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Webinar on

Extractables and Leacheables in Drug Development

Learning Objectives

- *Understanding the different types of extractables and leachables*
- *Recognize the importance of extractables and leachables evaluations*
- *Learn the necessary steps of extractable and leachable evaluations*
- *Learn how to deal with extractables and leachables associated with potential safety concerns*
- *Learn the concept of Permitted Daily Allowance*
- *Recognize the difference between extractable and leachable assessment when the active ingredient is a small molecule or a biological product*
- *Influence and motivate cross-functional colleagues to embrace their critical roles in successful extractable and leachable evaluation programs*

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An effective extractable and leachable evaluation is essential for the overall success of any pharmaceutical drug development program for both small molecules and biologicals agents.

PRESENTED BY:

Dr. Stefano Persiani is currently Director of Translational Sciences and Pharmacokinetics at Rottapharm Biotech, Italy. He graduated in Pharmacy at the University of Milan, Italy and completed a Post-Doctoral fellowship in the Department of Pathology of the University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania, USA, and later as a Research Associate in the Department of Pharmaceutics of the University of Southern California, School of Pharmacy in Los Angeles, California, USA.

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On-Demand Webinar

Duration : 60 Minutes

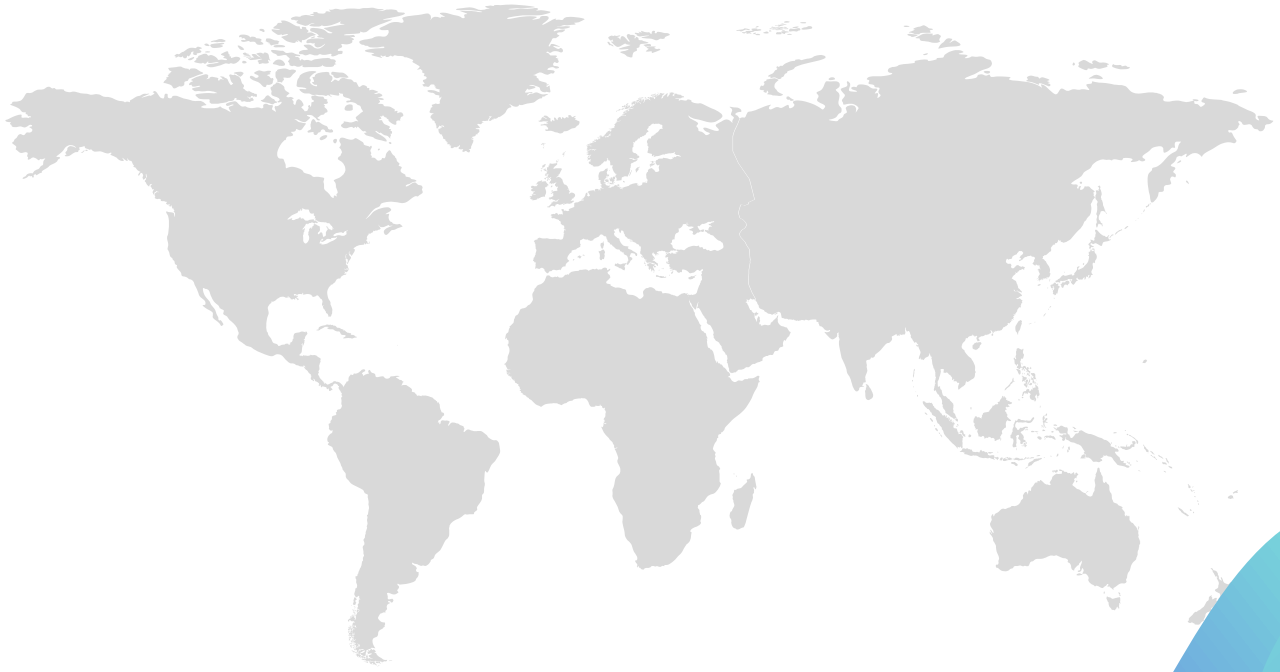
Price: $200

