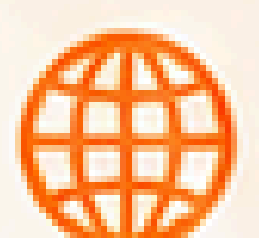




BLOG

From Lab Bench to Launch: MedPharm's Integrated CDMO Model for Topical Semisolid and Liquid Products

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The Cost of Fragmentation

Developing a topical or transepithelial product often involves multiple organizations, technology transfers, quality agreements, and handoffs between teams. As programs progress, timelines can lengthen, and critical product knowledge can become fragmented. Data can become disconnected from its origin, and when questions arise during development, registration, or commercial supply, there may be no single organization with a complete understanding of the product and its history. By bringing early- and late-stage development, analytical testing, stability studies, and manufacturing together within a single organization, sponsors can maintain continuity throughout the product lifecycle and reduce the risks associated with fragmented development.

Topical and transepithelial products are particularly sensitive to development discontinuity. Product performance is influenced by formulation composition, microstructure, rheological behavior, manufacturing conditions, and interaction with complex biological barriers. Seemingly minor changes introduced during technology transfer or scale-up can have unintended consequences for product performance. Altering mixing shear may shift drug release characteristics, while changing an excipient grade can affect viscosity, preservative efficacy, physical stability, or drug delivery. For this dosage class, the scientific and technical knowledge generated during development functions as an asset in itself, not merely as documentation.

MedPharm addresses this by consolidating the pathway within a single organization, carrying topical, semisolid, and liquid products from pre-formulation through commercial manufacture, with analytical and stability infrastructure integrated alongside production.

Organizational Background

Founded in 1999 with origins at King's College London, MedPharm has concentrated for over twenty-five years on topical, transdermal, and transepithelial delivery across dermal, nail, ocular, mucosal, and respiratory routes.

Originally built around formulation development and performance testing, the organization has expanded into an integrated CDMO with development, analytical, stability, clinical manufacturing, and commercial manufacturing capabilities. Today, with operations in Guildford, UK, and Durham, North Carolina, MedPharm provides sponsors with a development pathway that can remain within a single organization from early formulation design through commercial supply.

MedPharm's scientists are recognized subject matter experts in topical drug delivery, contribute regularly to discussions that shape regulatory thinking in the field, including EMA guidance on topical product characterisation, and have been involved in the development of numerous recently approved topical new chemical entities.

Early-Stage Development

Early-stage development begins with understanding the API, intended route of delivery, and target product profile. For innovator products, this knowledge guides formulation design and the selection of excipients capable of achieving the desired performance, stability, and patient experience. For generic and reformulation programs, development may also include detailed evaluation of raw materials, excipient grades, and supplier variability to understand their impact on product characteristics and equivalence. Pre-formulation studies build on this by establishing drug-excipient compatibility, achievable drug loading, and the need for stabilization strategies such as pH adjustment, antioxidants, or chelating agents. Together, these activities establish the formulation strategy and create the development rationale that guides decisions throughout the remainder of the program.

Formulation development then proceeds under Quality-by-Design principles consistent with ICH Q8, balancing delivery performance, physical and chemical stability, safety, and patient acceptability, with device and packaging considerations addressed early when integral to product performance.

Performance testing employs in-vitro release testing, in-vitro permeation testing, and ex vivo tissue models to differentiate formulation candidates and generate data that informs key development decisions. In addition, these approaches are increasingly used to support regulatory submissions, particularly for generic products and where additional evidence of product quality and performance is required.

Intellectual property considerations are evaluated throughout development, as insights gained from formulation design, performance testing, delivery characteristics, and manufacturing approaches can all contribute to product differentiation and patent protection beyond the original composition-of-matter claims.

Late-Stage Development and Clinical Supply

Process development applies Design of Experiments methodology to define relationships among critical process parameters, material attributes, and quality attributes. To mitigate scale-up risk, MedPharm employs a consistent manufacturing platform spanning 10 L to 1,500 L at its US site, limiting confounding variables such as mixing geometry and shear history that otherwise alter emulsion microstructure across scale. For programs requiring rapid progression into early clinical studies, MedPharm's UK facility provides flexible development and GMP manufacturing capabilities using bespoke processing vessels and adaptable filling platforms. GMP clinical trial material for non-sterile semisolids and liquids is produced at both sites, with capabilities aligned to the needs of different stages of development. The UK facility supports flexible early-phase manufacture and specialized dosage forms, while the US facility provides larger-scale manufacturing capabilities to support late-stage clinical development and commercialization. Analytical validation, manufacturing, and ICH stability testing are coordinated as a single workstream.

Commercial Manufacturing and Stability

The Durham commercial facility manufactures creams, gels, ointments, lotions, and topical and oral liquid formulations under GMP, including dedicated containment suites for high-potency compounds. A 2025 FDA inspection concluded with no Form 483 observations and a No Action Indicated classification. Filling and packaging lines support tubes, jars, pumps, and unit-dose formats with serialization capability for regulatory track-and-trace compliance.

In-house ICH-qualified stability chambers maintain standard and region-specific storage conditions, supporting long-term, accelerated, stress, photostability, and comparator studies. Because semisolids can fail through phase separation, viscosity drift, or preservative loss despite passing assay testing, in-house stability control shortens shelf-life determination and preserves data continuity within a single quality system, MasterControl eQMS, compliant with ICH Q10 and EudraLex Volume 4, spanning R&D through commercial release.

Implications for Sponsors

For organizations lacking internal CMC infrastructure, or larger companies seeking to advance a stalled formulation or established product, this integrated structure offers a single accountable scientific partner across the full development lifecycle. In topical and semisolid development, product and process are inseparable, and the institutional knowledge connecting them is most easily lost across organizational boundaries. The value of an end-to-end CDMO model lies not in convenience alone, but in preserved continuity of scientific knowledge.

MedPharm operates from Guildford, Surrey, UK, and Durham, North Carolina, USA. Program inquiries: busdev@medpharm.com; scientific inquiries: sciencechat@medpharm.com.