Whitepaper

InfinityQS®
Quality Re-imagined

8 Essential Tools for Your Quality Toolkit

Advice from quality experts to help you simplify your job and keep your manufacturing processes in control.

Contents

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Introduction

Product quality is at the core of every manufacturer's mission. Over time, the definition of quality and the measures taken to achieve quality goals may shift and take on a different meaning depending on your role within the organization. What doesn't change is the need to keep product within specification and under budget — every time.

This quality toolkit provides you with resources to establish your objectives, align your team, and ensure that you build a foundation based on real-time intelligence.

We have pulled from more than 100 years of combined experience from former quality managers, industrial statisticians, and engineers across all industries who understand your daily challenges and the goals you strive to achieve.

With this guide, you will learn how to simplify your job and hone the essential skills that allow your team to work effectively.

Set the Foundation: SPC Simplified

When it comes to Statistical Process Control (SPC), it's easy to get lost in the weeds and forget what you are really trying to accomplish. The whole point is to make better products for the customer. To do that you have to perform the same exact processes over and over across every production line. Most important, it has to be done as safely and efficiently as possible so you don't waste time or money.

When Walter A. Shewhart developed control charts, the powerful charts and plots were created with paper and pencil. Today, SPC can occur in real time. When you stop and think about it, SPC doesn't have to be overly complicated. Watch the process, collect data, make that data useful, and then make decisions based on that useful information. It's as simple as that. Perform these tasks and you will be running to target while reducing variation.

Data » Information » Decision

Don't get caught up in what program you are going to deploy. Will it be Lean, Six Sigma, or Lean Six Sigma? Will you use this software program or that one? Should you outsource, or will you take it on internally?

Traveling around the world and seeing many different companies make lots of different products in lots of different ways has brought me a new appreciation for SPC. It is not how you do it as much as "Are you doing it?" Keep in mind a couple of things: Strategy and Execution. Make sure the measurement devices are accurate, the sampling frequency is correct, and the data entry is fool-proofed. These are great and noble things and should be worth the time.

However, the largest and most crucial step that I believe is being most overlooked in SPC today is using the data to make decisions, which is where execution comes in. In the execution phase, product is being made efficiently and decisions are being made based on the data.

You collect data and have databases full of it. You've made all of the checks and the auditors are proud. You work extremely hard to collect accurate data. You have tools that automatically collect data from testing centers, computers, and other systems. You have all these nice charts where data lives and breathes.

At the end of the day, how did you utilize that data to make decisions to improve processes? How much did you reduce variation? Are you stopping to look at our products to see whether they are being made more consistently? Are you identifying the root causes of your variation and instituting control plans to prevent them from returning — or are you going to have to revisit this next year?

Here are some examples of the things you can focus on:

› Collect data that is relevant for SPC – Don't collect data just because it is there.

› Focus on key characteristics – It's not reasonable for operators to react to dozens of charts.

› Implement a system that highlights exceptions and doesn't require users to look at every chart – This is especially useful when many characteristics are collected.

› Provide clear instructions for operators when an exception occurs.

› Review the data in a timely fashion – "Timely" may mean different things for an operator, supervisor, manager, and director.

When you slow down long enough to think about what you are doing and why, the better your SPC programs will be. Carve out a little time, grab a cup of coffee, think about your current SPC implementation, and ask yourself, "How has my data helped me improve my process?"

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Shop Talk: Error-Proof Your Processes

Manufacturers love to hear the words “in control” when talking about processes. From a Statistical Process Control (SPC) point of view, an in-control process means that a process is stable or predictable. After putting in the work to get a process in control, how do you make sure it stays in control?

Every process has variation. While some sources of variation may be known and considered minor, others, if deemed critical, must be detected and removed in order to maintain a stable process.

Drs. Shewhart and Deming identified the following two sources of process variation:

› **Common Cause** – Variation that is inherent as part of the process. Examples of Common Cause include natural wear and tear, changes in humidity, old machines, and so on.

› **Special Cause** – Variation that is outside of the normal process. Examples of Special Cause include operator error, broken parts, power outage, and others.

SPC provides statistical methods to observe the performance of a process to predict, identify, and remove sources of variation. Below are several methodologies that can be applied to help maintain a stable process:

› **Real-Time Data** – Data collection in real time provides early detection. Immediate corrective action can be taken to minimize making bad products.

› **Control Charts** – Control charts provide process performance relative to specified control limits and therefore can differentiate between common and special causes of variation.

› **SPC Control Rules** – When a process triggers a control rule, it is detecting an “out of control” or non-random condition. Depending where the data lies in the control chart, further investigation will be warranted.

› **Corrective Actions** – Methods for eliminating a source of variation may include proper training, well-defined process standards, and developing a robust process through process refinement.

Variation is present in all things. The challenge is to identify what is and is not natural variation and then create an action plan to eliminate the variation. The approach listed above will help to maintain a historically established level of variation.

