Industry-Specific Performance Benchmarking: Pharmaceutical Construction Projects

Hwang, B.
Department of Building, School of Design and Environment, National University of Singapore
(email: bdghbg@nus.edu.sg)

Abstract

The study was driven by a recognition that the pharmaceutical sector had recently experienced fundamental changes and that an approach to comprehensive project benchmarking had not been widely adopted to date. Competitive benchmarking requires industry-specific metrics in absolute terms. This study developed a framework for evaluating pharmaceutical capital facility projects using metrics tailored to the specific characteristics of these unique projects. This framework made a flexible data collection and reporting system possible. Preliminary findings from an initial sample of 40 pharmaceutical projects confirm that meaningful industry-specific metrics can be produced. These metrics allow the industry to measure project performance more accurately, get meaningful project performance comparisons, and ultimately establish credible norms.

Keywords: performance measurement, performance benchmarking, pharmaceutical projects, project management, construction industry

1. Introduction

The increasingly competitive global economy requires organizations to adopt business strategies that increase the value of their facility delivery programs. As a proven technique for improving project performance, benchmarking is a critical component of a mature project delivery system. Benchmarking gives organizations a methodology for gathering information and understanding project performance and best practices, both externally and internally. Whether the driver is cost, schedule, quality, or a combination thereof, benchmarking is an essential part of any continuous improvement process and a boon to capital facilities programs.

In 2007, the revenues of the U.S. pharmaceutical and medicine manufacturing sector amounted to $170 billion, having increased by 69% since 1998 (BEA 2009). Despite this increase, which was accompanied by a significant expansion of capital facilities, Jörg (1999) argued that a lack of benchmarking knowhow has persisted in the pharmaceutical industry, even considering the presence of a number of benchmarking approaches and models. The author suspected that this knowledge gap was not the result of insufficient information or any lack of understanding of the various benchmarking sequence models; rather he attributed it to incompetence in project organization, survey design, and above all, the processing and analysis of benchmarking data. Because of their intensive qualification and validation procedures, pharmaceutical projects often demand a distinct project management, and thus benchmarking approach. For example, Cole (1998) reported that the pharmaceutical industry is unique in its procedures and methods of manufacture since the integrity of its products must be ensured by three main functions: current Good Manufacturing Practice (cGMP), Quality Assurance (QA), and Quality Control (QC). While these functions are necessary to some degree for all projects, they are more pronounced for the pharmaceutical industry. Another distinction is that the cost of the process equipment common to the industry is a significant proportion of a project's total installed cost (TIC), thus distorting factors such as TIC / process equipment, frequently referred to in the process industry as Lang Factors (Dysert 2001).

Taking all of these considerations into account, this paper presents a industry-specific benchmarking framework for pharmaceutical construction projects, developed and validated using actual project data. The objectives of this study are: (1) to develop metrics tailored to pharmaceutical capital facility projects; and (2) to develop data collection and reporting systems that meet the needs of the pharmaceutical industry for benchmarking.

2. Background

2.1 Characteristics of the pharmaceutical industry

The pharmaceutical industry has experienced fundamental changes caused by increased competition, industry globalization, and numerous mergers (McCormick 2003). McCormick asserted that the industry faced multiple internal and external challenges such as high research and development costs,

government regulations, and stringent manufacturing requirements. These changes and challenges appeared to have caused sharp competition within the industry, raising the case for a relevant, timely, accurate, and cost-effective pharmaceutical benchmarking system.

The pharmaceutical industry employs unique procedures and manufacturing methods to ensure the integrity of the products it produces (Cole 1998). Since pharmaceutical products are critical to health care they must be manufactured to the highest quality standards. Cole (1998) explained that such stringent quality requirements result in the pharmaceutical manufacturing being a highly regulated business. In addition, regulatory requirements for pharmaceutical facilities and their construction are continuously tightened and apply not only to validation and qualification phases, but throughout the life of the facilities, from conceptualization through decommissioning (Cole 1998; Kolkebeck 2005). Due to the regulatory scrutiny they receive, pharmaceutical companies typically require considerable resources in terms of time, money, and specialized personnel to construct and validate a pharmaceutical facility. According to Wrigley (2004), validation activities consume a significant percentage of time and money in most pharmaceutical capital projects, with validation cost having increased over the years in proportion to ever rising standards. For typical pharmaceutical plant expansion projects, total validation costs may run from 4 to 8% of the total project cost (Wrigley 2004). As validation costs increase, the cost and time required to deliver pharmaceutical facilities has escalated.

While industry definitions of validation and qualification for pharmaceutical facilities vary in the wording, they essentially agree that the two procedures when operated under the same prescribed conditions "will consistently produce a product that meets the preset specifications and quality attributes." (Aleem et al. 2003). Aleem et al. (2003) documented the validation process as a series of successive and systematic steps: installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ). The details of each step can be found in the research conducted by Hwang et al. (2008).

