

CPIP-EA-2 Applicant Professional Experience (page 1 of 2)

Professional Experience (Please check one for each form submitted)
 A minimum of five CPIP-EA-2 forms are required.

Submit this form with form CPIP-EA-1

Competency 2 - Leadership and Professionalism

- Exemplar I - Leadership
- Exemplar II - Decision Making
- Exemplar III - Communications and Interpersonal Behaviors
- Exemplar IV - Professional Development

Competency 3 - Integration/Innovation/Change Advocacy

- Exemplar I - Innovation and Problem Solving
- Exemplar II - Cross-Functional Integration
- Exemplar III - Risk-Based, Cost-Effective Approaches

Competency 4 - Quality and Continuous Improvement Focus

- Exemplar I - Continuous Improvement Mindset
- Exemplar II - Quality by Design

Please complete entire section in English language (type or print clearly)

Date: [REDACTED] Applicant Name: [REDACTED]
 Year(s) in which experience occurred: [REDACTED] Position Title: [REDACTED]
 Company Name: [REDACTED]

Exemplar Experience Description

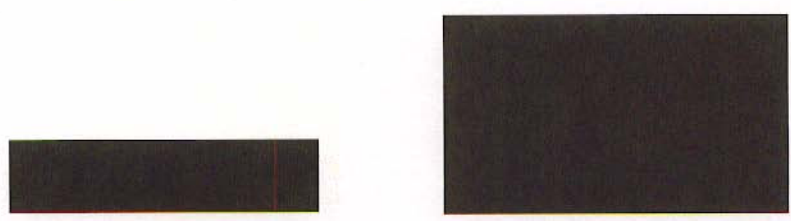
Exemplar I - Continuous Improvement Mindset

I review the trends in manufacturing processes as well as Quality Control testing periodically as part of the Annual Product Review. This review allows me to identify areas of concerns as well as areas for continuous improvement. Statistical control charts are typically be used to detect any adverse trends arising. This is often used as a tool to anticipate any problems that may arise and allows preventative actions to be taken promptly before an out of specifications batch is produced. For example, if a particular quality attributes appeared to have drifted from its previous mean, (For example, LOD₂₀₀₅ = 6.5%, and LOD₂₀₀₆ = 7.0%), this may suggest that there is a process or testing parameters that is out of statistical control.

Besides data review, I visit the manufacturing plants frequently and provide feedback to Production of any areas of concerns or suggestion for improvement. The interaction with the shop floor will enable me to know the situation in Production better. In cases of deviations, I will inspect the facility personally to ensure that the situation is adequately addressed. For example, in the event of an equipment failure, I will be on site to understand the nature of the failure (fatigue failure of metal, or poor welding of joints, etc...) and work closely with Engineering to see how these can be prevented from happening again.

My team and I are consistently seeking new ways to improve our ways of working. One of the achievements that my team accomplished was the implementation of Laboratory Information Management System of Quality Module in SAP. Previously, all records used for analytical testing were issued by Central Documentation to Quality Control laboratory. The status of the batch was assigned on the paper records and subsequently in SAP. The management of analytical test data, control of blank records for testing, printing of Certificate of Analysis was managed manually outside the SAP system. (Continued)

CPIP-EA-2 Application continued on the next page



CPIP-EA-2 Applicant Professional Experience (page 2 of 2)

Exemplar Experience Description (continued)

Exemplar I – Continuous Improvement Mindset

(continued)

Many processes were automated with the implementation of SAP LIMS. These include:

1. the automatic issuance of worksheets (blank records) for analytical test recording
2. system checks to ensure that all test results that out of specifications are highlighted
3. the automatic printout of Certificate of Analysis with customer information
4. the automatic data download required for Annual Product Review

Besides the above, other benefits include elimination of typographical errors in Certificate of Analysis preparation; better data integrity and security of information used in the Annual Product Review and improved productivity across the entire quality functions. The SAP QM module was an extensive validation exercise that took months to conceptualize, plan, implement, test and validate. It was only possible with a continuous improvement mindset of the all members of the IQC team.