It’s not time to uncork a bottle of champagne just yet. First, a little reminder. Don’t confuse control limits with specification limits, which represent the desired final product. When a process is in control, that does not always mean that the process is “good.” In other words, it is possible to have a process that is in a state of statistical control but producing bad or out-of-specification parts.

What if you’ve got a process that is in control and producing products that are well within specification limits? Does continuous improvement mean that process should be improved at all costs? This is where the economics of SPC come into play. If you are running a process in control with a high capability, it probably isn’t worth the time and cost necessary to improve that process. Moreover, you may even consider reducing your sampling frequency and focus your efforts on another process that is struggling.

An in-control process simply implies that a process has performed to a degree of stability in the past and that stability is expected to continue going forward. If the process is producing good products, this means you can expect the process to continue to do so. The same is true if the process is producing bad products. Having a process that will allow for a predictable outcome of saleable goods and services is the first step. Making that process perform within desired specification is the ultimate goal.

So, identify process variation, use Manufacturing Intelligence to make strategic decisions, and put yourself in control.

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Build a Business Case for an SPC Quality Hub

When you're investigating an SPC system, it can be difficult to build a business case for it. For a quality engineer, the value in having easy access to data seems obvious, but this can be a hard sell to an organization focused on cost and payback opportunities for capital projects. There are a number of ways an SPC system can be used to drive improvement and reduce costs. Look in these areas to identify and then make the business case for an SPC system.

› **Incoming Raw Materials / Supplies** – Incoming inspection of raw materials data can be very valuable in determining the best suppliers. However, in a paper-based system, the data is difficult to analyze. An SPC system can be used to quickly document the inspections and be available for analysis of the data.

  » When the data is available for analysis, it can be leveraged with the various raw material suppliers to drive both quality and cost improvements.

› **Compliance** – An SPC system can be used to evaluate and improve compliance to procedures. As with raw material data, an SPC system can help to quickly evaluate compliance to procedures.

  » An SPC system drives major savings compared to the time it takes to evaluate paper records. Further, the paper, printer, storage, and retrieval costs can effectively be eliminated.

› **Investigation** – As in the case of compliance, complaint investigation can be much improved with an SPC system. Data can be quickly retrieved to evaluate for root cause analysis and also to determine whether other products might be affected.

  » During a recall, this quick retrieval and analysis of the quality data can be invaluable not only for improving the products affected by the recall but also for preventing in-process materials from facing the same issue.

› **Quality Improvement** – The data retrieval and analysis that can be used for compliance and investigations can also be used to determine areas of improvement in the factory. This data can be used to break through preconceived ideas about problems and to direct improvements using easily compiled data.

  » Reductions in scrap, rework, product giveaway, machine setup, product sorting, and inspections are all improvements that impact the bottom line and are precisely the improvements that SPC targets.

Who could possibly say no to these types of improvements? Often, the most difficult part of establishing a business case for SPC is quantifying how much money is currently being wasted on issues like these and how much you can expect to gain from implementing a modern SPC system. This quantification will most likely require baselines of your current process, predictions based on past experiences, and predictions based on current production volumes and process knowledge. Examples might include:

› Reducing product giveaway by x% will result in $y savings.

› By performing a study on line 1, scrap was reduced by x% and resulted in $y savings. Extrapolate these results to other lines if an SPC system is implemented.

› The quality department spends x hours/week retrieving and organizing record implementing an SPC system; we expect this to be reduced by y hours/week, resulting in $z savings.

› Consolidating from 3 suppliers to 2 suppliers for these materials will give us a volume increase that will allow better pricing.

These examples are very general and serve only as a starting point, but they demonstrate the thoughts that every customer who has driven cost down through improved quality has had.

A modern SPC solution can be used in many ways above and beyond traditional SPC. You get all of the benefits of SPC, allowing operators to quickly and efficiently make sound quality decisions about the product that they are running. In addition, modern SPC also allows for instant product and process analysis that was time-consuming with paper-based SPC and other manual data collection systems.

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Assembly Required: 11 Skills Your Quality Team Needs

As you may already know, all the departments in a company are fully interrelated. Most of the time, the quality department plays a central role that impacts all other departments' metrics.

For example, if a product does not meet the standard quality levels, that impacts sales. Any reworks, recalls, and returns can cause changes in the planning department. Not to mention, you may have to break a production line schedule to make up the deficit, which affects manufacturing.

The question now is: How do you make sure you have a robust quality process that helps the business flow smoothly?

Everything starts with a strong quality team. To be successful, you need to focus your efforts on developing and deploying the correct set of skills for your team. The sets of skills that any member of a quality team should possess are:

1. Problem solving
2. Effective interaction with other departments/suppliers
3. Effective use of data analysis tools (e.g., root cause analysis, Pareto charts, and box-and-whiskers charts)
4. Leadership
5. Analytical and research skills
6. Willingness to learn new methods and systems
7. Ability to manage multiple priorities
8. Teamwork
9. Communication skills
10. Judgment and decision making
11. Understanding of variation introduced by measurement devices

Most important, it is critical to have a great leader who can keep people motivated and continuously coach employees to meet the highest quality standards. It is also important to remember that people in management positions become role models for their subordinates.

