

Whitepaper

Infinity<sup>QS</sup><sup>®</sup>  
Quality Re-imagined

## Quality Re-Imagined

Do more than “manage” quality—  
use it to transform your business.



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# Quality: From Problem to Solution

**Tired of quality problems? Change your perspective. Stop thinking of quality as a final checkbox to be marked. Start envisioning the true value of the quality-related data that is available across your enterprise. Reduce waste, streamline audits, optimize processes, impress customers, and improve competitive strategies — all by re-imagining the role of quality in your business.**

Quality seems to be a never-ending problem for manufacturers, regardless of industry. Systems for tracking product quality are often seen as burdens that must be shouldered to avoid greater costs down the road. You can be drowning in quality-related data, yet still find yourself hit by recalls, rework, and regulatory audits. How do you solve the quality problem?

The surprising answer: Stop thinking of it as a problem.

Too often, quality-related data is scribbled down on paper forms, lumped into spreadsheets, and ends up gathering dust in filing cabinets or siloed in databases or file servers across your organization. But with the right approach — and the right tools — you can use that data not just to improve your products or boost operational performance, but to transform your business into an industry leader. **It's time to re-imagine quality.**

## The Quality Conundrum

From food recalls to faulty auto parts, quality issues can have devastating effects on any manufacturing organization's reputation and earning potential. Trying to track quality issues across processes within a plant — or worse, across sites that are scattered around the globe — consumes time, resources, and cash. Whatever your industry, whether you're a small manufacturer or a global brand name, you're likely scrambling to find a solution to the "quality problem."

- › **Food and beverage.** Food and beverage manufacturers are all too familiar with the importance of quality — and the costs of maintaining it. Tight, complex regulatory standards demand quality checks at multiple stages of production and packaging. Quality failures can result in violations of regulations from the U.S. Food and Drug Administration (FDA) and other safety-control agencies — and hefty fines. Manufacturers constantly deal with meeting fill or weight requirements: Underfill, and you need to rework or scrap product to avoid violating Label Stated Content and Maximum Allowable Variation (MAV) or Tolerable Negative Error/Limits of Error requirements. Overfill, and you risk going over budget on materials. Automated processes, such as container fill and closure, must be monitored to avoid waste and help ensure compliance.
- › **Life sciences.** For medical device and pharmaceutical manufacturers, nonconformities can literally be a matter of life or death. Fill and count requirements, acceptance sampling, and traceability pose extra demands for these manufacturers and their personnel. Quality data is crucial but often difficult to access. For many manufacturers, simply getting off paper systems and onto digital data collection is a primary objective. And because any system that you implement must go through a time-consuming and expensive validation process, choosing the right system is critical.
- › **Automotive and aerospace.** Whether you're machining components or manufacturing electronics, precision is key. Adhering to demanding customer specifications requires traceability, real-time visibility, compliance to procedures, and process optimization. Sophisticated measurement equipment and gauging are used to verify product conformance and provide the reports that customers require. All these efforts are used for the ultimate goals of minimizing scrap, rework, and downtime while maximizing production throughput.
- › **Packaging and general manufacturing.** Consistency matters. In addition to dimensional specifications, visual defects are a major concern to many manufacturers. As many companies expand to multiple locations, the challenge to produce consistent product is multiplied by the difficulty of maintaining standard, consistent processes. This issue is especially prevalent when sites or staff are added during mergers or acquisitions or when businesses expand internationally. Getting the same information from different legacy systems can be difficult and time-consuming. Implementing new solutions across various entrenched infrastructures and operating systems can be downright nightmarish.

Regardless of your industry, finding a way to standardize and make the most out of quality data is a pressing challenge for manufacturers. As part of this effort — and thanks to technology trends— many organizations end up with an overload of data, including (but not limited to) the following:

- › Product data collected by operators, lab technicians, and so on
- › Product data from inspection equipment such as coordinate measuring machines (CMMs), vision systems, and others
- › Regulatory- and compliance-related information
- › Supplier and raw-material data
- › Process data from automated systems
- › Disparate quality results from standalone systems acquired over time

But what happens to all this information? Too often, the answer is “not much.” Sure, if a flaw or fault is noted, you go into firefighting mode. And when audits roll around, you spend hours or days sifting through reams of paper or loads of Microsoft Excel files to pull together the necessary reports.

Many companies hope to use this data to reduce recalls and rework or to cope with audits. But they have no way to share and apply their information beyond a single line or plant.

