

# The Analytical Advantage: How Dalton's Scientific Expertise, Regulatory Rigour, and Cross-Functional Integration Deliver Programme Value Across the Development Lifecycle

*How integrated analytical services accelerate development timelines, strengthen regulatory submissions, and deliver consistent quality across every programme milestone.*

## Executive Summary

Analytical testing is the invisible infrastructure of pharmaceutical development. When it is planned well, integrated with manufacturing, and executed by a team with full programme context, it accelerates development timelines, strengthens regulatory submissions, and contributes actively to product quality at every stage.

This whitepaper highlights how Dalton's analytical/microbiological services, built on scientific expertise, regulatory-ready systems, and strong cross-functional integration, are a strategic development asset, not simply a cost centre or a tick-box function. It covers the full scope of analytical requirements across the development lifecycle, the specific ways in which Dalton's capabilities contribute to programme speed and quality, and what a fit-for-purpose analytical strategy looks like at each development and regulatory milestone.

## 1. Analytical Testing: A Strategic Driver at Every Stage of Development

The conventional view of pharmaceutical QC is that it is a release function: something that happens after manufacturing, validates what was made, and provides the certificate of analysis that allows a batch to be released. On that framing, analytical testing is sequential, downstream, and reactive.

In practice, analytical scope of work is on the critical path, starting from early-phase development. It usually includes project activities, such as:

- Pre-formulation study to characterize API physical and chemical properties, such as solubility, polymorphism, hygroscopicity and to support formulation development.
- Forced degradation studies to support analytical development on method specificity.
- Method validation to ensure the method produces dependable, accurate, and reproducible results.

Each of these is a genuine critical path dependency. Identifying them early and ensuring the analytical programme is resourced and sequenced to meet them, is one of the highest-leverage planning decisions a development team can make.

## 2. The Full Scope of Analytical Requirements Across the Development Lifecycle

Pharmaceutical analytical services span a wide range of techniques and objectives. Understanding the full scope, and how each element connects to regulatory requirements and programme milestones, is the foundation of effective analytical planning.

| Analytical Service Area                         | Scope   | Development Programme Value   |
|---|---|---|
| <b>Physical &amp; chemical characterisation</b> | Particle size distribution, solubility, hygroscopicity, melting point   | Pre-formulation data package  |
| <b>Potency &amp; purity determination</b>       | HPLC, UPLC, UV/Vis, titration; chiral methods; related substances and degradation product profiling; residual solvent analysis.                     | IND release and stability methods; specification setting; degradation pathway characterisation                        |
| <b>Microbiology &amp; sterility assurance</b>   | Sterility testing, bioburden, bacterial endotoxin (LAL), environmental monitoring, antimicrobial effectiveness testing, container closure integrity | Drug product release; ongoing environmental monitoring in GMP fill-finish; container closure integrity validation     |
| <b>Stability program</b>                        | ICH Q1A–Q1E zone conditions; accelerated, intermediate, and long-term storage; photostability (ICH Q1B); stress testing / forced degradation        | IND stability data package; shelf-life determination; degradation product characterisation for regulatory submissions |
| <b>Method development &amp; validation</b>      | New method development; method transfer; ICH Q2(R1) full validation (specificity, linearity, range, accuracy, precision, LOD/LOQ, robustness)       | Fitness-for-purpose methods at IND; full validation package at NDA/MAA; transfer validation to commercial site        |
| <b>Reference standard qualification</b>         | Primary and working standard characterisation; certificate of analysis generation; requalification on expiry  | Regulatory-compliant reference standards; traceability chain for all quantitative methods                             |

The breadth of this capability requirement is important context for analytical programme planning. A provider that covers only release testing (potency and purity methods for batch release) serves a subset of the overall need. A programme that also requires pre-formulation characterisation, stability study management, method development and validation, microbiology, and container closure integrity testing depends on careful project planning from the beginning. The key success factor is effective communication and knowledge-sharing across functional teams and throughout project life cycle.

## 3. The Dalton Analytical Difference: Expertise, Rigour, and Integration

Dalton's analytical capability is defined by the depth of scientific expertise, the rigour of its systems, and the quality of cross-functional integration that the team brings to every programme. Six capabilities highlight this distinction, and each has direct implications for drug development cycle.

## 1. Deep Expertise Across the Full Analytical Lifecycle

Dalton provides end-to-end analytical support, from early method development through validation, release testing, and stability studies, ensuring scientific continuity and regulatory alignment at every stage.

