Process Understanding: Critical for Process Development, Part 2

Ronald D, Snee, PhD; Snee Associates, LLC, Newark, Delaware

This is part two of a two-part piece. Part one can be found here [1].

How Do We Develop Process Understanding?

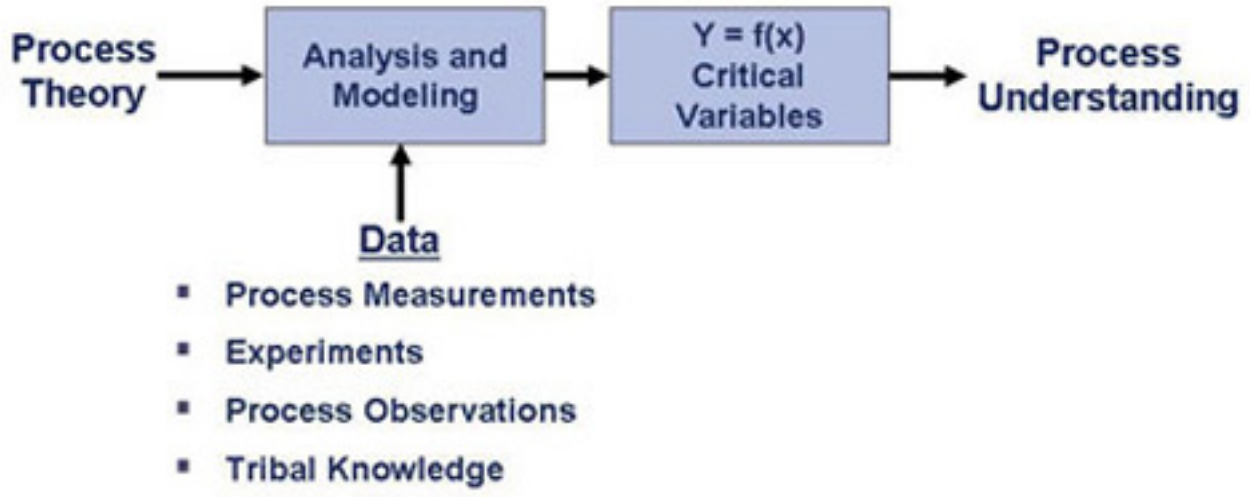
Consistent with the FDA (2004) definition of process understanding noted previously in this article, we see in Figure 1 that a critical first step in developing process understanding is to recognize that process understanding is related to process variation. As you analyze process variation and identify root causes of the variation, you increase your understanding of the process. Process risk is an increasing function of process variation and a decreasing function of process understanding. Increasing process understanding reduces process risk and increases compliance.

Figure 1. Developing and Using Process Understanding

In Figure 2 we see that analyzing the process by combining process theory and data (measurements and observations, experiments and tribal knowledge in the form of what the organization knows about the process). Science and engineering theory

when interpreted in the light of data enhances process understanding and results in more science and engineering being used in understanding, improving and operating the process.

Figure 2. Routes to Process Understanding



The integration of theory and data produces a process model, Y=f(X), and identifies the critical variables that have a major effect on process performance. Fortunately there are typically only 3-6 critical variables. This finding is based on the Pareto principle (85 percent of the variation is due to 15 percent of the causes) and experience of analyzing numerous processes in a variety of environments by many different investigators (Juran and Godfrey 1999).

Tools Used to Develop Process Understanding

As we see in Figure 2 process analysis is strongly data based, creating the need for data-based tools for the collection and analysis of data and knowledge-based tools that help us collect information on process knowledge. We are fortunate that all the tools needed to develop the needed process understanding described above are provided by QbD and Process Analytical Technology (FDA 2004) and Lean Six Sigma methodologies (Snee and Hoerl 2003, Snee 2007).

It all starts with a team which includes a variety of skills including formulation science, process engineering, data management and statistics. In my experience Improvement teams often have limited formulation science and data management skills. Process knowledge tools include the process flow chart, value stream map, cause and effect matrix and failure modes and effects analysis (FMEA).

