

System Requirements

Document Anticipated sub-systems to be covered and rationale:

Sub System	Key Internal Factors / Actions	Key External Factors / Actions
Management Controls	Internal Factors: 1. 2. 3. 4. Actions 1. 2. 3.	External Factors: 1. 2. 3. Actions 1. 2. 3.
CAPA	Internal Factors: 1. 2. 3. Actions 1. 2. 3.	External Factors: 1. 2. 3. Actions 1. 2. 3.

System Requirements (cont.)

Sub System	Key Internal Factors / Actions	Key External Factors / Actions
Design Controls	<p>Internal Factors:</p> <ol style="list-style-type: none"> 1. 2. 3. <p>Actions</p> <ol style="list-style-type: none"> 1. 2. 3. 	<p>External Factors:</p> <ol style="list-style-type: none"> 1. 2. 3. <p>Actions</p> <ol style="list-style-type: none"> 1. 2. 3.
Production and Process Controls	<p>Internal Factors:</p> <ol style="list-style-type: none"> 1. 2. 3. <p>Actions</p> <ol style="list-style-type: none"> 1. 2. 3. 	<p>External Factors:</p> <ol style="list-style-type: none"> 1. 2. 3. <p>Actions</p> <ol style="list-style-type: none"> 1. 2. 3.

Support Process

Logistics Actions	Support Team Actions	Request Process Actions

Subject Matter Experts

Identify SMEs		Action Plan for Preparation
Organization gaps	1. 2. 3. 4.	1. 2. 3. 4.
Critical Topics	1. 2. 3. 4.	1. 2. 3. 4.