

Cross-contamination in Shared Facilities Guidance by PIC/S goes into force July 1st, 2018

On July 1st, 2018, the Pharmaceutical Inspection Convention Scheme (PIC/S) on Cross-contamination in Shared Facilities Guidance goes into force. This includes the additional guidance on establishing **health-based exposure limits** (HBELs) for shared facilities. These Chapters of the PIC/S GMP Guide have now been aligned with principles of Quality Risk Management. Chapter 3 and 5 of the PIC/S GMP Guide have been revised to include requirements to prevent cross-contamination, and the HBEL guidance discuss the requirement for PDEs (aka ADEs) in shared facilities. At first review, these guidance documents appear to almost mirror the EMA's guidance on similar topics.

The impact on these documents is significant since many regulatory agencies throughout the world use them in their inspection process. In addition, companies that previously weren't required to follow the EMA's guidance because they did not import products into the EU, are now required to follow the guidance if they are located in any of the 52 **PIC/S member countries**. In addition, Armenia, Brazil, Italy, Pakistan, the Russian Federation, and Saudi Arabia have all in the "pre-applicant" stage of accession into the PIC/S organization.

Key guidance documents that should be carefully reviewed include:

- [PI 043-1 CROSS-CONTAMINATION IN SHARED FACILITIES](#)
- [PE 009-14 \(Part I\) GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS PART I](#) Chapters 3, 5, & 8 are based on the equivalent Chapters of the EU GMP Guide with some minor differences in terms of language.
- [PI 046-1 GUIDELINE ON SETTING HEALTH BASED EXPOSURE LIMITS FOR USE IN RISK IDENTIFICATION IN THE MANUFACTURE OF DIFFERENT MEDICINAL PRODUCTS IN SHARED FACILITIES](#)

Reference: [Cross-contamination in Shared Facilities Guidance by PIC/S goes into force July 1st, 2018 \(affygility.com\)](#)