

# Holistic SPC

The role of Statistical Process Control in a holistic approach to process understanding and improvement at Napp Pharmaceuticals.

By Tom Cochrane and Norman Greig\*

**N**app Pharmaceuticals is part of a worldwide association of independent pharmaceutical companies that have been developing vital new drugs for more than half a century.

Napp first introduced statistical process control in 1995 in their quality control laboratory to monitor the variability in the key parameters of their raw materials and to monitor finished product parameters.

As processes became more complex they needed to better understand and control processes upstream from the finished product analysis and downstream from the raw materials.

"We went from being results focussed to becoming process focussed. To improve results, you must understand and improve the process," says Tom Cochrane, business process development manager at Napp Pharmaceuticals.

The manufacture of a slow release spheroid product was the ideal starting vehicle for applying statistical process control direct to the plant floor. This was because of the following critical business issues:

- Manufacturing supported international markets
- Short lead times
- Growing sales

High utilisation in area-24 hour operation

- Complex process with many influencing variables
- End result unpredictable

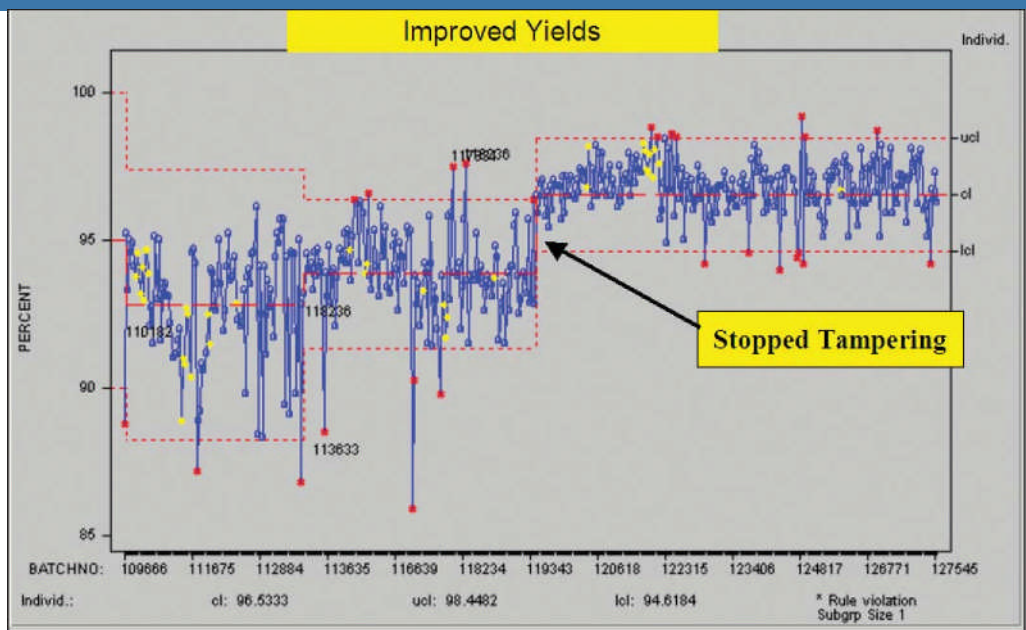
## Solutions

The keys to effective process improvement and management, are communication of the right data in the right format, to the right people at the right time, so that they can make the right decision.

A critical enabling factor is the provision of the tools and methods which help formulate decisions, reduce reaction time, measure improvements objectively and provide common communications.

To deliver this requirement, NWA Quality Monitor with Quality Analyst software was chosen. It provides a number of benefits, including user customizable data entry, help, alarms and output charts together with simple data entry screens and charting commands for plant operators. It also provides ready integration with further investigative and analysis software. CCS Associates provided the SPC consultancy and training services in support of the Napp team.

Napp employs a holistic approach to process improvement based on Continual Improvement



Teams (CIT). A cross functional team structure was essential with participants from QC, QA, Manufacturing, Engineering, Training and Process Support. This made up the core team but other groups were involved, such as Regulatory, Supplier Development and, externally, on the expertise of raw material suppliers and equipment manufacturers. The CIT group philosophy was to give everyone an equal say on the basis that no one department had all the answers.

The objectives of the CIT were to:

- Investigate and eliminate special cause variation
- Identify and eliminate possible failure modes
- Reduce common cause variation.

All CIT members were trained in entering and interpreting data in their respective area. Training workshops were run on process mapping, control charts, brainstorming and cause and effect diagrams. This was then documented in each area's standard Operating Procedure.


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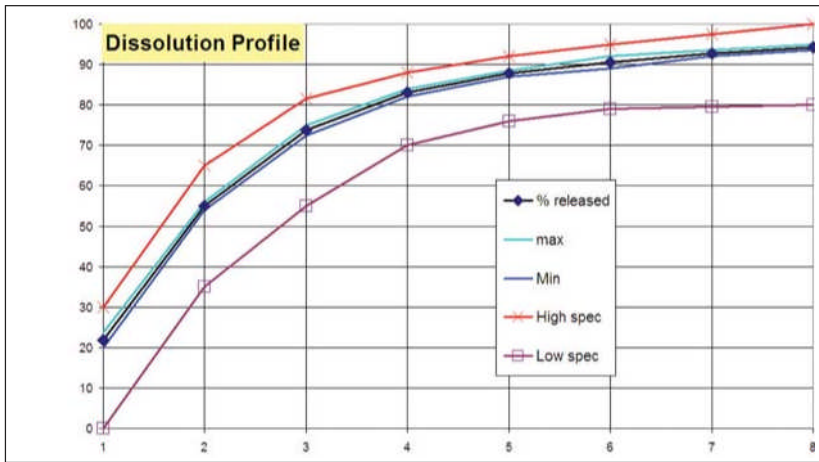
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**Continuous improvement**

Quality Analyst charts, fishbone diagrams and brainstorming were the main tools used to understand the variation in the various stages of the process. The steps were;

1. Gather data and plot on a chart
2. Analyse performance
3. Identify cause and effect
4. Make improvements
5. Monitor to find if improvement is effective

These were dealt with systematically and the actions taken were monitored using charts. An example of the benefits of the CIT approach was at the yield stage of the core manufacture where there was considerable variation due to variable amounts of waste being produced.

When investigated, it was found that the process allowed the operator to alter settings, such as impeller and feeder speeds, based on how he felt the step was running. As there was no change in the input materials, the decision on how the process was running was conjecture and was dif-

ferent, depending on which operator you spoke to. The end result was a classic case of "tampering", resulting in the introduction of variation into the process.

The CIT team reviewed and fixed the batch process parameters. The control chart (on page 31) shows that not only was the variation in the yield reduced but also a sustained process increase of 3-4% was achieved..

Initially this process had been chosen because of the unpredictability of the end result. The end result being the in vitro dissolution of the coated spheroids. If coating went right first time the batch would be blended and encapsulated. If the dissolution was too fast, then an additional step of further coating would have to be carried out.

A control chart was set up capturing the window value batch to batch. At the start of the project, the number of batches Right-First-Time was 79%. Today that figure is 97 %, with the remaining 3 % being attributed to well understood known causes (see Chart below)

Tom Cochrane said, "Quality Analyst and Quality Monitor are the bedrock of our process improvements. We use control charts to identify how the process is performing at each stage and monitor the effects of changes made by our Continuous Improvement Teams. It has enabled us to understand our processes better and also be able to visually communicate improvement to all the teams and management". Bob Clarke, quality director, who started the SPC approach at Napp Pharmaceuticals in 1995 added, "Quality Analyst gives you a means to visualise variation because if you don't understand the variability in your process then you're just guessing."

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