If a typical process engineering review meeting at your organization involves engineers staring at scores of presentation slides and feeling overwhelmed, you may want to consider the metrics you're using. High-level metrics like throughput yield and scrap may seem like logical choices for regular product reviews, and they are useful at a business level; however, they tend not to trigger actionable improvement discussion.

In contrast, the same powerful tools that engineers use in their everyday product development and process management applications can have enhanced benefits when put to work for broader decision making about improvements. Integrating tools like failure mode and effects analysis (FMEA), gauge repeatability and reproducibility (GR&R), and statistical process control (SPC) provides a quality improvement framework that organizations can use to monitor process health, prioritize improvements, and assign resources to actions that warrant most attention.

Figure 1 shows how FMEA, GR&R, and SPC can be analyzed in the context of relationships between critical to quality (CTQ) and critical to process (CTP) parameters, leading to creation of a “process health card.” In eight steps, you can build your own process health card and begin using it at your engineering review meetings. With your focus strongly on metrics of practical interest to product and process engineers—GR&R results, SPC stability status, and the potential risk to the organization of rejecting good parts or accepting bad parts (misclassification) which impacts the organization’s cost of poor quality—you should find it easier to engage in the actionable discussions that the meeting should foster.

Step 1: Identify CTQs and CTPs

It is not unusual for the different product lines in any business unit’s portfolio to have many quality characteristics in common and others that are entirely unique. Defining and documenting quality characteristics for each product line is a crucial activity that should be the responsibility of cross-functional teams.

First, assemble a team consisting of product line management; account management; and research and development, quality and manufacturing engineering, and customer representation. Where customer representation is not practical, the quality department, marketing, sales, or account management should provide support on behalf of the customer. This team is assigned with critical to quality (CTQ) characteristics identification.

For the same product line, assemble a second team for the purposes of critical to process parameter (CTP) identification related to the CTQs. Include manufacturing, quality, equipment, and production engineers, and invite R&D engineers where applicable. It is beneficial to maintain the team members of R&D, quality, and manufacturing engineering from the CTQ team in the CTP identification exercise.

The team assigned with the task of identifying the critical to quality characteristics should use resources like voice of the customer tables, customer surveys, scorecards, market needs, engineering specifications, and contracts to identify basic and perceived requirements and delights for the product. The team should further brainstorm any new expectations for the product. (This exercise will yield critical to quality characteristics that are both qualitative and quantitative, but this article focuses on the quantitative.)
This eight-step model begins with CTQ and CTP identification and leads to the creation of a process health card. Integrating tools like FMEA, GR&R, and SPC provides a quality improvement framework for monitoring process health, prioritizing improvements, and assigning resources.
Next, the team assigned with CTP identification starts a brainstorming discussion. The inputs come from a combination of historical product knowledge, experience with the product, quality tools like cause-and-effect diagrams, and statistical methods like correlation and design of experiments. The output should be a set of CTPs for each CTQ. The need-CTP tree diagram in Figure 2 offers a helpful way to represent this process visually. See slide 9 of the accompanying presentation for a specific example.

**Step 2: Create a CTQ-CTP Relationship Matrix**

Existing products under regular review should already have CTQs and CTPs identified, and relationships between them should be understood. If you have not formally documented them, hold a brainstorming meeting to develop a relationship matrix. Figure 3 illustrates the concept of the relationship matrix; a detailed example appears in slide 11 of the accompanying presentation.

As you and your team identify a relationship between a CTQ and a CTP, collectively agree on the degree of that relationship, classifying it as significant (triangle), moderate (circle), or weak (square). Inputs come from a combination of historical product knowledge, engineering judgment, experience with the product, quality tools like cause and effect diagrams, and statistical methods like correlation and design of experiments.1

For new products, you should be able to create the relationship matrix as you brainstorm and document CTQs and CTPs for the first time. Make sure CTQ identification involves strong customer representation, and CTP identification relies on stronger engineering representation.

**Step 3: Conduct a Process FMEA**

Creating customized severity, occurrence, and detection scales for the nature of your business or industry can make a difference for the overall effectiveness of your process health card.2 A common tendency among quality practitioners in every industry is trying to use the severity, occurrence, and detection scales provided by the Automotive Industry Action Group (AIAG). One size does not fit all. The scale description and occurrence rate works for the automotive industry and its ancillaries. It may not work well for wafer fabrication or biomedical industries. Quality professionals must recognize the appropriate failure modes and severity levels within their own industries and consider technology maturity levels, occurrence rates, and detection mechanisms in place.