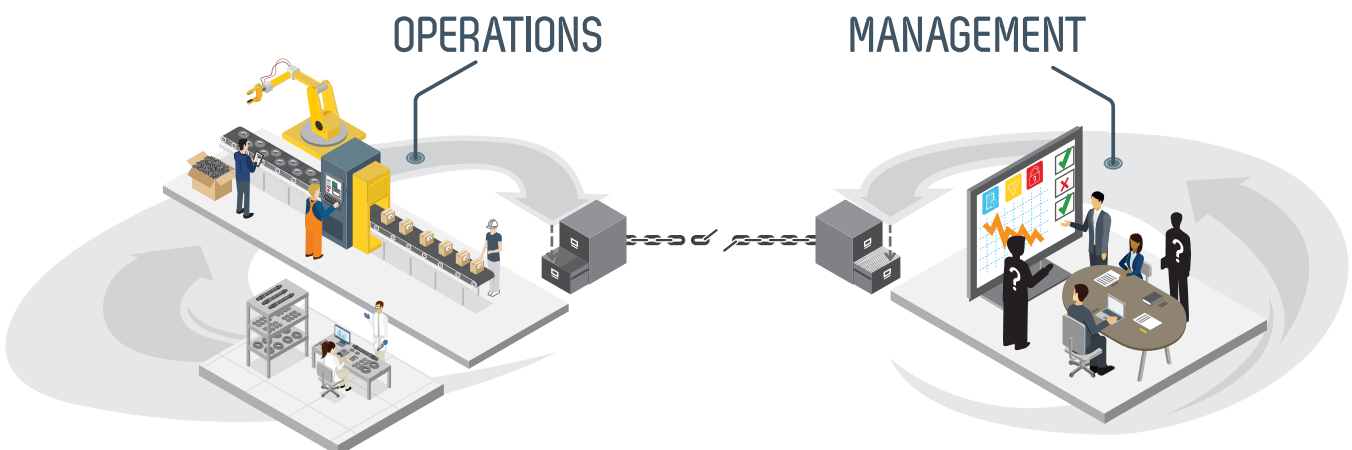
**Most can't imagine that this same information could be the key to unlocking dramatic improvements in yield, compliance, and resource utilization — without extra equipment, costs, or resources.**

But with an aggregated, end-to-end view of production sites across your entire enterprise, you can do more than stop the line when a problem is detected. You can formulate strategic insight that drives continuous transformation in quality, processes, and overall operations.

## Before: SEPARATED & SILOED



When data is scattered and non-standardized, it's impossible to visualize and analyze what's happening — in real time or over time.



## Re-Imagine Where Quality Can Lead You

When your organization *re-imagines quality*, quality management becomes an ongoing, transformative opportunity for the whole enterprise.

You begin to do more than just collect and respond to data. You can mine your supply chain, production lines, and more for actionable insight that sparks continuous improvement — not just for one product, but across entire lines, sites, and operations.

Where does this process start? You'll want to consider a Manufacturing Intelligence solution that can help you do more than just check quality data for problems. When evaluating options, look for the following functionality:

- › **Go digital.** First, you need a solution that can work with your existing infrastructure to pull in quality data directly from your processing lines and equipment. Ditch the paper checklists — and the human error that often accompanies them. Manual entry is susceptible to mistakes driven by fatigue, distraction, or a desire to impress management. Plus, manually recorded data means added time for re-entry into databases or reporting systems.
- › **Look for extensive, targeted functionality, off the shelf.** You might think that the free “bolt-on” quality features that come with some ERP solutions or measurement systems are a good deal. But such systems are far from robust and can hamstring manufacturers. Invest in an established quality system to get the best functionality from a vendor who specializes in and understands quality. Look for a system that delivers extensive, configurable features off the shelf; custom coding costs more up front and eats up more cash in upgrades and support.

- › **Stay flexible.** The ideal solution gives you the flexibility to determine which types of information to accumulate, how often, and at which level of granularity. Your intelligence solution should provide a method for establishing parameters — and for alerting and notification when quality strays outside those boundaries. Make sure the system you choose can collect the kind of data that is important to your organization, in a way that works for your operators. In addition to collecting the data in real time, the system should store that data for use in strategic decision making.
- › **Unify data.** Speaking of storage, look for a solution that provides a central, *unified data repository*. Too often, manufacturers collect data only to find it siloed, non-standardized, and difficult to integrate. Centralized storage and reporting provides the means to get a big-picture view of what's happening across time and across shifts, lines, and sites — even when those sites are in different regions or countries.
- › **Simplify and save.** Naturally, any solution should be efficient to deploy and easy to operate. Look for a solution that doesn't demand additional expenditures to upgrade your legacy systems, meet a steep learning curve, access “premium” functionality, or scale out as your implementation — or available technology — advances. Watch out for systems that offer fast, inexpensive deployments but then require you to redo your work over and over again or buy new add-ons any time you want to add functionality or product numbers.
- › **Standardize and customize.** Advanced reporting and configuration capabilities are important in getting full benefits from your quality transformation. Standardized options save time and resources. Yet the solution that you choose should also be configurable to meet your reporting needs and customer demands. And your vendor should be willing to provide a customized demo, so you can see what the solution can do to meet *your* unique needs.

