

Quality assurance

Customer satisfaction and product quality are our primary goals. Therefore, we operate a certified system of quality management according to ISO 13485 and a pharmaceutical manufacturing plant with a production permission for human drugs according to § 13 of AMG (Arzneimittelgesetz – Law for the Approval of Human Drugs). External inspections are effected by the TÜV Product Service, the Office of Drug Surveying as well as audits by our customers and business partners.

In order to reach these goals and to offer our customers and business partners superior quality and best support we have instituted the following:

- The incorporation of GMP-grade manufacturing of pharmaceutical agents and drugs as well as for the development and manufacturing of medical products have been integrated into our quality management system.
- Arzneimittelgesetz (AMG – Drug Approval Law)
- Medizinproduktegesetz (MPG – Medical Products Approval Law)
- EU-GMP-Guideline
- ICH directives
- ISO/EN/DIN standards
- Gentechnikgesetz (Gene Technology Law)
- Infektionsschutzgesetz (IFSG – Law for Protection Against Infection)
- Unfallverhütungsvorschriften (UVV – Prescriptions for Prevention of Accidents)
- clear, short and efficient internal and external communication channels
- continual assessment and improvement of all quality assurance and control proceedings
- close cooperation with and continual assessment and auditing of our suppliers
- continuous information and training of our highly motivated and qualified employees
- independent internal inspections in all divisions of the company

A wide spectrum of proven, recent and innovative analytical technologies and methods provides multiple analysis options. The close cooperation between our research, development and quality control teams allows us to perform in best time standardized, product-specified, or elaborated analyses upon request.



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