

Case study

Innovative Training Methods  
To Reduce Deviations



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| Business Background & Context | A global biotech company suffering significant losses due to delays in starting up production. Additional major costs incurred in rework associated with deviation management.   |
| Problem & Goal                | In one year alone the formulation support team raised 88 deviations during the ramp up phase of 98 process change projects. As a result, 25% projects were delivered late. The goal was to reduce the number of deviations during ramp up of production during process change by 50%.  |
| What was Done                 | <p>3 day kaizen event involving operators and technicians.</p> <p>Key Improvements</p> <ul style="list-style-type: none"><li>• A more effective, standardized method of training operators in new validation protocols.</li><li>• Operator involvement in defining the content and the most effective method of training to meet their needs</li><li>• Clear definitions of roles and responsibilities during validation protocol training and process management</li><li>• A template for the training manual which trainers adapt to meet the specific needs of the process change protocol (SOP)</li><li>• Weekly process reviews with operators to review issues, propose and implement solutions and sustain the improvements</li></ul> |
| Business Impact               | Three month after implementation ZERO deviations were raised during 20 validation runs. Operators also reported that the new training methods removed a lot of the frustration and rework. Estimated annual savings of over €700,000.  |