With these capabilities, you move beyond a *reactionary* mindset and into a *proactive* quality approach. The result? An ever-enhanced organization, unified and focused on the combination of product quality, time to market, and profitability.



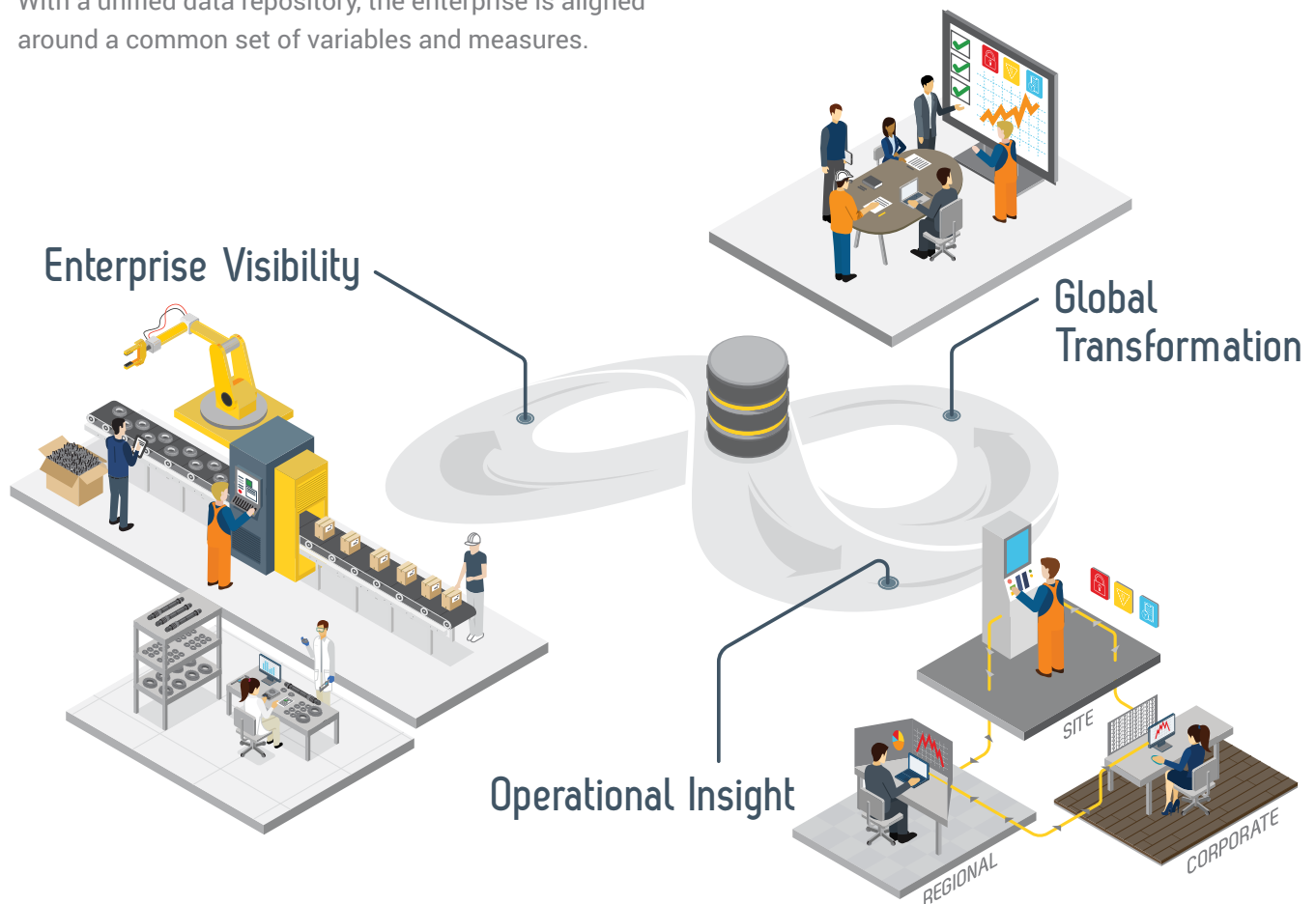
# Transform Quality—and Your Business—with the Excellence Loop

The process of re-imagining quality creates a cycle of continuous improvement — something that the enterprise-quality experts at InfinityQS® call the *Excellence Loop*. Unification of all your quality data provides **enterprise-wide visibility** into every operation and product. With this visibility, you gain true **operational insight** that can fuel not just improved product quality but also proactive, strategic decision making. You gain the ability to **globally transform** your business through process improvements, cost reductions, and better resource utilization.

