

REFERENCE

# MEDICOM<sup>®</sup>

## Medicom Pharma GmbH

### Full GDP Service:

### QM System Upgrade, Inspection Readiness, Training and long-term GDP Compliance Consulting

#### The Customer

Medicom Pharma GmbH has been offering products for healthy living since more than 25 years, focusing on premium vital substance combinations. The company distributes its product portfolio across Europe, primarily in the direct business and through the Medicom online shop. Dosage forms range from soft gel capsules to direct granulates and tablets to tinctures. As a pharmaceutical entrepreneur and wholesaler, Medicom is also subject to supervision by the competent authority.

#### The Project

The initial project was to revise the quality management system, including assistance in communication with the competent authorities. After this was successfully concluded, gempex provided support with all good distribution practice matters over the years in the daily GDP business and as the lead consultant. Further projects such as the warehouse relocation and establishing a new site were successfully implemented. The full range of GDP services offered by gempex was utilised – from consultancy to realization.

#### The Task

The existing QM system had to be fundamentally upgraded and inspection readiness needed to be achieved. The QM system was integrated into routine operations on an ongoing basis, improved in terms of efficiency and tailored to the customer. Communication with the competent authorities was another support focus, for instance during the approval of another operating establishment and the relocation of the external warehouse. Thanks to good preparation and verification through self-inspections, official inspections were successfully passed multiple times at all sites. The accompanying consultancy and support in the day-to-day business were complemented by regular employee training. A stable QM system with clear, efficient processes was realized.

#### The Realization

Initial, intensive support for the customer transitioned to ongoing assistance covering all GDP matters. All current QM issues were addressed in regular team meetings and solutions were defined and implemented. For instance, documentation was amended, self-inspections were carried out and the load on QM functions in the daily business was reduced.

#### The Result

Over time, gempex advised and assisted Medicom with all GDP-related matters and provided targeted support for the development of the internal processes. Now the customer is positioned to complete all QM tasks themselves.



*gempex GmbH supports leading companies in the chemical and pharmaceutical industries with the implementation of quality requirements according to GMP, DIN ISO 9001 and comparable quality standards. The professional management of validation and qualification projects, including consulting for the planning and construction of facilities, are its main activities. This includes permanent support for everything related to the customer's ongoing GMP operations.*

Key performance
<ul style="list-style-type: none"> <li>• Full range of GDP Services</li> <li>• Quality Management Concept</li> <li>• QM System Update</li> <li>• GDP Consultancy and Implementation</li> <li>• Qualification</li> <li>• Inspection Services and Self-inspection</li> <li>• Change Management</li> <li>• Training</li> </ul>