DRUG DEVELOPMENT SOLUTIONS
Part of Alliance Pharma, Inc.

Microsampling

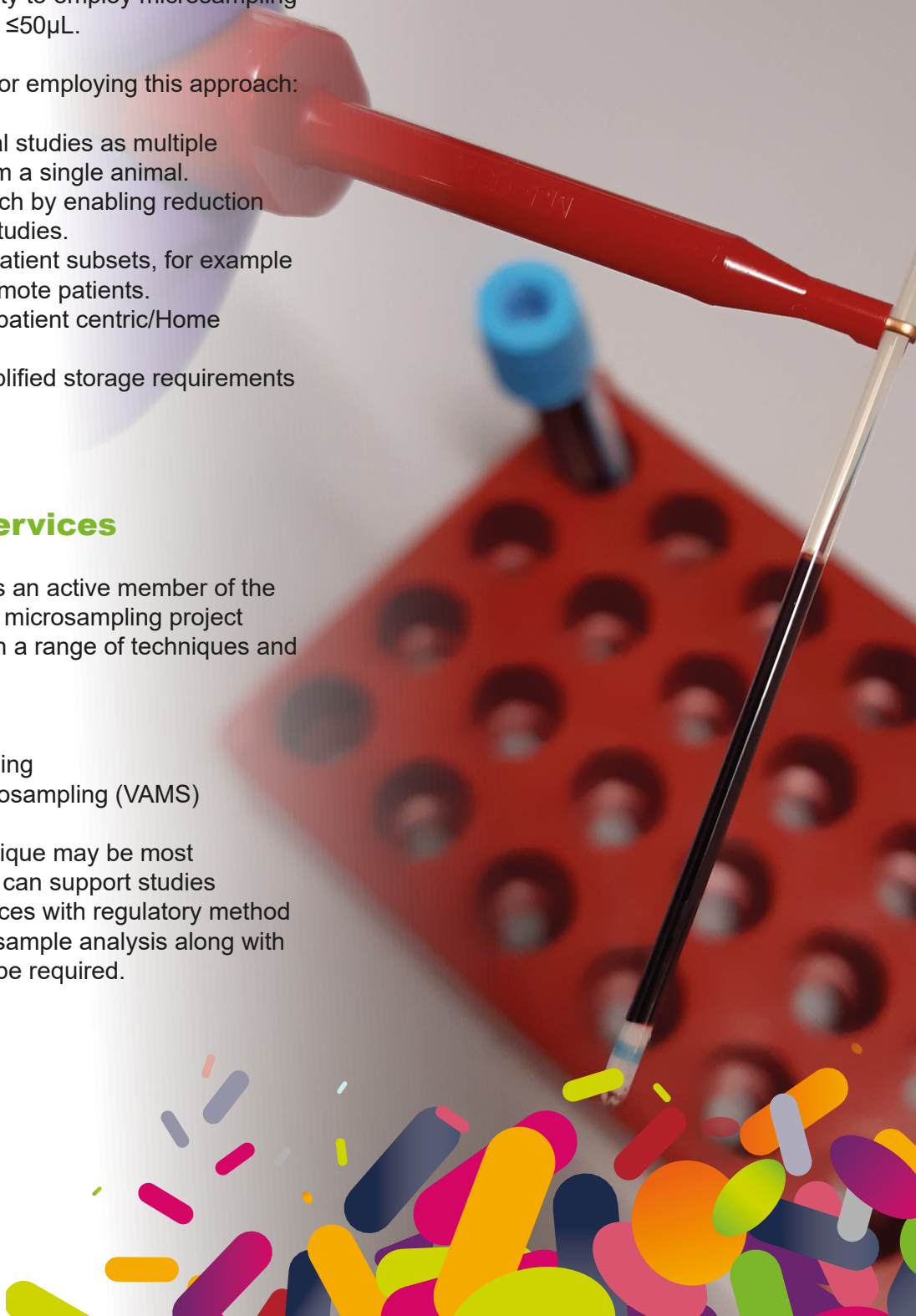
Reducing sample volumes for bioanalysis

Improvements in bioanalytical techniques have reduced the amount of sample required for the assessment of drugs and biomarkers in blood, plasma and serum.

This has opened the opportunity to employ microsampling devices that obtain samples of ≤50µL.

There are a myriad of drivers for employing this approach:

- Better profiling in preclinical studies as multiple endpoints are obtained from a single animal.
- To support the 3Rs approach by enabling reduction and refinement in animal studies.
- To aid sampling in at-risk patient subsets, for example paediatric, critically ill or remote patients.
- Studies looking to employ patient centric/Home sampling.
- Improved stability and simplified storage requirements (in some cases).



Our bioanalytical services

Drug Development Solutions is an active member of the European Bioanalytical Forum microsampling project teams and has experience with a range of techniques and devices including:

- Dried blood spots
- Capillary liquid microsampling
- Volumetric absorptive microsampling (VAMS)

We can advise on which technique may be most appropriate for your study and can support studies employing microsampling devices with regulatory method development, validations and sample analysis along with any bridging studies that may be required.

Tackling the analytical challenges

There are additional considerations to take into account to determine if a microsampling technique is suitable for a study that would traditionally be done by microsampling.

These include pre-analytical parameters such as the sampling process, handling small volumes at the sampling site, stability assessments, stabilisation steps, storage and transport.

Analytical factors include assay sensitivity, liquid handling capabilities, and, for dried blood samples such as VAMS, a consistent recovery across different haematocrit, drug concentrations and sample age.

At Drug Development Solutions we can advise on these considerations, offer validation services to cover a number or pre-analytical scenarios and have developed generic analytical protocols which can be applied to a wide range of compounds.

Additional support services

Sourcing stable-labelled internal standards

- We strongly recommend purchasing a stable isotope label standard early on in the development of the methodology.
- We have partnerships with established suppliers and can readily source reference materials of exceptionally high quality, potentially saving a significant amount of time during the method development stage.

Logistics

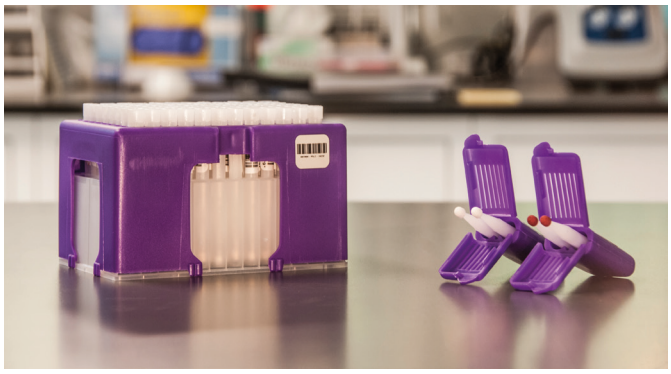
- We have a dedicated team that can provide kit assembly and label design.
- Bespoke kits can be prepared for your study including pre-aliquoted protein and peptide stabilising or solubilising additives.

Pharmacokinetic and Toxicokinetic Analysis

- We perform preclinical and clinical non-compartmental analysis to calculate parameters including AUC, Tmax, Cmax, t½.
- Comprehensive reporting options for both individual and mean data. We can also assist in data interpretation.

Analytical & Materials Science Solutions

- Extractables and Leachables
- Trace Analysis (Organic and Inorganic)
- Structural Elucidation and Impurity ID
- Elemental Impurities (ICH Q3D)
- Material Science
- ICH Stability Studies



Let's discuss your project:
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LEARN MORE

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