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Shane P Smith

ExtLe Solutions Ltd., UK

Six essential do's and don'ts for an effective GMP extractable and leachables strategy

The subject of extractables and leachables has become an increasingly hot topic within regulatory agencies over recent years, especially with the increase of single use technologies in the manufacture of API/BDS and drug products. In addition, new guidance documents and pharmacopeial updates are driving the need for a thorough understanding of how extractables and leachables may affect the quality and efficacy of a drug product. This presentation will discuss key issues to consider whilst developing and executing a scientifically robust, and cost/resource effective GMP extractables and leachables strategy.

Biography

Shane P Smith is the Managing Director of ExtLe Solutions Limited, a company based in Cambridge in UK. He has over 30 years of experience in Industrial Analytical Chemistry, with well over half of that time spent in the Pharmaceutical sector. From 2004, he has worked for GlaxoSmithKline's world class extractables and leachables team at Stevenage in the UK, managing projects for global cross-site project teams, and having ultimate responsibility for extractables and leachables sections of regulatory files submitted to agencies in North America, Europe and other territories. He has left GlaxoSmithKline in early 2016 to pursue a career as an Independent Consultant.

spsmith@extlesolutions.com

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