After:  
**ALIGNED & INFORMED**



With a unified data repository, the enterprise is aligned around a common set of variables and measures.



## Enterprise Visibility: Start with What You Have

When you unify all your quality-related data, from all sources, into a standardized and centralized database, you can visualize more than the quality of a single product. You get real-time visibility of your entire enterprise, from end to end — including suppliers, incoming inspection, raw materials, in-process checks from shop floor operators and the quality lab, process data, packaging, and finished products.

In yesterday's paradigm, you manually collected and stored data from one process or site. Quality systems were in place simply to enable you to fix any problems that popped up. After the problem was fixed, you were done with the data.

But today, you have the ability to collect data from practically every angle and at both the micro and macro level. This capability gives you access to incredibly precise, rich data from across all your lines and plants. And that data can point not just to problems you need to fix, but to the greatest opportunities to streamline processes, reduce costs and safety risks, increase yield, improve precision, and more.

In the food and beverage or pharmaceuticals industries, for example, filling a specified amount of product is critical. Regulatory and economic concerns mandate how much product must be in each package. Underfilling results in regulatory issues, whereas overfilling equates with lost profit. A quality system that provides true Manufacturing Intelligence gives you both real-time and historic visibility into all your filling lines so that you can easily determine which lines present regulatory concerns as well as which lines are giving away the most product (see **Figure 1**).

This same principle of understanding and reducing variation applies to every industry. Gaining visibility into all your quality data — and being able to access all that data from one location — enables aggregation and analysis that you can use to improve not only your product quality, but also your profitability.

Note that the unification of data is a major factor of true visibility. Beware of solutions that store quality data in silos across your enterprise. When your data is stored in such a fragmented way, you only get a micro view: What's in front of you here, today. A solution that aggregates data into unified, centralized storage can give you the long-term, large-scale view that puts your decision making on the next level.

Also, watch out for products that demand systems changes or upgrades to roll up data to the enterprise level. Yes, aggregation requires standardization, but look for a solution that can work with existing systems and a multitude of databases and technologies. And ask about self-service reporting capabilities, which can significantly reduce your use of IT resources.

## Food producer cures reporting and overpacking headaches

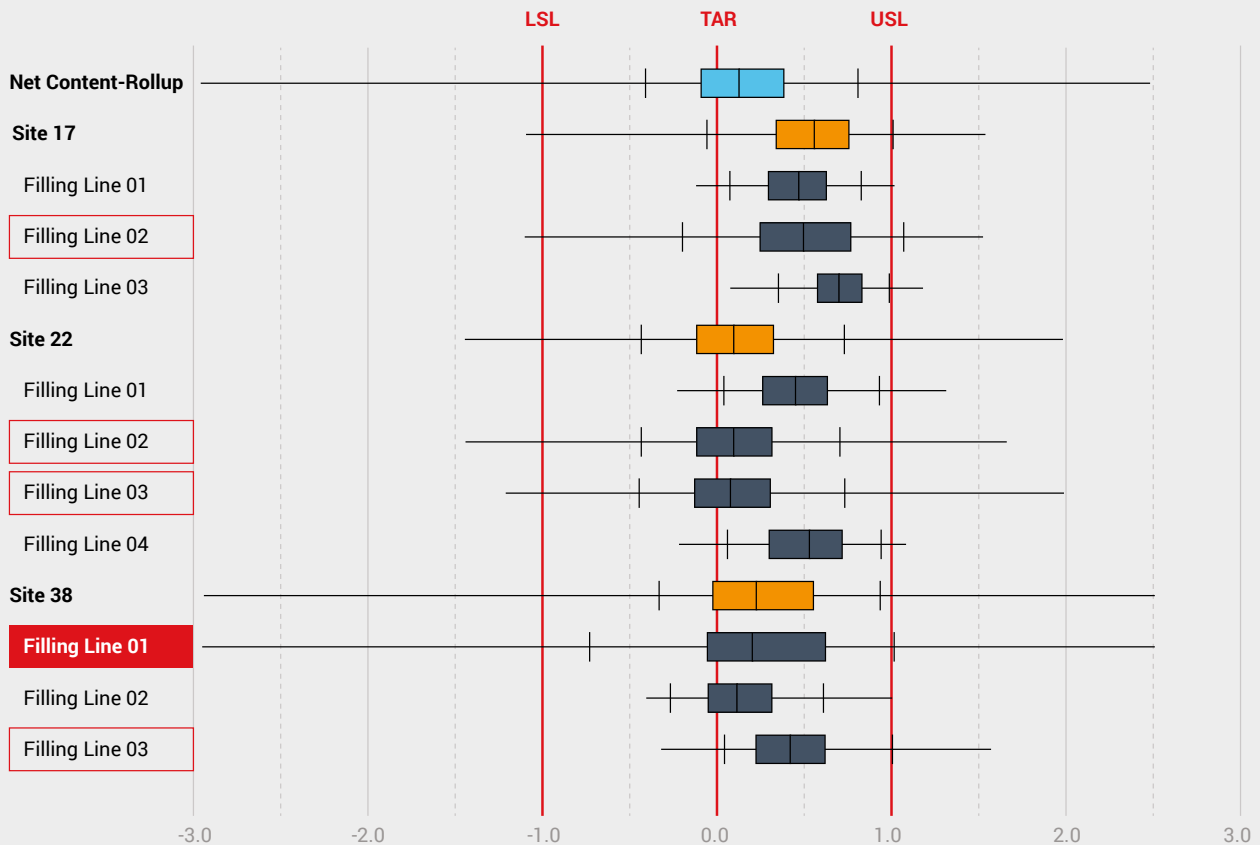
For many manufacturers, eliminating paper-based data collection is as far as they've imagined. And it's a fantastic first step. But don't stop here — there's so much more you can do with your quality data.