Therefore, a great quality leader must be a great communicator who can express the importance of meeting the metrics and goals within the quality department. When I say "great communicator," I mean someone who can fully grasp and explain these concepts:

› What is the purpose of what we are doing?

› What is our contribution within the company?

› How do we impact other departments?

Having the right set of skills in your quality team is the foundation to building a strong quality department that will allow you to develop robust quality processes. Since quality is one of the key departments, you will be paving the way to improve your organization. On top of that, you can rest assured that you will have a better working environment while fostering a "culture of quality" that will hopefully expand beyond the quality department!

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Safety First: Avoiding Costly Recalls

This article first appeared in Supply & Demand Chain Executive as "Are you Hungry for Change?"

Food & Beverage players must take the right steps to improve control and efficiency of perishable supply chain processes.

Consumers have more reasons now than ever before to be skeptical about the food they eat in restaurants and that they purchase at the local grocery store. Major food recalls on a consistent basis have become part of the norm in the U.S. For example, meatball manufacturer Buona Vita Inc. recalled more than 300,000 pounds of various frozen meat and poultry products due to possible listeria monocytogenes contamination, according to the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). The U.S. Department of Agriculture also announced in May 2012 a recall of approximately 20,520 pounds of lamb koftis from August Foods Inc.

With a growing list of recalled perishables, not to mention the 24-hour news cycle that shines a light on the impact that recalls have on public safety and health, consumers are more aware of quality issues that can arise at any step in the supply chain — be it in fertilizing the crops and feeding the cows or in cooking, processing, packaging, and distributing goods. Manufacturers and produce companies need to step up to the plate to meet FDA regulations and ensure safety and precision in their supply chains.

Recoil from recall

While not all companies are fortunate to survive major recalls with unscathed brands, those that do find that the associated costs come in waves. First, recall execution produces a series of unexpected expenses to cover the logistics, personnel, overtime, and loss of product. However, the true costs cannot be weighed until a company factors in public health and future lost revenue due to damage to the corporate brand. In the most egregious cases, recalls are followed by costly legal proceedings and possibly even congressional subpoenas.

To establish standards that help companies avoid recall events as a result of contamination, the U.S. Food and Drug Administration (FDA) passed the Food Safety Modernization Act (FSMA) in 2011. This vital legislation establishes the foundation for a 21st century food safety system.

Additionally, the FDA published guidelines on food safety hazards to the seafood industry; issued a ruling requiring that the country of origin be visible for all imported food; drafted guidelines for the food supplement industry; and established the Food Safety Preventive Controls Alliance (FSPCA), an organization that develops training courses and material to prevent contamination of food during production.

With these regulations coming into play, food manufacturers and importers are under pressure to implement the new safety protocols outlined in FSMA by proving they have the ability to quickly identify and respond to issues, enable visibility into production across the globe, and provide an audit trail that tracks product and process genealogy throughout the supply chain.

Yet, quality challenges are even more complex with imported food. According to the USDA, in 2011, the United States imported more than $98 billion worth of agricultural products. Amazingly, less than 2% of imported food is inspected, and much of this meat and produce does not yet have the lot number or genealogy data required to support traceability in the case of product recalls.

Moving forward, international food companies and manufacturers will not only be held accountable for the safety of ingredients received from their suppliers but they must also demonstrate the same level of responsiveness, visibility, and genealogy as their domestic counterparts.

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Initiate the right food safety steps

Some manufacturers are taking these increasingly stringent regulations in stride. However, many still struggle with basic challenges such as data collection and reporting, and only about one-third are able to track supplier quality. Though the ability to meet emerging regulatory requirements may seem like an elusive goal for many manufacturers, there are six vital steps these and other food companies can take to improve control and transparency across their supply chain.

Set standards for products and processes — Establish and broadly communicate guidelines that will standardize data such as product codes, units of measure, bills of material, specifications, process parameters, and lot numbering to plants and suppliers. This is vital to ensure normalization of data across functions, processes, and suppliers. Access to global standards should be controllable, centrally available, easily accessible, and easily deployable across production facilities and supply chain partners.

Automate the collection of quality-related data — Ensure that test results from existing systems, such as Statistical Process Control (SPC) and Supervisory Control and Data Acquisition (SCADA) systems are captured and electronically recorded as they happen. Accuracy and precision related to the product and process results and events are especially important in the food industry. Relying on operators or waiting until the batch is complete will result in inaccurate data collection or a delay in the implementation of corrective actions.