Webinar Description

Leachables from pharmaceutical container closure systems can present potential safety risks to patients. Extractables studies identify potential leachables and therefore assess and mitigate the above risks based on the dosage forms and the administration route. When safety concerns are detected, approaches for the toxicological evaluation of extractable and leachable have been developed and applied by pharmaceuticals and biologics manufacturers. These approaches may differ depending on the nature of the final drug product, the formulation, the route of administration and the length of use. Available regulatory guidelines provide compound-specific indications but do not provide a general and comprehensive approach to safety evaluations of leachable and/or extractable. This webinar provides a general overview of this topic and the possible approaches to safety evaluations of extractable and leachable.

Who Should Attend ?

Project managers
Regulatory affairs
Pharmaceutical development scientist
Toxicologists
Drug discovery scientists
CMC scientists
Clinical development scientists



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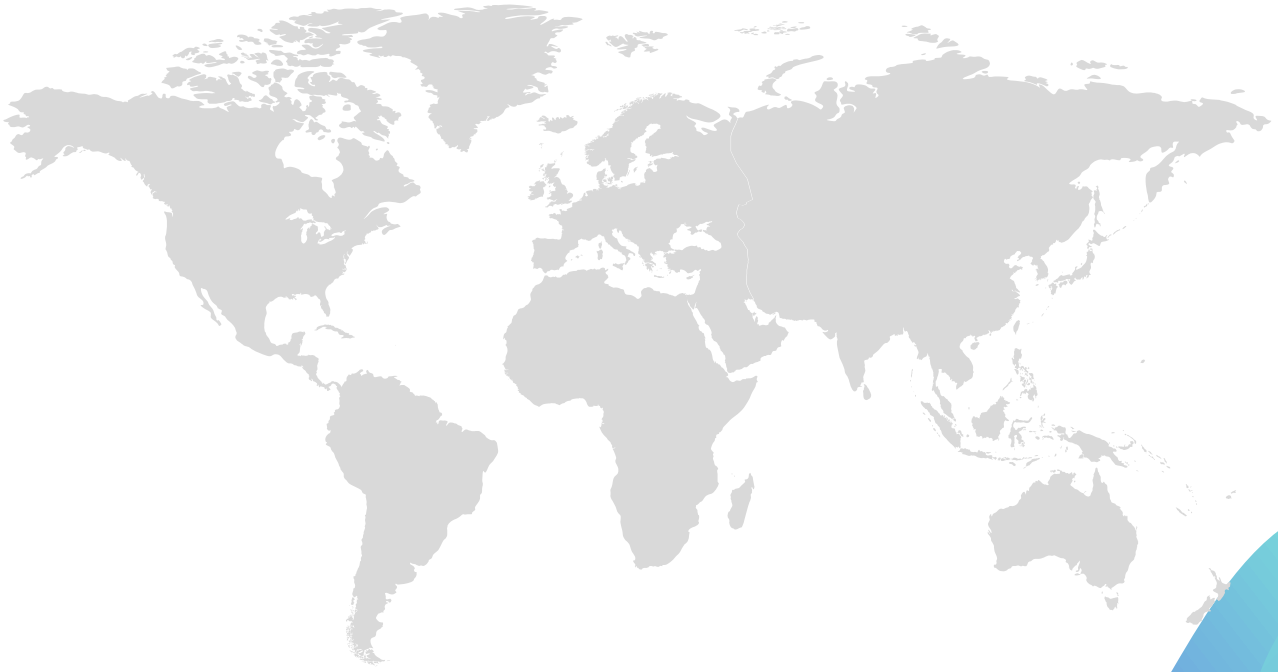
Why Should Attend ?

An effective extractable and leachable evaluation is essential for the overall success of any pharmaceutical drug development program for both small molecules and biologicals agents. In this webinar expert speaker, Stefano Persiani will focus on the basics of an effective extractable and leachable program. A case study will be presented to further provide a focus on the concepts discussed.



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