

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

Exemplar Experience Description (continued)

carried out 4 audits to verify GMP compliance in some manufacturing areas. The manufacturing process was evaluated and improved, presenting this results to the management area and accepted the new flow activities, cooperating in the process validation. The project 4 was involved with process validation and development of the validation and documentation system for a [redacted] manufacturing firm in [redacted] with the purpose to get FDA approval. I developed the Validation Master Plan, SOP'S of the quality system and protocols for the qualification of 2 areas and 8 equipments related with the process. As well as I achieved audits in order to verify the FDA compliance. The FDA approval was gotten. Each week, written reports in English must be sent to the headquarters in USA notifying the advances of the project. I had 6 people in my charge. The fifth project involved the development of a Quality System for a [redacted] firm in [redacted] I had 6 people in my charge. I developed SOP's, Quality Manual, Validation Master Plan and Site Master File, as well as, I reviewed the layout for the new facility in order to get compliance with GMP and Good Engineering Practices. Reports of advances had to be sent to the CEO of the company each two weeks in [redacted] I had to evaluate suppliers to give services of engineering and construction. I developed the basis to contract them. The sixth project involved the design qualification of the new facility for [redacted] for a [redacted] according to FDA and [redacted] requirements. I participated as GMP auditor reviewing the compliance and sending reports in English and [redacted] to the headquarters and [redacted] management. I identified improvements in the design in personnel and materials flows, equipment location and process logical flow. I reviewed the Validation Master Plan and protocols to qualify the areas, developed by them. I gave training in Good Validation Practices.

[redacted]

I hereby certify that I am personally knowledgeable of and have witnessed the experience(s) identified herein.

Relationship to CPIP applicant during the experience(s) date(s): Supervisor

[redacted] Applicant Witness Signature

Date (Y/m/da) [redacted] Telephone [redacted]

