Introduction

2020 Quality Benchmarking Study
A Global Initiative to Baseline Pharmaceutical Quality Management

Welcome to the 2020 Quality Benchmarking Study (QBS)! Dun & Bradstreet and the University of St.Gallen are partnering to conduct this study, which is funded by the U.S. Food and Drug Administration (FDA). The study will benchmark manufacturing performance and quality management practices in comparison to global baselines and reported activities of peer establishments in the pharmaceutical industry.

Help grow the economy and improve public health by sharing information about your establishment’s quality management practices. Participate and learn how your establishment compares to its peers through a free, customized quality metrics industry comparison report prepared for you by Dun & Bradstreet and the University of St.Gallen.

You will need to consult with colleagues and your internal records in order to complete some of the questions. We ask that you fill out the questionnaire as completely as possible.

Throughout the questionnaire, you will encounter terms that are underlined like this. To see a definition of these terms, please refer to the glossary associated with this document.
Survey Respondent Contact Information

Your Contact Information
Please tell us how we can reach you for any follow-up questions about your responses, and to deliver your benchmarking report. All fields are required.

First Name: 
Last Name: 
Job Title: 
Country Calling Code: 
Telephone Number (including area code): 
E-mail Address: 
Establishment Identification

Establishment Information
Below is the information already available to us about your establishment. Please verify the information and edit as necessary.

For address information, please use the physical address of your establishment, if it differs from the mailing address.

D-U-N-S® Number: 
Establishment Name: 
Doing Business As name (if any): 
Street Address: 
City: 
State/Province: 
Postal Code: 
Country: 
Country Calling Code: 
Telephone Number (with Area Code): 
Fax Number (with Area Code): 
Website Address: 
Manufacturing Activities

The questions on this page will ask about manufacturing activities performed at your establishment. Please consider processing, testing, packaging, storing, and other activities when selecting your responses.

What type(s) of manufacturing does your establishment perform? Please select all that apply.

- Label/Relabel
- Manufacture Active Pharmaceutical Ingredient (API)
- Manufacture Finished Dosage Form (FDF)
- Manufacture Pharmaceutical Intermediates
- Pack/Repack
- Particle Size Reduction
- Testing Laboratory
- Other: _______________________

Do you currently market products in the United States?

- Yes
- No, but we have an application pending
- No, and we don't have any applications pending
In which of the following categories do you market products in the United States, or have an application pending? Please select all that apply.

- □ Abbreviated New Drug Application (ANDA)
- □ Active Pharmaceutical Ingredient (API) or Bulk Ingredient
- □ Biologics License Applications (BLA)
- □ Combination Products (Device/Drug or Device/Biologic)
- □ Cosmetic
- □ New Drug Application (NDA)
- □ OTC Monograph
- □ Unapproved Drug
- □ Other: ____________________________

Please indicate the dosage form(s) for products that you either market in the United States, or have a pending application to do so. Please select all that apply.

- □ Aerosol
- □ Gas
- □ Capsule
- □ Liquid
- □ Ointment/Suppositories
- □ Positron Emission Tomography (PET)
- □ Parenteral Drug
- □ Powder
- □ Tablet
- □ Transdermal or Topical Delivery System
- □ Other: ____________________________
What type(s) of manufacturing does your establishment perform? Please select all that apply.

☐ Contract Manufacturing Organization (CMO)
☐ Generics producer (own brand)
☐ Patented drugs producer (own brand)

Since you identified your establishment as a CMO, please indicate the percentage of contract manufacturing activities, including testing, your business performs.

☐ 1%–20%
☐ 21%–40%
☐ 41%–60%
☐ 61%–80%
☐ 81%–99%
☐ 100%

**OPEX KPIs**

Which of the following products does your site produce? Please select all that apply.

☐ Chemical/Small Molecules Drug Substances/API
☐ Biologic/Large Molecule Drug Substances
☐ Sterile Drug Products
☐ Non-sterile Drug Products
OPEX Performance
Operational Excellence (OPEX) Performance and Key Performance Indicators (KPIs) in areas such as maintenance, quality, delivery and people.