Although the definitions for IQ, OQ, and PQ are clear and distinct, it should be noted that in practice there are no rigid divisions between the different qualification stages. They tend to overlap and sometimes there is significant duplication of tasks at different stages (Aleem et al. 2003).

2.2 General benchmarking in the pharmaceutical industry

An organization must have an effective and efficient benchmarking system to fully appreciate benefits from its efforts. According to Maleyeff (2003), performance benchmarking in the pharmaceutical industry has become a component of numerous certification and accreditation systems and many organizations include benchmarking as a component of their performance management system. However, compared to other industries the pharmaceutical industry has been relatively slow to implement comprehensive project benchmarking or other performance measurement systems (Kennedy 1998). This late adoption might be due to concerns over the sharing of information though the benchmarking process. Since competition is keen and speed to market paramount in the industry (Leichter and Turstam 2004), companies are reluctant to share data related

to products or even to the facilities that produce them. Another reason for the unwillingness of pharmaceutical firms to embrace benchmarking might be the lack of universal standards. Such standards are difficult to establish because of the differences among industries and the complexity of the statistical methods involved (Maleyeff 2003). Also, the collaboration needed to develop consensus definitions required for benchmarking is difficult to obtain due to restraint of trade concerns. Nevertheless, Jörg (1999) argued that benchmarking is needed in the pharmaceutical industry since it has enormous potential for raising organizational efficacy and efficiency. Jörg (1999), Maleyeff (2003), and Wilkins (2003) listed the following requirements for successful benchmarking in the pharmaceutical industry: (1) include experts from inside the company; (2) identify the benchmarking partners; utilize external consultants; (3) join a benchmarking group; (4) validate benchmarking data before data analysis; (5) develop a report or graph justification; (6) interpret benchmarking results achieved by analytical means; and (7) avoid comparing "apples to oranges". The requirements guided this study to develop industry-specific metrics and a benchmarking system using the metrics, measuring and comparing performances of pharmaceutical construction projects.

3. Research method

In order to achieve the objectives of this research described in the Introduction section, a research team was formed, including industry representatives from five of the leading pharmaceutical companies (Abbott Laboratories, Amgen, Eli Lilly, GalxoSmithKline and Merck), and staff from the Construction Industry Institute (CII) Benchmarking and Metrics (BM&M) program.

The team discussed and identified the industry priorities and needs through monthly workshops and then developed a customized pharmaceutical project questionnaire. In addition, pharmaceutical metrics that took into account specific characteristics of the industry were developed to set up their norms. The developed metrics are introduced in the subsequent section. Data collection effort was then initiated by integrating the paper-based questionnaire into the CII BM&M website to allow industry participants to submit recently completed project data via the online system. Then, validation of the collected data was performed to minimize or eliminate inconsistencies or errors in the data, and once completed, data analysis was performed. The preliminary analysis results are also presented later.

The development of a pharmaceutical reporting system commenced while the data were analyzed. Using the reporting system, the Pharmaceutical Project Key Report for each project's performance and Aggregate Key Report for each company's aggregate performance sorted by major project types could be generated and returned to all companies that submitted projects. More details on the reports are provided in Chapter 7.

4. Framework and definition of pharmaceutical metrics

4.1 Metric framework

When organizing for this effort, it became apparent that some metrics would apply to most pharmaceutical project types while others would be relevant to only a few types. For instance, pharmaceutical laboratory construction projects require performance metrics that would not be meaningful to either bulk or secondary manufacturing type facility construction. To address these issues and to ensure that projects to be benchmarked are properly grouped, a hierarchical structure as the framework for metric development was established as shown in Table 1.

Various types of pharmaceutical projects were categorized into three major categories. The major categories are bulk manufacturing, secondary manufacturing, and laboratories. Subcategories were also developed for each of the categories as shown in the table. Pharmaceutical bulk manufacturing projects are divided into biological, pilot plant, and chemical (small molecule), with biological projects being further subdivided into vaccines, fermentation, and cell culture projects. Pharmaceutical secondary manufacturing projects are grouped into three types: pilot plant secondary, fill finish, and pharmaceutical warehouse. Only fill finish has additional breakouts divided into parenteral and non-parenteral and both of these categories have three additional subcategories. According to the structure, there are four types of pharmaceutical laboratories: research, quality control (QC)/quality assurance (QA), vivarium, and process development. Research laboratories are divided into biological or chemical laboratories, and process development laboratories are categorized as stability or clinical.

