Human Radiolabeled Mass Balance (hAME) Studies for Regulatory Submission

Part I: A Comprehensive Overview and Practical Guide

Wim Tamminga, PhD, VP and Global Head of Early Phase Clinical at QPS

Join Wim as he discusses a comprehensive overview and practical guide on how to conduct an hAME study. Reserve your spot today, limited space is available for Part I in this series.

Overview:

In this webinar, QPS will provide a comprehensive overview and practical guide to get the most out of your hAME study, covering the many nuanced steps and considerations.

Through this discussion, Wim Tamminga will walk through main objectives of an hAME study and the ethical and regulatory considerations for hAME studies. In addition, he will cover formulation of mock batches, releasing of a subject based on radioactivity, an overview of the timelines, data analysis and reporting.

QPS can offer all services required for traditional hAME studies, including studies with radiolabeled compounds (approx. 100 μCi and therapeutic dose of IMP) and micro-tracer studies. To better describe the various study types and components, Wim will present three Case Studies, based on recent experiences in our QPS Netherlands facility.

Click Here for Key Learning Objectives

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