

“Digital by Design” (DbD) approach to develop a Universal Deep learning AI architecture for automatic chromatographic peak integration .

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Abstract

Chromatographic data processing has garnered attention due to multiple FDA 483 citations and warning letters, highlighting the need for a robust technological solution. The healthcare industry has the potential to greatly benefit from the adoption of digital technologies, but the process of implementing these technologies can be slow and complex. This article presents a “Digital by Design” managerial approach, adapted from pharmaceutical quality by design principles, for designing and implementing an artificial intelligence (AI)-based solution for chromatography peak integration process in the healthcare industry. We report the use of a convolutional neural network model to predict analytical variability for integrating chromatography peaks and propose a potential GxP framework for using artificial intelligence in the healthcare industry that includes elements on data management, model management, and human-in-the-loop processes. The component on analytical variability prediction has a great potential to enable Industry 4.0 objectives on real-time release testing, automated quality control, and continuous manufacturing.

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