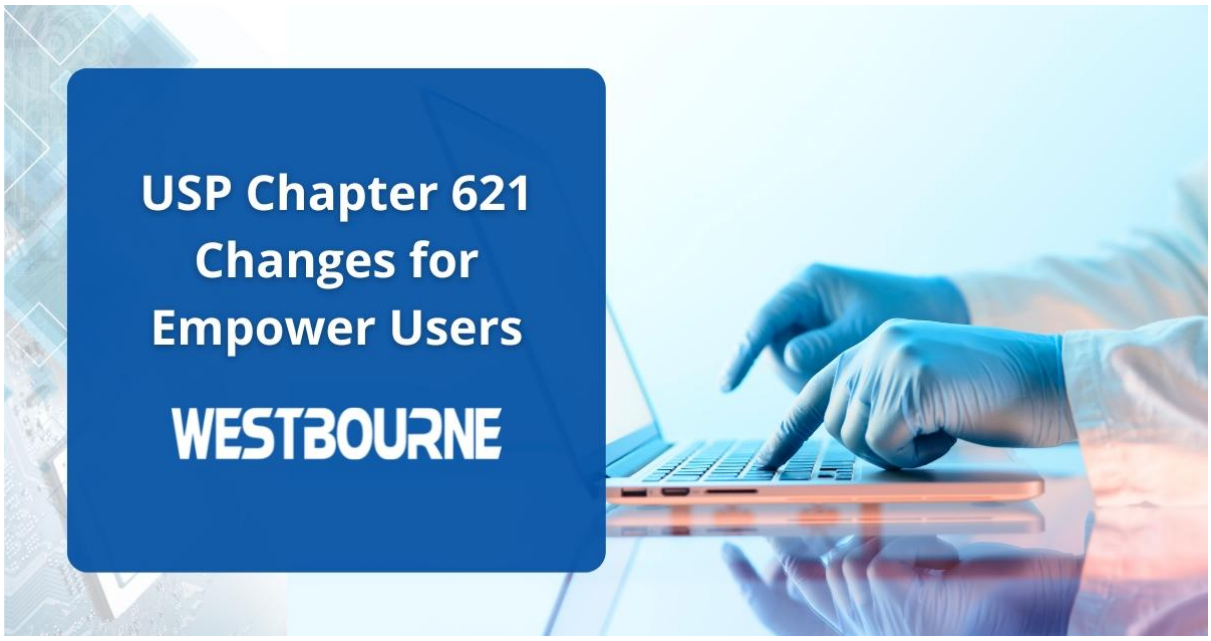
What Empower Users Need to Know About Changes to USP 621



USP Chapter 621 Chromatography has been updated by the United States Pharmacopeia (USP). Why has the chromatography chapter been updated, what are the main changes compared to the previous version of Chapter 621, and how will the changes impact Empower users?

What is USP 621?

USP 621 is a quality standard for the pharmaceutical industry. It ensures consistency in chromatography procedures and terms, as well as defining allowable method adjustments.

Why Has USP 621 Been Updated?

Advances in technologies over the past number of years have enabled the development of new, effective, and efficient chromatographic methods. The updated version of USP Chapter 621 reflects these method and technological advances.

For example, with the updated standards, it is now easier to use tools provided in software applications like Empower to take advantage of the productivity gains and efficiency savings that are possible by using advanced chromatographic methods.

The updated USP 621 is also part of the United States Pharmacopeia's harmonisation initiative. That initiative involves the US Pharmacopeia working with other organisations, including the European Pharmacopeia and Japanese Pharmacopeia, to achieve the international harmonisation of pharmacopeial standards.

When Did the New Standards Go Live?

The updated version of USP Chapter 621 Chromatography came into effect on 1 December 2022.

What Has Changed in the Updated Version of USP 621?

Many of the main changes in USP 621 relate to definitions and allowable adjustments.

Definitions

- New definitions have been introduced, including Plate Height and Plate Number, as well as definitions for size-exclusion chromatography, including Total mobile phase time and Distribution constant.
- Formulas for Plate Number (previously referred to as Plate Count) and Resolution have been modified to use half-height (HH). Tangent width no longer appears in the updated USP 621.
- Signal-to-noise measurements are now based on 20 times the peak width at 50 percent height, replacing the previous 5 times peak width at 50 percent height.
- Tailing factor has been renamed as symmetry factor, harmonising USP 621 with the European Pharmacopeia and Japanese Pharmacopeia.

Allowable Adjustments

In the previous iteration of USP 621, modifications to gradients were very restricted. For example, it was not possible to make changes to the gradient profile or particle size/column length.

New allowable modifications to gradients have now been defined in the updated USP 621.

For example, for gradient profiles, it is now possible to make adjustments based on flow rate, column dimensions, and particle size. Modifications to flow rate, column dimensions, and particle size are also now allowed within specified parameters.

These changes in USP 621 now mean there is greater alignment between gradient tests and isocratic tests.

The allowable adjustment changes in the updated USP 621 could have a significant impact on the performance of pharmaceutical labs. According to an analysis by Waters scientists, significant time and solvent savings can be achieved using the modern liquid chromatographic methods that are now possible with the updated version of USP 621.

What Do These Changes Mean for Empower Users?

The new USP 621 might mean you will need to update several elements of Empower, including processing and reporting methods.

Our team at Westbourne IT is here to provide whatever support you need. Our Empower experts can help you update your system to transition to the new USP 621 standards. We can also provide consultative and training support. Get in touch today.