

# WDT – Our ambition is to manufacture quality. For you.

## What we are!

Quality creates confidence. We stick to our principles. Especially in the area of contract manufacturing we comply with all legal requirements (Medicines Act (AMG), GMP-guidelines). The GMP certification is regularly issued by our local competent Medicines Agency. Furthermore, our production is regularly audited by our national and international clients. Special technologies and the ability to handle both, small and large projects, are our main characteristics.

## What we do!

#### **Contract manufacturing**

On the national and international market we are specialist for

- sterile liquids for injections (narcotics, hormones and other injectabilia) in vials
- non-sterile liquids, ointments, creams and hydrogels in tubes, cans and vials
- production of sterile suspensions containing penicillin- and cephalosporin in dry cow tubes and vials
- · antibiotic intrauterine bolus
- · supplementary feedstuff
- · special packaging / picking and packaging

#### Biologics in our sera and vaccines unit

The range of products and services we offer is absolutely comprehensive. In stables and barns which are classified as historical buildings we manufacture high-quality biologics. Our horses are kept under best animal welfare conditions. Our product range comprises

- · vaccines (incl. dermatophyton and trichopyton)
- · autologous bacterial vaccines
- immune sera (e.g. Tetanus, and other sera)
- · tuberculins (poultry and bovine)

In addition, we offer

· support with the execution of clinical studies (e.g. on our horses)









## We will support you all the way!

No matter how challenging your project is, we offer the adequate service, like e.g.

- · development and optimization of formulations
- process validation
- · development of test methods and analytical validation
- performance of physical and chemical analytical tests as well as microbiological studies and evaluation of the results
- · stability tests according to ICH guideline
- final release of contract manufactured products according to AMG/ AMWHV to be placed on the market
- · compilation of the annual PQR
- · compilation of registration dossiers for marketing authorizations

## Quality is important to us!

Our laboratories work according to a GMP-compliant quality management system. Control of raw materials and products takes place under strict hygiene requirements under chemical and microbiological aspects.

For this reason we use state-of-the-art analytical equipment and methods, like e.g.

- · HPLC (UV-, PDA- and RI-Detektors)
- · viscometry
- · UV/Vis-Spectrophotometer, titrator, infrared spectrometer
- testing for microbial contamination of non-sterile products (determination of colony forming units and proof of specified bacteria)
- · detection of bacterial endotoxins

#### **Quality Management**

Within the framework of our manufacturing process, all new products go through extensive qualification and validation procedures. Any changes in processes, analytical methods and equipment are evaluated and monitored by using a risk-based GMP-compliant Change-Control-Management.

## Full-service package!

Thanks to many years of experience we are in a position to offer custom-made solutions. Full-service means the complete package from formulation development to production to dispatch. Upon request and as an additional service, we take care of the shipment of the products we manufacture for you also to foreign countries. For the transportation of temperature-sensitive goods we cooperate with qualified and audited forwarding agents.





#### How to contact us

#### **Magdalene Schauer**

tel: 05131 705-136 fax: 05131 705-133 email: schauer@wdt.de