



USP International Excipient Workshop

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PRESENTATION ABSTRACT

- Title:** Regulatory Perspective on Assuring Excipient Quality
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- Abstract:** Pharmaceutical excipients are defined as drugs and are thereby subject to the adulteration provisions of the U.S. Food, Drug & Cosmetic Act. An excipient is considered adulterated unless it complies with applicable specifications (e.g. USP monograph requirements) **and** unless it is manufactured and held in accordance with Good Manufacturing Practices (GMP) appropriate for its intended use. Furthermore, even if it conforms to its specification, any excipient that has been diluted with or substituted by an unapproved, undeclared substance is considered adulterated. The entire excipient supply chain plays an important role in GMP; proper distribution and storage practices protect the integrity and quality of the excipient while supply chain security can help prevent the tampering and diversion that can lead to adulteration.

Problems in the excipient supply chain can have an adverse effect on excipient quality, and in the worst cases, also on patient safety. Therefore, FDA is seeking new tools to maximize use of its limited resources, including technological solutions. FDA's oversight of excipients could be augmented by information sharing with foreign regulatory counterparts and via an expanded global presence. An increased level of excipient regulatory authority may be on the horizon for FDA amid concerns about exposure of the public to unsafe excipients and APIs.

Whatever the outcome of deliberations by lawmakers, the CGMP regulations require finished drug manufacturers to assure the quality and integrity of every excipient batch prior to its use as a drug component. Manufacturers can build quality assurance through various means including auditing of suppliers, implementation of adequate specifications, and monitoring of excipient quality throughout the supply lifecycle. Furthermore, the ability to verify excipient traceability to a qualified manufacturing site helps ensure the integrity of the supply chain was maintained such that the batch received is truly qualified for its intended use.

A Quality Management System (QMS) is the foundation for excipient GMP. What constitutes appropriate GMP is determined via understanding of the intended use of the excipient. Thus, excipient GMP assures that the user's quality requirements are consistently met and

works in tandem with a robust QMS to build quality into drug products. Establishing an effective communication link enables excipient and finished drug manufacturers, and the intermediary supply chain, to share information to cooperatively manage quality of the excipient.

After attending this session, the attendee will understand main root causes of excipient adulteration and will be equipped with the knowledge to implement practices and tools to prevent adulteration. The attendee will also appreciate the manner in which excipient quality and integrity are assured by application of a QMS by finished drug manufacturers and by all members of an excipient supply chain.

References: FD&C Act, sections 201(g) and 501(a-d)