

Guidance for Developing a Quality System Assessment (QSA) Program

This document can be used to help a company develop a quality manual which addresses all of the requirements of the QSA Program. When implementing a quality management system based on the QSA Program, the content of the quality manual must reflect the QSA Program requirements, although it does not need to match the format. A company must create a quality manual that describes its processes and procedures.

Some important points to remember:

- A quality manual must describe the company's processes and procedures as they relate to the QSA Program. You can reference existing procedures, work instructions, forms, etc within the quality manual.
- Say "what" you do and "how" you do it. It is not sufficient to simply state that you do something.
- Write in present tense (what are you doing) instead of future tense (what you will do).
- Use what you already have in place as long as it meets the QSA Program requirements. You can reference existing procedures, work instructions, forms, etc within the quality manual. (see #4)
- The QSA Program requires 4 documented procedures, at a minimum....7.2.3; 7.2.4; 9.1.2; and 10.1.4. It is easiest to reference the documented procedures within the quality manual and include them as attachments. When attached, the documented procedures can be revised as necessary without having to reissue the entire quality manual. If the documented procedures are included within the body of the quality manual, then the entire manual must be reissued when the procedures are revised.
- It is best to include the plant's name, the document's name, and the document's revision status on every page.
- Include the plant's physical location and the program contact's information either within the letter requesting service or in the quality manual.
- If the products produced under the QSA Program will fluctuate, then the QSA Program should not be included within the scope of the program. Instead, they should be outlined an attachment to the quality manual. This facilitates any additions or deletions to the product list without having to revise the quality manual.