

Case study

Product Release Lead Time Reductions



Business Background & Context	Final product release lead-time was too long due to quality and processing issues with documentation
Problem & Goal	The batch documentation for a complex sterile product was very complex. The 'right-first-time' (RFT) from documentation for final batch release was <10% and release lead-time after the final processing step was too long (4 days) The goal was to dramatically improve RFT and to reduce the lead-time
What was Done	 Documentation was simplified (remove unnecessary activity) A Documentation Room (D-Room) was created to allow documents to 'flow' through the process with errors being quickly corrected Structure was added to documentati,1on activities Visual Management techniques were employed Documents processed in sequence rather than 'by preference'
Business Impact	Documentation RFT improved to >90% Lead-Time dramatically reduced 4 days to <1 day Documentation seen as core part of the process rather than a necessary evil