PDA Training Container Closure Systems

Workshop – Your Task

PDA
Parenteral Drug Association

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- Your company is developing a drug product with a temperature sensitive biological API, that adheres on glass surfaces significantly.
- The drug product is a lyophilized drug. Shipment and storage of final drug product needs to be at 2 to 8° C – at least for launch phase of the product.
- The drug is injected subcutanously by the patient every other day. The injection is performed manually – at least for the launch phase of the product.
- For convenience of the patient the diluent for reconstitution is in a pre-filled syringe that shall be co-packed with the drug product vial.
- Marketing wants to sell the drug in US, EU, Latin America and Asia/Pazific.
- In the 3rd year after launch Marketing wants to change the product from a vial/syringe system to a dual-chamber syringe. For ease of injection an injector for the dual-chamber syringe is requested.

Workshop Tasks

- Set-up the target profile of container closure system
- Prepare a development plan considering regulatory requirements
- Summarize the risks of the specific CCS, e.g. interactions of filling with CCS, shipping assessment, user interface issues

- ➢ Group A: Drug product vial with diluent syringe
- ➢ Group B: Dual-chamber syringe