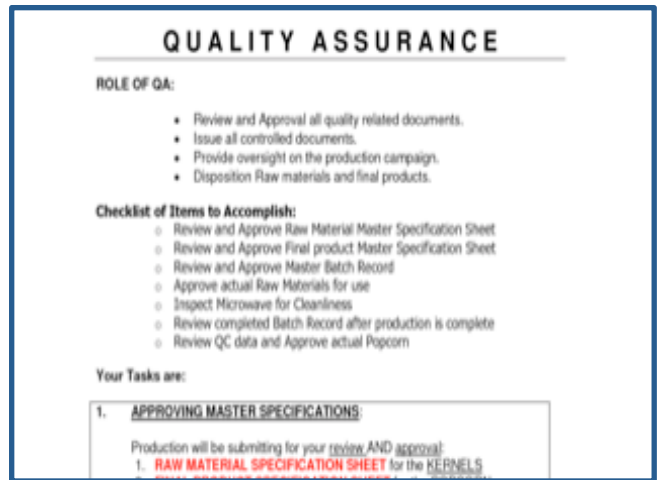


Case study

Batch Record Error Reduction



<p>Business Background & Context</p>	<p>Insulin Pen assembly & packaging operation with throughput of 115 million pens per year. High error rate in batch records resulting in significant (weeks) delays, inventory build up awaiting release, and high level of QC effort spent resolving issues (4 hours per day)</p>
<p>Problem & Goal</p>	<p>56% error rate due to missing signatures, missing data, incorrect times & dates, Unclear explanations for line stoppage and quality events. Goal – Right First Time (RFT) for batch records of 75% by end 2013</p>
<p>What was Done</p>	<p>Problem tackled using Rapid Improvement Kaizen approach 50 improvements proposed 15 improvements implemented during the event including</p> <ul style="list-style-type: none"> • Simplifying batch records • Visual management to track recurring errors • Improving definitions to clarify and mistake proof <p>Further 30 improvements actioned post the event since required validation for compliance</p>
<p>Business Impact</p>	<p>Assembly – RFT increased from 39% ->50% Packaging – RFT increased from 44% ->51% Trends suggest RFT target will be achieved by mid 2013 (6 months ahead of schedule) Reduced QC workload allows 3 QC technicians to be transferred to new production line Inventory reduced Estimated annual savings overall of 400,000 Eur</p>