The next set of questions will ask you to provide key performance indicators (KPIs) for a 12-month period. You may choose the 12-month period that is most appropriate and convenient for your internal systems (e.g. a calendar year, fiscal year, or 12-month rolling period).

Please indicate the starting month of the 12-month period you have chosen.

[Blank Box]

Year:

[Blank Box]

Context Factors
The metrics in this section are not key performance indicators themselves, but will provide context for the KPIs related to maintenance, quality, delivery, and people below.

Total number of FTEs:
Please include all full-time equivalents working at your establishment, including contractors and temporary employees. To enter decimal numbers, use a period (.) as a decimal point. For example, if your establishment has ten and a half full-time equivalents, enter "10.5" into the box.

[Blank Box]
For each of the product technologies that you selected on the previous page, please provide the average of KPIs for the 12-month period starting with the month you indicated above.

<table>
<thead>
<tr>
<th></th>
<th>Chemical/Small Molecules Drug Substances/API</th>
<th>Biologic/Large Molecule Drug Substances</th>
<th>Sterile Drug Products</th>
<th>Non-sterile Drug Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of FTEs by Technology:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total FTEs assigned to the technology, including contractors and temporary employees</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Days on hand (DOH):</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Average Inventory value less write downs x 365 divided by the Cost of Goods Sold (COGS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test Volume:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of release and long-term stability tests conducted per year (number of tests equals number of individual sample items analyzed)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Batches Produced:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of all batches produced (production started in the reporting period)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Maintenance KPIs

Please provide the average of KPIs for the 12-month period starting with the month you indicated above. You do not need to type the percent symbol (%) in the box itself. For example, if a proportion is 999 out of a thousand, enter "99.9" in the box.

<table>
<thead>
<tr>
<th>Maintenance FTEs / Total FTEs:</th>
<th>Chemical/Small Molecules Drug Substances/API</th>
<th>Biologic/Large Molecule Drug Substances</th>
<th>Sterile Drug Products</th>
<th>Non-sterile Drug Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of Maintenance FTEs as a percentage of Total FTEs assigned to the technology</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# Unplanned maintenance:

Proportion of time spent on maintenance that was unplanned as a percentage of the overall time spent on maintenance

<table>
<thead>
<tr>
<th>Unplanned maintenance:</th>
<th>Chemical/Small Molecules Drug Substances/API</th>
<th>Biologic/Large Molecule Drug Substances</th>
<th>Sterile Drug Products</th>
<th>Non-sterile Drug Products</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

# Quality KPIs

Please provide the average of KPIs for the 12-month period starting with the month you indicated above. For decimal numbers, please use a period as the decimal point. For percentages, you do not need to type the percent symbol (%) in the box itself. For example, if a proportion is 11 out of a thousand, enter "1.1" in the box.

---
### Quality FTEs / Total FTEs:
Proportion of Quality FTEs as a percentage of Total FTEs assigned to the technology

### Rejected Batches:
Number of rejected batches (not meeting established requirements and therefore quarantined for scrap, rework or reprocessing) in the reporting period

### Deviations:
Number of all deviations that have occurred in the 12 months reporting period

### Recurring Deviations:
Number of recurring deviations in the reporting period. A deviation is recurring when a closed CAPA has previously addressed the same root cause in the same process/equipment.

