

# Statistical Process Control: A Mandate for the Pharmaceutical Industry

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The value of statistical process control (SPC) technology is undeniable; the solutions providers of SPC within the pharmaceutical industry have often neglected the unique sector challenges and their approach has often identified the weaknesses.

Pharmaceutical industry projects are not reusable for similar parts or processes, but must be recreated for each part within a part family. Some of the technologies communicate these projects are text files (not a database, so if they are deleted accidentally they are lost); similarly limited formula functions are available (some math, logic functions). These may seem like rudimentary issues; however they defy the efficacy of SPC.

Other discrepancies or inefficiencies are found among many SPC solutions providers who require the Design of Attribute sample size function force the user to manually enter a defect entry for every piece in a sample, including zero values for pieces that have no defects. Major pharmaceutical operations managers complain that, "We could not get gage entry to work, and could not get technical support to solve the problem."

Complaints about some systems included the fact that the user must set up their own database, getting IT involved and that security features were stored in an .ini file (test file that is exposed to any user with knowledge how to find and manipulate it.)

Evan Miller, President of Hertzler Systems, and leading SPC solution GainSeeker noted that, "Encoding this information in a database is absolutely essential. Too often Variable Statistical Analysis is weak in other SPC solutions because it's easy to blend data from two features on one characteristic on one histogram giving a chart that does not represent the process. We addressed this issue and made sure that the X-axis labels are in appropriate increments and can be automation scaled to receive real-time meaningful information. Similarly actual values are displayed on charts and non-normal analysis need not be forced."

Some of the SPC features that are most valued in the pharmaceutical sector include a Variation Wizard, a Drill Down Wizard, and comprehensive control charts. These may seem axiomatic in statistical functionality but without drill downs, and Pareto chart displays by major and minor categories, misleading statistics result.

GainSeeker contains more than two hundred statistical tables to capture available statistics in real-time, whereas so many SPC solutions contain alert weaknesses since tests do not get applied until the data entry process is stopped. Rapid database retrieval speeds and flexible web reporting functions, including real-time charts are visible according to Miller, rather than fed into a predefined site.

Agnes Shanley, Editor in Chief of PharmaManufacturing.com recently reported that, "It's too soon to guess what the FDA will look like, but it is safe to say that the period of introspection is over. President Obama has already nominated a deputy commissioner who has been openly critical of the industry. Guidance developed over the past decade will now be driving what promises to be a much tougher enforcement agenda. The time is over for waiting for more explicit guidance from FDA, or waiting to see how other companies implement these approaches. If anyone doubts that, they should heed the words of Joe Famulare, deputy director of compliance at CDER, who ended a very upbeat presentation during the webcast by dissecting the language in a hypothetical consent decree letter. Mentioned specifically were process control and control of variability."

Shanley correctly suggests that drug companies that do not get smarter about addressing variability and its root causes at their facilities, and start employing statistical methods and Quality by Design concepts, may pay very dearly for this failure.

Miller asserts that, "Technology tools like GainSeeker are becoming critical as the principles outlined in the process validation draft guidance become law. Specifically, process understanding, control of variability, root cause analysis, and statistical tools for real-time data are driving the future of the pharmaceutical industry."

Author Profile:

Thomas R. Cutler is the President & CEO of Fort Lauderdale, Florida-based, TR Cutler, Inc, ([www.trcutlerinc.com](http://www.trcutlerinc.com)). Cutler is the founder of the Manufacturing Media Consortium of three thousand journalists and editors writing about trends in manufacturing. Cutler is a member of the Society of Professional Journalists, Online News Association, American Society of Business Publication Editors and Committee of Concerned Journalists, as well as author of more than 300 feature articles annually regarding the manufacturing sector. Cutler can be contacted at [trcutler@trcutlerinc.com](mailto:trcutler@trcutlerinc.com).