For example, one major U.S. food manufacturer deployed the InfinityQS ProFicient™ quality management solution to streamline quality control and move away from its cumbersome paper-based system. Hours were being wasted as employees manually recorded individual readings, calculated averages, plotted paper charts, and performed manual calculations — yet product was still being lost through overpacking.

With the InfinityQS solution, the manufacturer was able to identify opportunities to improve run capability and raw material usage, resulting in increased cost savings and a higher-quality product. With the InfinityQS solution's advanced reporting suite, the manufacturer can now run reports in seconds, down from as many as 10 hours previously.

Figure 1

### Why should you use box-and-whisker plots?



Box-and-whisker plots are a great way to make comparisons, both visually and quantitatively. Visually, you are looking at a histogram from the top down, allowing different distributions to be compared to each other. Quantitatively, the box-and-whisker locations allow you to see what proportion of the data is out of specification — or nearing that point. When properly normalized, a box-and-whisker plot allows you to make comparisons between different products, processes, and even features on a single plot.

One powerful aspect of a box-and-whisker plot is the ability to roll up data and begin to answer some questions. For example:

- › If this was your organization, would you be pleased with the overall performance of Net Contents?
- › If you have limited resources to send to a site, which site is having the most problems?
- › While many of the filling lines shown have non-compliant product, which filling lines can be easily adjusted to avoid non-compliance? Maybe the knowledge and/or setup from those lines can benefit other lines.
- › Maybe equipment differences justify budgeting for equipment upgrades, maintenance, or operator training.



## Operational Insight: Analytics to Use What You Know

Do you know which production lines or sites run your products most consistently? How about which cause the most headaches? Do you know where to focus your improvement efforts to get the biggest gains? Do you know what visual defects are affecting your products, which products are at the highest risk, and where these products are produced? Do you know whether the third shift is performing as well as the first and second shifts?

