INTRODUCTION TO BIOTECH PHARMA SERVICES:

Biotech Pharma Services (BPS) is a pharmaceutical company focusing on growth through the acquisition and in-licensing of Hematology, Oncology, Autoimmune, Urology, Neurosurgery, Nephrology as well as Generic assets, marketing of Authorized Generic products and the development of specialty generic products. BPS offers over more than a decade of pharmaceutical experience including product licensing, product development, regulatory affairs, distribution, product launch, contracting and commercialization. BPS goal is to bring quality pharmaceutical products – Branded and Generic to the Middle East market.

Multi-disciplinary team of qualified regulatory affairs senior experts is at your disposal for all aspects of your marketing authorization applications for human medicinal products. BPS Regulatory Affairs can help you explore the shortest route and timeframe to put your products on the market, and support the Life Cycle Management of your products.

BPS will closely collaborate with your team, and develop a tailor-made regulatory strategy for your product (portfolio) and guide you through the different procedural hurdles and authority interactions. We support all procedures (national and centralized GCC procedure) with preparation, review and submission of your Marketing Authorization Applications.

Post-registration, BPS Regulatory Affairs will support the maintenance and Life Cycle Management of your products, with support to your variations, line extensions, renewals, PSUR submissions and responses to Authority requests.

BPS regulatory affairs department insure the implementation of the good regulatory practice.

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Our Regulatory Support will include:

1) Regional reach and active regulatory network provide local coverage in most of MENA markets.
2) Up to date regulatory intelligence to provide the best regulatory strategy.
3) Ensure the quality of submission to MENA agencies to maximize the successful review.
4) Dossier compilation and maintenance.
5) eCTD Preparation and maintenance.
6) Conversion of CTD to eCTD.
7) Nees preparation.
8) Utilize competitive Gap Analysis to provide regulatory intelligence that supports product benchmarking.
9) Lifecycle Management.
10) Validation of Labels & Artwork.
11) Medical Translation.
12) Bundle Regulatory Activities.
13) Develop Solutions for potential regulatory hurdles and ensure the quality of submission to the regional agencies.
14) Drug Store Hub agency.
15) Pharmacovigilance Management.

We hope that the above brief will provide you with some details required of our regulatory services and we always happy to improve our process for a better achievement.

Thanking you in advance.

Sincerely Yours,
Biotech Pharma Services

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