SCENARIO SHEET

Navigating analytical irregularities with independent testing

THE SITUATION

Pharmaceutical organisations require precise, reproducible analytical results as their API progresses through development and manufacturing. Sometimes, unanticipated discrepancies in stability, product yield and other key areas can arise when performing later stage testing.

Identifying the root cause of these issues is critical to ensuring product quality, consistency and efficacy. However this process can be challenging due to the complexity of formulations, the need for sensitive analytical methods and specialised equipment requirements. By working with an experienced independent partner on these investigations, organisations can more effectively isolate variables and understand the source of process irregularities.

THE CHALLENGES

Analytical sensitivity

In order to appropriately evaluate discrepancies and identify the root cause of inconsistent results, a variety of specialised analytical methods may be required. Consider an example where long-term stability studies show typical results, while accelerated studies result in lower assay or mass balance issues. An outsourced partner should first evaluate and implement the customers' methods, then perform tests such as extraction and degradation studies to determine where the issue arises. Detecting subtle changes in product attributes necessitates highly sensitive techniques and equipment, as well as the expertise to determine appropriate analytical methodology which is suitable to make these determinations.

Maintaining data integrity

Particularly when it comes to drug product testing, root cause analysis can generate large volumes of data that must be carefully examined and evaluated. For example, HPLC work may result in numerous peaks of interest which must all be evaluated across multiple sample preparations. In addition, any degradation or changes in the samples during testing can introduce confounding variables and compromise the reliability of the results, making it critical to carefully manage samples. Maintaining the integrity of experimental data and mitigating external influence is essential to ensuring that analytical results are credible and valid.

Isolating results

Any number of challenges can cause inconsistencies in analytical results, from the equipment being used, to the lab's environmental conditions, to the sample being analysed. To properly isolate variables and understand the cause of inconsistencies, scientists must first rule out any challenges related to equipment or the lab environment. This requires a careful assessment of system suitability, then a thorough testing approach that aligns closely with the original laboratory conditions. Once these potential causes have been ruled out, extensive and careful comparative analysis is required to discern variations in formulation, manufacturing processes or storage conditions that might be contributing to discrepancies.

The Sterling solution

At Sterling, our extensive analytical experience combined with full-lifecycle expertise enable us to perform thorough, standalone analytical testing and help our customers isolate inconsistent results.

Comprehensive analytical capabilities

At Sterling, we have a history of solving complex scientific problems at every stage of the lifecycle. Our experienced analytical teams are adept at understanding which methodologies are best suited to a certain stage or challenge, and providing our customers guidance every step of the way.

We utilise specialised equipment to support a range of testing requirements, from such as HPLC, mass spectrometry, NMR and gas chromatography. In addition, our team provides extensive expertise in analytical study design and execution for extraction studies, degradation profiling, filtration studies and others. Our analytical capabilities span the product lifecycle from preclinical development to commercial. No matter the stage, we leverage a thorough, proven approach to generate high-quality and accurate results for our customers.

Controlled testing to pinpoint root causes

When a customer encounters unanticipated inconsistencies in their analytical studies, we perform thorough root cause analysis to help pinpoint the source of any issues. For example, a customer may encounter low assay values under certain storage conditions. Our team can perform testing to isolate a range of potential causes, such as understanding the impact of filters on sample preparation, determining whether certain capsule types interact with the API, or assessing how much moisture a product might take on in certain storage conditions. We perform testing in a controlled environment to avoid introducing additional variables and ensure accurate results.

Flexible, collaborative approach

Flexibility and scientific adaptability are crucial in navigating unforeseen issues in standalone analytical testing. Our analytical team is committed to working the way our customers do and addressing their specific requirements. Whether a customer designs experiments for our team to independently leverage and test, or a customer requires guidance around the best-suited analytical approach for their specific challenge, we provide the same level of quality, service and expertise.

We provide robust analytical services both as a standalone offering and as part of larger development programmes. In any scenario, we foster close collaboration and communication with our customers to ensure we are aligned on our approach, remain transparent about our findings and any challenges, and provide clear guidance when communicating results and recommending next steps.

> "While Sterling is experienced at providing analytical services across the full lifecycle and as part of our customers' larger development efforts, we are equally happy to perform standalone testing and help customers overcome any discrepancies in their analytical results. By serving as an independent partner and applying our full-lifecycle perspective, we can help to efficiently isolate potential causes and get to the root of the issue."
>
> **- Chris Shaw**
> *QC & Analytical Services Manager, Sterling Pharma Solutions*

Ready to learn how we can help you achieve thorough, accurate, and repeatable analytical results?

Visit **sterlingpharmasolutions.com** to learn more.

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