

EudraLex Vol. 4 Annex 1 – Strategy Definition

Zamann Pharma Support offers specialized consultancy aiding clients in developing strategies to adapt to the latest requirements outlined in the revised EudraLex Vol. 4 Annex 1. We assist in creating a comprehensive pathway for the adaptation project, ensuring alignment with regulatory standards and industry best practices

Microbiological Aspects

We analyze the updated requirements related to microbiological quality, including microbial monitoring, environmental monitoring, and control of microbial contamination.

Our experts assist in developing strategies for implementing robust microbiological control measures to ensure product quality and compliance with Annex 1.

Aseptic Processing

We provide guidance on the enhanced requirements for aseptic processing, including validation of aseptic processes, facility design, and personnel training. Our consultancy assists in developing strategies for implementing advanced aseptic techniques and technologies to meet the standards set forth in the revised Annex 1.

Contamination Control Strategy

We help clients establish comprehensive contamination control strategies, addressing aspects such as cleanroom design, sterilization processes, and control of particulate and microbial contamination. Our team collaborates with clients to develop approaches for mitigating contamination risks and ensuring product quality, safety and efficacy.