1. **Establish a global quality hub** — Build a centralized data repository that contains the standardized data reviewed above, along with test results and other data collected during production and inspections. Define an entity for each measurement and specify the linkages between test results, operators, processes, and time stamps. This will enable full traceability — forward and backward — easily meeting FDA regulations. A global quality hub also preserves data integrity, establishes the system of record, and sets parameters to support continuous improvement programs.
2. **Identify the right Key Performance Indicators (KPIs)** — As part of a global quality initiative, establish a score card that includes product quality metrics for ingredients, intermediates, and finished product — along with process quality metrics that monitor the performance of various pieces of equipment throughout production. Provide training and open communication for scorecard goals and work with managers and partners to ensure that these metrics are incorporated into departmental objectives and supplier agreements.
3. **Provide real-time visibility and enable real-time response** — Leading technology and analytic tools enable online access to product quality test results and monitor production equipment performance. This empowers quality engineers, production managers, and other decision makers with the ability to respond to uncommon situations before major issues happen.
4. **Create a culture of quality** — Most companies have an opportunity to improve quality by implementing Six Sigma and Lean manufacturing quality programs across the company and the supply chain. In addition to being able to meet the toughest quality standards, these programs should also define governance processes, and foster employee and partner growth and support through training and certification programs.

More informed consumers, continued recalls, and emerging legislation are putting manufacturers and importers under additional pressure to meet and beat quality expectations. By setting internal standards, empowering employees and leveraging technology, manufacturers should be better prepared to meet FDA regulations both locally and throughout the supply chain.

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Modern Tools: Cloud Data and Quality Control

This article first appeared in Industry Week as "China Embarks on a New Push for Quality"

As its economy slows, China looks to Six Sigma and other quality efforts to mitigate potential weaknesses.

"When you drink water, remember the spring."

This Chinese proverb reminds us of the connection between the spring, the water, and the drinker. The slightest variation in the source affects the quality of water that either quenches our thirst or sends us searching for another source. Similarly, the products made in China depend on the quality habits of the manufacturer, and ultimately impact a global customer base.

Chinese manufacturing is often considered synonymous with a large, focused workforce that produces goods with a premium on cost and convenience, perhaps at the expense of quality. However, the reality today is that China, like all industrialized nations, has a spectrum of quality that ranges from poor to superior. In the past, heightened demands for products allowed for quality discrepancies, but now a shift in consumer and production quality expectations creates new standards to reverberate through the manufacturing community.

As Growth Slows, Quality Is Not a Luxury

Over the past 30 years, China's economy saw an unprecedented boom with an average growth rate at 9.9%. The manufacturing industry in particular took advantage of the unparalleled growth opportunities in the Chinese landscape. With fewer environmental, labor, and regulatory hurdles than other nations, China's production opportunities were abundant.

In a new economy, with less demand and increased competition, manufacturers can no longer rely on abundance to drive down costs. In 2010, China's economy — the world's second largest — grew at a rate of 10.4%; in 2011 the rate dropped to 9.2%. The Chinese leadership set the 2012 growth target at 7.5% and for the first time is acknowledging that the economy is slowing.

A report by the World Bank and a Chinese government think tank, titled China 2030, offers an even more stunning outlook. According to the report, China's economy is in danger of a sharp slowdown as it transitions from a middle-income society to a high-income society.

China 2030 is an influential report among China's upcoming generation of leaders. It details reform and provides a roadmap that challenges China to transition away from the policies that brought so much success in the past 30 years, and approach the new challenges of the future in a very different way.

The Chinese government, along with its companies and citizens, has become acutely aware of the impact of quality on building its global brands and is taking steps to embrace and encourage change in its manufacturing culture.

The Chinese government is expanding its Certified Quality Engineer (CQE) system, promoting a National Quality Award program and deploying a series of initiatives on Lean Six Sigma, quality invigoration programs, and national quality legislation. China is making strides to advocate quality and reward those who support the initiative.

Professor Sun Jing teaches quality concepts at Tsinghua University in Beijing. Through her coursework, she sees first-hand how attitudes toward quality are changing.

"Quality was of almost no concern to Chinese manufacturers 20 years ago. Whatever was produced could be sold, high quality or not; the demand was that great. Today, manufacturers have a better understanding of the impact quality has on their business success," Sun comments.

Many U.S. companies have already implemented quality programs that take into account this new understanding and emphasis on quality. For example, Trek Bicycle Corp. works with Chinese manufacturers to supply specific parts for its bikes and looks for suppliers who share its same ideas on quality and have the same drive for smarter manufacturing.

"We selected our suppliers strategically based on their core competency and the ever-growing challenges of producing the highest quality, best performing products in the industry," says Stephen Anderson, Lead Quality Engineer at Trek.

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McDonald's is another U.S. company that is strengthening its emphasis on quality in China. When the Olympics air this summer, McDonald's will take advantage of the large Chinese audience with an ad campaign that portrays the Golden Arches as the fast-food brand in China with the best quality.