*Most important: Do you have the data to back up any of your conclusions?*

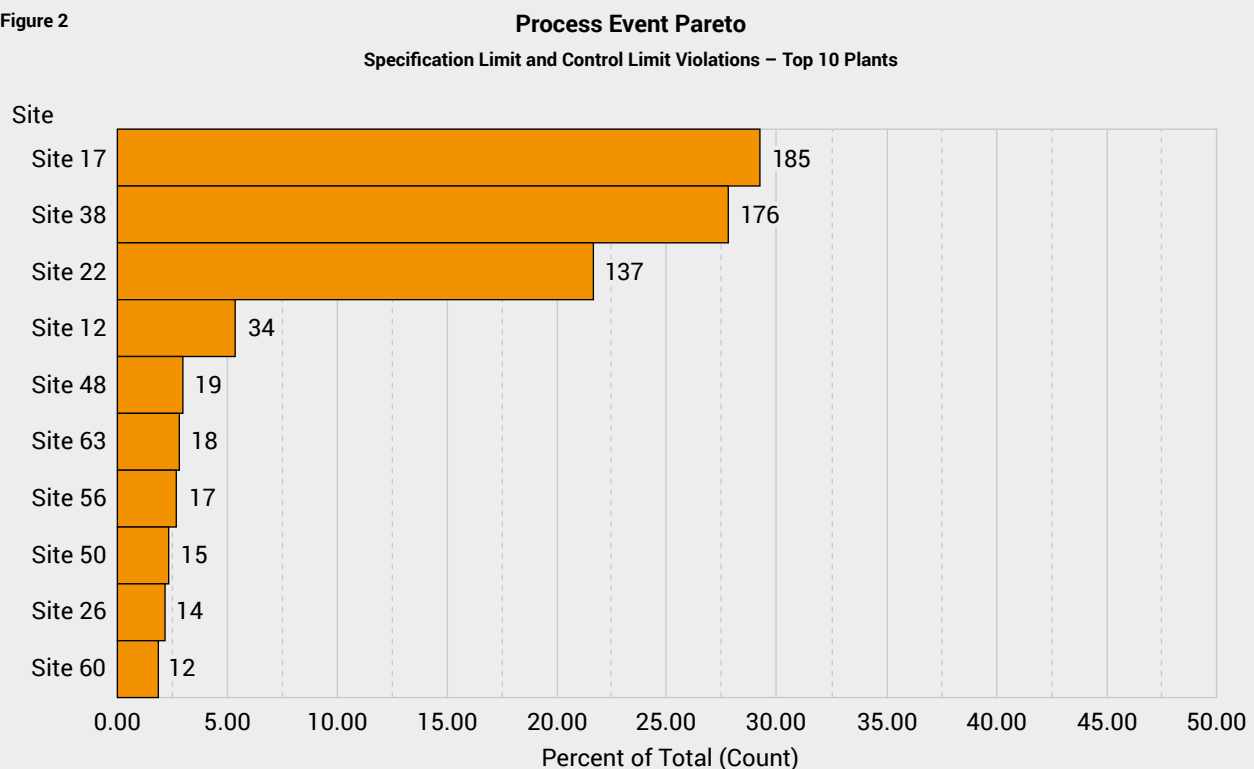
With your supply chain and production line data unified and easy to access, you can generate useful and actionable insight about your processes, suppliers, and manufacturing operations. Improved analytics and reporting enable you to begin to apply best practices consistently across all plants, lines, processes, and products.

The answers to your biggest questions and concerns are suddenly at your fingertips, rather than buried in a sea of data.

To reap these benefits, look for a Manufacturing Intelligence solution that features a top-notch analytics engine and intuitive reporting options to sort through to the most important points and to make your data more easily consumed and understood. When you demo products, ask for a good look at reporting options – and suggestions on how to get the most from them.

For example, suppose that you're collecting data at 50 manufacturing sites and want to determine which sites are having the most issues. Can you get that information quickly? Better still, can you identify which specific processes at those sites are to blame? You can – if you're using a quality solution that supports strategic operational insight (see **Figure 2**).

Figure 2

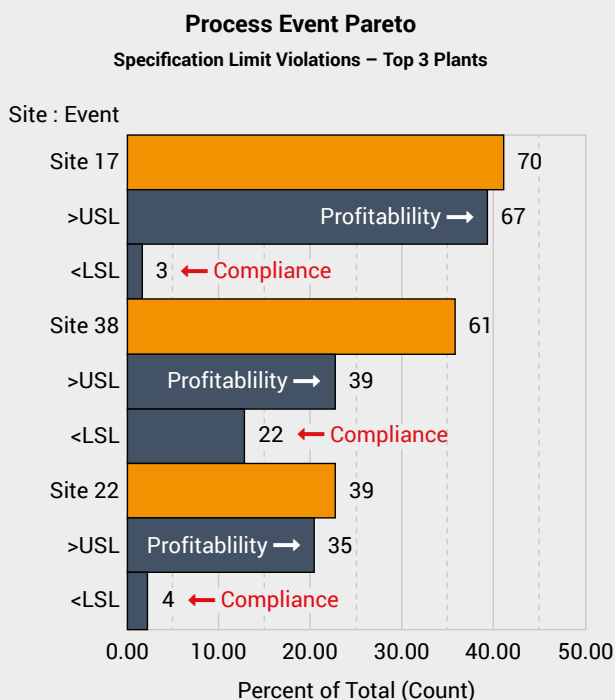


When looking at an organization with many sites, an important first step is to understand which sites, if any, require assistance. A pareto chart that documents events such as exceeding specification limits can allow you to easily determine whether you have “problem sites” that should be addressed. In this example, Sites 17, 38, and 22 have significantly more events than other sites.

