

Annex 1 Compliance Checklist

<input type="checkbox"/>	Review the new Annex 1 guidelines and ensure that you understand the requirements
<input type="checkbox"/>	Conduct a gap analysis to identify areas where your current practices do not align with the new requirements
<input type="checkbox"/>	Develop an action plan to address any gaps identified in the gap analysis
<input type="checkbox"/>	Ensure that you have appropriate personnel and resources in place to implement the action plan
<input type="checkbox"/>	Ensure that all personnel involved in manufacturing, testing, and packaging are appropriately trained on the new requirements
<input type="checkbox"/>	Implement cleaning and disinfection procedures to meet the new requirements
<input type="checkbox"/>	Establish processes for controlling environmental monitoring and sampling
<input type="checkbox"/>	Implement processes to control and monitor the quality of raw materials and components
<input type="checkbox"/>	Establish processes for controlling and monitoring the manufacturing process, including the use of aseptic techniques where appropriate
<input type="checkbox"/>	Establish processes for controlling and monitoring the packaging process
<input type="checkbox"/>	Establish processes for managing deviations, investigations, and corrective actions
<input type="checkbox"/>	Conduct regular reviews of the manufacturing process to identify areas for improvement
<input type="checkbox"/>	Establish a system for maintaining and controlling documentation, including procedures, specifications, and batch records
<input type="checkbox"/>	Ensure that all equipment used in the manufacturing and testing process is qualified and validated
<input type="checkbox"/>	Develop a plan for implementing the new requirements and ensure that it is regularly reviewed and updated