"We're not out to have the most stores in China, but we want to have the highest quality," noted Kenneth Chan, Chief Executive of McDonald's China, in a recent interview with the Wall Street Journal.

Building Change through Collaboration

Now that quality is on the forefront of China's manufacturing initiative, the challenge is for companies to work in a way that takes advantage of the country's strengths and mitigates potential weaknesses. Between 1997 and 2009, China invested in the expansion of its communications pipeline with the construction of a new network that brought 3G coverage to most of the country. This investment has huge implications for the masses of manufacturers and suppliers that are moving in the direction of sharing data with their vendors through the cloud.

Trek has leveraged its Chinese partners' internet access and enhanced its supplier relationships by opening avenues of real-time collaboration. The company has seven strategic suppliers in China that track key quality characteristics and push that quality data into the cloud.

Quality teams in Trek's Waterloo, Wisconsin-based headquarters can analyze and evaluate an incoming shipment as it is produced. If production begins to drift away from specification, both supplier and customer receive a real-time alert and can immediately work together to make corrections. This real-time collaboration creates a leaner manufacturing environment when compared to the alternative of waiting for the inventory to arrive, and then returning it halfway across the world if it does not meet the customer's quality requirements.

"Our suppliers in China are realizing the benefits of process control techniques and data analysis in new product development, as well as in production, with reductions in overall cycle time," Anderson says. "Developing this type of relationship with suppliers in Asia allows us to constantly increase market share through team work."

Proactive Quality through Collaborative Statistical Process Control

Add to those benefits the ability for Trek to gain true visibility into the enterprise by comparing process capabilities by line, shift, or plant. When adverse events begin to occur, the data guides Trek's engineers to quickly identify a cause and take corrective action.

"Making the process visual through control charts and capability studies allows for short and long-term process changes that ultimately drive down scrap and the need for sorting and rework," Anderson adds.

Post-mortem analysis is important for understanding why issues occurred in the past, but in order to excel, companies need to be proactive and keep small issues from becoming big problems.

When asked about collaboration and trends in manufacturing quality control, Sun responds, "Actually, it is not just a question; I think collaboration is a smart answer. Collaboration is the key to leveraging the major trends in Chinese manufacturing. Data and scientific management is becoming the most important factor of success for Chinese manufacturers. This is driving rapid growth in data-based process control tools."

Sun also predicts, "The area of data management is relatively new, but now businesses are starting to understand the impact of quality at every point in the product lifecycle. Those who are able to understand the real value of quality will be able to survive. Those who have the correct quality consciousness and are equipped with appropriate quality assurance weapons will be the ones that succeed."

Trek carries that quality consciousness into its plans for the future as the company builds its system out. "Trek's culture is focused on the absolute need to remain innovative. The next steps are built around more advanced statistical techniques and methods that are consistent with principles of Six Sigma and Lean manufacturing," Anderson says.

The economic, logistical, and operational complexities of international manufacturing are vast, but many of the solutions are quite simple. The technology today is optimized for international deployment, can fit into virtually any IT scenario, installs quickly, and is easy to use.

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With the growth and accessibility of data-driven decision-making, more and more companies like Trek are confronting enterprise and supply chain quality in a very serious way.

“When you drink water, remember the spring.” This simple concept, connecting the drinker to the spring, is driving innovation and streamlining global business processes in a way that no one 20 years ago could have dreamed. This shift is not something that is happening — it has already happened, and the manufacturers that will succeed are not the ones that spend the next five years trying to catch up.

Quality System Blueprints

This article first appeared in Control Engineering as "Are you Quality Obsessed? 7 Steps to an Effective Quality System."

How to Establish an Effective Quality System: Statistical Process Control (SPC) Can Help.

Manufacturers today are under more pressure than ever to ensure the quality of their product, especially given the growing number of strict industry regulations. If the smallest part or ingredient is out of spec and a recall occurs, it is not only the manufacturer but the entire supply chain that is at fault. All it takes is one negative headline about a defective engine or a contaminated package of spinach to jeopardize a brand's reputation.

The companies that avoid negative press are the ones that truly embrace quality as a business function and recognize the value of an enterprise quality system. These manufacturers exert a tremendous amount of effort to secure their respective industry standards — whether Six Sigma, the Good Housekeeping Seal of Approval, or positive reviews on CNET — and interestingly, all demonstrate the same habits when it comes to ensuring the quality of the products they produce.

By emulating the habits of these quality-obsessed manufacturers, you can make certain that a quality product runs through your facility and reaches the consumer, while making your entire manufacturing organization more effective along the way.

1. **Brag about your quality.** Customer satisfaction can make or break a manufacturer. Therefore, it is imperative to give upper management the data they need to build customers' confidence in your product. Sure, you can claim to produce a top-quality product, but sometimes your word is not good enough. Buyers want to see data that is meaningful to them, not just the required Cp (variation measurement) and Cpk (center tendency measurement). With a Statistical Process Control (SPC) solution, you can present upper management with data that quantifies quality in clear terms.