With the right data and the right system, you can easily return information about your products, processes, shifts, employees, jobs, lots, production orders, suppliers, and just about any other criteria.

But returning that data is just the beginning. The real power is the *insight* that the data, combined with your experience, provides. Such simple yet powerful analysis can help you determine exactly where to send your resources and which kinds of issues they will face (see **Figure 3**).

Figure 3



Drilling into the data can reveal more information about the sites that were identified. In this example, overfilling (exceeding upper specification limit: >USL) means lost profits and underfilling (exceeding lower specification limit: <LSL) means compliance issues. Depending on the severity of the type of event, you may prioritize sending more resources to one site or sending different resources to address the specific issues. Visibility into data is often not enough; putting it in the context of your operations allows you to make sense of the data and formulate the best actions to take.

## A single setup delivers infinite possibilities

An automotive company integrated the InfinityQS solution – which uses a relational database structure – with its legacy MES and ERP systems to provide detailed, real-time quality analysis at the process level. This deployment gave the company the versatility to support an analysis of parts across production processes and to quickly and easily manage thousands of parts in a single setup (as opposed to the hundreds of thousands of data files that other systems would have forced it to configure).

Comparative analyses of any part, across any process, is now available with just a few clicks of a mouse. The manufacturer can drive and sustain continuous improvement, monitor processes to ensure effectiveness, keep adequate records, and apply CAPA where necessary. Process improvements on one line, in one plant, led to **\$400,000 in annual savings**.

Note that a major aspect of successful analytics and reporting is ease of use. The InfinityQS solution provides easy-to-configure, flexible, targeted reports. You don't need a statistician to interpret them — but the statistics and manufacturing experts at InfinityQS are happy to help you find the best functionality to meet your needs.

The InfinityQS solution also makes data more readily available so that you can get immediate reporting results and extensive reporting possibilities. Now you can see variations from part to part, shift to shift, day to day, month to month, and so on. Processes are dynamic and have natural variations. By studying them across time, you can determine vital information, such as which processes or practices provide the best efficiency.

As you can see, these evaluations needn't be a complex undertaking. Now that your data is unified, you can pull up the data you need in minutes, not days.

**One InfinityQS customer went from spending a day and a half gathering audit data to 15 minutes. Another reduced a mock recall from 4 or 5 hours to half an hour.**

Beyond the gains in responsiveness, think about the hours of labor that these capabilities can save — hours that can be spent improving your processes and products.

This level of insight opens up a new realm of possibilities for your company. You're no longer stuck in reactive mode, putting out fires as problems crop up. You're using your quality data to plan ahead, perform better — and outpace the competition.

### **Global Transformation: Go Beyond the Reactive**

And now comes true, global transformation for your business. You have the capability to apply your insights to streamline, optimize, and transform processes and operations, across the enterprise. Unified, aggregated, historical insight initiates continuous improvement.

You can now tell that a particular line runs better than others at the same facility. In addition, you can determine why, and better yet, how to make *other* lines in other locations consistent with that level of performance. You see which factors matter, and which don't. You begin to streamline all your processes. Consistency and efficiency increase throughout and across production sites. You get hard data that verifies results and enforces accountability. You no longer think just about what you did yesterday but about what you *can do*, tomorrow or next year. And you begin to see real, measurable benefits to your bottom line.

### **Experience true transformation**

A global beverage manufacturer, whose IT department drove an effort to improve quality documentation and analysis, needed to deliver real-time visibility within individual sites and across its dozens of factories — while keeping its existing IT infrastructure intact.

By tracking trends in quality data, this company uses the InfinityQS solution to launch process improvements, conduct vendor comparisons, reduce unnecessary testing, and configure real-time alarms at individual sites and at the corporate level across all its locations.

## Get Excited About Quality

Of course, humans are naturally resistant to change. Implementing a new quality system — especially one that can promote such drastic transformation on an enterprise scale — can meet some initial resistance.

One solution is to start a guided demo or pilot on one line or workstation while involving your site's operators, managers, and engineers. Get their input on their most tedious, time-wasting tasks: the data that takes forever to record, the measurements that are difficult to track, the reports that they wait hours to receive from IT, the analyses that chew up time and resources.