The essence of the hierarchical structure is to produce the most accurate comparison results. For example, the project performance of a syringe project, one of the project types under secondary manufacturing, fill finish, and parenteral in Table 1, should be compared to that of other syringe projects in order to get the most meaningful comparison results. However, there may not be enough syringe projects to provide benchmarks. In this case, to obtain reasonable comparisons, the project is then compared with all projects in the parenteral category, rolling up to one higher level in the structure. If there are not enough projects at that level, the next potential comparison dataset for the syringe will be fill finish, followed by the highest level, that is secondary manufacturing. As in this example, all other subtypes can be compared to the similar projects within the boundary of the hierarchy. This is a strength of the structure developed for the benchmarking system.

Details of the project types and the underlying reasons for the classifications are explained in the research documented by Hwang (2006).

Table 1: Hierarchical Structure of Pharmaceutical Project Types

Pharmaceutical Bulk Manufacturing	Biological	Vaccines	
		Fermentation	
		Cell Culture	
	Pilot Plant		
	Chemical (Small molecule)		
Pharmaceutical Secondary Manufacturing	Pilot Plant Secondary		
	Fill Finish	Parenteral	Syringe
			Delivery Device
			Vial
		Non-Parenteral	Inhalants
			Solid Dosage
			Cream Ointment
	Pharma Warehouse		
Pharmaceutical Laboratory	Research	Biological	
		Chemical	
	Quality Control/Quality Assurance		
	Vivarium		
	Process Development	Stability	
		Clinical	

4.2 Metric definitions

Having developed the framework for benchmarking pharmaceutical projects, performance metrics tuned to characteristics of pharmaceutical construction projects were formulated as listed in Tables 2 and 3. The developed metrics are organized as cost, schedule, and dimension (area) metrics. Table 2 presents metrics referred to as absolute metrics. These metrics are calculated as ratios, for example of actual dollar costs to other measures such as other costs, dimensions, and some cases counts. Absolute schedule metrics are calculated in a similar manner as ratios of various activity durations to dimensions or counts. The absolute dimension metrics provide ratios of dimensions; usually square feet to other dimensions or counts. Absolute metrics make it possible to measure pharmaceutical project performances in terms of hard dollars, time, and gross square footage (GSF). For the absolute cost metrics, adjustments for location and time were required to develop a pharmaceutical project database maintained in current dollars at a common location and details of the procedure can be found in the research conducted by Hwang et al. (2008). As shown and footnoted in Table 2, the metrics can apply to all three pharmaceutical project types, or may be limited to just bulk or secondary manufacturing, or laboratory only.

Table 2: Absolute Pharmaceutical Metrics

	Description
Cost Metrics	$TIC / $Process Equipment Cost[1]
	$Hard Cost / $Process Equipment Cost[1]
	$Process Const. Cost / $Process Equipment Cost[1]
	$Facility Const. Cost / GSF
	$TIC / GSF
	$Soft Cost / $TIC
	$Soft Cost / $Hard Cost
	$Process Automation Cost / IO Point Count[1]
	($Design + $Construction Mgmt.) / $TIC
	$Facility Construction Cost / GCF
	$TIC / GCF
	($Qualification + $Validation Cost) / $TIC
	($Qualification + $Validation Cost) / $Process Equipment Cost[1]
	($Qualification + $Validation) / (# IQ + OQ Protocols)[1]
	($Qualification + $Validation) / Validated Equipment Piece Count[1]
	$TIC / Total Equipment Piece Count[1]
	$Hard Cost / GSF
	$Process Equipment Cost / Validated Equipment Piece Count[1]
	$Process Installation Cost / Validated Equipment Piece Count[1]
	$Soft Cost / Total Equipment Piece Count[1]
	$Design & Construction Management Cost / Total Equipment Piece Count[1]
	$TIC / LF Benchtop[2]
	$TIC / Lab Population[2]
	$TIC / Total Building Population[2]
	$Hard Cost / LF Benchtop[2]
	$Hard Cost / LF Hoods[2]
	$Hard Cost / (LF Benchtop + LF Hoods)[2]
	$Hard Cost / Lab Population[2]
	$Hard Cost / Total Building Population[2]
	Description
Schedule Metrics	(IQ thru OQ Duration) / (# IQ + OQ Protocols)[1]
	(IQ thru OQ Duration) / Validated Equipment Piece Count[1]
	(Design thru OQ Duration) / GSF
	(Design thru OQ Duration) / GCF
	(Design thru OQ Duration) / Total Equipment Piece Count[1]
	Description
Dimension Metrics	(Process Space SF + Process Related Space SF) / GSF[1]
	(Process Space SF + Process Support SF) / GSF[1]
	Mechanical SF / GSF
	Shell Space SF / GSF
	(Lab SF+ Lab Support SF) / Lab Population[2]
	(LF Benchtop + LF Hoods) / Lab Population[2]
	GSF / # Total Building Population[2]

1. Metrics for Pharmaceutical Bulk or Secondary Manufacturing Projects Only
2. Metrics for Pharmaceutical Laboratory Projects Only

