TOSCA
PHARMA SERVICES

A new company but
20 Years of Experience

based in the Heart of Europe
in Vienna, Austria

WHO is TOSCA ?

We are focus on services and support for companies in the Pharmaceutical and Health-Care sector.

Our employees have an excellent pharmaceutical education and have worked in various pharmaceutical companies in the past. With their **experience and different specialisation** we can offer you a broad know-how to cover a **wide range of topics**.

A highly qualified and dedicated team offers expertise in the areas of **Regulatory filings** as well as **Life Cycle Management, Quality Management, Serialisation, Pharmacovigilance** and **Medical/Clinical Writing.**

Our History

TOSCA has developed out of the Regulatory and Quality Department of a regional pharmaceutical company active in Central Eastern Europe (CEE) and the CIS-countries. With the experience of almost **two decades and handling of more than 200 registrations** in this region we have a profound knowledge of the regulations and specifics of these markets.

Founded as a separate company three years ago **TOSCA** has developed into a **full-fledged service company for the pharmaceutical industry**. With the experience of submissions to the US-FDA and to several authorities in the MENA region we can now offer a broad geographical coverage to our customers. Our **offices in Vienna, Kiev and Dubai** will service you in a fast-responsive and professional way.

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Some of our Services

Regulatory

- Regulatory Due Diligence and Strategy
- Gap Analysis of existing dossiers/ASMFs
- MAA Dossier- Review and Compilation of Modules 1-5 for many regions (EU, Switzerland, Australia, EA/EU, CIS and GCC).
- eCTD/NeeS Publication Services.
- Readability test and Bridging reports.
- Preparation and Translation of SmPCs, PILs & Labelling for many languages.
- Support for Life Cycle Management-Variations, Renewals, MA transfers

Quality Management

- Preparation of customer and authority inspections (e.g. local authorities)
- System analysis and troubleshooting
- Training System set up
- Deviation management
- Support for Change Control processes (CCs)
- Set up and support of Corrective and Preventive Actions (CAPAs)
- Creation of work instructions (SOPs)
- Creation and implementation of concepts for supplier qualification and re-qualification

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Pharmacovigilance

1. Provision of QPPV and 24/7 Safety Contact Person Services
2. Follow up, validation & assessments of ICSRs
3. Preparation and submission of AEs and APRs in the appropriate format to the regulatory bodies, in compliance with the statutory timelines
4. Development of Country-specific Supportive Documentation Related to Safety Reporting
5. Performing literature search and obtaining literature articles and reviews, to guarantee up to date information
6. Pharmacovigilance SOP writing and maintenance
7. Establishing and maintaining PSMF
8. Preparation of periodic safety update reports (PSURs)

Please ask also for our Services in **Medical Writing** (Clinical and Preclinical Expert Reports) and on **Audits** (internal/external).

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