### Deviation Closure Time:
Average deviation closure time in days

### Confirmed Out-of-Specification (OOS) Results:
Number of release and long-term stability test results that fall outside the
specifications or acceptance criteria, where the OOS result is confirmed

**Invalidated OOS results:**
Number of release and long-term stability test results that fall outside the specifications of acceptance criteria, where OOS result was identified as an aberration of the measurement process

**Delivery KPIs**
Please provide the average of KPIs for the 12-month period starting with the month you indicated above. For decimal numbers, please use a period as the decimal point. For percentages, you do not need to type the percent symbol (%) in the box itself. For example, if a proportion is 11 out of a thousand, enter "1.1" in the box.

| Dosage Units: Total number of dosage units distributed in the reporting period |
|---|---|---|---|
| Chemical/Small Molecules Drug Substances/API | Biologic/Large Molecule Drug Substances | Sterile Drug Products | Non-sterile Drug Products |

| Customer Complaints: Number of product quality complaints received for the products in the reporting period |
|---|---|---|---|
| Chemical/Small Molecules Drug Substances/API | Biologic/Large Molecule Drug Substances | Sterile Drug Products | Non-sterile Drug Products |
**Service Level – Delivery (OTIF):**
Perfect order fulfillment
(percentage of orders shipped in time from your establishment (+/- 1 days of the agreed shipment day) and in the right quantity (+/- 3% of the agreed quantity) and accurate quality) **to your customers**

**Service Level – Supplier (OTIF):**
Perfect order fulfillment
(percentage of orders shipped in time to your establishment (+/- 1 days of the agreed shipment day) and in the right quantity (+/- 3% of the agreed quantity) and accurate quality) **from your suppliers**

**Adherence to standard lead time (Lab):**
Proportion of batches that have been tested & released within the defined standard lead time as a percentage of all batches tested and released
People KPIs

Please provide the average of KPIs for the 12-month period starting with the month you indicated above. For decimal numbers, please use a period as the decimal point. For percentages, you do not need to type the percent symbol (%) in the box itself. For example, if a proportion is 11 out of a thousand, enter "1.1" in the box.

<table>
<thead>
<tr>
<th></th>
<th>Chemical/Small Molecules Drug Substances/API</th>
<th>Biologic/Large Molecule Drug Substances</th>
<th>Sterile Drug Products</th>
<th>Non-sterile Drug Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety level:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reported incidents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>due to accidents that</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>required medical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>consultation per year</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sick leave:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>absent due to sick</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>leave as a percentage</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>of the total working</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>time per employee.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do not include</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>parental or family</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>leave.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Organization Enablers

Enablers serve as an Operational Excellence (OPEX) Performance maturity assessment and will help to understand performance gaps. These are often associated with high operational performance. The enablers explored in this section focus on organizational practices.

To what degree are product and process development linked to ensure close collaboration?

- Product development and process development teams do not work together.
- Product development and process development do reach out to work together when either side has an urgent need (e.g. for trouble-shooting).
- Product development and process development have established channels to work together when either side feels it is beneficial.
- Product development and process development teams follow a defined procedure to ensure regular exchange.
- Product development and process development teams work extensively together to ensure full alignment at all times.
- Not applicable/Don't know

If you have any further comments about the collaboration between product and process development, you may enter them here.
What is the primary focus of your process performance and product quality monitoring system?

- Metrics are primarily based on operational performance and not actively collected for process improvement.

- Metrics focusing on quality are used to improve compliance, but are only reviewed within the quality unit.

- Metrics are visually displayed and routinely reviewed by employees to inspire continuous improvement.

- Metrics are visually displayed and routinely reviewed by employees. Leading indicators have been identified, they are used to improve quality.

- Metrics are visually displayed and routinely reviewed by employees. Leading indicators have been identified, are utilized in predictive analyses, and they are used to improve quality.

- Not applicable/Don't know

If you have any further comments about your process performance and product quality monitoring system, you may enter them here.
To what extent does your quality system facilitate continual improvement?

- We have a quality system that is not used for continuous improvement.
- We have a quality system that is only used for continuous improvement if there is a specific request.
- We have a quality system that is routinely used for continuous improvement.
- We have a quality system that is routinely used for continuous improvement and we incorporate external feedback (e.g. customer feedback, external audits).
- We can demonstrate PQS (Pharmaceutical Quality System) effectiveness and drive all types of post-approval changes to facilitate continuous improvement.
- Not applicable/Don't know

If you have any further comments about your quality system's facilitation of continual improvement, you may enter them here.
Do you establish formal knowledge management program with your suppliers (e.g. direct product components, substances) and contract manufacturers ensuring you are immediately informed about all important changes?

