BSTL

experts in parenteral chemical & biological drug stability testing

Contact BSTL today to arrange a discussion of your needs and how BSTL can find a solution to your stability requirements.

Email sales@biopharmatesting.co.uk | Tel 07841204528

www.biopharmatesting.co.uk

© The antibody illustration used in this leaflet is the property of BSTL and should not be used without obtaining written permission from BSTL.

Biopharma Stability Testing Laboratory Limited
BioCity Nottingham, Pennyfoot Street, Nottingham NG1 1GF

BSTL

experts in parenteral chemical & biological drug stability testing

Guidance on the application of extended stability data for aseptically manipulated monoclonal antibodies*



*Published by the NHS National Pharmaceutical Research and Development Group. 1st Edition: April, 2015

How BSTL can help you comply with the NHS guidelines

BSTL can assist you with the 2 core guideline requirements for shelf life determination: expert critical review of data in published scientific papers & generation of bespoke stability study data.

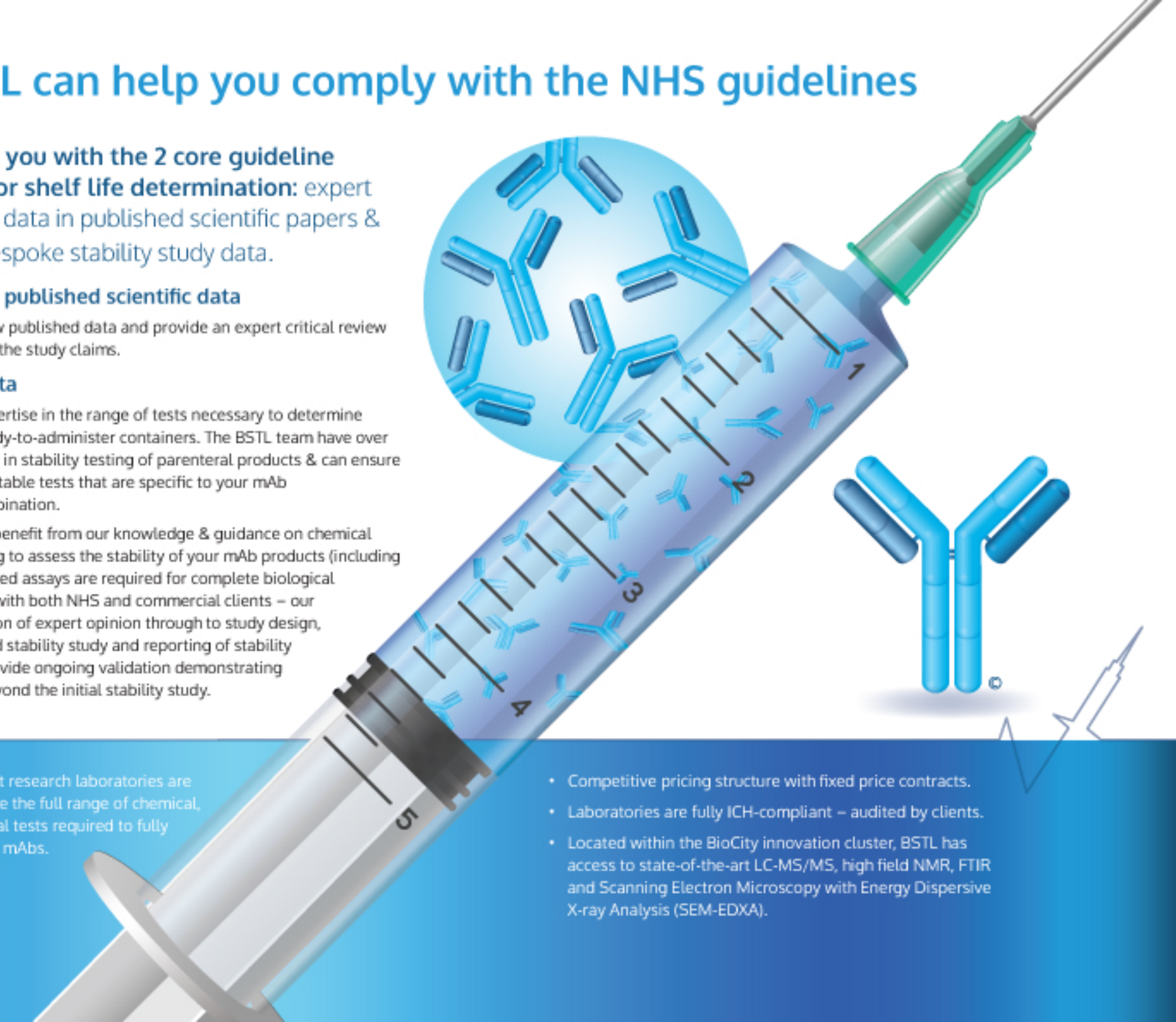
Expert opinion on published scientific data

BSTL experts can review published data and provide an expert critical review of the validity of ALL of the study claims.

Bespoke study data

BSTL analysts have expertise in the range of tests necessary to determine stability of mAbs in ready-to-administer containers. The BSTL team have over 50 years of "know how" in stability testing of parenteral products & can ensure that you include ALL suitable tests that are specific to your mAb product/container combination.

Contact BSTL today to benefit from our knowledge & guidance on chemical and bioanalytical testing to assess the stability of your mAb products (including what ELISA and cell-based assays are required for complete biological assessment). We work with both NHS and commercial clients – our services include provision of expert opinion through to study design, performing an extended stability study and reporting of stability results. We can also provide ongoing validation demonstrating product consistency beyond the initial stability study.



- BSTL's state-of-the-art research laboratories are equipped to undertake the full range of chemical, physical and biological tests required to fully assess the stability of mAbs.

- Competitive pricing structure with fixed price contracts.
- Laboratories are fully ICH-compliant – audited by clients.
- Located within the BioCity innovation cluster, BSTL has access to state-of-the-art LC-MS/MS, high field NMR, FTIR and Scanning Electron Microscopy with Energy Dispersive X-ray Analysis (SEM-EDXA).