When these team members experience the results of automating measurement-device outputs, efficiently grouping

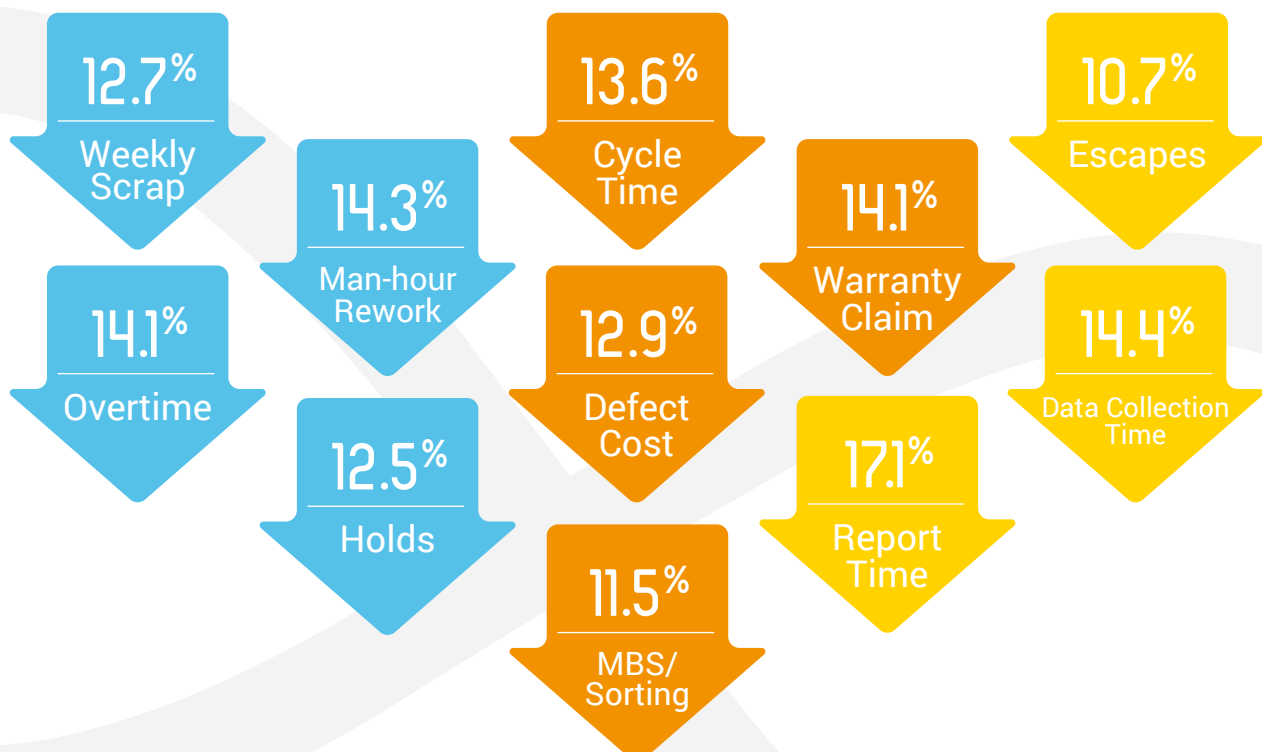
and ordering tests, and transitioning from paper to electronic data entry — and see how they can free up time for other, less tedious tasks and deliver results at an exponentially faster rate — you might find operators and supervisors queuing up to be next in line for deployment.

Are you excited about your quality data? With the right manufacturing intelligence, you will be. Re-imagining quality — across one process, one site, or your entire enterprise — opens up an infinity of possibilities. Improve your process. Increase efficiency. Impress customers. And don't break the bank in the process.

It's all possible. **You just need to re-imagine it.**

## Measurable Results

InfinityQS has helped hundreds of companies around the globe fundamentally improve their manufacturing processes. Our clients report significant reductions in their costliest metrics<sup>1</sup>:



<sup>1</sup> Source: InfinityQS Customer Survey, 2015.



## About InfinityQS International, Inc.

InfinityQS International, Inc. is the global authority on enterprise quality. The company's manufacturing intelligence solution delivers unparalleled visibility across the enterprise, from the shop floor to the boardroom, enabling manufacturers to re-imagine quality and transform it from a problem into a competitive advantage. Powered by centralized analytics, InfinityQS solutions provide operational insight to enable global manufacturers to improve product quality, decrease costs and risk, maintain or improve compliance, and make strategic, data-driven business decisions.

Headquartered near Washington, D.C., with offices in Seattle, London, Beijing, and Shanghai, InfinityQS was founded in 1989 and now services more than 40,000 active licenses with more than 2,500 of the world's leading manufacturers, including Kraft Foods, Ball Corporation, Boston Scientific, Graham Packaging, and Medtronic. For more information, visit [infinityqs.com](http://infinityqs.com).

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