Table 3 provides another class of metrics sometimes called relative metrics. These metrics are often presented as percentages or ratios of planned versus actual, or in some cases, ratios of phase data to overall project data. These metrics are usually considered "softer" metrics in that they require additional data to assess bottom-line impacts. An absolute metric such as $Hard Cost per Gross Square Feet is usually considered to convey more information of value than the relative metric Project Cost Growth. The metric Project Cost Growth compares actual cost to budgeted cost and is more difficult to interpret because performance depends on actual cost and the quality of the original

estimate. Some of these metrics are specific to the pharmaceutical industry while others may be appropriate for various types of industrial facilities. The application of these definitions and the roll up of specific project types in accordance with the hierarchical structure are the essence of the definitions. Definitions and formulas of the relative metrics are included in Hwang et al. (2008).

Table 3: Relative Pharmaceutical Metrics

	Description
Cost Metrics	Project Cost Growth
	Delta Cost Growth
	Installation Qualification Cost Growth
	Operation Qualification Cost Growth
	Pre-Project Planning Phase Cost Factor
	Design Phase Cost Factor
	Procurement Phase Cost Factor
	Construction Phase Cost Factor
	Startup Phase Cost Factor
	Installation Qualification Phase Cost Factor
	Operation Qualification Phase Cost Factor
	Description
Schedule Metrics	Project Schedule Growth
	Delta Project Schedule Growth
	Pre-Project Planning Phase Duration Factor
	Design Phase Duration Factor
	Procurement Phase Duration Factor
	Construction Phase Duration Factor
	Startup Phase Duration Factor
	Installation Qualification Phase Duration Factor
	Operational Qualification Phase Duration Factor

5. Development of the benchmarking system

The development of pharmaceutical specific metrics was a major milestone for this study. However, use of the metrics required their integration into a system that tracked additional data to permit a comprehensive analysis of project performance. For example, to properly evaluate the metrics, knowledge of the nature of the project, that is whether it was a grassroots, modernization, or addition could prove to be most important to the final analysis. As a result, the developed metrics were integrated into CII's project benchmarking system that was developed and tested over a ten year period for use as a benchmarking tool. The system enables the collection of important cost, schedule and other performance data and most importantly captures critical information on the use of best practices to improve project delivery. By integrating the pharmaceutical metrics and framework into the CII benchmarking system, it could be possible to obtain a comprehensive assessment of pharmaceutical construction project performances, permitting the analysis of the pharmaceutical metrics as part of the complete project delivery system.

A benchmarking system requires a survey instrument, a means of collecting data, a database for comparisons, and an analysis and reporting subsystem. Upon integration of the pharmaceutical metrics into the CII system, the pharmaceutical benchmarking system was programmed to take advantage of CII's web-based data collection and reporting system. The integrated online system takes advantage of web technology to provide interactive assistance and error checking to better ensure the quality of data entered. Following data entry and validation with industry participants, preprogrammed algorithms calculate the metrics and search for like project data sets for comparison.

Then, individual project and company aggregate reports are returned via the online system to the participants for near real time feedback.

Data on 40 pharmaceutical projects was obtained during the first round of data collection using the online system. Table 4 summarizes the characteristics of the 40 projects by project type, nature, size, and location.

Table 4: Pharmaceutical Projects Database Description

Project Characteristics	Number of Projects (Total = 40)
Type	
Bulk Manufacturing	12
Secondary Manufacturing	10
Laboratory	18
Nature	
Addition	12
Grass Roots	16
Modernization	12
Size	
<$15MM	4
$15MM ~ $50MM	20
$50MM ~ $100MM	5
>$100MM	11
Location	
Domestic	30
International	10

6. Pharmaceutical metric norms

Data analysis resulted in the establishment of pharmaceutical metric norms for cost, schedule, and area (GSF) by the three project types (bulk manufacturing, secondary manufacturing, and laboratory). As sufficient data become available, additional analysis will be provided in accordance with the hierarchical structure presented in Table 1. This chapter presents only a few examples of the metric norms developed to date and these are shown in Figures 1 through 3.

Figure 1, provided for illustration, shows facility construction cost per gross square footage (GSF) in current U.S. dollars at a common location - Chicago. In the figure, quartiles are used to categorize project performance data. The quartiles are shown graphically in Figure 1 as green (first), blue (second), yellow (third), and red (fourth). This numbering and color coding system graphically depicts metric performance where green or first indicates the 25 percent of the projects with best performance and red or fourth indicates the 25 percent with the worst performance. As with most performance metrics, low numbers indicate better performance. Mean values are indicated by the symbol ■, and the ♦ symbol identifies the median, the cutoff between the second and third quartiles.

Figure 2 illustrates another cost metric norm with similar quartile rules as Figure 1. The chart provides the ratio of soft cost to total installed cost (TIC). Soft cost is the sum of the costs for

qualification and validation, and design and construction management. The resulting information can be used by an organization to compare their current soft cost expenditures to that of their peers.