The data-based tools include design of experiments, regression analysis, analysis of variance, measurement system analysis and statistical process control. The DMAIC (Define, Measure, Analyze, Improve and Control) process improvement framework and its tools are particularly useful for solving process problems. A natural by-product of using DMAIC is the development of process knowledge and understanding, which flow from the linking and sequencing of the DMAIC tools.

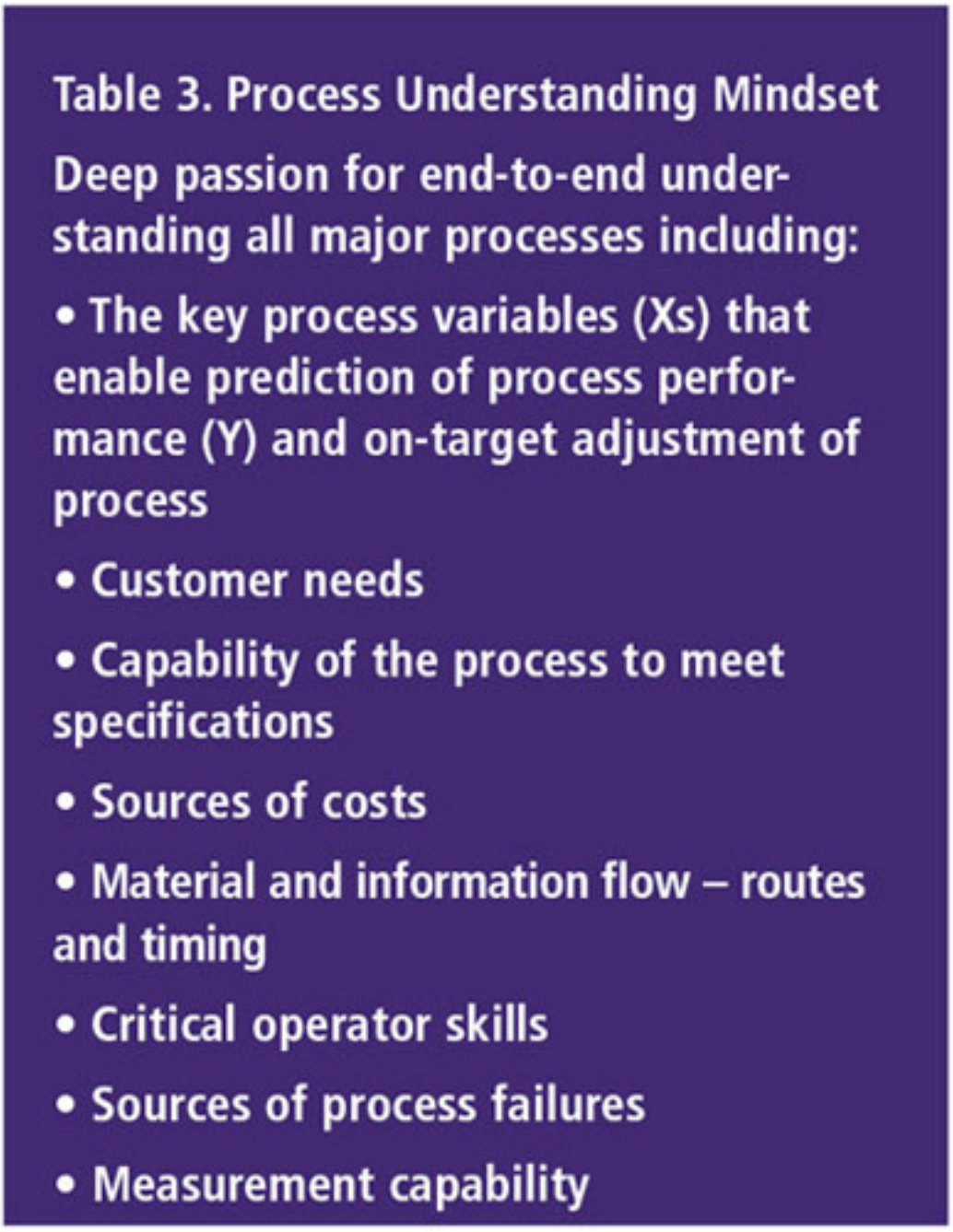
How to We Spread the Use of Process Understanding?

