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Late-phase Development. Regulators Are Now Increasingly Requesting Additional E&L Data For Early Phase Clinical Trial Material, Especially When The Products Are Nonstandard Or Lack A Vendor-provided Extrac Jan 7th, 2024

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Extractables And Leachables

Covered In 21 CFR 211.94 (a), 21 CFR 600.11 (h), And The FDA Guidance On Container-closures (2, 4, 5). They Are Also Mentioned In 21 CFR 600.3 (b) (6). An Understanding Of Extractables And Control Of Leachables Is Expected As Part Of

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