PRA Health Sciences

QC Laboratory as part of CMC Services at PRA's Laboratories for Drug Development

Introduction

The quality control laboratory facilitates the acceleration of drug development, supporting Clinical Phase I and II studies. From method development/implementation, clinical formulation development, validation/qualification of analytical methods to supporting stability and compatibility studies and quality control analysis of GMP drug product batches.

Innovation

We offer all relevant qualitative and quantitative assays to determine identity, purity, and stability of drug substances and products, including radioactive materials, in accordance with pharmacopeial monographs or according to your specifications. We routinely apply UPLC for ultimate separation efficiency and sample throughput. The close proximity of our pharmacy and intensive collaboration with their experts guarantee rapid decision making and accelerated formulation development to optimally support your clinical trial.

Capabilities and Equipment

To support our Clinical Trials, we have the following techniques and/or equipment:

- U(H)PLC systems with UV, DAD, ELSD, MS and Radio Flow detection (Assay, Identity, Purity)
- Dissolution tester (Dissolution)
- Disintegration tester (Disintegration)
- Osmometer (Osmolality)
- Endotoxins (LAL) detection system (Endotoxins)
- Particle counter (Sub Visible Particles)
- Karl Fisher titrator (H2O Determination)
- Spectrophotometer – UV absorbance (OD280)
- pH meter (pH)
- Turbidity meter (Turbidity)
- Density meter (Density)
- Light Viewer (Visible Particles)
- Liquid Scintillation Counter (Total Radioactivity)
- IR analyzer (Identity)
- Stability Chambers (+25°C/60% RH and +40°C/75%RH)
- Isolator (GMP-A / ISO 5)

Capacity and People

The QC Lab have dedicated Project Managers (4), a Quality Control Manager, and an Operation Team consisting of 15 analysts to support your First in Human studies (oral and parenteral), hADME studies, absolute bioavailability studies, and other Phase I/IIa studies, including oncology studies.

Our Project Managers can support Full Services, including outsourcing management of API synthesis as integrated drug development model, presented in Gantt Charts. Qualified Vendors for pharmaceutical microbiology and non-routine QC analysis.

Contact Our Experts

HENK POELMAN
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Project Director in the Assen, NL, Bioanalytical Laboratory and Head of the QC Lab. Over 30 years (bio)analytical experience, of which over 15 years in CMC, quality control, and isotope analysis to support Phase I clinical and ADME trials.

COREY OHNMACHT
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Director of Bioanalytical Science in the Lenexa, KS, Bioanalytical Laboratory. Over 14 years of industry experience in separation science and mass spectrometry for the analysis of small molecules, peptides, and proteins. Specialty in detection enhancement derivatizations and free drug analysis.

Equipment

- (U)HPLC-UV/DAD Analysis (Ph. Eur. 2.2.29)
- Osmolality (Ph. EUR. 2.2.35)
- Bacterial Endotoxins (Ph. Eur. 2.6.14)
- Particulate contamination Sub-visible particles (Ph. Eur. 2.9.19)
- Particulate contamination Visible particles (Ph. Eur. 2.9.20)
- Relative Density (Ph. Eur. 2.2.5)
- Clarity Degree of Opalescence (Ph. Eur. 2.2.1)
- Water: Micro Determination (Ph. Eur. 2.5.32)
- UV-VIS spectrophotometry (Ph. Eur. 2.5.32)
- Extractable volume (Ph. Eur. 2.9.17)
- Near-Infrared spectroscopy (Ph. Eur. 2.2.40)
- pH (Ph. Eur. 2.2.3)