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Analytical Method Validation for Biopharmaceuticals, Part 3

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Over the history of the biotechnology industry, biopharmaceutical companies have expended considerable effort characterizing and tracking the entire suite of product attributes using available technology, uncertain of the biological significance of the various attributes. Product specifications for purity were based on chromatographic patterns capable of tracking the consistency of manufacturing, but unable to track specific attributes, due to the heterogeneous nature of the chromatographic peaks.

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