GMP & GDP service

Quality management for medicinal products

We provide support and advice about all aspects of pharmaceutical quality management. One of our core services is to perform compulsory legal functions on your behalf, including that of qualified person (QP) in accordance with sect. 15 of the German Drug Law (AMG) or as responsible person for wholesale distribution (§52a AMG). If necessary, we can provide a certified quality management system, including our own manufacturing and import authorisation. This allows us to import and release medicinal products either in your name or in our own name.

Weitere Informationen:
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Our range of GMP services includes:

- GMP/GDP consulting / training
- Conduction of requirement- / gap analysis
- Design and/or updates of QM systems
- Support during GMP/GDP inspections
- Assistance with self- or mock inspections
- Supply-chain qualification and supervision
- Coordination and performance of audits
- Assuming responsibility as the qualified person (QP)
- External responsible person for wholesale distribution
- Batch release of medicinal products and investigational medicinal products
- Import release for medicinal products and investigational medicinal products from companies outside the EU or EEA

Diapharm supports pharmaceutical companies in efficiently integrating GMP/GDP requirements into their own quality management systems, complying with them and proving compliance to regulatory agencies during inspection. We develop complete GMP/GDP quality management systems and provide advice on quality assurance.

Our batch release service also offers companies the option of releasing medicinal products on the market without having a manufacturing authorisation of their own.

Get in touch with us!

Your benefits:

- **You benefit from our QP's longstanding experience**
- **Assuming of responsibility and batch release**
- **Performance of audits and analyses**

Diapharm