

Mallinckrodt



COVIDIEN

API Manufacturing & Lifecycle Validation

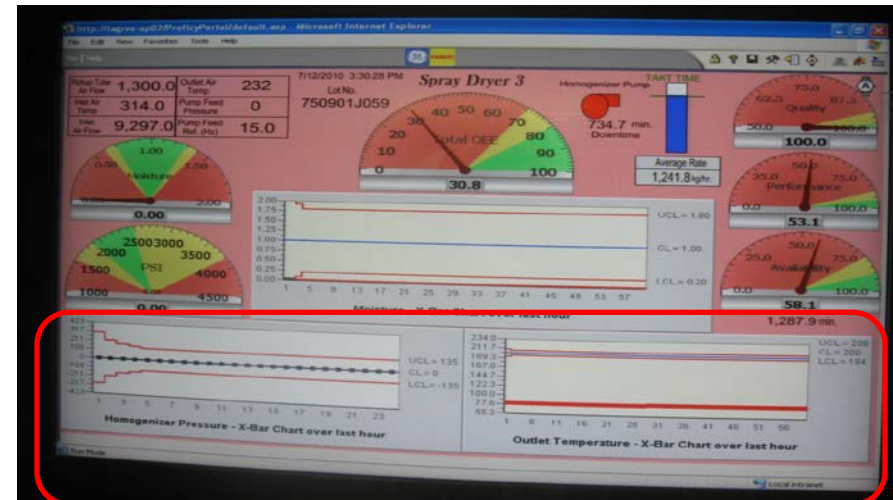
Successes and Lessons Learned

April 15, 2013

Change for the Better

- The guidance has challenged us to dig deeper
 - CPP rationalization
 - Step-by-step evaluation of processes by FMEA
 - Process verification through CQA and CPP data
- Increased utilization of leading indicators
 - Switching focus to E-batch records & better control systems
 - Drive to live SPC of critical process parameters
 - Enhanced batch review and release criteria for continuous processes
- Process Verification Pilot Program

We have to review our processes more often, in greater detail



Key Learnings

- CPP data acquisition
 - CPP (process) data not as readily available as CQA data
 - With more than 300 products in 17 buildings, CPP data entry presents challenges
- Enhanced use of statistical tools
 - We needed statistical rationale for the number of consistency runs
 - We needed policy on application of statistical tools for lot-to-lot comparisons
- CPP Rationalization
 - To manage a legacy process, focus on the “critical” few vs. trivial many

Vision for Process Data Review and Control Progression

LIFECYCLE VALIDATION

Online verification of CQA s and CPPs for Parametric or real time release

PAT

SPC

Integrated manufacturing data network applies statistical models to CPPs collected in real time to control the process centered within Design Space

CPP
Review

Validated systems to record and report CPP data for timely review & analysis

QBD

Product Development Process Yields CPP Identification and verification through DOE