- There is no formal knowledge management program with suppliers and contract manufacturers.
- There is a knowledge management program with suppliers and contract manufacturers, but it is not applied in practice.
- There is a formal knowledge management program with suppliers and contract manufacturers. It is part of the structured supplier onboarding, but not followed up after that.
- There is a formal knowledge management program with suppliers and contract manufacturers. It is part of the structured supplier onboarding and applied in our routine collaboration.
- There is a formal knowledge management program with suppliers and contract manufacturers. It is part of the structured onboarding, routinely applied and our partners are audited to adhere to the process.
- Not applicable/Don't know

If you have any further comments about knowledge management with your suppliers, you may enter them here.
To what degree do you receive feedback from your internal and external customers on quality delivery performance (e.g. on time in full rate)?

- We do not receive feedback from our customers.
- We only receive feedback from our customers when there are complaints.
- We gather feedback from our customers in an annual customer satisfaction survey.
- We have a process to routinely gather feedback from our customers.
- We have an established feedback process with our customers that gives them opportunity to provide timely information on every order.
- Not applicable

If you have any further comments about your customer feedback system, you may enter them here.
Social & Employee Enablers

Social and Employee Enablers
Enablers serve as an Operational Excellence (OPEX) Performance maturity assessment and will help to understand performance gaps. These are often associated with high operational performance. The enablers explored in this section focus on organizational practices as it relates to employees and social behaviors.

To what degree do shop floor employees know how products impact patients?

- Employees cannot explain, and senior management doesn’t communicate, how the product impacts patients.
- Employees can explain how patients use the products but not the impact of quality. Senior management only communicates about the effect of quality and supply when it is the dedicated purpose (e.g. part of townhall's agenda once per year).
- Employees can explain how patients use the products and the impact of quality. Senior management highlights the effect of quality and supply even if it is not the dedicated purpose of the communication (e.g. during gemba walks).
- Employees can explain how patients use the products and the impact of Critical Quality Attributes. Employees can hear directly from patients.
- Employees can explain patient expectations, how the products are used, and the impact of Critical Quality Attributes. Employees have external opportunities to connect with patient support efforts.
- Not applicable/Don't know

If you have any further comments about your shop floor employees' awareness of products' impact on patients, you may enter them here.
To what degree is your senior management involved in evaluating the outcome of process performance and product quality review?

- Senior management is not involved in evaluating the outcome of process performance and product quality review.
- Senior management only approves or confirms that process performance and product quality review was conducted.
- Senior management is briefed about critical outcomes of process performance and product quality reviews by middle management.
- Senior management discusses the outcome of process performance and product quality review in detail with the colleagues who conducted the review.
- Senior management does not only discuss the outcome of process performance and product quality review but also drives deriving improvement actions.
- Not applicable/Don't know

If you have any further comments about senior management's involvement, you may enter them here.
To what degree do you engage your shop floor employees to identify improvement ideas and to act on these?

- We do not engage shop floor employees to identify improvement ideas.
- We engage shop floor employees to identify improvement ideas by providing a suggestion system.
- We engage shop floor employees to identify improvement ideas by providing a suggestion system and dedicated training how to identify improvement ideas.
- We engage shop floor employees to identify improvement ideas by providing a suggestion system and dedicated training how to identify improvement ideas. There is a transparent evaluation process and employees always receive feedback.
- We engage shop floor employees to identify improvement ideas by providing a suggestion system and dedicated training how to identify improvement ideas. There is a transparent evaluation process, employees always receive feedback and selected shop floor employees are involved in executing resulting improvement projects.
- Not applicable/Don't know

If you have any further comments about shop floor employees' role in identifying ideas for improvement, you may enter them here.
What proportion of your shop floor employees are cross-trained, so they can fulfill a broad range of tasks (e.g. perform several jobs on the same line or across several lines) and substitute for colleagues if necessary?

