

<b>[insert your company name]</b>	<b>Form #:</b>
<b>Site Inspection Proof Binder Contents</b>	<b>Effective:</b>
	<b>Supersedes:</b>

**Site Name:** \_\_\_\_\_

*Instructions: check off the following items as they are completed and added into the binder*

### Section One: Basic Information

- ☐ Site address, phone #'s, business hours
- ☐ Top-level organization chart for the site
- ☐ Overall site diagram with workflows (note any sterile or quarantine areas)
- ☐ List of products made/assembled at site (include reference to NDA/BLA/510K)
- ☐ List of products distributed from the site
- ☐ List of critical vendors
- ☐ List of 1st tier distributors
- ☐ Overall quality policy for the site
- ☐ Index of SOPs and policies
- ☐ List of any recent inspections or 3rd party audits
- ☐ List of current company certifications and recent awards
- ☐ For any nearby sites, geographic relationship map
- ☐ (Logistical list of nearby restaurants, tips for visitors, etc.)

*Note: if you will provide this binder in electronic format, consider adding a completed copy of this form to the digital media.*

### Section Two: Supplemental

- ☐ Specific SOPs and policies (relevant to inspection cause)
- ☐ Specific CAPAs or OOS's (relevant to inspection cause)

*Add rows as necessary – consider adding additional documents referenced in any previous regulatory inspection response (e.g., in your response to previous FDA-483 findings), in recall handling reports, and so on.*

<b>Additional Comments</b>

-End of Form-