VERISTAT

Preparing Global Marketing Authorizations: 10 Keys to Success

Veristat combines scientific expertise, regulatory strategy, and operational excellence to support the successful preparation and submission of marketing applications (e.g. NDA/BLA, MAA, NDS).

Support From Early Strategy to Final Approval

Our experienced project teams partner with sponsors from early development through clinical development, to marketing authorization and post-approval commitments. Whether you're planning your first NDA or MAA or expanding into new markets, Veristat delivers expertise, continuity, compliance, and confidence.

"Marketing Authorizations are complex long-term projects where we partner with our client companies to bring new therapies to patients. Our dedicated regulatory project managers make sure everything stays on track — plans are clear, timelines are met, and messaging is consistent — from early planning through agency interactions and beyond."

Daphne Smyth, VP, Regulatory Strategy, Veristat

The 10 Keys to Success

01

Start Planning Early

- Begin planning for commercialization at the start of your pivotal/registration trial, and have a submission plan in place one year (at the very latest) before your target submission date
- Refine the company Target Product Profile for the product and develop a commercialization plan

02

Dedicate a Regulatory Project Manager

- Assign a regulatory project manager (PM) with a scientific regulatory background to coordinate efforts across key functions—clinical, regulatory, biostatistics, and publishing—and ensure cross-functional team integration
- Establish clear communication plans between Veristat, your internal teams and external advisors

03

Establish a Document Strategy & Medical Writing Plan

- Use shell writing and phased drafting to avoid last-minute pressure
- Unify messaging across all CTD modules to present a clear, cohesive story
- Strategic writing aligned to global regulatory expectations

04

Conduct Early Review of Data

- Engage biostatistics experts early to ensure data compliance and obtain expert statistical input for endpoints, ISS/ISE, and integrated narratives
- Conduct early expert review of non-clinical and clinical data
- Ensure compliance of CMC data with the target region, confirm timelines for commercial production, be aware of the availability of stability data

05

Understand Global & Local Regulatory Requirements

- Leverage resources with deep knowledge of FDA, EMA, MHRA, Swissmedic, and more
- Integrate regulatory and scientific consulting
- Use submission pathways tailored to each region's requirements
- Obtain full-service support for post-submission queries and commitments

06

Maximize Agency Meetings

- Obtain early scientific advice/hold Pre-IND meetings, develop an internal strategy
- Utilize End-of-Phase 2 meetings, Pre-NDA/BLA/MAA meetings, Advisory Committee meetings, etc.
- Consult with internal and external experts to get the most out of agency meetings by being well prepared and informed

07

Secure a Marketing Authorization Holder or Commercial Partner

For companies without a legal presence in the EU, UK, or Switzerland, Veristat can act as your applicant or MAA holder — accelerating market access without the need for immediate commercial setup

- In-house QMS and establishment license
- Dedicated regulatory and PV infrastructure and experienced team

08

Final Step: Electronic Publishing — Don't Compress the Timeline

- Have a detailed plan in place, overseen by the PM
- Avoid the risk of compromising data integrity, quality, and compliance
- Eliminate potential for rejection or need for extensive corrections
- Avoid extra costs due to rework and potential resubmissions

09

Be Prepared for Agency Questions During Review

- Every agency has different timelines for issuing questions and getting responses back – be ready
- If submitting marketing applications in multiple regions simultaneously, be staffed to respond to individual agencies, have a detailed decision tree for any changes requested
- Obtain full-service support for post-submission queries and commitments

10

Plan for Post-Approval Success

- Anticipate post-marketing commitments, safety reporting, and lifecycle management
- Ensure readiness to transition from submission to commercialization

"Submission success isn't just about delivering documents — it's about delivering strategy, consistency, and partnership at every step."

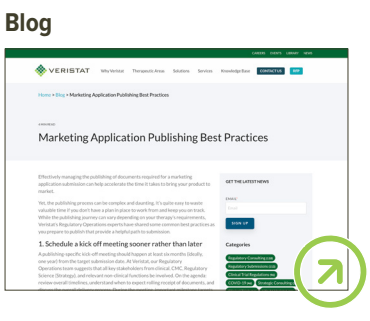
Sarah Hopwood, VP, Medical & Regulatory Writing, Veristat

Resources

Fact Sheet

Case Study

Blog



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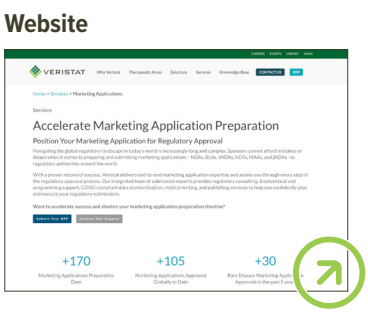

Start Early. Stay Ready. Submit with Confidence.

Whether your team needs full submission support or expert backup, Veristat offers the flexibility, depth, and global reach to efficiently bring your therapy to market.

veristat.com