Drug Master File (DMF) and Active Substance Master File (ASMF)

Regulatory Support

Our Regulatory Affairs experts can prepare, maintain, and submit compliant DMFs and ASMFs in eCTD format to the appropriate regulatory agency on our clients' behalf. We ensure every submission meets global regulatory expectations while minimizing delays and facilitating smoother product development timelines.

How Intertek can help

Our Regulatory Affairs team can advise and provide regulatory support for pharmaceutical products in all stages of development (preclinical to post-market). We collaborate with clients to bring products to the market in the most efficient and cost-effective manner within an evolving and increasingly challenging regulatory environment.

We can help companies like packaging suppliers, excipient suppliers, and drug substance suppliers build and maintain compliant electronic DMF/ASMF submissions.

Our services

- General DMF/ASMF support for the U.S., Canada, and EU
- DMF/ASMF gap analysis services, including the preparation of a gap report
- Preparation of DMF/ASMF Modules 1, 2.3, and 3
- Formatting, compilation, assembly, publishing, and submission of the DMF/ASMF in eCTD format
- U.S. Agent services
- Regulatory support with U.S. establishment registration and drug listing
- Filing of new EU CEP applications, CEP amendments, and CEP notifications
- DMF/ASMF maintenance activities:
  - Regulatory strategy
  - Preparation and submission of responses to regulatory agency requests for information
  - Annual report submissions
  - Administrative amendments (Letter of Authorization, name/address changes, etc.)
  - Quality amendments (e.g., amendments to Module 3 CMC sections);
  - Withdrawal submissions

The Intertek advantage

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

Total Quality. Assured.

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