Figure 3 depicts mechanical area norms. In this case, lower scores are not always better when considering non-monetary issues. This chart provides insight into what portion of total space is used as mechanical space, and this knowledge can be used perhaps to assess mechanical space requirements versus more discretionary administrative space requirements.

While only general preliminary conclusions are appropriate due to the small sample size, the results show that mean, median, and data ranges vary as expected for the three project types (bulk manufacturing, secondary manufacturing, and laboratory). This may imply that performance norms are different by project types and that the metrics framework is appropriate for benchmarking comparisons. Project stakeholders should recognize and expect differences in performance and should establish realistic performance targets. As sufficient data become available, more detailed breakouts can be provided in accordance with the hierarchical structure presented in Table 1.

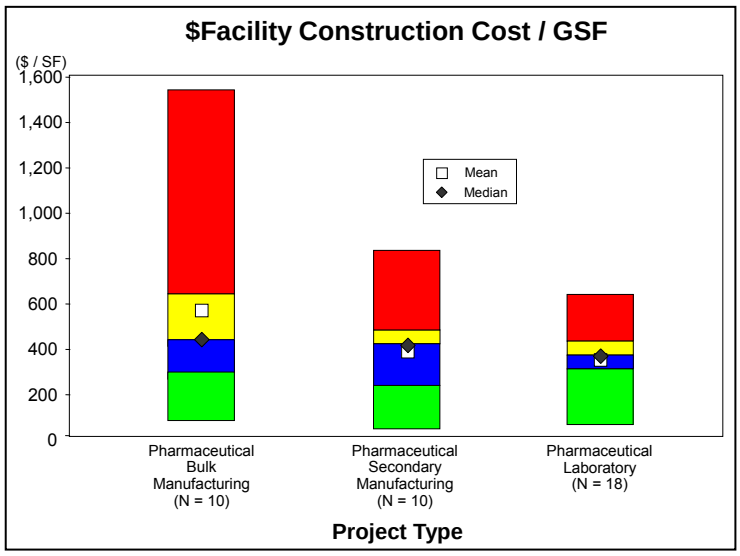


Figure 1: Facility Construction Cost per Gross Square Footage (GSF)

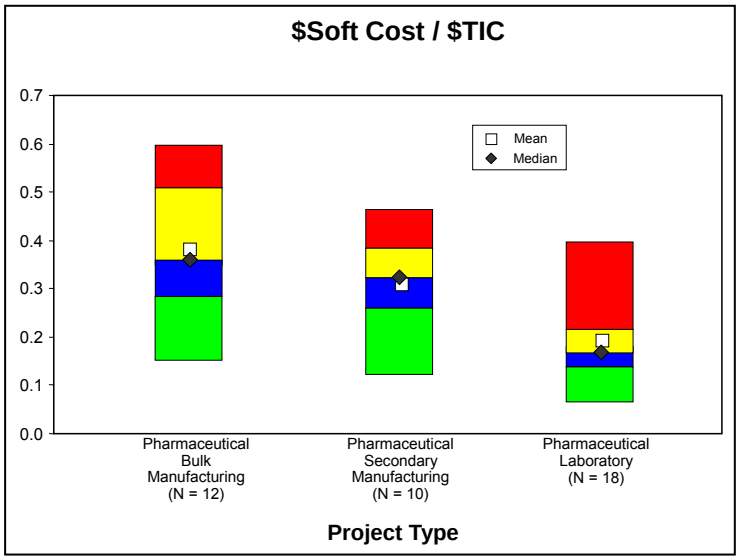


Figure 2: Soft Cost per Total Installed Cost (TIC)

