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|  | Do you have experience with production equipment validation in a pharmaceutical environment?  Describe? | * Yes. At Immunomedics Pharmaceuticals, I validated Fedegari Autoclave per EN285 standards. * I created a PQ protocol, executed the protocol using a Kaye Validator, and drafted summary reports. |
|  | What types of Equipment or Systems did you qualify? | Equipment: Fedegari Autoclave. |
|  | Did you write the protocols, and did you execute the protocol? | Yes, I wrote and executed protocols.   * Autoclave PQ Protocol at Immunomedics. * At Aphena Pharma Solutions, I generate, review, and approve engineering studies and process validation protocols and reports related to blending, cleaning, packaging, and serialization. |
|  | Provide Examples of when Qualifications were successful and when they did not meet acceptance criteria and how did you resolve? | Successful Qualification*:*   * Autoclave PQ qualification was successful at Immunomedics.   Unsuccessful Qualification:   * During a recent blend of a consumer product, the final blend solution did not meet API specification. * We reviewed the batch record and discovered that all the process parameters were within range. * I hypothesized that there were problems with moisture evaporation. To confirm this fact, our lab performed a Karl Fisher test to find the moisture content of the final blend solution. * The lab results confirmed water evaporation during the blending process. * To resolve this issue, I made a small lab batch and added water to the final blend solution to match the customer formula. * The lab batch results confirmed that the API specs were within range and water was evaporated in the blending tank. * The batch record was revised to add extra quantity of water at the end of the blend. |
|  | What is your experience with cleaning validation?  Have you executed any cleaning validation protocols? | * I have experience with cleaning validation. I have generated cleaning protocols, where I calculate surface area, volume of product contact, API limits, and detergent limits. * I have also executed cleaning validation protocols for 100-gallon and 1000-gallon tanks and various fill and packaging lines. |
|  | Do you have first-hand experience dealing with the FDA, or an FDA audit?  What is your regulatory audit experience? | * Yes, at Immunomedics I assisted my team in responding to an FDA audit. During the audit, we provided validation documents to the FDA. |
|  | Tell me about a failed result, what next steps were taken and how could the outcome have been prevented? | * In one instance, we discovered that our operators had transferred a completed blend product to the wrong drum—instead of transferring the product in a stainless-steel drum, they placed it in a HDPE drum. The reason this mistake occurred is because the batch record referred to the stainless-steel drum as an “SS” drum, and they were not aware of this acronym. Instead of referring to the stainless-steel drum as the “SS” drum in the batch record, we decided to include the drum’s part number for easier identification. Clearer communication could have prevented this outcome. |
|  | What is you experience qualifying new equipment?  Qualifying a new Manufacturing Facility? | * I qualified a new autoclave at Immunomedics. * I qualified new temperature control units. |
|  | Describe a time when you identified a process improvement. How would you implement the change? | I am always looking to improve systems.   * At American Custom Drying, I reduced the amount of downtime between cleaning by making a simple change to our cleaning procedures. Rather than only doing one step of our cleaning procedure at a time across all pieces of our equipment, I requested that we do multiple steps of the cleaning procedure on one equipment at a time so that that equipment could be ready to use as quickly as possible. This reduced 6 hrs of cleaning downtime. * In another instance, I improved the vitamins spray drying process, which led to a threefold increase in production rate. There, I did an engineering study and discovered the need for a larger nozzle, higher pressure, and more solids in the blend. Because of my engineering study, the batch record was revised to reflect new process parameters. * At Aphena Pharma Solutions I found inefficiencies with our fill and packaging line. I helped improved the process by adding an extra rotary table in front of the sleever and two more fill pumps, which led to a 40% speed increment saving of $20,000 a day. |
|  | Have you worked in a cross-functional team that includes consultants and other quality individuals that do not necessarily report into you?  What is most important for successful team collaboration? | * Currently I’m working with cleaning contractors to revise a cleaning master plan and to perform a gap assessment as per latest ISPE regulations. * For a successful team collaboration, it is important to have clear projects expectations and regular communication. |