

## **Cerulean Associates LLC**

### **Supplier Quality Management Compliance Framework**

## **List of FDA Recommended Supplier Quality Management SOPs and Policies**

A review of FDA guidance documents and warning letters issued from 2011-2014, FDA's Federal Register notice of September 2011 (Federal Register, vol. 76, no. 188), and the GHTF/IMDRF guideline SG3-N17 *Guidance on Control of Products and Services Obtained from Suppliers* (2008) shows that FDA expects to see a fairly well-defined set of standard operating procedures (SOPs) and policies governing supplier quality management and purchasing controls.

Emphasis in nearly all of these policies and procedures is on how they help control finished product safety, efficacy and overall quality.

### **Overall**

- Policy: Supplier Quality Management (e.g., your program overview document)

### **Purchasing Controls**

- Determining Sourcing Needs – Products and Services
- Selecting Potential Suppliers
- Qualifying a Supplier
- Finalizing Supplier Controls
- Monitoring and Maintaining Supplier Compliance
- Re-Evaluating a Supplier
- Retaining Supplier Quality Records – Supplier Dossiers

### **Incoming Materials**

- Receiving and Testing Incoming Product Components, Containers and Closures
- Reviewing and Verifying Incoming Labeling and Packaging Materials

### **Warehousing and Distribution**

- Warehousing – Raw Materials and Components, In-Process and Finished Products
- Distributing and Tracking Finished Products (e.g., good distribution practices)

All of these are in addition to standard quality system procedures such as internal audits, corrective action and preventative action (CAPA), recordkeeping, quality system management reviews, recall handling, and so forth.

Keep in mind that this list does not necessarily mean you must have these specifically entitled as stand-alone SOPs; instead, FDA expects your procedures and policies to address each of these areas. Whether you can put all of the above into three SOPs or thirty SOPs will be dependent on your organization, how detailed you like your SOPs, how much you take advantage of process mapping, how much you can take advantage of forms to move workflow activities along, etc.

Note that creating, implementing, training on, and auditing these procedures and policies should be tasks on that master FDA site compliance plan.

For more practical supplier quality advice, articles, case studies and SmarterCompliance™ Toolkit checklists and templates, visit the Cerulean website: [www.ceruleanllc.com](http://www.ceruleanllc.com)

Example supplier quality management-related checklists to consider:

- Verifying Supplier Dossier Contents
- Reviewing a Supplier's Part 11 Computerized Systems Validation Efforts
- Verifying a Supplier's Overall 21 CFR 11 Compliance Status
- Steps to Verify Hosted IT Vendor Controls for 21 CFR 11
- Checklist of Do's and Don'ts for Quality and Technical Agreements

For expert supplier quality and compliance help, contact Cerulean today  
[www.ceruleanllc.com](http://www.ceruleanllc.com)