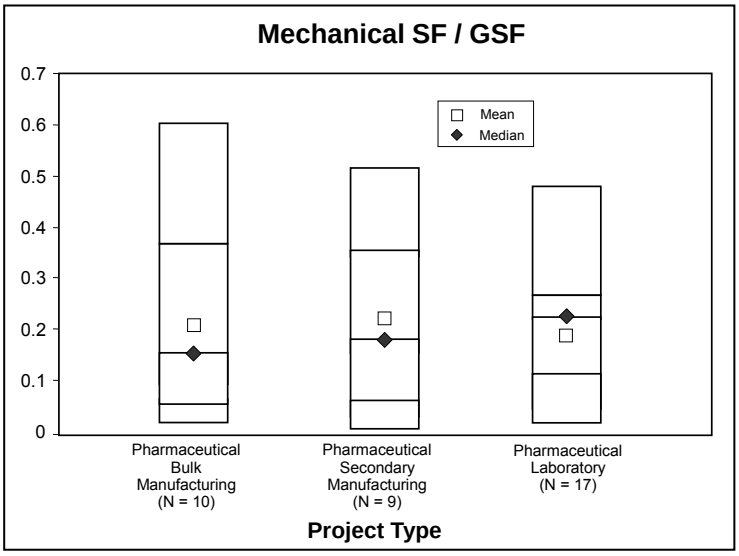


Figure 3: Mechanical Square Footage per Gross Square Footage

7. Performance reports

In general, two levels of reports are planned for the pharmaceutical metrics: Project Key reports and a pharmaceutical Data Report. Key reports are confidential project and company aggregate reports with comparisons to the pharmaceutical project database. The Data Report is not project specific and provides statistical summaries of metrics from the pharmaceutical database. Key reports have been developed and are addressed further in the following section. The data report is planned as a future activity and thus is briefly introduced at this moment.

7.1 Key reports

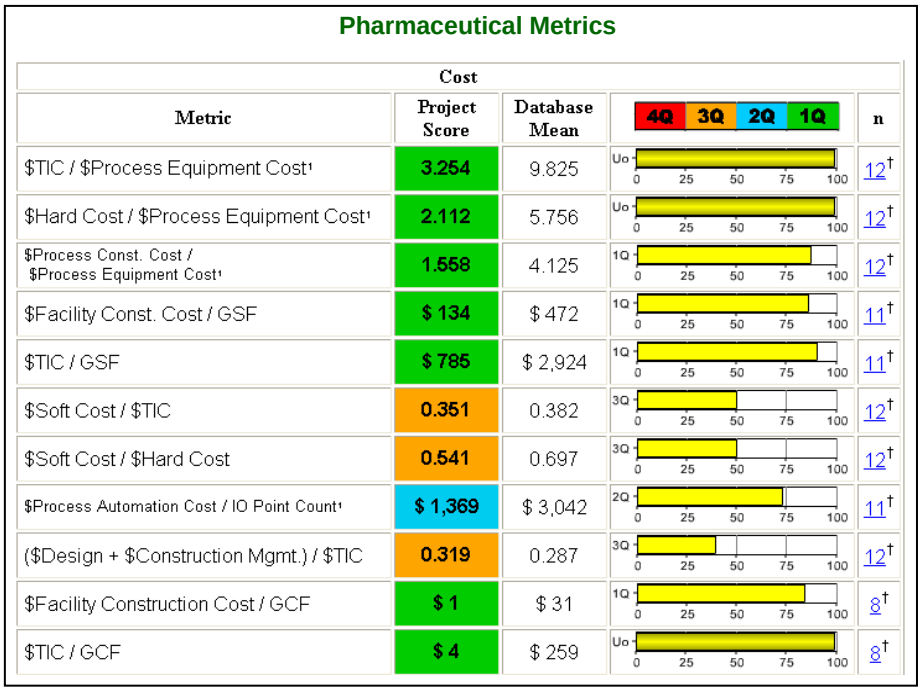
Pharmaceutical Key Reports have been developed to provide participating companies confidential, high level summaries of performance and best practice use with comparisons to Pharmaceutical database. Projects are compared with the most similar projects available to achieve the most meaningful results. For most pharmaceutical projects, this currently results in projects being benchmarked at the project type level (bulk manufacturing, secondary manufacturing, or laboratories). As pharmaceutical metric norms are developed, more detailed breakdowns will be provided as sufficient data accumulates. Key reports are returned to all companies that input data into the developed benchmarking system and are available on-line for those with access to the system. Figures 4 through 6 provide extracts from sample key reports. The standardized general information format for a selected pharmaceutical project is shown in Figure 4, including the conversion factors necessary for exchange rates, location, and time. Cost metrics are adjusted for location using the Hanscomb Means Index for international projects and the RS Means Indices for domestic projects. The indices adjust cost data to Chicago for common reference. Time adjustments are made using the RS Means Historical Index to convert all cost data to dollars in 2004 as an example.

Project General Information

Company Name	testco		Project Driver		Schedule
Project Name	Testco Pharma Project 0720		PPP - Startup Duration		161 Weeks
CII Project I.D.	O8032		Design - Startup Duration		124 Weeks
Industry Group	Light Industrial		PPP - OQ Duration		167 Weeks
Project Type	Pharma Bulk Mfg.		Design - OQ Duration		131 Weeks
Project Subtype	Fermentation		IQ - OQ Duration		15 Weeks
Cost Category	$50MM - $100MM		Construction Duration		98 Weeks
Project Nature	Grass Roots		Mid Point of Construction		23-Dec-2002
Location	Intl		TIC	Actual Cost (LC)	GBP 47,000,000
City	London			Actual Cost (USD)	$ 75,684,380
Country	England			Chicago 2004 Cost (USD)	$ 69,075,304
Hanscomb Means 2002 Index	London	Chicago	Currency Exchange Rate		1 USD = 0.621 GBP
	131.3	100.0	GSF		82,000
RS Means 2002 Index	London	Chicago	GCF		1,700,000
	N/A	N/A	PDRI		117
RS Means Historical Cost Index	Chicago 2002	Chicago 2004	PPDI		15
	128.7	143.7	% Modularization		10 %

Figure 4: Key Report – General Information

Figure 5 shows the pharmaceutical cost metrics section from a sample report. Metric scores, database means, performance quartiles, percentile bars, and sample size are provided for the metrics. The quartile statistics that are shown offer a ready comparison to the database where in general, quartile 1 (green) represents the highest performing projects and quartile 4 (red) the lowest. The percentile bars depict location within the distribution and have varying interpretations depending on the specific metric.



