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EXTRACTABLES AND LEACHABLES STRATEGIES FOR PHARMACEUTICAL PRODUCTION TUBING

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ABSTRACT

In order to mitigate the risks of potentially harmful substances leaching from contact materials or process tubing into a medicinal/pharmaceutical product which may present a health risk to the patient, a robust approach to extractables and leachables (E&L) studies is required in order to gain a good understanding of the materials in the tubing products.

In this short article, our expert, Dr Tino Otte, Senior Scientific Consultant, describes the steps of a rigorous E&L study that can be taken to ensure safe and high-quality materials and tubing products.

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