Your Roadmap for Purchasing Controls and Supplier Evaluation based on FDA's Recommendations

Each manufacturer shall establish and maintain:

REQUIREMENT	ACTIVITY	MANUFACTURER REMARKS
Evaluation of suppliers, contractors, and consultants	A procedure to evaluate suppliers.	
	The manufacturer shall define and maintain quality requirements.	
	Suppliers, contractors, and consultants must comply with manufacturer's technical specifications or quality requirements.	
	Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet manufacturer technical specifications or quality requirements.	
	Each supplier, contractor, and consultants' evaluation shall be documented.	
	Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.	
	Maintain records or list of approved or acceptable suppliers, contractors, and consultants.	
	Periodically review and update records or list of approved or acceptable suppliers, contractors, and consultants.	

Purchasing data	Maintain data that clearly describe the technical specification of the purchased product (raw materials, components) or services.	
	A quality agreement with the suppliers, contractors, and consultants	
	Purchasing documents where supplier agrees to notify the manufacturer of changes in the product or service	
	Certificate of analysis or test report or safety specification sheet or MSDS (as applicable).	

Reference:

1. ISO 13485:2016 (E) – Medical Devices – Quality Management systems – requirements for regulatory purposes. Clause 7.4.1 Purchasing Process, 7.4.2 Purchasing Information
2. TITLE 21 – Food and Drugs; Chapter I—Food and Drug Administration, Department of health and human services, Subchapter H – Medical Devices; PART 820 - Quality system regulation, Subpart E—Purchasing Controls; Sec. 820.50 Purchasing Controls

DISCLAIMER: This document neither creates nor confers any rights towards any person or organization and does not enforce to abide by the content. It is only intended to support organization(s) or individual(s) referring to this document to understand the purchasing controls requirements as recommended by U.S FDA in accordance with 21 CFR Part 820.50. The simple usage does not automatically imply the fulfillment of any regulation. Please refer to the applicable guidance for complete detail.

Additional Resources:

The Ultimate Guide to Next-Generation Supplier Management
(eBook)

Supplier Quality Agreements for Supply Chain Risk, Mitigation and Compliance
(Whitepaper)

Doc. CQEQMS-053 Ver1.0, eff. November 9th, 2021

About ComplianceQuest

ComplianceQuest is an award winning, 100% cloud based **Next Generation AI-Powered Enterprise Clinical, Quality, Health and Safety Management Solution (QHSE)** natively built and run on the **Salesforce platform**. Our unified and connected solutions help companies of all sizes deliver quality products and services in the safest, most sustainable way by mitigating risk, problems, and inefficiencies while protecting customers, patients, employees, suppliers and brand.

For more information, or to request a demo with a ComplianceQuest expert, contact ComplianceQuest today.

Visit www.compliancequest.com • **Email us at marketing@compliancequest.com** • Call us at 408-458-8343