Pharmaceutical Metrics

Cost				
Metric	Project Score	Database Mean	4Q 3Q 2Q 1Q	n
$TIC / $Process Equipment Cost¹	3.254	9.825	Uo 0 25 50 75 100	12†
$Hard Cost / $Process Equipment Cost¹	2.112	5.756	Uo 0 25 50 75 100	12†
$Process Const. Cost / $Process Equipment Cost¹	1.558	4.125	1Q 0 25 50 75 100	12†
$Facility Const. Cost / GSF	$ 134	$ 472	1Q 0 25 50 75 100	11†
$TIC / GSF	$ 785	$ 2,924	1Q 0 25 50 75 100	11†
$Soft Cost / $TIC	0.351	0.382	3Q 0 25 50 75 100	12†
$Soft Cost / $Hard Cost	0.541	0.697	3Q 0 25 50 75 100	12†
$Process Automation Cost / IO Point Count¹	$ 1,369	$ 3,042	2Q 0 25 50 75 100	11†
($Design + $Construction Mgmt.) / $TIC	0.319	0.287	3Q 0 25 50 75 100	12†
$Facility Construction Cost / GCF	$ 1	$ 31	1Q 0 25 50 75 100	8†
$TIC / GCF	$ 4	$ 259	Uo 0 25 50 75 100	8†

Figure 5: Key Report – Cost Metrics

As shown in Figure 6, actual values for quartile cutoffs can be accessed in both tabular and graphical formats in the online version of the report by clicking the n number or yellow percentile bar. The resulting graphic includes the selected project's score for the selected metric, data slice comparisons, mean, median, and quartile cutoffs. Also show by the arrow is the project's exact position within the distribution.

An aggregate key report is provided annually for each company showing the number of projects submitted and mean metric values for these projects. The means are also compared to the database for a high level assessment of company level performance.

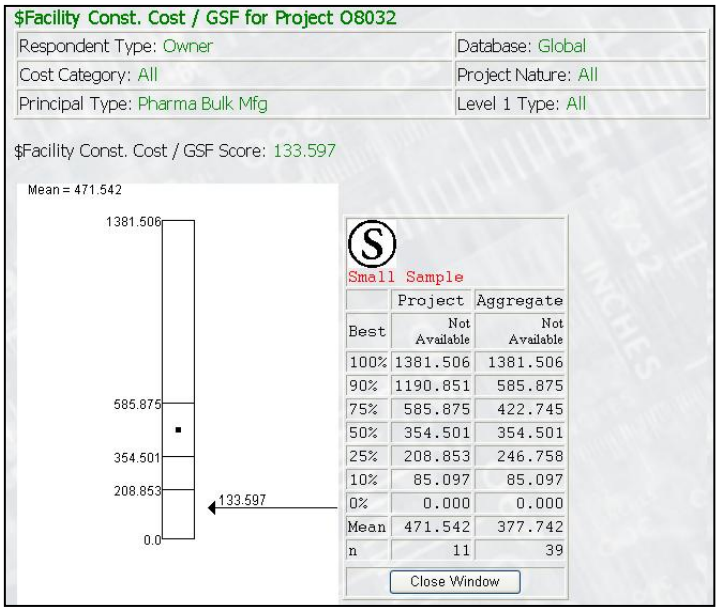


Figure 6: Key Report – Quartile Chart and Table

7.2 Data report

The data report is an online interactive report that permits the user to mine metric norms from within the database. Figures 1, 2 and 3 are example norms produced by the data report. The data report allows the user to slice the data by sector and metric of interest. Quartiles of performance, means and median are depicted. Current data report output is manually generated, however, programming to fully automate the report is scheduled to begin this fall.

8. Conclusions and path forward

The unique characteristics of the pharmaceutical industry, regulatory requirements to intensive validation and qualification, largely explain the increased resources required for pharmaceutical capital facility construction. As a result, most of the previous studies argued that the industry is unique in its processes and needs to do benchmarking reflecting this uniqueness. Yet, the industry has been relatively slow to implement benchmarking due to organizational culture reluctance to share information and the previous studies have rarely researched the development and evaluation of pharmaceutical industry-specific metrics or benchmarking systems tuned to these processes.

