COURSE OBJECTIVES

By the end of this learning event, participants will be able to:

1. Define 25 basic terms important in handling time and temperature sensitive pharmaceutical products.
2. Given a situation, propose recommendations to improve compliance with “good distribution practice” (GDP) guidelines.
3. Given a nonconformance in the transport of pharmaceutical product, analyze data to identify the cause, potential impact to the product, and formulate preventive measures.
4. Given a list of elements that could be in a quality agreement, justify five elements you consider to be most beneficial.
5. Given an example of an operational component in a pharmaceutical cold chain, differentiate the practices as to whether or not they reduce risks.
6. Given a mode of transportation, identify hazards, and assess and identify methods to control the risks to pharma, biopharma, and vaccine products that are consistent with GDP.
7. Given a cold chain operation, evaluate which risks require a contingency plan in line with GDP/GSP.
8. Given a stock situation with different vaccines, various expiry periods and batches and VVM status, decide which products to be dispatched against a requisition order.
9. Create a decision tree for dispatch of vaccines involving all relevant factors.
10. Develop an action plan for the successful implementation of a policy change in in-country vaccine distribution.
11. Conduct a risk assessment for a given risk question related to temperature monitoring of temperature-sensitive pharmaceutical products in a storage facility.
12. Given a mode of distribution in the last mile, assess and control the risks to pharma, biopharma, and vaccine products consistent with GDP.
13. Assess and control the risks to pharma, biopharma, and vaccine products in a given power cut situation.
14. Given a list of risks and control options, prioritize which risks to reduce first.

15. Compare the advantages and disadvantages of a min-max thermometer to other temperature monitoring devices used in the last mile.
16. Given a video of someone performing a shake test, evaluate the process followed, the results obtained, and justify whether the vials can be used.
17. Conduct a shake test to decide whether a given freeze-sensitive vaccine has been affected by freezing.
18. Create a report on the results of a shake test.
19. Given two different scenarios of temperature exposure, expiry date, VVM status and opened/unopened multi dose vials, judge whether the vaccines are suitable for use.
20. Given a client, conduct critical analysis of the cold chain management system and make recommendations to improve the performance of the system in line with GDP/GSPs.