For drug development programmes, this continuity matters: the scientist who develops a method understands its intent, its limitations, and the regulatory questions it must answer. Continuity of analytical expertise across the lifecycle reduces rework, prevents specification gaps, and produces a more coherent CMC data package.

## 2. Robust QC Laboratory Capabilities

Dalton's analytical laboratories are equipped to perform a wide range of compendial and non-compendial tests with precision and reliability. Every batch released by Dalton is supported by rigorous quality data that meets the standards required for GMP compliance, regulatory submission, and patient safety.

For development teams, this breadth of capability means that every analytical need across the programme, from identity and potency to sterility and container closure integrity, is addressed within a single, audited quality system.

## 3. Strong Method Development and Optimisation

Dalton's scientists design and refine analytical methods tailored to each molecule's characteristics, improving sensitivity, specificity, and robustness. Fit-for-purpose methods are fundamental to drug development: a method that is not sufficiently sensitive will miss clinically relevant impurities; one that lacks specificity cannot distinguish the active from its degradants.

Robust method development reduces analytical variability, supports reliable specification-setting, and accelerates progression from early development to commercial readiness.

## 4. Regulatory-Ready Data and Documentation

All analytical work at Dalton is performed under rigorous GMP controls, generating high-quality data packages built to withstand regulatory scrutiny from FDA, Health Canada, PMDA, and other major agencies. Regulatory-ready documentation is not an administrative output, it is a scientific one: data integrity, audit trails, and method validation packages that are complete and agency-compliant from the outset.

Result: reduce review cycles, minimise deficiency responses, and protect submission timelines at IND, NDA, and beyond.

## 5. Rapid Problem-Solving and Technical Troubleshooting

Dalton's analytical team has deep experience in identifying root causes of impurities, degradation pathways, and process inconsistencies. In drug development, unexpected analytical findings are not exceptions, they are a routine part of the process.

The ability to respond quickly, characterise the issue accurately, and implement a scientifically defensible resolution is what determines whether a finding delays a programme or becomes a data point that strengthens the submission.

## 6. Integrated Support with Manufacturing and Formulation

Close coordination between analytical, manufacturing, and formulation teams at Dalton ensures that methods are fit-for-purpose, scalable, and aligned with process development needs at every stage. This cross-functional integration reduces rework, improves development efficiency, and ensures that the analytical programme evolves in step with the manufacturing process it is designed to support.

Strong cross-functional alignment, underpinned by shared systems, clear programme ownership, and effective knowledge-sharing, is the organisational foundation of analytical programme success.



Across all programmes, Dalton’s analytical team brings the technical depth, regulatory knowledge, and cross-functional collaboration to keep analytical work on pace with programme milestones. Whether the critical path runs through stability data, release methods, or microbiological testing, effective communication and shared programme ownership ensure that analytical outputs are delivered with the quality and timeliness that development teams depend on.

What distinguishes Dalton is not proximity, but competence: scientists with deep expertise in each analytical discipline, methods designed and validated for the specific molecule, documentation built to regulatory standard, and a cross-functional culture that treats analytical quality as a shared programme objective. That combination of expertise, rigour, and integration is what makes Dalton’s analytical services a genuine development asset, from first characterisation through to commercial approval.

## Conclusion: Analytical Services as a Strategic Asset

The development teams that reach IND submission on time, with a complete and defensible CMC package, are not necessarily the ones with the most analytical resources. They are the ones who planned their analytical programme with the same rigour they applied to their formulation and manufacturing strategy, who understood the regulatory requirements at each stage, identified the critical path dependencies early, and had access to analytical capabilities that responded in real time to programme needs.

Dalton’s analytical/microbiological services, grounded in scientific expertise, robust analytical capabilities, rigorous method development, regulatory-ready documentation, rapid problem-solving, and strong cross-functional integration, change the analytical function from a downstream checkpoint into an active contributor to development speed and regulatory quality. That contribution is present at every stage of the programme: in every batch released with high-quality data, every stability pull tracked by the team that designed the programme, and every method development iteration that advances without delay. When challenges arise, the same expertise and integration that drive everyday efficiency also enable the rapid, well-coordinated response that protects programme timelines.

**At Dalton Pharma Services, analytical/microbiological capability is not a service attached to manufacturing. It is integrated part of the same programme.**