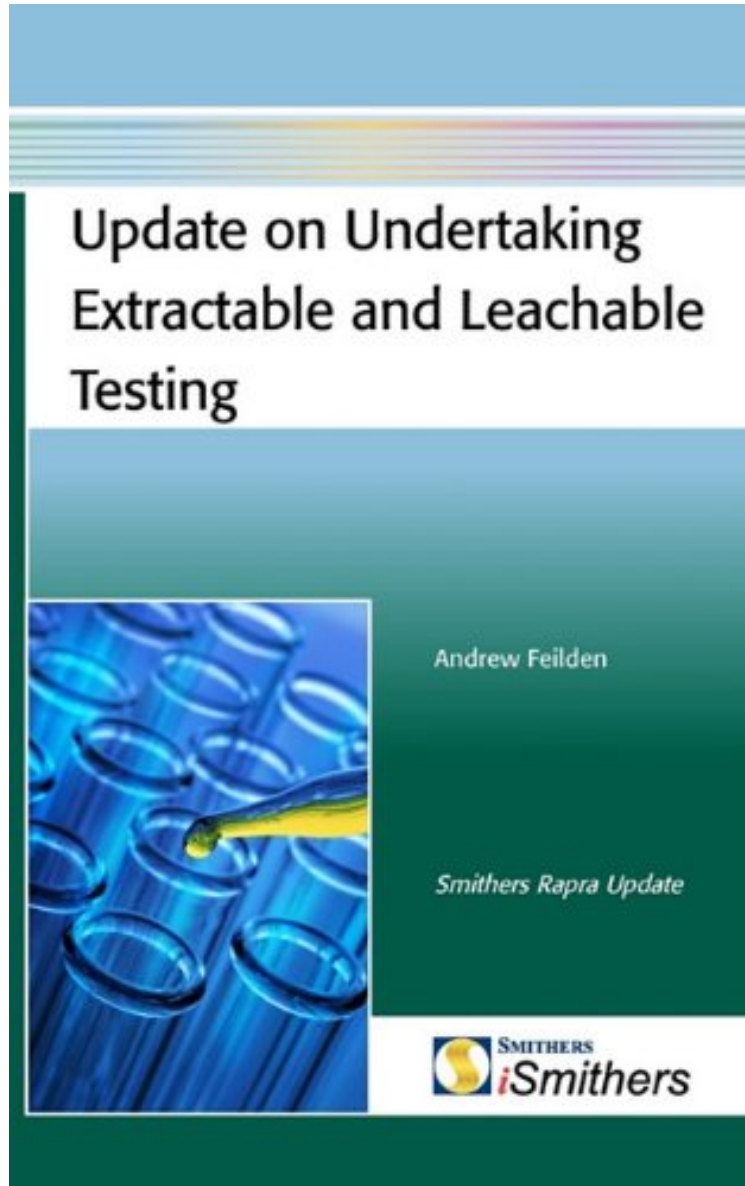


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Update on Undertaking Extractable and Leachable Testing

Andrew Feilden

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The assessment of all materials - and especially elastomeric and plastic components - for the presence of leachable and extractable components, forms an important part of the submission for approval of a new drug system or medical device. This Update gives a detailed, state-of-the-art review of the selection of techniques, available to the analyst, to perform a controlled extraction study for leachables and extractables, with an overview of the factors to consider when selecting the extraction technique. This book will be of interest to Chemists and RD managers.

About the Author Dr Andrew Feilden gained a degree and D.Phil from York University. He joined the analytical science department at AstraZeneca in 1998, where he is now responsible for the extractable and leachable testing. He is a recognized expert in the field of extractables and leachables being a member of the IPAC-RS container closure group (International Pharmaceutical Aerosol Consortium on Regulation and Science) and the ELSIE group (Extractable and Leachable Safety Information Exchange).