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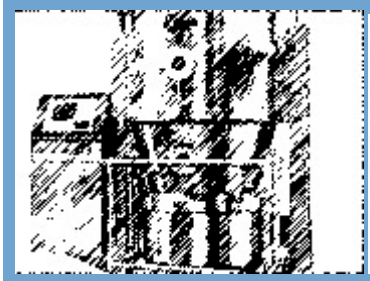


Written by David M. Jones

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Electronically Acquired Data: A Process Troubleshooter's Best Friend

Modern production equipment is typically configured with electronic controls. Suplementing the ability to control the process variables, contemporary systems are also configured with data acquisition. Unfortunately, CFR Part 11 issues caused many companies to continue to use hand-written in-process data sheets (data taken by the process operators), ignoring the power and independence of the electronically acquired data. If a company's equipment has this feature, it is strongly recommended that a transition is made to the use of electronic data for batch records or at least for use as a process monitoring and troubleshooting tool.

Ideally, a consequence of an effective development program is a relatively simple process that can be replicated using a 'recipe' that will run without operator intervention. It should be sequenced for all of its steps, including air handler pre-conditioning, machine tower and core material warm-up, spraying, drying, cooling and discharge (where applicable). The data acquisition system will write the data to a file that is unique to the batch number of the material being processed. Some companies use the acquired data as a substitute for an operator's hand written in-process data for the developing batch record. An advantage is the resolution – the operator takes 'point in time' readings, usually at 15 minute intervals (depending on the duration of the process). The control system typically allows the user to establish the recording interval, and in most cases, it ranges from 30 to 60 seconds. At this rate, the resolution is 15-30 times greater than the hand written batch data. A further advantage is that the machine writes the data independently. In some cases, operators will wait for a rogue variable to come back into the defined operating range before recording a reading that may trigger an investigation. Hand written data is accurate for the point in time that it is written, but it is often of little help in troubleshooting a batch that had some type of non-standard evemt during processing. However, the use of data to support troubleshooting alone is *not* recommended. It must also be used to verify conforming batches. A reasonable question is: "How do you know these so-called non-standard events (excessive drift by a CPP, or critical process parameters, for instance) are NOT occurring in the GOOD batches?" Unfortunately, plotting of data is somewhat time consuming, and it would be cumbersome to plot every batch, good or bad. It is suggested that a recipe is configured with alarms for all CPP. It is common for the manufacturing instructions to incorporate operating ranges for CPP. If these are not identified experimentally (a benefit of Design of Experiments), they are likely to mirror the operating ranges identified during the OQ (operational qualification) phase of the equipment installation. If the alarms are configured to bracket these ranges, the process is essentially 'self-policing'. A batch that experiences no alarms during processing is expected to meet the product's CQA (critical quality attributes).

Processing issues can occur at any time – interruptions due to lightning strikes, utility failures, spray nozzle defects, etc. In most cases the batch is not impacted to the extent that it must be discarded. If it meets all CQA and any other additional testing required under SOP (where applicable) it can be released for further processing. When an adverse event occurs, someone must write a deviation report. The investigation will conclude if it is a potential recurring problem requiring corrective action or if it is an isolated incident. The most useful tool for defining the event is likely to be the acquired data. For this reason, it is strongly recommended that *everything* that the machine controls or monitors, including PID output values be written to the database. The recording interval should be as short as possible – not more than 60 seconds, and if possible, 10 seconds or less. Resolution yields revelation and confidence in the results of the troubleshooting effort.