

Services

Portrait

Partners

References

Contact

Links

Home

Services

AMZD Wagner provides professional support regarding planning, documentation and submission of drug regulatory applications and variations (human and veterinary drugs) as well as in the field of quality assurance and batch release.

We can also support you in making first contacts and in subsequent negotiations with the authorities (Swissmedic, FOPH, etc.).

We offer solutions for in-house processing of individual projects and global solutions, which can also be outsourced to us.

Our services include:

- **Project management**

- Development of approval strategies including planning of deadlines and costs
- Evaluation of available regulatory documentation with regard to:
 - Completeness of the documents to be submitted
 - Requirements specific to Switzerland and Swissmedic checklist
 - Deficiencies for correction (preparation of a constructive deficiency list)

- **Regulatory Work**

- Revision of regulatory documentation:
 - Modification, improvement and completion of documentation (CTD dossiers) according to Swiss requirements and regulations
- Processing of administrative documents (Swiss module 1) as, for example:
 - Accompanying letter and forms
 - Drug-related texts (medical specialist and patient information, packaging elements)
 - Overall Table of Contents (OToC)
- Submission of applications, for example:
 - Regulatory applications (NCE/NAS, NA/generics, IE, ND, NDR, etc.)
 - Variations (Quality, texts, package sizes, etc.)
- Subsequent submission of statements and additional documents in reply to authority requests and requirements
- Maintenance of products after approval, regarding for example:
 - Submission of applications for availability under private health insurance to Federal Office of Public Health (FOPH)
 - Submission of PSURs
 - Submission of renewal applications

- **Quality management**

- Support in the field of quality assurance, for example:
 - Management of documents
 - Development and revision of internal guidelines "Standard Operating Procedures (SOPs)"
 - "Change Management"
- Support in the field of batch release, for example:
 - Release plan (system/ procedure)
 - Technical management/representation

- **Training and support**

- Tailor-made seminars and workshops
- Introductory training and support of "Junior staff"

- **Print and scanning service**

- Printout of entire documentation (e.g. CTD dossier) from CD or DVD
- Printing of tab sheets
- Printout of brochures
- Scanning of documents for digital archiving

± Show | close details



