#### CENTER FOR DRUG EVALUATION AND RESEARCH

#### POLICY AND PROCEDURES

#### Office of Pharmaceutical Quality

#### Establishing Impurity Acceptance Criteria As Part of Specifications for NDAs, ANDAs, and BLAs Based on Clinical Relevance

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#### PURPOSE

This MAPP provides guiding principles and approaches for establishing drug substance and drug product impurity acceptance criteria for non-mutagenic impurities in new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs), based on the consideration of clinical relevance.<sup>2</sup>

While ICH Q3A(R2) and Q3B(R2)<sup>3</sup> apply to new molecular entities produced by chemical synthesis, the principles of these guidances and the principles of this MAPP may apply to other drug substances and drug products, including some semi-synthetic and fermentation products, and synthetic peptides, <sup>4</sup> submitted in NDAs and ANDAs.

The principles in this MAPP may also apply to:

 Establishment of acceptance criteria for DNA-reactive (i.e., mutagenic) impurities that are generally controlled at tighter limits according to the ICH M7.<sup>5</sup>

In this MAPP, impurity can refer to process- and product-related impurities including degradation products for drug substance and drug product.

<sup>&</sup>lt;sup>2</sup> In this MAPP, clinically relevant acceptance criteria are defined as a set of acceptance ranges to which an impurity should conform in order for the product to be safe and effective when used as labeled.

<sup>3</sup> See 5 and 6 in References.

<sup>\*</sup>ICH Q3A(R2) and Q3B(R2) exclude certain NDA and ANDA products (e.g., peptides, oligonucleotides, fermentation products, and semi-synthetic products).

<sup>&</sup>lt;sup>5</sup> See 7 in References section.

# **Wholesale Drug Distributor Policies And Procedures Manual**

Zhe Xu

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