New Proposed Chapter- Supplier Qualification by User of Upstream Supply Chain for Pharmaceutical Excipients

Type of Posting: General Announcement
Posting Date: 30–March–2018
Input Deadline: 30– April–2018
Expert Committee: Excipient Monographs Expert Committee 1 and 2

Proposed New Title: <XXXX> Supplier Qualification by User of Upstream Supply Chain for Pharmaceutical Excipients

Suggested audience: Excipient makers, distributers and users

Estimated proposal PF: *Pharmacopeial Forum* 45(3) [May–Jun. 2019]

Background and objective(s): USP is requesting early input from stakeholders on a newly proposed sponsor-driven General Chapter <XXXX> *Supplier Qualification by User of Upstream Supply Chain for Pharmaceutical Excipients*, which will be published for comment in Pharmacopeial Forum 45(3) [May–Jun. 2019].

This informational general chapter numbered above 1000 will provide guidance to help minimize risk to product quality caused by insufficient supply chain development and management by users.

The pharmaceutical industry has expressed repeated concerns of not being able to reliably and consistently ensure the supply of incoming materials used in their products. It is widely believed that the lack of reliability of incoming material is based on poor performance of suppliers, and is therefore the basis of many supply chain management practices. Through recent findings, a major paradigm shift was recognized in that all of the failure modes were related to risks either induced by the manufacturers themselves, or could have been avoided by the manufacturers. These findings were not solely related to poor performance of suppliers as originally surmised. This critical paradigm shift has enabled the industry to focus solutions on reducing risk caused by the manufacturers, and therefore, actually reduce risk to the final product.

The direct impact of this paradigm shift is that it:

- Shifts resources from trying to improve supplier performance to improving internal performance that affects the ability of the suppliers to perform well.
- Enables industry to take ownership of the failure modes impacting supply chain integrity.
- Enables industry to develop solutions that will reduce risk to product quality.
- Enables global regulators to understand critical root causes to supply chain integrity and therefore product quality risk.

Based on the identified areas of opportunity, a toolkit of solutions have been developed that establish internal alignment across functions on material and supplier requirements prior to engaging the supplier that includes a robust set of risk elements to evaluate for supplier selection and the relative importance of those risk elements on the product and business.

Description of scope and application:
This work serves as the foundation for the informational general chapter numbered above 1000 approach, which gives industry the flexibility to adopt the solutions in a way that makes the sense for their level of maturity, their product types, and their business. This approach also allows regulators to utilize these solutions as resource tools, instead of requirements, and will enable regulators to better assess the quality of supply chain development and management in context with product risk and company maturity.

Anticipated proposed design phase activities: Following publication in PF, USP plans to hold a USP workshop at USP in Autumn 2019.

Anticipated implementation timing: Routine

Contact: Catherine Sheehan, M.S., M.S., (301-816-8262), cxs@usp.org)