The purpose of this paper was to develop a system for evaluating pharmaceutical capital facility projects with metrics specific to the characteristics of these unique projects. Development of the data collection instrument included the uniqueness of the industry and relevant industry metrics. Furthermore, analyzing the data collected via the instrument, the preliminary data analysis ensured that the industry-specific metrics can be produced and should be meaningful for pharmaceutical

capital facilities benchmarking. Based on the analysis results, the customized pharmaceutical project key report developed as a feedback tool for projects, included data for performance, and provided an approach for comparison to data within the pharmaceutical database.

It is believed that the developed benchmarking system operated by the set of industry-specific metrics, the survey instrument, the means of collecting data, the database for comparisons, and the analysis and reporting subsystem will provide the industry with a reliable method of measuring and evaluating their project performance, and a basis for continuous performance improvement through benchmarking

The path forward calls for validation of the development to get wider acceptance of the industry and this may result in modifications of the developed metrics and questionnaire. Modifications to the questionnaire will also result in changes to the current key report. After modifications to the metrics and questionnaire are completed, a second round of data collection is required to commence to further enrich the dataset. Perhaps the most significant effort remaining is that of detailing the data mining tool, the data report, to allow the user to custom design reports of interest. The overall objective, however, is to implement this industry-specific benchmarking system to grow the database as a tool to assist with the improvement of capital facility projects for the pharmaceutical industry.

Acknowledgement

This paper is based on a research project sponsored by Abbott, Amgen, Eli Lilly and Company, GlaxoSmithKline, and Merck which was conducted by the Construction Industry Institute. Special appreciation is extended to the participants from the companies. Without their dedication to establishing common definitions and their efforts to collect data using these definitions, development of the Pharmaceutical Capital Facilities Benchmarking framework would not have been possible.

References

Aleem, H., Zhao, Y., Lord, S., McCarthy, T. and Sharratt, P. (2003). "Pharmaceutical process validation: an overview." Proceedings of the Institution of Mechanical Engineers, 217, Part E, 141–151.

Bureau of Economic Analysis (BEA). (2009). *Gross Domestic Product by Industry in Current Dollar*, (available online http://www.bea.gov/industry/gdpbyind_data.htm [accessed on 11/12/2009]).

Cole, C. G. (1998). *Pharma Production Facilities Design and Applications* (2nd ed.), Taylor & Francis Inc., Bristol PA.

Construction Industry Institute (CII). (2005). *Pharmaceutical Benchmarking Summary Report*. BMM2005-10 (Oct.), Construction Industry Institute, The University of Texas at Austin, Austin, TX.

Dysert, L. (2001). "Sharpen Your Capital Cost Estimation Skills." Chemical Engineering, 108(11), 70-81.

Hanscomb, Faithful & Gould (Various Reports April 2000 to October 2004). *The Hanscomb/Means Report: International Construction Cost Intelligence*. International Construction Cost Indices and Associated Excel Spreadsheets.

Hwang, B.G. (2006). *Development of a Performance Measurement System for Pharmaceutical Capital Facilities Projects*. Ph. D. Dissertation, The University of Texas at Austin, Austin, TX.

Hwang, B.G., Thomas, S., Caldas, C., Degezelle, D. (2008). "Development of a Benchmarking Framework for Pharmaceutical Capital Projects." Construction Management and Economics, 26(2), 177-195.

Jörg, K. (1999). "Putting Benchmarking into Pharmaceutical Practice: New Benchmarking models are not necessarily the way to superior performance." Pharma Marketing Journal, February/March, 6-14.

Kennedy, T. (1998). *Pharmaceutical Project Management*. Marcel Dekker Inc., NY.

Kolkebeck, K. (2005). "Pharmaceutical Building Automation for Manufacturing." HPAC Engineering, May, 25-30.

Leichter, G. and Turstam, L. (2004). "An Alternative Approach to the Modular Design and Construction of Large-Scale Bulk Biopharmaceutical Manufacturing Facilities." Pharmaceutical Engineering, May/June, 8-22.

Maleyeff, J. (2003). "Benchmarking Performance Indices: pitfalls and solutions." An International Journal, 10(1), 9-28.

McCormick, K. (2003). *Manufacturing in the Global Pharmaceuticals Industry: Key Drivers, Company Strategies and Regulations*. Urch Publishing Ltd., Rockville, MD.

RS Means. (Various Years 1999 to 2005). *Means Building Construction Cost Data. Various Cost and Historical Indices*. Reed Construction Data.

Wilkins, M. J. (2003). "Learning from the other Guy: Benchmarking and Best Practices." Control Engineering, January, 33-39.

Wrigley, G. C. (2004). *Facility Validation: Theory, Practice, and Tools*. CRC Press LLC, Boca Rayton, FL.