Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
This document provides guidance in the conduct of Quality Assurance Self-Appraisals (QASA) to verify and assure the effectiveness of on-going quality systems, practices, and programs and to identify potential procedural gaps or system weaknesses at Manufacturing Production and logistic Sites.

1. The Site Quality Team should prepare and maintain a master list of Site operations that may be subjects of the QASA program. Collectively, that list should cover all major regulatory-related operations at the Site. Illustrative examples for production Sites include, but are not limited to, the following

• Manufacturing,	• Shipping,
Packaging	• Receiving
• Labeling& Label Control	• Solvent Recovery
• Engineering	• Quality Assurance
• Purchasing	• Validation
• Quality Control Labs	• Safety
• Production Control Labs	• Security
• Human Resources	• Medical Device Design Controls

Illustrative examples of definable operations for Logistics Centres include, but are not limited to, the following:

• Receiving and Shipping,
• Returned Goods,
• Carrier Identification,
• **Rejected** Goods,
• Carrier Inspection,
• Safety,
• Personnel Training,
• Security,
• Product Status Controls,
• Visitor Controls,
• Public Warehouses,
• Inventory Controls, and
• Temperature Controls During Product Transport,
• Sanitation and Pest Controls.

The Site Quality Team should review the above lists at least annually, and adjust them to broaden the coverage, when necessary.

