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Addendum 2

Page 3, the following definition shall be added:

3.1.22
supply chain
Suppliers and associated sub-supplier(s) required for product realization.

Page 11, Section 5.4.3, bullet d) shall be replaced with the following:

d) include identification of, or reference to, products, components and/or activities deemed critical to the design;

Page 11, Section 5.4.3, the NOTE shall be replaced with the following:

NOTE Identification of criticality of products, components, and/or activities can be maintained outside of the design and development process.

Page 12, Section 5.6.1.1 shall be replaced with the following:

The organization shall maintain a documented procedure to ensure that purchased products, components or activities conform to specified requirements.

The procedure shall address:

a) identification of critical products, components or activities;

b) initial evaluation and selection of suppliers based on their ability to supply products, components or activities in accordance with the organization‘s requirements (see 5.6.1.2 and 5.6.1.3);

c) type and extent of control applied to the supply chain for critical products, components or activities;

NOTE Section 5.6.1.6 contains additional requirements for outsourced activities.

d) criteria, scope, frequency, and methods for reassessment of suppliers; and

e) maintaining a list of approved suppliers and scope of approval.

Pages 12 and 13, Section 5.6.1.2 shall be replaced with the following:

For purchase of critical products, components or activities, the initial evaluation of suppliers by the organization shall be site-specific for each supplier and shall include the following:

a) verification that the supplier’s quality management system conforms to the quality system requirements specified for suppliers by the organization;

b) verification of the type and extent of control applied by the supplier, internally and to their supply chain, in order to meet the organization's requirements; and

c) assessment of the supplier to ensure its capability to meet the organization's specified requirements by one or more of the following:

   1) performing an on-site evaluation of relevant activities, or

   2) performing first article (see 3.1.11) inspection to ensure conformance to stated requirements, or

   3) identifying how the supplied product, component or activity conforms to stated requirements when limited by proprietary, legal, and/or contractual arrangements.

Page 13, Section 5.6.1.3, bullet c) shall be replaced with the following:

c) assessment of the product or component upon delivery, or activity upon completion.

Page 13, Section 5.6.1.4, shall be replaced with the following:

The organization shall determine the supplier reevaluation frequency based on supplier risk and supplier quality performance.

For the reevaluation of suppliers of critical products, components or activities, the requirements of 5.6.1.2 shall apply.

For the reevaluation of suppliers of noncritical products, components or activities, the requirements of 5.6.1.3 shall apply.

Page 13, Section 5.6.1.6, the following note shall be added after the first paragraph:

NOTE See 5.7.1.5 for requirements when a process requiring validation is outsourced within the supply chain.

Page 14, Section 5.6.2, the following note shall be added at the end of the section:

NOTE Applicable specifications may include or be derived from the customer, API product specifications, design output, and/or industry standards.

Page 14, Section 5.6.3, the first paragraph shall be replaced with the following:

The organization shall maintain a documented procedure defining the verification or other activities necessary for ensuring that purchased products, components or activities meet specified purchase requirements.

Page 14, Section 5.6.3, the following shall be inserted after the first paragraph:

For critical products, components or activities, the procedure shall include the following :

a) review of the organization's required documentation from the supplier; and

b) verification that the applicable versions were used when specifications, drawings, process requirements, inspection instructions, traceability, and other relevant technical data are specified per 5.6.2. b).

Additionally for critical products and components, the procedure shall include requirements for the testing or inspection methods, frequency and responsible party for these activities. The requirements shall be based on risk associated with supplier product quality.

Page 15, Section 5.7.1.5, the last sentence of the first paragraph shall be replaced with the following:

Where an organization chooses to outsource a process that requires validation, the organization shall require that the supply chain conform to these requirements (see 5.6.1.6).

Page 16, Section 5.7.1.5, the last paragraph shall be replaced with the following:

The organization shall validate those processes identified by the applicable product specification as requiring validation. If these processes are not identified, or there is no product specification involved, the processes requiring validation (if applicable to the product) shall include, as a minimum:

g) nondestructive examination;

h) welding;

i) heat treating; and

j) coating and plating (when identified as critical to product performance by product specification or the organization).

Page 20, Section 5.11.2, bullet c) shall be replaced with the following:

c) changes in suppliers of critical products, components or activities (see 5.6.1.1); and/or

Page 22, Section 6.4.2, the first sentence of the first paragraph shall be replaced with the following:

The organization shall maintain a documented procedure to correct nonconformities and to take corrective actions, both internally and with suppliers, to eliminate the causes of nonconformities in order to minimize the likelihood of its recurrence.

Page 23, Section 6.4.3, the first sentence of the first paragraph shall be replaced with the following:

The organization shall maintain a documented procedure to determine and implement preventive actions, both internally and with suppliers, to eliminate the causes of potential nonconformities in order to minimize the likelihood of their occurrence.