Most important, do not hide your data from the top brass; transparency is vital. To begin effectively bragging about quality, create a list of metrics and divide them into two groups: metrics that are impressive now, and metrics that, if improved, will help achieve higher organizational goals.

2. **Do what counts.** Now that you know the importance of data, keep in mind that more does not necessarily mean better. Data collected must have value, and should be concise. Consider the following when determining whether the data you are collecting is meaningful: If the data values significantly change from the norm during production, would the change lead to a corrective action? Also, if a corrective action is needed, is there a procedure in place to deal with it?

Before monitoring a process, make sure you have an effective sampling strategy and systems in place to take corrective action. Be sure to decide which employees can take action based on real-time data intelligence and provide them with the necessary reports to do their job the best they can.

How can you know who needs the data?

In the case where data is already being collected and reported, be bold and challenge the status quo. At one large airframe manufacturer, a new manager wanted to find out who needed or was even reading the numerous scheduled reports his department generated. He decided to stop all publications and wait for the phone to ring. He got all his answers in just a couple of weeks. Using the feedback from the few that contacted him, he completely revamped the reporting content and schedules.

3. **Give the process a leading role.** True SPC involves three components: the process, the test characteristics being monitored, and the part being produced. When collecting data, the most important of these factors is the process, as it controls the consistency of the final product and influences manufacturing as a whole.

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The process is needed to produce test characteristics, and test characteristics are needed to produce parts. Therefore, it is vital to include processes in your data collection and analysis. You will achieve new insights by monitoring even the seemingly smallest pieces of the process, such as which nozzle filled a particular container.

Remember the machines (processes) in your plant that are most critical to quality and make sure that you have a system that can measure their performance.

4. **Keep it simple.** With the right SPC software, capturing data should be a simple process. If data collection is difficult, an organization risks capturing inordinate amounts of meaningless data. Select an SPC platform that displays only what is helpful to the user. Visualizations, charts and even user-friendly spreadsheets are ideal. The software should also automate calculations and prompt users when specific quality checks are due. It's important to make sure that your shop floor systems are optimized for your shop floor environment so data can be accurately collected.

5. **Expect a value chain reaction.** Always remember, suppliers are an extension of your factory. The quality of the suppliers' products directly affects your final output. For example, what happens if an automotive manufacturer unknowingly assembles a car with a supplier's defective transmission? With cloud-based SPC, manufacturers can extend quality throughout the supply chain — all the way down to the suppliers — so the faulty transmission, for instance, never even makes it to the production line.

The transparency provided by cloud-based SPC will ultimately increase profitability for both the supplier and the manufacturer by reducing scrap. If you are considering implementing a supply chain-wide, cloud-based SPC solution, begin by discussing the value of sharing real-time data with your customers and suppliers.

6. **Always be vigilant.** Control chart plot points will send one of two messages: Do something or do nothing. As the "first life of a data point," both are equally important. When you see the "do something" message, you should be able to decide on a course of action simply by comparing the data point with the previous plot point.

You must also understand the natural process variations so that you know when to avoid taking action. Don't tamper with the process if the signals are telling you to "do nothing." Make the control charts more meaningful by finding the earliest possible point to capture the data and be vigilant with responding to those messages.

7. **Always dig deeper.** What happens to all the real-time data you've collected? A process capability database houses the once real-time data. You can use this database to gain insight on how to improve processes in the future. Even the simplest data, such as lot numbers and raw material suppliers, can provide value and help you pinpoint their effects on a process' output.

Furthermore, the process capability database can make additional calculations that can lead to more accurate business decisions on a variety of levels, including make/buy, scheduling, and raw material usage. You can improve your organization's ability to use data analysis to predict the future by identifying attributes that affect process outputs.

These seven simple steps will increase your organization's understanding of the impact quality has on operational efficiency and the bottom line. Data is your greatest asset for gaining visibility into causes of quality issues and quick analysis often equals quick resolution. The correct approach to quality control yields benefits ranging from reduced scrap, rework, and warranty claims to audit and recall management; from supplier benchmarks to customer satisfaction.

Perhaps more important, these seven steps lay the framework for making your company more data driven. By working smarter, you will eliminate the day-to-day headaches caused by fighting fires and replace them with a balanced, systematic approach to quality control.

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Do It Yourself

Article first appeared in Quality Digest as "Seven Criteria for Real-Time SPC Software."

Congratulations! You and your colleagues have made the decision to implement a Statistical Process Control (SPC) software solution.

Now what? There are many options to choose from, and deciding which product is right may seem to be a daunting task. At first glance, nearly all SPC applications look the same. Each creates control charts, histograms, capability indexes, and other statistical analyses. Most allow data collection for shop floor usage and have some kind of management-friendly reporting features. But of the hundreds of SPC software products that are available on the market today, what makes one better or different from the others?

