HWI Campus

Strategies for pharmaceutical entrepreneurs from non-EU-countries

Companies from non-EU countries or "Third countries" who intend to enter the European market need smart strategic plans for the implementation of regulatory requirements in the EU. The HWI Campus provides individual concepts for these companies:

- HWI may act as applicant during marketing authorisation/registration procedure in EU
- HWI provides the infrastructure for the establishment and registration as pharmaceutical entrepreneur at HWI Campus
- HWI supports the application procedure for an EU import licence (according to §72 AMG)
- HWI supports the application procedure for a wholesale licence (according to §52a Abs. 6 AMG)
- HWI provides EU release testing and EU batch release
- HWI supports the establishment of a QA system and pharmacovigilance system

Network & Services

HWI provides location, infrastructure, services and a broad network of experts, potential partners and potential clients in the pharmaceutical business.

Services available at the HWI Campus are:

- quality control
- quality assurance
- QP, QPPV
- batch release
- pharmacovigilance system and services
- analytical and drug product development
- life cycle management for drug substances drug products, medical devices
- Administration, IT
- warehouse (GDP) and distribution services nearby

your success is our success

For further questions please contact:

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HWI group

Brexit will turn U.K. into a “Third Country“

Following the Brexit, the United Kingdom (U.K.) will become a “Third country”. In consequence, marketing authorisation holders based in the U.K. need to have a registered office and/or a manufacturing site with a corresponding manufacturing authorisation in the EU/EEA.

Also EU batch release and pharmacovigilance activities have to take place in the EU as well as the QP and QPPV have to be resident within the EU.
This was clarified by the European Commission and EMA in their “Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use“, published in May 2017.

HWI Campus supports companies with their entry into the EU and offers attractive and efficient solutions throughout the complete life-cycle of the products.

HWI group

HWI group provides a wide range of individual and specialised services for the pharmaceutical, medtech and biotech industries.

Over the last 25 years, HWI group has gained a wealth of regulatory as well as scientific knowledge and long-term experience to support our clients.

Our services are located in five business units – laboratory services, reference standard services, vigilance & quality services, drug development, and regulatory affairs services & life cycle management.

HWI Campus - Facts

Area:	11,000 sqm
Buildings:	offices, lab area, conference room
Free location:	9000 sqm
Airport:	Frankfurt FRA (75 min)
	Karlsruhe FKB (35 min)
Train station:	ICE (15 min)
IT:	Internet connection via fibre optic cable, up to 100 Mbit simultaneously, 10 Gbit inhouse network

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