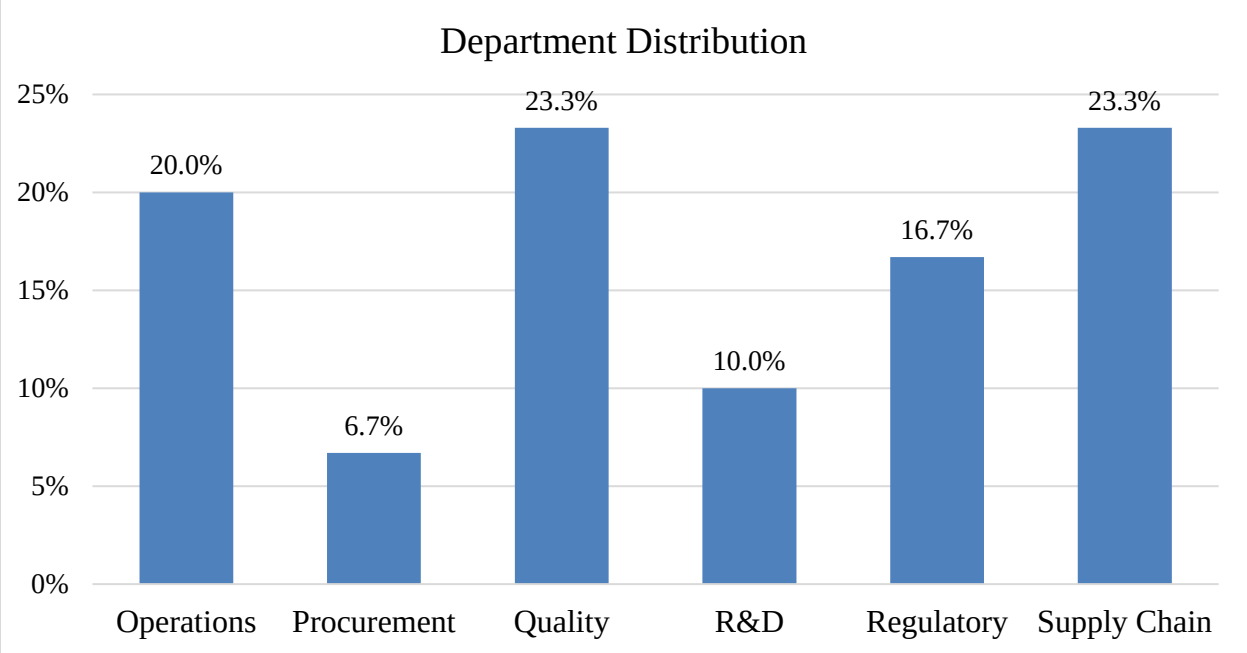

Figure 2

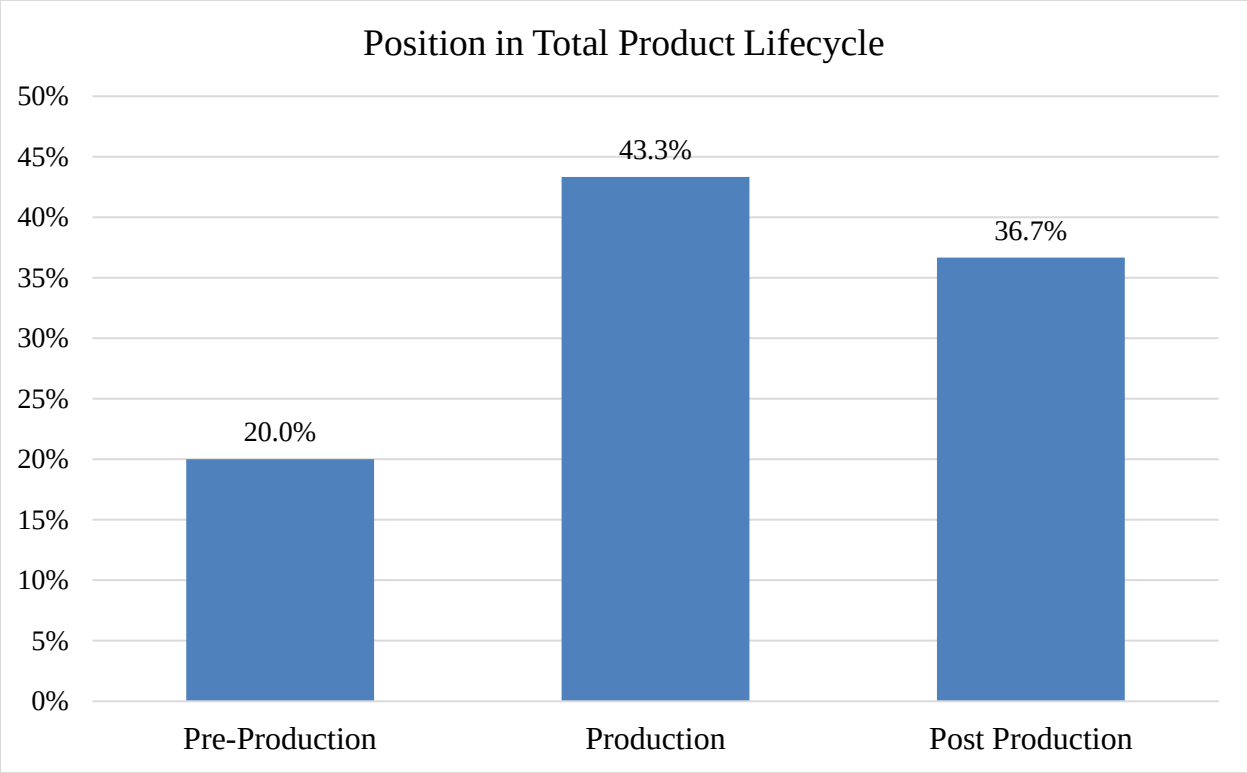
Position in Total Product Lifecycle
50%
45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
20.0%
43.3%
36.7%
Pre-Production
Production
Post Production

Figure 3

IX. Appendix

Appendix 1: CQO Forum Charter

Chief Quality Officer Forum

CQO Forum Statement of Purpose: Quality Leaders collaborating on leading-edge solutions that drive the future of the industry with and for all stakeholders.

CQO Forum Goal Statement: To redesign the field of Quality in a way that maximizes the value of the company for all stakeholders.

- Improve the effectiveness and efficiency of Quality for all stakeholders
- Improve the assurance of product quality for all stakeholders

Problem Statement: The pharmaceutical and medical device industries of today are advancing rapidly to address the healthcare complexities of patients around the globe. However:

- Historically-repeated product and process failures continue to compromise the assurance of product quality in a way that impacts patients and the business
- The tools available to assure product quality are not sufficient to enable the organization to *predict* circumstances that lead to failure, and therefore *prescribe* the processes, criteria and specifications needed to avoid failure
- Industry and regulators operate as though bound by the regulations, instead of evolving to meet the demands of the 21st century

Opportunities and Progress:

1. **Develop Quality professionals who can lead in the Quality Organization of the 21st Century**
   - Identify the skillsets needed for Quality of the 21st Century
   - Establish innovative training curriculum and methodologies to transform Quality professionals