To conduct the process FMEA:

- Identify the critical process flow of the product line and hold a team brainstorming session to identify all probable failure modes, causes, and interim and end effects.
- Document current controls as you would in standard FMEA practice.
- Further develop the FMEA to include the severity, occurrence, and detection ratings from your customized scales.
- Calculate risk priority numbers (RPNs) by multiplying the severity, occurrence, and detection ratings.
- Prioritize risks based on RPN values.

Although you will want to use severity, occurrence, and detection scales that have been developed for your industry, you should resist the temptation to customize further for practical reasons, let us consider the coefficient of determination . . . Strong: $\geq 0.8$

Moderate: 0.6-0.79

Weak: 0.3-0.59

Ignore less than 0.29.
different product lines within that industry. All semiconductor products, for instance, can use the same semiconductor industry severity, occurrence, and detection scales. Similarly, all biomedical products can use the same biomedical industry scales, and all software products products can use the same software development industry scales. Using industrywide scales will achieve consistency and allow for comparison of RPN scores from different product lines.

**Step 4: Develop a Control Plan**

Develop a control plan based on the knowledge and information you acquire from the FMEA. Minimally, the control plan identifies the critical quality characteristics (CTQ) and critical process parameters (CTP) that must be monitored, those that are responsible for the occurrence rate in your high RPN values. If practical, cover all CTQs and CTPs pertaining to the product line. The control plan also provides information on measurement method, frequency, equipment, reaction plan, and more, and it acts as a conduit for SPC parameter identification and equipment identification for GR&R assessment.

Integrating GR&R results and SPC monitoring ensures that only the measurement systems offering the best GR&R percentages and the highest numbers of distinct categories (ndc) are chosen for SPC monitoring applications.

**Step 5: Conduct Gauge R&R Studies**

Conduct your gauge R&R studies before you use the equipment for SPC applications. For variable SPC, the %GR&R should be less than 24% of the tolerance of measurement being used (AIAG recommends less than 10%). Also review the number of distinct categories, as the process measurement data will be used for SPC monitoring. If the measurement application is attribute data, use attribute GR&R. Attribute agreement analysis is recommended before proceeding with attribute SPC charts.

Gauge R&R studies conducted in the last six to 12 months should first be reviewed to determine if changes have occurred in factors such as test station, test operator, software/firmware test method, or equipment maintenance schedule. These changes can affect pre-existing GR&R results and will necessitate starting with a new baseline.

**Step 6: Statistical Process Control (SPC)**

From developing your control plan you have already identified the CTQs and CTPs that are important for reducing the risks of your process. Now you need to set up SPC monitoring. Although real-time monitoring is always advisable, it may not be practical in many industries due to equipment interface issues or economics. On the other hand, performing an offline data analysis of SPC after one week has passed may not be useful. Engineers must estimate an acceptable lag in time between actual data generation and analysis. Risk to the manufactured units, manufacturing volume, data accessibility, resource availability, and other factors all figure into the estimate.

SPC monitoring and the knowledge derived are dependent on the time sequence of the data collection. Engineers can easily make mistakes by performing offline SPC based on measurement sequence rather than manufacturing sequence. A major error like this will change the entire SPC interpretation, so validating the data sequence correctly is important.

The maturity of your SPC implementation can be assessed via the level and depth of special cause investigation, an area of weakness for many organizations. Integrating FMEA with SPC can help. When you integrate FMEA with SPC, you acquire an out-of-control action plan (OCAP) database of special causes to consider for out-of-control situations.

SPC limits established in the last six to 12 months should be reviewed for changes in process variation, significant mean line shift, and process stability. Extended periods of lack of stability call for identification and correction of special causes, followed by a new study to re-establish baseline control limits and process capability indexes.

**Step 7: Using Process Capability and GR&R to Identify Improvements**

Ideally the GR&R value should be less than 10% of the product/process tolerance, and Cpk should be greater than 1.33. In industries where the technology is not very mature, meeting these expectations is more of a long-term objective. For practical reasons, consider the band of 25–40% as high GR&R values, and up to 24% as low GR&R values. Similarly, consider a Cpk of less than 1.1 to be low.

