

Abstract

In Vitro / In Vivo Correlation (IVIVC): Measurements and Simulations to Estimate Aerosol Drug Delivery

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In vitro testing (from the Latin “within the glass”) provides researchers the ability to characterize medical aerosols and how the performance of their generation and delivery varies across a broad range of variables.

In vitro testing can be relatively inexpensive and allow us to study isolated variables that can not be well studied in more complex systems, such as patients. In vivo testing (again from the Latin “within the living”) is typically more time consuming, expensive, and risky, with results complicated by a large array of variables that are difficult to discretely isolate in complex organisms. In silico testing (from the Greek “in Silico” refers to computer based modeling.

Aerosol drug delivery is impacted by a broad range of patient and environmental variables (e.g., breathing maneuvers, air flows, breathing patterns, airway conditions, as well as ambient temperature and humidity). In vitro testing helps to understand a wide array of variables issues of aerosol generation and interface with devices and their delivery devices with the goal of establishing some predictive models as to how the aerosol and device may impact dose delivery to patients. Establishing In vitro/in vivo correlations (IVIVC) initiates the vital cycle of theory development and clinical feedback essential to develop predictive models of aerosol behaviour and drug delivery. Models vary in predictive value based on the methods used for characterization, the variables applied, and the transition from the simplicity of the bench to the complexity of the patient. Even poor initial IVIVC can help to develop iterative “feedback loops” that provide new insights and may lead to more accurate models and improve predictive capabilities of bench work. Establishing IVIVC helps allow relatively rapid improvement of devices and formulations at low cost and no risk to patients, minimizing the frequency, cost and time associated with clinical trials and in vivo testing.