   - Determine the undergraduate and graduate curriculum needed to feed highly qualified professionals into pharmaceutical and medical device Quality Organizations

2. **Create the Quality Organization of the 21st Century**
   - Develop leading-edge tools that will result in an increased right-first-time rate in all job functions and operations
   - Shift paradigms on the role of Quality such that Quality can maximize organizational agility to support product, and therefore, business success
   - Include regulators on the path for input on, and preparation for, a new face of Quality and the tools used to assure product quality

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- Define "quality" such that all internal stakeholders can own and buy-in to the assurance of product quality

Progress: The Chief Quality Officer Forum agreed upon draft wording for the Role of Quality for the 21st Century, which will guide the work we do to redesign the field of Quality:

Role of Quality for the 21st Century: To optimize patient health and business success by mobilizing enterprise-wide quality effectiveness through innovative systems and critical thinking grounded in science, data, stakeholder awareness and regulatory intelligence.

Xavier MHSA Involvement: The Chief Quality Officer Forum would like to have support for:

1. **Metrics that are Critical to Cross-Functional Peers.** Through the contacts provided by the CQOs, Xavier students can interview cross-functional peers to understand which metrics are critical to their operations. We can then compare those metrics to those of Quality to see where there are areas of synergy and conflict. This will help Quality develop metrics that will help mobilize enterprise-wide quality effectiveness. [Note: "Q" is meant for the Quality department, whereas "q" is meant for product quality and/or quality of work].

