

Author: B.Eng. Peter Bäuerle, GBA Pharma GmbH

Titel: "Understanding and Addressing User Rights Configurations in Computer System Validation under GMP: Challenges and Considerations for Users"

Topic: Dealing with the complexity of user rights configurations: Important considerations for effective user management in computer system validation under GMP. Navigating the diverse landscape of user rights settings in software systems from different vendors presents a challenge when it comes to ensuring regulatory compliance and data integrity.

Abstract:

In the field of computer system validation according to Good Manufacturing Practice (GMP), effective user management is a crucial aspect that poses challenges for both users and software developers. The lecture provides valuable insights into the complexity of user rights configurations in software systems from different vendors from a validation perspective and aims to improve users' and developers' understanding of GMP-related user management challenges.

The differences in user rights settings can be significant, with some systems offering predefined, immutable user groups while others offer more granular control over individual permissions. In addition, there are systems that lack the user group function at all.

Understanding the available user rights options and their implications is important for implementing robust user management strategies. Documenting and communicating these settings is important to ensure regulatory compliance and maintain data integrity.

The diverse configurations of user rights in software systems pose challenges during the computer system validation process under GMP. It is crucial to adapt validation strategies to account for these variations and to ensure a successful validation outcome.

The lecture highlights the impact of different user rights configurations on the validation process and emphasizes the importance of customization and compliance within the specific settings of software systems. It serves as a valuable resource for users and software developers, providing insight into the challenges and considerations associated with GMP-compliant user management.