

When gravimetry is debated by sponsors of clinical studies

Cancer research has grown significantly in recent years with the advent of targeted therapies and immunotherapies. Hospital pharmacies with clinical trials and production units need to manage and produce these new drugs. Unlike the industry, where processes are automated, hospital pharmacy processes are often manual. The flow of these experimental drugs should be secured.¹ Hospital pharmacies can choose from several production in-process control methods, the most common of which is human-visual double-checking or computer-assisted preparation with automated visual control by camera or automated gravimetric control by connected scales.

This method, which uses computer-assisted double-checking, has proved reliable and less error-prone in limited studies.^{2,3} These controls are based on pre-entered weights (eg, content, container) and density values of the molecules. However, despite its effectiveness, clinical trial sponsors often do not mention the gravimetric production method as a safer method in their trial documents. This control method is already approved by the Swiss health authorities and is often accepted by the pharmaceutical industry in over 90% of cases during implementation or feasibility visits, following in-depth discussions.

Some sponsors are still reluctant, probably due to a lack of up to date knowledge of hospital practice, and refuse to provide exact density values of their molecules to enable the parameters to be set in the production software, arguing that these

data are confidential. If the density value is missing it can be determined empirically; a default value of 1 g/mL is set in the software (most molecules are close to this value), then the exact volume is taken during the first production run and the density value is adjusted according to the requested volume by the software. However, using the confirmed density value gives a more accurate production.

This letter opens the debate on computer-assisted gravimetric production control methods. Why do some sponsors reject this method of production control when it is recognised by the scientific hospital community, the health authorities and one of the world's top five pharmaceutical companies has approved it in every clinical trial document (eg, pharmacy manual) and provides the pharmacist with the exact density value?⁴

How can we persuade pharmaceutical companies to adopt the gravimetric method over volumetry? The gravimetric method, being more innovative, safer, and reliable, presents a significant opportunity to enhance the safety of drug circuits in clinical trials, renowned for their high-risk nature. Despite the pioneering efforts of hospital pharmacies and their use of diverse software packages in this realm, there is a compelling case for pharmaceutical companies to embrace the superior capabilities of the gravimetric method. For us, the safety factor must be paramount and it is time to change practice.

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