



How to coordinate international clinical method transfers

We have an upcoming clinical study that will be conducted in Europe. Although the bioanalytical method was fully validated at one of your North American facilities, is it possible to transfer the bioanalytical method to one of your European sites, while ensuring our tight timelines are met?

As “One Charles River”, our goal is to provide the same exceptional quality of service across all sites. The validated method can be transferred to our Edinburgh site, and validated according to the specifications determined at our North American facilities, in line with industry and regulatory guidance. The same holds true for any cross-site validation (Montreal, Nevada or Edinburgh). Both involved sites will be in close contact to ensure smooth transition and that the method is performed using the same validated equipment, software and standardized procedures. This includes the Watson Laboratory Information Management System and Charles River Portal Access.

In line with current guidance, a partial validation, which generally consists of at least one precision and accuracy assessment, would be performed to ensure reproducibility of the method across sites.

The analytical methods are validated in accordance with the guidance set by the appropriate regulatory bodies including the United States Food and Drug Administration (FDA) GLP regulations (21 CFR Part 58) and the Organization for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice (ENV/MC/CHEM (98)17), as well as the FDA’s Bioanalytical Method Validation Guidance for Industry (May 2001), European Medicines Agency (EMA) Guideline on Bioanalytical Method Validation (effective February 2012), and the various White Papers applicable to ligand-binding assays.

The study scientist will collaborate with the sample management team, as well as Quality Control (QC) and Quality Assurance (QA) groups to establish a working schedule that meets the timelines communicated, assuring an efficient database lock transfer.

Our systems and processes are designed to be acceptable to regulatory authorities worldwide. Quality-assured reports are issued with a 98% or better on-time reporting record, which has been maintained consistently since 1998.