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Analytical Method Validation for Biopharmaceuticals, Part 1: Introduction and System Suitability

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Photo by Geoffrey Whiteway

This contribution, because of its length, will appear in approximately six consecutive issues of this journal. The content will use consecutive references and figure numbers/captions throughout. Each installment will remain available online at the usual website as you receive newer sections. Each section will also be available to download for subscribers. Content will be subdivided as follows: Introduction System Suitability Considerations Robustness Considerations for HPLC Methods Validation Design, Peptides and Biopharmaceuticals Identity — Characterization Methods Using HPLC and/or HPLC-ESI-MS,...