- 1%–20% of shop floor employees
- 20%–40% of shop floor employees
- 40%–60% of shop floor employees
- 60%–80% of shop floor employees
- >80% of shop floor employees
- Not applicable/Don't know

If you have any further comments about cross-training, you may enter them here.
To what degree are Quality Excellence and Continuous Improvement trainings rolled out to train employees in tools (e.g. Lean/Six Sigma)?

☐ We do not run Quality Excellence and Continuous Improvement trainings.

☐ Some Quality Excellence and Continuous Improvement trainings are provided from time to time. However, there is no structured concept in place.

☐ We run a structured generic Quality Excellence and Continuous Improvement training program. However, it relies on off-the-shelf approaches provided by external trainers and certification organizations.

☐ We run a structured program of Quality Excellence and Continuous Improvement trainings tied to our individual needs. The structured training program is developed, tied/customized to our organization's needs and deployed by our internal specialists (train the trainer approach).

☐ We run a structured program of Quality Excellence and Continuous Improvement trainings tied to our individual needs. The structured training program is developed, tied/customized to our organization's needs and deployed by our internal specialists (train the trainer approach). There is a defined process to evaluate the effectiveness of the training program.

☐ Not applicable/Don't know

If you have any further comments about your training program, you may enter them here.
Technical & Tool Enablers

Technical and Tool Enablers

Enablers serve as an Operational Excellence (OPEX) performance maturity assessment and will help to understand performance gaps. These are often associated with high operational performance. The enablers explored in this section focus on organizational practices as it relates to technology and other tools used in your processes.

To what degree are potential bottleneck machines identified and proactively supplied with additional spare parts?

- Bottleneck machines are not identified.
- Bottleneck machines are identified, but not in a dedicated process and not supplied with additional spare parts proactively.
- Bottleneck machines are identified in a dedicated process, but not supplied with additional spare parts proactively.
- Bottleneck machines are identified in a dedicated process, but only some are supplied with additional spare parts proactively.
- Bottleneck machines are identified in a dedicated process, which is updated regularly, and fully followed up by supplying additional spare parts proactively.
- Not applicable/Don't know

If you have any further comments about your treatment of bottleneck machines, you may enter them here.
What is your use of statistical tools to measure, track, and implement continuous improvement? For example, this could be a knowledge base of the relevant multifactorial relationships (e.g., between formulation, process, and quality attributes).

- Identify and collect data that measures manufacturing performance
- Identify, collect, and analyze manufacturing performance data
- Link performance data to business objectives and communicate performance to the organization
- Use statistical techniques to quantify process performance, and establish baselines for key attributes
- Use statistical techniques to drive performance improvement and establish culture of continuous improvement including management reviews
- Not applicable/Don't know

If you have any further comments about your use of statistical tools, you may enter them here.
To what degree do you use statistical process control (SPC) in your processes?

- SPC not or rarely utilized, no equipment with real-time monitoring
- SPC partly (>30%) utilized, no equipment with real-time monitoring
- SPC often utilized (>60%), little (<30%) equipment with real-time monitoring
- SPC always utilized, some (>30%) equipment with real-time monitoring
- SPC always utilized, >80% of equipment under real-time monitoring
- Not applicable/Don't know

If you have any further comments about your use of statistical process control, you may enter them here.
Do you apply a formal quality risk management (QRM) process for all products and are your employees trained accordingly?

- We do not have a formal quality risk management process.
- We have a formal quality risk management process. However, it is not always applied and employees are not trained on the procedures.
- We have a formal quality risk management process. It is always applied for all new products/processes and SMEs (Subject matter experts) are trained according to it.
- We have a formal quality risk management process. It is always applied for all new products/processes and all relevant employees are trained accordingly.
- We routinely review our existing quality risk management documentations (e.g. review initial assessments and mitigations based on production experience after a certain time). Procedures are clearly defined and employees are trained accordingly.
- Not applicable/Don't know

If you have any further comments about your quality risk management process, you may enter them here.
To what degree do you make use of standardized tools and procedures (e.g. FMEAs, 5 Whys, Ishikawa) for root cause analysis (RCA) to get a deeper understanding of the influencing factors?