With that in mind, use this checklist to narrow down the long list of possible SPC vendors.

Real-time vs. post-analysis

There are two main categories of statistical software that perform SPC functions: real-time SPC and post-analysis. Both products serve a niche and are not viewed as competitive. Post-analysis software is typically used on an office computer by engineers, scientists, and statisticians. They typically type or import data into a spreadsheet, then apply different statistical analyses to portions of the data. Post-analysis software is used offline, away from the manufacturing environment, and focuses on exploratory analyses such as experimental design (DOE) techniques, multiple linear regression, ANOVA, MANOVA, and other high-end statistical studies. Operators rarely, if ever, interact with such a product.

Real-time analysis is focused on data collection and analysis on the shop floor. Real-time SPC products are designed to be used by operators for collecting data at the time of manufacture and making that data instantly accessible across a corporate network. Real-time products often come preconfigured to allow communication with electronic gauges (i.e., scales, micrometers, and coordinate measurement machines). They also have a clear focus on SPC analyses such as control charts, histograms, and box-and-whisker plots.

With each new data point entered into a real-time system, quality professionals have the information necessary to make a process change or simply confirm that everything is running properly. An alerting/alarming feature is typical with real-time products so that operators and support personnel can take immediate action to adjust processes that are not performing as they should.

The remaining items in this article are focused on critical distinctions in real-time SPC software products.

Database design

Most SPC software can store its data in sophisticated relational databases. However, some SPC products don't use the abilities afforded by a relational database. Such SPC products use a flat-file database approach, where a single part requires that a separate, unique part file/databank/ data collection be created. The structure is flat in that it only houses data for a single part. Control limits, data values, and specification limits are housed within these data files.

Because most manufacturing companies produce hundreds of different part numbers that can be manufactured on a variety of processes, the total count of unique data files/databanks can be staggering. Therefore, the use of a flat-file system can be extraordinarily difficult to maintain, especially when you have a large number of parts and processes to monitor and control.

SPC software products that use a relational database design require far less maintenance and are much simpler to manage.

The easiest way to determine if the software uses a relational database is to perform a simple test. Take a common feature name (like overall length) that is shared among several part numbers. Let's suppose that you check overall length on 100 part numbers. To match operator terminology, say that you now decide to change the name from overall length to "OAL."

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To perform this task, do you:

A. Have to go to 100 places where “overall length” was used and change the text to “OAL;” or

B. Go to a single place in the database and make the change once?

If the answer is B, then your SPC system is using a relational design and managing it is simple: A single name change can occur once, and all previously stored data will automatically become associated with “OAL.” If you must go to every part file/databank/data repository to change the name, then it is a flat system, and it will take a great deal of time and patience to make changes.

Using a relational database design will allow you to efficiently manage all aspects of the SPC system. Issues that may be related to a flat database are:

› Administrators, engineers, and managers will need to hunt through lots of different files for part-specific data or process-specific data.

› You will need an extremely large database because flat files are inherently inefficient. They leave lots of empty holes in the database that take up room, but do not actually store any information.

› Any updates to specifications, part names, test names, or process names will require a massive search-and-replace effort among all affected files.

› Charting and analysis are limited to the data that reside in a single file. Any cross-analysis among multiple files is either not supported or requires lots of copy-and-paste routines to bring the data together.

› The bottom line is that relational database design was created to make an SPC deployment easy and also to make the administration of the system simple, fast, and efficient.

Data-collection flexibility

Regardless of which SPC solution you select, you will need to set up data-collection routines and create analyses. Both should be flexible. However, configuring a data-collection plan should not only be easy; it should also be flexible enough to allow data collection for many different part numbers, even if those parts have different specifications.

Developing a data-collection routine is critical to the success of your SPC solution. The result should be data-entry simplicity for operators. They should find it easy to enter data for many different part numbers without being required to browse through hundreds of part files or spreadsheets. Nor should operators be required to exit the SPC application, hunt through many menus to find what they need, and then reopen the SPC application. Instead, operators should be able to select their part number and enter data without extraneous effort.

What about an operator who is running two or more machines (i.e., processes) at the same time? The data-collection routine should be flexible enough to accommodate not just hundreds of different part numbers but also all of the processes that the operator might be running. That is, a single data-collection routine should be flexible enough to manage data entry from any part and any process for which an operator is responsible.

Having flexible data-collection routines also benefits the SPC system administrator, making it easy to create and deploy data collection. Not only should the software be easy for operators to interact with; it must also be efficient for an administrator to set up and maintain.

Data-analysis flexibility

To uncover the most meaningful improvement opportunities while maximizing return on investment, SPC software must incorporate flexible analysis features. Although beneficial for shop floor use, a control chart only helps to control one process at a time. Most dramatic cost reductions come from comparing and contrasting many different processes, parts, shifts, and other items. By doing so, statisticians and engineers can identify critical differences and solutions that can save the company a lot of money.