High GR&R and low Cpk, identified in the red (upper left) quadrant of Figure 4, is the most undesirable combination. The next most undesirable is low Cpk and low GR&R (lower left quadrant, in yellow). The low GR&R helps alleviate the situation, but a low Cpk is an indicator of low first-pass yield from the process. The CTPs and CTQs that come under these categories are also highlighted in these colors in the process health card to attract attention and trigger improvement discussions. The combination of high GR&R and high Cpk can be tolerated until the red and yellow items are resolved. Green is the ideal zone.

Alpha and beta risks in this exercise are a bit unconventional as compared to their use in hypothesis testing and acceptance sampling. Here, they are closer to false acceptance and false rejection (misclassification). Without digressing into a discussion of the historical definitions of these risks, for ease of

![Figure 4. GR&R – Cpk Grid](image-url)
understanding, let us say the combinations above can cause accepting bad parts (consumer risk) and rejecting good parts (producer’s risk). These risks are lowest in the green zone and vary in degree in the other combinations. Write a Microsoft Excel macro or use a simple formula in Minitab to estimate the probability of parts contained in the false acceptance/false rejection area.

Figure 5 illustrates scenarios of low/high Cpk and low/high GR&R. The graphs presented here, and in slides 24 – 27 of the accompanying presentation, are exaggerated for ease of visual demonstration. See slides 29 and 30 of the presentation for graphs that are technically appropriate.

**Step 8: Prioritize Improvement Efforts**

The relationship matrix you created in step 2 will be your key for deriving actionable improvements during process review meetings, provided that you also select the most useful metrics to discuss. At your next team meeting, try focusing on outputs of GR&R and SPC analysis using the table format presented in Figure 6. You are, of course, looking to spot issues of instability and/or process variation. The relationship matrix, however, helps you translate those issues into opportunities for improvement. Any issues of instability or process variation that you identify for a CTQ (an effect) will show a corresponding instability in one or more CTPs (causes). Similarly, instability in a CTP could impact one or more CTQs.

In the example in Figure 6, out of several CTQs and CTPs from a given product line, CTQ1 and CTP3 are prioritized for improvement actions. By improving CTQ1 and CTP3, we can reduce the producer/consumer risks to a set goal deemed acceptable by the customer and by manufacturing. As we improve gauge R&R to less than 10% and improve process capability indexes to greater than 1.5, we will be able to move items from the red, yellow, and blue zones into the green zone, based on prioritization.

Figure 6 presents the approach at one glance, incorporating a CTQ-CTP relationship matrix that is used for interpretation. The columns help track GR&R and SPC and review due dates. You can also customize the table to help focus attention on points needing discussion. For instance, you might add a column to display RPN values from your FMEA that pertain to a specific CTQ or CTP. Or you might incorporate information to demonstrate the monetary impact of a red or yellow situation.

**Beyond the Process Review Meeting**

At your next process engineering review meeting, just as attendees are settling in for a long slideshow of high-level metrics, try surprising them with SPC and GR&R metrics using the table in Figure 6 instead. Then, when you use a CTQ-CTP relationship matrix to put those metrics into context, the engineers in your audience will be more likely to respond with specific ideas you can begin to implement immediately.
Beyond triggering meaningful improvement discussions during metrics reviews, this approach offers broader uses. For instance, understanding process behavior with respect to the cause and effect relationships among CTPs and CTQs helps establish a knowledge database that can contribute to quick resolution of process issues in the long run. The SPC-GR&R status table could very well serve as a trigger for Six Sigma projects, and maintaining a table of indexes on CTPs also helps in planning processes for new product development. Additionally, reviewing SPC and GR&R results in the context of CTQs and CTPs presents an easy way to demonstrate fulfillment of ISO 9001:2000 requirement 7.2.2.c, “Review of requirements related to the product,” showing your organization’s capability of meeting defined requirements.

Perhaps most important are the advantages to be gained from more formally integrating FMEA, SPC, and gauge R&R. Powerful even as standalone applications, these tools provide optimal benefits when integrated into an overall quality improvement model, as illustrated in Figure 1.

REFERENCES

1. Mikel Harry advocates the use of such a matrix for developing CTQ trees, instructing, “Locate CTQs on columns and CTPs on rows. Each column-row intersect constitutes a ‘causal opportunity,’ the strength of which must be rationally measured or otherwise evaluated.” See “Ask Dr. Mikel Harry”: http://www.isixsigma.com/forum/ask_dr_harry.asp?ToDo=view&questId=82&catId=11.

2. Resource Engineering’s “FMEA Investigator” Quality Training Portal, also supports FMEA customization.

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