- Standardized tools/procedures for RCA are not in place
- Standardized tools/procedures for RCA are in place, but rarely used (<50% of investigations) without systematically rolled-out trainings
- Standardized tools/procedures for RCA are in place and widely used (>50% of investigations), and trainings are rolled out systematically
- Standardized tools/procedures for RCA are in place and widely used (>50% of investigations), and trainings are rolled out systematically; RCA effectiveness is assessed
- Standardized tools/procedures for RCA are in place and widely used (>50% of investigations), and trainings are rolled out systematically; RCA effectiveness is assessed and trainings are adapted accordingly
- Not applicable/Don't know

If you have any further comments about your tools and procedures for root cause analysis, you may enter them here.
Do you measure corrective and preventive action (CAPA) effectiveness and identify CAPAs that are not effective?

- We only use our CAPA system for documentation, i.e. we do not review the overall list of CAPAs, proportions of overdue CAPAs, or trends.
- We use our CAPA system for documentation and review, e.g. the overall list of CAPAs, proportions of overdue CAPAs, or trends.
- We have defined measures in place and are able to assess the overall effectiveness of the CAPA system. Furthermore, distinct ineffective CAPAs can be identified.
- We have defined measures in place assessing the overall effectiveness of the CAPA system and identifying distinct ineffective CAPAs. Additional actions for all ineffective CAPAs are derived.
- We have defined measures in place assessing the overall effectiveness of the CAPA system, identifying distinct ineffective CAPAs and deriving additional actions. The measures are reviewed and updated regularly.
- Not applicable/Don't know

If you have any further comments about your CAPA system, you may enter them here.
To what degree have you implemented 5S (Sort, Set in Order, Shine, Standardize, Sustain) and continuously improve it?

- We do not have formal procedures in place to implement 5S.
- Formal procedures for putting all tools and fixtures in their place exist, but are only partly (<50% of areas) adhered to.
- Formal procedures for putting all tools and fixtures in their place exist that are fully adhered to, but are static not optimized.
- Formal procedures for putting all tools and fixtures in their place exist that are fully adhered to, they are adapted/optimized unregularly, e.g. when requested by management.
- Formal procedures for putting all tools and fixtures in their place exist that are fully adhered to; optimization constantly is our priority.
- Not applicable/Don't know

If you have any further comments about your 5S program, you may enter them here.
To what degree do you utilize charts/boards showing the current performance status (KPIs) in your manufacturing areas and QC labs?

- We do not utilize performance charts.
- Performance charts are used in some areas (<50%) to show KPIs, but not systematically used and updated.
- Performance charts across some areas (<50%) show KPIs and are systematically used and updated.
- Performance charts across most areas (>50%) in manufacturing and QC show KPIs and are systematically used and updated.
- Performance charts across all areas in manufacturing and QC show KPIs. The set-up and structured usage of performance boards is continuously reviewed and improved.
- Not applicable/Don't know

If you have any further comments about your use of performance charts, you may enter them here.
Management Comments

Establishment Management Comments

How well does the marketplace reward your company's investment for this specific manufacturing site in continuous improvement and mature quality systems?

<table>
<thead>
<tr>
<th>Rating</th>
<th>1 - Not At All</th>
<th>2 - Poorly</th>
<th>3 - Neither Low or High</th>
<th>4 - Positive</th>
<th>5 - High</th>
<th>6 - Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Because you selected "Positive" or "High" to Question 1.a., please select as many items from the list below that represent marketplace acknowledgement of value.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased Sales</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased Market Share</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased Stock Value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased Brand Recognition</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please use the space below to provide additional input related to this topic.
In your role as a leader, what management practices and operational processes help you to balance the pressure for continuous improvement with shareholder expectations?