Chief Quality Officer Team (as of 11/5/18):

First	Last	Company
Charlene	Banard	Shire
Ros	Burke	Boston Scientific
Flemming	Dahl	Novo Nordisk
Teri	Lyng	GSK
Bob	Miller	Gilead
Tony	Mire-Sluis	AstraZeneca
Corlis	Murray	Abbott
Johna	Norton	Eli Lilly
Pam	Schofield	P&G
Brian	Schultz	Fisher & Paykel Healthcare
Peter	Shearstone	Thermo Fisher Scientific
Jacques	Zimmowitch	Elanco

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Appendix 2: Charter

Project Charter

Project Name	Quality and Operational Metrics		
Sponsoring Unit	Xavier Health		
Project Sponsor	Name: Marla Phillips Office Location: ALU133		Phone: (513) 238-4338 Mail: phillipsm4@xavier.edu
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Problem Statement
Quality lacks an understanding of the negative impact they have on the business of their company, as well as the positive impact they can have.

Business Needs Addressed by the Project
By assessing the key metrics of cross-functional departments within the pharmaceutical and medical device industries, Quality can better determine how their actions can support the goals of the overall business. A comparison of the metrics Quality tracks versus those of their peers will identify opportunities for Quality to improve their understanding of the business and their ability to drive that business.

Project Goal
To evaluate how the cross-functional departments within each chief-quality officer's (board members) company measure the success of their own operations. A comparison of those metrics to the metrics typically tracked by Quality will lead to a greater understanding of the business for Quality.

Project Scope
- Develop a questionnaire for leaders to provide insight on how their specific department measures quality within the total product life-cycle.
- Obtaining data from pharmaceutical and medical device companies regarding operational metrics addressed by cross-functional departments
- Analyzing various operational metrics from departments such as R&D, procurement, regulatory, supply chain, and operations to identify areas of opportunity for synergy and elimination of waste.

Product or Service Created by the Project (Deliverables)
- Presentation Report
- Cross-functional peer quality metric analysis

Date chartered: 1/17/19	Project Start Date: 1/17/19	Target Completion Date: 5/3/19
Approval signature of the sponsor:		Date:

Appendix 3: Survey

Purpose

The purpose of this questionnaire is to look at critical metrics used during pre-production, production, and post-production to assess any conflicts and/or synergies with cross-functional business partners.

These responses will enable the Xavier University Master in Health Services Administration students conduct an assessment to support the Chief Quality Officer Forum that your organization is participating in.

****In order to have valid research results, we must record the origin of our data. Please provide the following information, which will not be shared with anyone outside of the Xavier team.*

Background Demographics

Organization Name	
First Name	
Last Name	
Work E-mail Address	

Industry

- ○ Medical Device
- ○ Pharmaceutical
- ○ Other

Current Department

- ○ Supply Chain
- ○ Research & Development
- ○ Operations
- ○ Procurement
- ○ Regulatory
- ○ Other

How many years of experience do you have in your industry?

Questionnaire

1. Is your focus area and the metrics you track mainly in:
   - Pre-Production (R & D, Tech Transfer)
   - Production (Post-Tech Transfer, Commercial Operations)
   - Post-Production (Product on the Market)

2. What are the top three metrics that are critical for your area of operation? List the equation **(numerator/denominator and *units)*** and why each is important (Business Relevance, Consumer Benefit)

Metric 1

Equation	
Reason for Measurement	
Relevance to Organizational Goals?	

Metric 2

Equation	
Reason for Measurement	
Relevance to Organizational Goals?	

Metric 3

Equation	
Reason for Measurement	
Relevance to Organizational Goals?	

3. Are you aware of any Quality Department metrics that conflict with the goals that you are trying to achieve?

4. Are you aware of any Quality Department metrics that support the goals that you are trying to achieve?

5. What actions do you think the Quality Department can take to better support your goals?

6. ***Final Response:*** Please provide any other aspects we should consider when assessing the synergies and conflicts between your functional area and the Quality Department.

Appendix 4: Raw Survey Data – Full Demographics

[Note: raw data was removed from the report, since permission was not given from individuals to have their names and/or companies referenced]