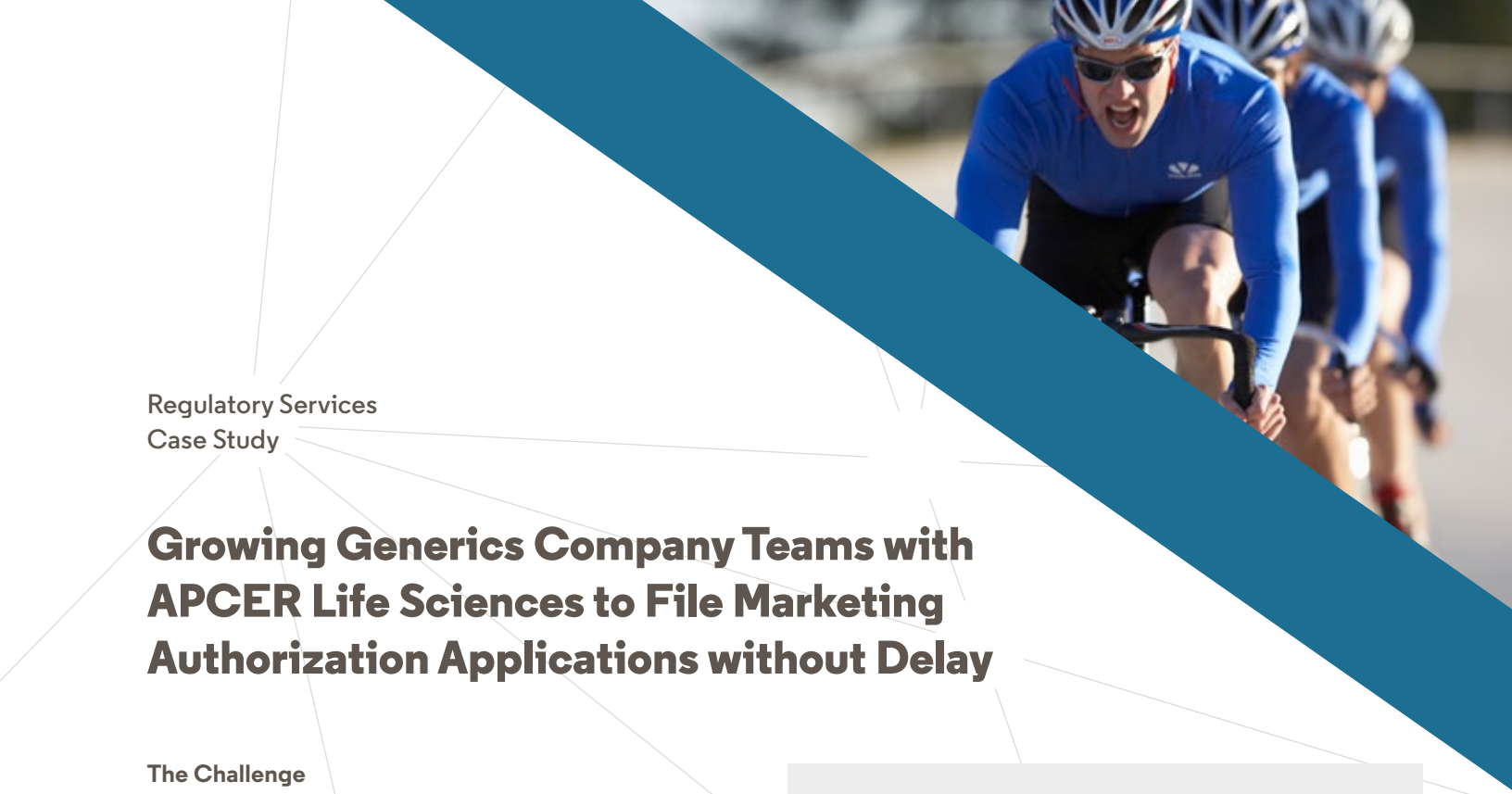

Regulatory Services
Case Study

Growing Generics Company Teams with APCER Life Sciences to File Marketing Authorization Applications without Delay

The Challenge

A fast-growing generic pharmaceutical company, which manufactures and markets products across a diverse range of therapeutic areas in more than 50 countries, had the opportunity to file a marketing authorization application (MAA) to the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA).

Although much of the content for the Common Technical Document (CTD) had been prepared, the company's regulatory team in the UK was experiencing capacity constraints. They estimated that an additional 6-12 months was required to complete and submit the application.

The company needed to find additional resources that would allow them to apply for approval without delay and launch a cost-effective alternative treatment to the UK market as quickly as possible.

The Solution

After evaluating several contract research organizations and functional outsourcing firms, the generics company partnered with APCER Life Sciences to bolster its regulatory capacity. APCER not only had the capabilities needed for dossier submissions in Europe but also had built a positive relationship with the generics company through prior engagements in the area of pharmacovigilance.

APCER quickly formed a project team and took ownership of the MAA submission process, including:

- Updating the Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL)
- Preparing the Risk Management Plan (RMP) and Summary of Pharmacovigilance System (SPS)
- Reviewing and signing clinical and non-clinical overviews
- Preparing application forms and arranging for mock-ups
- Reviewing Modules 2 and 3 and recommending changes to meet submission requirements in the UK
- Converting and validating the entire dossier to the Non-eCTD electronic Submission (NeeS) format with appropriate table of contents, hyperlinking, bookmarking, and folder structure
- Submitting the MAA via the MHRA Common European Submission Platform (CESP) portal
- Handling the response to requests for further information (RFI) after submission

The Results

The first MAA was submitted to the MHRA within two months of APCER receiving documentation. With a total elapsed time of 15 months to approval anticipated, the company will be able to launch the generic product much sooner than originally estimated.

Building on the success of the initial project, the partnership continued with additional dossier submissions. Within one year, APCER Life Sciences submitted more than 10 MAAs to the UK MHRA on behalf of the generics company.

APCER's thorough review and accurate assessment of product documentation will help the company to gain approvals more quickly and avoid unnecessary variations post approval. For instance, APCER spotted some quality concerns in the documentation as a dossier was being prepared and advised its client that the product would not get approved. Although initially resistant to the idea of a reformulation, the company was convinced that such a step was necessary to preserve their time, expense, and reputation in the longer term.

Regulatory Services from APCER Life Sciences provided the company with:

- A responsive, reliable, replicable submissions process
- A single source for the preparation of all CTD modules
- A knowledgeable, experienced team for dossier submissions and query handling

The generic pharmaceutical company is now able to:

- Grow their product pipeline in the UK
- Develop a strong reputation with the MHRA
- Maximize resources to deliver value to the company and to patients

Together for better health

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory, and technology resources to ensure that patients receive the safest, most effective therapies possible.

Learn more at **www.apcerls.com**, or contact us at one of our global offices

Americas
(+1) 609 455 1600
americas@apcerls.com

Europe
(+44) 208 326 3220
europe@apcerls.com

Asia
(+91) 11 4650 0802
asia@apcerls.com

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