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BVMA member since 2005
 Audits passed in 2005, 2008,
 2011, 2014 and 2018



HISTORY AND MISSION

Health Research Services (HRS) Ltd, founded in 2000, run offices in UK, Germany, Moscow, Kiev and Warsaw. HRS GmbH is an independent contract research organisation offering specialist services in the areas of Consulting, Scientific Drug Research & Development, Project Management, Clinical Monitoring, Medical Writing and Regulatory Affairs. **HRS** provides expert services to turn basic research on promising new drug candidates into marketed medications.



HIGHLIGHTS

Re-approval and marketing authorisation from German regulatory authorities (BfArM) of a herbal medicinal product which has been classified as a NCE and the notification from the FDA in the US where it is also available. The preclinical and clinical research and development programme for this medication was set-up and conducted by **HRS** on behalf of the pharmaceutical manufacturer. **HRS** developed the patents for the use of this medication also in additional indications. This product is marketed abroad world-wide by **HRS** who coordinates the regulatory requirements and pharmacovigilance.

SERVICES

Service Provider for Pharmaceuticals and Nutrition Science so both the innovative area of personalized Health Medicine and therapeutic diet and food

Consulting and Project Management in all stages of drug development and Product Life Cycle

Scientific Drug Research & Development

The experienced scientists at HRS have professional experience in pharmacological, toxicological and clinical drug research and are dedicated

- ▷ To provide Preclinical Toxicology & Pharmacology Development Plans
- ▷ To provide Clinical Development Plans
- ▷ To present the actual research results as lectures on conferences as well as to the Sponsor's marketing and business development representatives
- ▷ To give trainings to Sales Representatives about recent research conducted with a specific medicinal product
- ▷ To provide scientific and medical consulting

Clinical Monitoring

Clinical Trials are monitored by qualified and experienced CRAs

Medical Writing

The HRS medical writers are excellently trained medical or scientific experts and are members of the European Medical Writers Association (EMWA)

Regulatory Affairs

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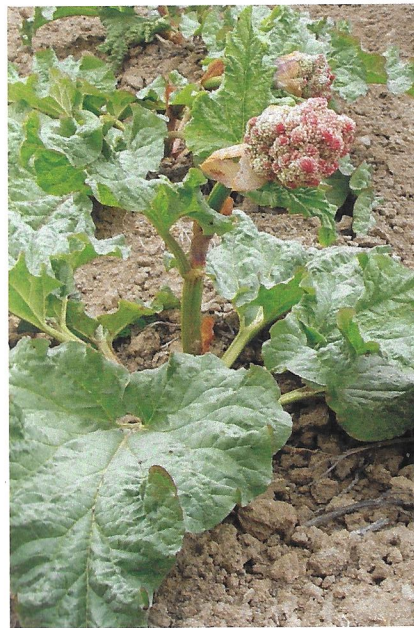
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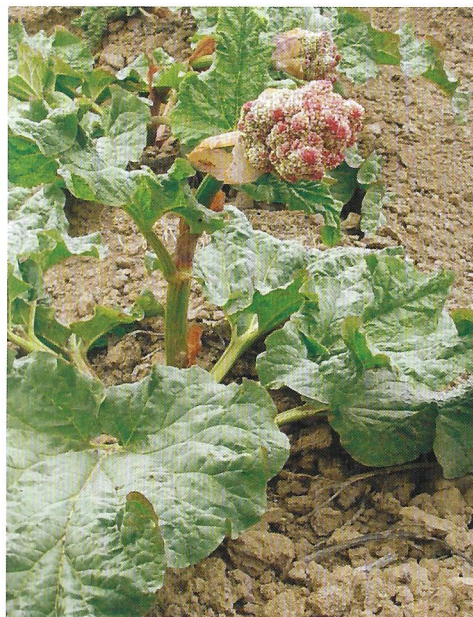
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Recent projects include the re-approval and marketing authorisation from German regulatory authorities (BfArM) of a herbal medicinal product which has been classified as a NCE and the notification from the FDA in the US where it is available since 2010. The preclinical and clinical research and development programme for this medication was set-up in 2002 and conducted by **HRS** on behalf of the pharmaceutical manufacturer, and this product is now marketed abroad world-wide by **HRS GmbH**, another company of **HRS**.

HRS developed the patent applications for the use of this medication for additional indications.

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Project Management in all stages of drug development and product life cycle

Clinical Monitoring

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- ▷ Who are permanently employed at **HRS** and have demonstrated training skills
- ▷ Who are experts in all phases of a clinical trial according to ICH-GCP
- ▷ Who have a reputation for high recruitment rates at the sites and good site motivation skills
- ▷ Who have the ability to slot into existing projects in order to identify potential problems and improve the timelines
- ▷ **HRS** Senior CRAs provide extensive monitoring competence in training new staff

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