



# BRIDGE

## Application Case Study

### Development of validated methods for QC testing

#### BACKGROUND

The Bridge Analytical Sciences and Quality Assurance facility at the University of Lincoln provides comprehensive capabilities for the development, optimisation, and validation of analytical methods to support regulated industries. Our team specialises in establishing robust, GxP-compliant protocols for a wide range of scientific instrumentation, enabling partners to meet stringent quality, safety, and regulatory requirements.

The facility houses an extensive suite of spectroscopy and analytical platforms – including NMR, FTIR, UV-Vis, Raman, GC-MS, LC-MS, and ICP-OES – supported by experienced scientists with expertise in method development, qualification, and validation. These capabilities allow us to design and implement validated testing workflows tailored to customer needs, ensuring reliable, defensible data suitable for high-stakes applications such as defence, pharmaceuticals, and advanced manufacturing.

#### The requirement for validated methods

For many UK-based SMEs, entering regulated supply chains, particularly those connected to defence, pharmaceuticals, or high-value manufacturing, demands a level of analytical assurance that goes far beyond routine quality control. Customers and regulators increasingly expect suppliers to demonstrate not only that their products meet specification, but that the analytical methods used to verify those specifications are themselves robust, defensible, and validated to recognised standards.

This requirement can be especially challenging for smaller organisations, where in-house analytical capacity may be limited and where the cost of developing validated methods can be a barrier to growth. Yet without validated methods, SMEs risk delays, rejected batches, or exclusion from high-value contracts.

#### Our approach to method development and validation

As a university-affiliated contract research organisation, we combine the depth of academic expertise with the operational discipline expected of an industrial analytical partner. Our environment is purpose-built for regulated work: controlled processes, documented workflows, and dedicated technical staff who specialise in method development and

validation rather than exploratory research. This structure allows us to deliver the scientific rigour of a research institution without the variability often associated with academic laboratories.

### **Outcomes and value delivered**

The validated method delivered a level of analytical assurance that enabled the customer to meet the stringent expectations of the UK MoD supply chain with confidence. By establishing a fully documented, reproducible workflow, we provided the customer with a dependable QC tool that could withstand audit, scrutiny, and long-term operational use.

Beyond meeting the immediate project requirements, the method now forms a durable asset within the customer's quality system in the form of a standardised, transferable protocol that supports consistent decision-making and reduces the risk of batch failure or regulatory delay. The structured validation process also equipped the customer with clear evidence of data integrity and traceability, strengthening their position within a competitive and highly regulated market.

For the SME, this demonstrates the strategic value of partnering with a university-affiliated CRO: access to advanced instrumentation, specialist expertise, and a professional, quality-driven environment without the overheads of building equivalent capability in-house.

### **CASE STUDY**

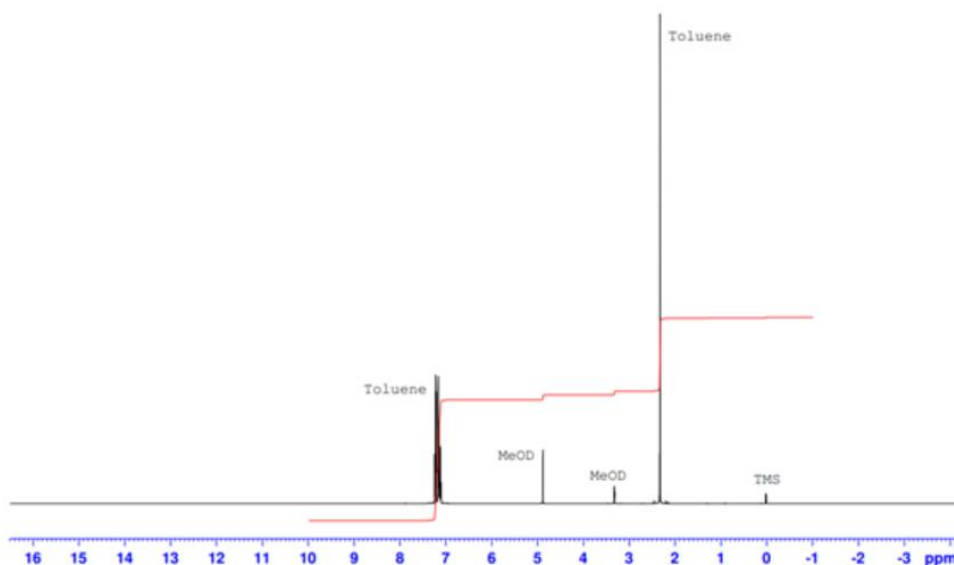
A Lincolnshire SME initiated a project with The Bridge in which they required validated QC conducted on a product that was needed to fulfil a large contract with a Government department. Their contract required precise quantitation of a compound within very strict tolerances. In order to carry out this work we needed to demonstrate that our instrumentation was capable of operating within these tolerances.

There are a number of different parameters that need to be assessed in order to validate a scientific instrument. These include: accuracy (the agreement between an experimental value and an agreed reference value); precision (the agreement between different replicates); and limits of detection (the limits below or above which an experimental value becomes unreliable). Each parameter will introduce its own source of error into the experimental values obtained and it was essential to quantify these sources of error to ensure they fell within the client's tolerances.

