

Pharmaceutical solutions from The Smithers Group — providing key services in drug development before and after formulation

SP Formulations (SPF) holds a broad perspective on formulation development. It is neither a simple transactional activity nor a discrete single step, as it has substantial impact on any subsequent development activities. However, a formulation should also be robust and adaptable to changes resulting from earlier-stage work, such as optimizing chemistry



during lead development. Developing a successful formulation is based on understanding physico-chemical characteristics of the active pharmaceutical ingredient, informing lead selection. A successful formulation will be robust and readily scalable for use in preclinical trials. Ideally, the formulation composition selected for use in preclinical testing is also clinically relevant, requiring minimal or no changes as clinical trials progress.

Synomics Pharmaceutical Services (“Synomics”), a member company of The Smithers Group, is co-located at the Wareham, Massachusetts facility. The origins of SPF are rooted in the needs articulated by Synomics’ clients for additional drug development services. Synomics offers a wide range of analytical and bioanalytical testing services, which can be contracted to support characterization needed throughout development. Working with the flexibility of an R&D environment or according to the rigor of GLP or GMP guidelines, the following analytical chemistry services are available to characterize APIs:

- Method development: HPLC, LC-MS, GC
- Method validation
- Method verification/transfer
- Sample analysis
- Lot and batch release testing
- Structure elucidation
- Detection and identification of impurities
- Residual solvent analysis
- Dissolution testing
- Product composition
- Content uniformity/impurities
- Impurity testing and characterization
- Raw material testing
- Placebo and excipient testing
- Physical-chemical properties
- Customized analytical testing

A range of product chemistry services are also available, including: adsorption/desorption, density, dissociation constant, hydrolysis, oxidation/reduction, partition coefficient, pH, physical state, and UV-visible absorption. Additional drug product characterization can be

obtained through the design and execution of comprehensive storage and stability programs to meet both FDA and ICH requirements. Stress testing via forced degradation and photostability (Option 1) are used to further characterize product stability and can provide a feedback loop into formulation development if needed.

Bioanalytical testing is also available: LC-MS/MS method development, preclinical and clinical bioanalysis, CYP450 analysis, *in vitro* metabolite identification, and biomarker services. Again, Synomics offers these services with the flexibility of an R&D environment or according to GLP guidelines, as needed.

Synomics' comprehensive quality management system reduces regulatory risk without adding inefficiencies or costs and has been internationally recognized by authorities and experts as an industry benchmark. The system integrates principles from FDA and AAPS initiatives for bioanalysis for clinical trials, bridging the regulatory requirements from pre-clinical to commercial development. Synomics identified a need for developing and maintaining specific regulations for bioanalytical testing of clinical samples and responded by working with scientific and regulatory professionals to develop the Bioanalytical Quality Standards Initiative (BQSI) guideline. BQSI is an industry working group dedicated to developing documented quality management standards for bioanalysis in support of clinical trials.

SPF can also work with a network of contract research organizations to facilitate additional testing and characterization appropriate to include in the context of formulation development. SPF is committed to deliver the level of quality you expect as if all services were offered under one roof. Our industry network can readily facilitate pharmaceutical testing services, including but not limited to: low levels metals analysis, antimicrobial effectiveness, microbial limits, membrane filtration, sterility, bacterial endotoxin testing, Caco-2 permeability, toxicology testing, and package validation testing.

There are several advantages of working through SPF to facilitate additional testing services: faster turnaround time via direct vendor contact, broad familiarity with drug or drug product requirements for testing, reduced delays between arranged testing, and providing the necessary active and placebo drug products, direct scientist-to-scientist interaction, saving time by leveraging existing external relationships, and rapid compilation of returned data into project reports.

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