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Make certain that any chart can display any data that resides in the database. To support this requirement, SPC charts should be generated using database queries. Queries should be easily modifiable to allow the viewing and comparing of any data you wish, even if specification limits are different from part to part.

To make fair comparisons between different parts, machines, and features, SPC software should also accommodate normalization techniques that can be applied even after data have been entered.

Make certain that your SPC software will handle data normalization on the fly. Users should have the option to collect data any way they want and not have to worry about how the data might someday be analyzed.

From an analysis standpoint, changing the query should be a snap. Data normalization should be simple as well. The SPC software that you're evaluating should have this level of flexibility in analysis. By supporting these flexible options, your SPC software should equip you to uncover meaningful opportunities for improvement and cost containment.

Correct control limits

For a control chart, it's critical that control limits are calculated properly. Not doing so can lead to a lack of alarms when emergencies actually exist, as well as to the creation of alarms when they do not exist. Either way, your SPC software must correctly calculate control limits, or you could be in trouble.

Here are three items to consider when determining whether your system correctly calculates control limits:

› Control limits should be based upon the process that made the part.

› Control limits should vary when subgroup sizes vary.

› Control limits should never be automatically recalculated.

First, control limits should be unique based upon a part number, the feature checked on the part, and the process that made it. When the same part is run on a different machine (process), then the control limits should change. If the software that you're evaluating calculates control limits solely based on a unique part and feature, it is leaving out of the equation the very thing we are trying to control: the process. Isn't that why we call it statistical process control?

Second, SPC software products should calculate control limits uniquely when subgroup sizes change. This should be true for the ubiquitous P-chart (for analyzing attributes data), but it should also hold true for variables data as well. For example, say an operator is required to enter five variable data values during each data-collection period. If one of the cavities in his or her mold, for instance, is plugged and only four data values can be entered, then X-bar control limits for the four data values should be wider than for a subgroup of five. If the SPC software doesn't change control limits when subgroup sizes change, it's statistically flawed.

Third, control limits should never be automatically recalculated. They should only be recalculated when a statistically significant, sustained change in the process has occurred. For example, imagine that your process has an ever-so-slight upward drift. Being slight, this drift is not perceptible unless you look at the data over several weeks. Now imagine that the control limits are automatically recalculated every seven days or every 50 points. If so, then the drift would be masked as the mean continues to slowly move upward. Therefore, it's possible that this important trend could be missed.

This is only one of many examples as to why control limits should never be automatically recalculated. Software that offers this feature indicates that either developers do not truly understand the nature of control limits, or they're not concerned about the statistical veracity of their reported control limits.

If any of the three items above is true, then the software you're evaluating violates fundamental statistical principles. Look closely and be careful: You don't want to select a statistical software package whose control limits fail to trigger alarms when they should.

Access to electronic media

Data collection on the shop floor should be simple and visually oriented. During data collection, the most useful SPC software products present part drawings to operators and visually walk them through the data-collection.

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Engineering drawings and photos presented to the operator should dynamically update when changeovers occur. When a new part is being made, the data collection sequence should update with the new engineering photos and the areas on the new part that need to be checked. In other words, the best SPC systems keep data-entry simple and visual for busy operators.

Additionally, operators should have instant access to important electronic media, such as engineering drawings, standard operating procedures, training videos, recipes, and work instructions. There should be no limitation to the type of application that can be opened. Doing so not only helps create a paperless shop floor environment, but it also provides the information that operators need to do their jobs the right way the first time.

Support

The best SPC companies put a lot of time and money into support services. To ensure that your provider will live up to its bold claims, put their support to the test:

› Call the company's application support during your evaluation period. See if you can reach them via phone and if they can effectively answer your questions.

› Speak with one of their in-house statisticians. Ask him or her some challenging SPC questions that relate to your business.

› Talk with some of their training staff. See if they can answer questions about setup and gauge communications.

› Call the implementation engineers. Ask them to tell you about the challenges in their last onsite installations.

› Make sure that the support staff has the ability to view your PC and work with it using safe collaboration tools such as WebEx.

All of these phone calls will help ensure that a vendor's technical support isn't just performed by harried, overworked programmers who use their tiny bit of free time to answer a couple of customer calls.

Any vendor of SPC software should employ industrial statisticians. If they're selling statistical software, you should expect them to provide statistical expertise, consulting, and advice. If they don't have statisticians in an SPC software company, it would be like taking your car to be fixed by an auto dealership that has no mechanics.

Look for thought leadership. Does the company employ experts who regularly give back to the quality community? By doing so, the SPC software company demonstrates that it is not just interested in your pocketbook, but is instead intent on delivering important statistical information and advice that can help you create the very best SPC system possible.

Summary

Hundreds of companies can create a control chart of data, but not many can manage your demanding needs. If you are serious about getting the best SPC software, focus on the items in this article and you will be able to separate the SPC software contenders from the pretenders.

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