Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

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Thoughts from a former regulator on platform technologies, platform technology designation, and the use of contract manufacturing/testing organizations for biotechnology products.

The biotechnology industry has employed platform technologies for many years, but it took time for both industry and health authorities to get comfortable with the concept. One could argue that the FDA's 1997 Guidance Document "Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use" promoted the use of platform technology by introducing the concept of generic or modular virus clearance. However, it took several years for industry to adopt this approach as other health authorities were not yet ready to accept data from one product to support the development of a different, structurally related product.

Today many sponsors use prior knowledge and platform technologies to help speed up product development, but there may not always be a regulatory benefit. In addition, small companies that have only one product haven't yet developed a platform. These companies may rely on CDMOs that have developed a platform technology, but it is challenging to use data from other sponsors that use the same platform.

FDA guidance and regulations concerning platform technologies and Drug Master Files (DMF) will be presented. The presentation will include personal thoughts on the use of platform technologies and DMFs for biotechnology based on over 30 years of regulatory experience.