### **Accuracy**

Figure 1 shows the results from a typical validation of accuracy experiment. An NMR spectrum was obtained from a Certified Reference Material (in this case, toluene) and the quantifications obtained were compared against the reference material's Certificate of Analysis. In this example, the NMR experiment obtained a purity of 99.9%, which compares

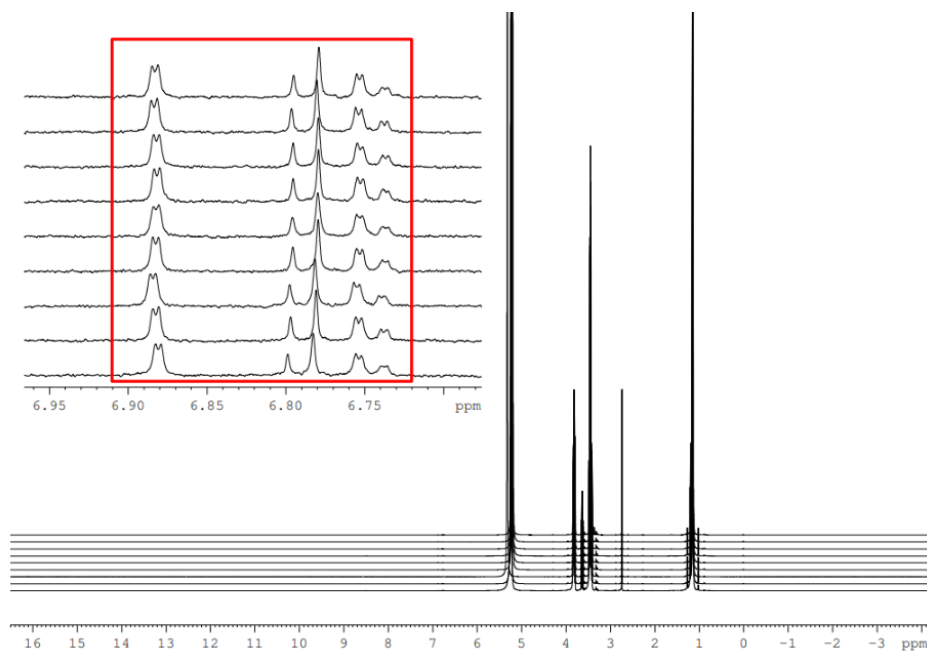
favourably with the value reported in the CoA of  $99.9 \pm 0.5\%$ . Therefore, negligible error was introduced as a result of this experiment.



**Figure 1.** <sup>1</sup>H NMR spectrum obtained from toluene Certified Reference Material.

## Precision

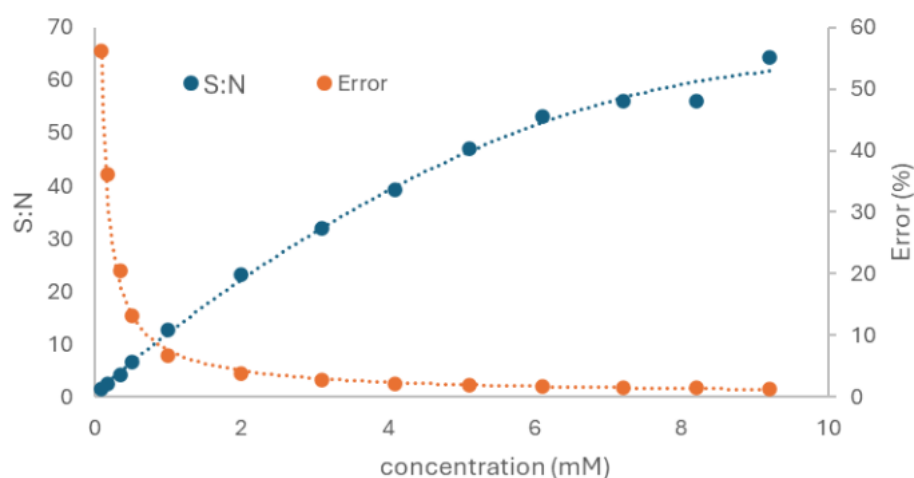
Figure 2 shows the results obtained from a typical validation of precision experiment. In this experiment the sample was prepared multiple times under different environmental conditions and the area in the red box quantified. The quantifications obtained from this experiment exhibited a standard deviation of 3.1%, well within typical tolerance requirements.



**Figure 2.** <sup>1</sup>H NMR spectra obtained from replicates carried out under different environmental conditions. Red box denotes chemical of interest.

## Limits of detection

Figure 3 shows the result of a typical validation of limits of detection experiment. In this experiment serial dilutions of the chemical were prepared and analysed by NMR and the signal-to-noise (S:N) ratios of the peaks of interest determined. The higher the S:N (i.e. the bigger the peak) the less error is associated with its quantification. The limit of detection (LOD) in quantitative NMR is commonly determined to be the concentration required to give an S:N of 3, whilst the limit of quantitation (LOQ) is commonly determined to be the concentration required to give an S:N of 40. The chemical undergoing analysis for the client was provided at a concentration far exceeding that required to exceed both these limits and was therefore amenable to quantitation. The experimentally determined S:N of *ca.* 60 corresponded to an error of *ca.* 1% (red line in Figure 3) for the calculated concentration.



**Figure 3.**  $^1\text{H}$  NMR peak signal-to-noise (S:N) at different concentrations of chemical (blue line). Different S:N ratios give rise to different degrees of error (red line).

The overall error of an experiment is a linear combination of all the potential sources of error ascertained during the validation tests. In this particular example the total error was determined to be  $\pm 3.18\%$ .

## SUMMARY

Working with The Bridge offers SMEs a rare combination of approachability, technical depth, and dependable quality. Our team has the technical proficiency to validate our state-of-the-art instrumentation to within the tolerances required by the customer. We can help you design in-depth and thorough QC protocols designed to operate within industry-accepted tolerances or implement already accepted gold-standard testing protocols. We bring the professionalism of a contract research organisation together with the scientific strength of a leading university, giving customers access to advanced instrumentation and highly trained specialists without the overheads of building capacity in-house. For organisations seeking reliable, defensible data and a genuinely collaborative partner, The Bridge provides an experience that is both reassuring and refreshingly straightforward.



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