We cannot end this discussion of process understanding without addressing how to help the organization make development of process understanding a focus for the organization. This requires a planned initiative which includes a management system to sustain the effort. We are reminded if you want something to happen on a regular and sustained basis you have to put a management system in place to guide and sustain the effort.

Following Kotter's model for creating lasting change (Kotter 1996); we begin with a sense of urgency and a vision statement which might look something like: "We know the elements of process understanding and work to create and use those elements in a way that creates competitive advantage for our organization."

After a gap analysis has been made and the organization knows its current state regarding process understanding, a deployment plan is constructed which includes the strategy to guide the effort, goals for the initiative, demonstration projects, needed personnel training and schedule for management reviews.

A significant goal for the initiative should be to create a "process understanding mindset" for the organization as well as the individuals working in the organization. They should be thinking process understanding at all times. Some critical elements of such a mindset are summarized in Table 3. At a bare minimum a knowledge base should be available to support each process containing the following information: the critical variables that have a major impact on the performance of the process, the nature and magnitude of the effects of each major variable including interactions with other variables and what studies and data were used to develop this knowledge and understanding.



Two elements of this approach require particular emphasis. First it is critical to success that the initiative includes demonstration projects that will create a positive contribution from developing process understanding in 3-6 months. In Kotter's terminology "short term wins" must be created. These successes will show the organization what increased process understanding looks and feels like, its value and provides clear evidence that the organization can do it.

Essential to success is regular management review. Just as an organization has a variety of financial reviews, an organization's approach for developing process must be reviewed on a regular basis. Such a review process should include monthly reviews of specific projects designed to increase process understanding and quarterly and annual reviews by senior management regarding process understanding – status in the organization and needed changes. If we have learned anything over the years of corporate change it is that periodic management review

is essential to the success of any effort to change how an organization works and to maintain the change.

An On-Going Process

Process understanding is not an abstract concept. It is fundamental to all aspects of the business and critical to success. The needed concepts, methods and tools are available and well tested. User-friendly process understanding enabling software is much more available and powerful than ever before and will continue to develop in the future. The trick is to continually iterate between data and theory building process understanding over time. It is critical to use change management techniques to embed the gains in the organization and its processes so the new and better ways of operating becomes an integral part of how processes are operated and product manufactured.

References

FDA (2004). "Guidance for Industry: PAT – A Framework for Pharmaceutical Development, Manufacturing and Quality Assurance", US Food and Drug Administration, Rockville, MD, September 2004.

FDA (2011). "Guidance for Industry: Process Validation: General Principles and Practices", US Food and Drug Administration, Rockville, MD, January 2011.

Juran, J. M. and A. B. Godfrey (1999). Juran's Quality Handbook, 5th Edition, McGraw-Hill, New York, NY

McCurdy, V., M. T. am Ende, F. R. Busch, J. Mustakis, R. Rose, and M. R. Berry (2010). "Quality by Design Using Integrated Active Pharmaceutical Ingredient – Drug Product Approach to Development", Pharmaceutical Engineering, July/August 2010, 28-29.

Snee, R. D. (2007) "Use DMAIC to Make Improvement Part of How We Work", Quality Progress, September 2007, 52-54.

Snee, R. D., P. Cini, J. J. Kamm and C. Meyers (2008). "Quality by Design - Shortening the Path to Acceptance", Pharmaceutical Processing, February 2008, 20-24.

Kotter, J. P. (1996). Leading Change, Harvard Business School Press, Boston, MA.

Snee, R. D. and R. W. Hoerl (2003). Leading Six Sigma – A Step-by-Step Guide Based on Experience with GE and Other Six Sigma Companies, Financial Times Prentice-Hall, Upper Saddle River, NJ.

For more information, please visit www.SneeAssociates.com *[2] or email* Ron@SneeAssociates.com *[3].*

Links:
[1] http://www.chem.info/Articles/2012/05/Plant-Operations-Process-Understanding-Critical-for-Process-Development-Part-1/
[2] http://www.SneeAssociates.com
[3] mailto:Ron@SneeAssociates.com