**Summation**

Thank you for completing the Quality Benchmarking Study! You have reached the end of the questionnaire.

Completing a survey online will produce a page which displays a record of your responses.
2020 Quality Benchmarking Study

GLOSSARY OF TERMS

5S: 5S is used to eliminate waste in the workplace and to uncover dysfunctional ways of work. The five S's comprise sort, set in order, shine, standardize, and sustain.

5 Whys: A guided team exercise for identifying the root cause of a problem. Five Whys is used in the “analyze” phase of the Six Sigma (define, measure, analyze, improve, control) methodology.

Batch: A specific quantity of a drug or other material that is intended to have uniform character and is produced according to a single manufacturing order during the same cycle of manufacture.

API: Active Pharmaceutical Ingredient

Bottleneck Machine: A bottleneck machine is one machine in a chain of processes/machines, such that its capacity limits the capacity of the whole chain.

CAPA: Corrective And Preventive Action

CMO: Contract Manufacturing Organization

Context Factors: Background information on the site, such as size and FTEs, technology, and product program. They allow to build meaningful peer groups for comparisons (“compare apples with apples”).

Continual Improvement: Recurring activity to increase the ability to fulfill requirements. (ISO 9000:2005).

Critical Quality Attributes (CQA): A CQA is a physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality.

DUNS Number: The Data Universal Numbering System is a proprietary system developed and managed by Dun & Bradstreet that assigns a nine-digit unique numerical identifier to a single business entity.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effectiveness</td>
<td>Effectiveness describes the “degree to which something is successful in producing a desired result; success.”</td>
</tr>
<tr>
<td>Enabler</td>
<td>Enablers represent capabilities of an organization that are associated with reaching a high operational performance.</td>
</tr>
<tr>
<td>Establishment</td>
<td>A place of business under one management, at one general physical location.</td>
</tr>
<tr>
<td>FTE</td>
<td>Full-Time Equivalent</td>
</tr>
<tr>
<td>Failure Mode and Effects Analysis (FMEA):</td>
<td>The process of reviewing as many components, assemblies, and subsystems as possible to identify potential failure modes in a system and their causes and effects.</td>
</tr>
<tr>
<td>Invalidated OOS:</td>
<td>Number of release and long-term stability test results that fall outside the specifications or acceptance criteria where the source of the OOS result is identified as an aberration of the measurement process.</td>
</tr>
<tr>
<td>Ishikawa</td>
<td>An Ishikawa diagram is a diagram that shows the causes of an event and is often used in manufacturing and product development to outline the different steps in a process, demonstrate where quality control issues might arise and determine which resources are required at specific times. It is also referred to as a fishbone diagram.</td>
</tr>
<tr>
<td>ITEM-HSG</td>
<td>Institute of Technology Management at the University of St.Gallen</td>
</tr>
<tr>
<td>KPI</td>
<td>Key Performance Indicator</td>
</tr>
<tr>
<td>Manufacture Finished Dosage Form (FDF):</td>
<td>A dosage form is the physical form in which a drug is produced and dispensed, such as a tablet, a capsule, or an injectable.</td>
</tr>
<tr>
<td>OpEx</td>
<td>Operational Excellence</td>
</tr>
<tr>
<td>OOS</td>
<td>Out of Specification - Number of release and long-term stability test results that fall outside the specifications or acceptance criteria.</td>
</tr>
<tr>
<td>OTC Monograph</td>
<td>The safety, effectiveness, and labelling of OTC active ingredients.</td>
</tr>
</tbody>
</table>
OTIF: On Time and In Full

Positron Emission Tomography (PET): Imaging technique that uses radioactive substances to visualize and measure metabolic processes in the body.

QC: Quality Control

RCA: Root Cause Analysis


SPC: Statistical Process Control. For example, batch records could include a series of charts depicting acceptance ranges, confidence intervals, and distribution plots (inter- and intra-batch) showing measurement results. (See also FDA Guidance for Industry PAT […], 2004).