



Dr. Werner Gielsdorf

Date and Place of birth	09 January 1951 in Neuwied/Rhein, Germany
Education	1976 Post-doc (Dr. Carl-Duisberg-Foundation) University of Zurich 1974 - 1976 Ph. D. from the University of Bonn (Drug Metabolism in Humans) 1969 - 1974 Studying Biology and Chemistry; Diploma in Biology and State examination in Chemistry. Main areas of research: pharmacokinetics, pharmaceutical biology, toxicology

Business ex-perience	1981 – until today: <ul style="list-style-type: none">• Management consultant in the Healthcare/Life Sciences sector• Management consultant to pharma firms, Donor organisations (EU, World Bank, UNCTAD/WTO), and public organisations/authorities• Professional management of clinical studies (planning, placement, coor-dinating/execution, monitoring/auditing, documentation, reporting), in particular in Central- and Eastern European countries and Near East• GCP, GLP, GDP trainer; also for defined areas of GMP• Consulting governmental bodies in the healthcare sector in Central- and Eastern Europe and Near East (public health, national drug policy, regu-latory/legislative issues, GCP, GLP, GMP, administration)• Founding a Centre of Excellence for the regional pharmaceutical industry and regulatory authorities (Jordan)• Expert in drug development and pharmaceutical issues for governmental bodies and the industry• Project Manager of Tacis projects sponsored by the European Commis-sion in Central- and Eastern Europe, and Jordan• Project Manager for International organisations, like UNCTAD, WTO, ITC• Restructuring of the entire pharmaceutical industry in an Eastern Euro-pean country (Ukraine)• Establishing a national Drug Regulatory Authority, including a training Centre for GMP/GDP and GCP inspectors• Optimizing the purchasing, warehousing, transportation and distribution of pharmaceutical wholesalers/distributors
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- On behalf of the Managing Board of the Treuhandanstalt (the then re-sponsible German Authority for the privatization of the previously state-owned companies in the former German Democratic Republic, GDR) developing, cross-checking, validating and auditing of privatization and restructuring concepts
 - Evaluating market opportunities and R & D portfolios for chemical companies and drug producers, in particular of the former GDR
 - Development, optimization and implementation of new organizational models within the German Federal Drug Regulatory Authority (BGA) and the Ukrainian GMP/GDP Inspectorate
 - Restructuring of an Upper Federal Authority, interim-management, internal planning and control, coordination of processes and procedures, and slim lining the organisational form of the institution
 - Developing a concept for the reduction of product (*i.e.* drug) development times for an International pharmaceutical firm to optimize its R & D project management
 - Developing and due-diligence of pharmaceutical companies, their products and marketing strategies
 - Creating and profiling of a Company in the area of advanced technologies and the environment
 - Turnaround Management in pharmaceutical manufacturers and whole-salers/distributors

1976 to 1981: Work in the areas of drug analytics, pharmacokinetics, and (analytical, forensic) toxicology

- Development of dedicated and specific analytical methods in the field of doping analysis, (forensic) toxicology, criminalistics, and drug monitoring

Language skills

- German – mother tongue
- English - fluent
- French – good working knowledge
- Russian – basic working knowledge

Description of relevant professional experience

• **Project Management:** On behalf of the European Commission (Takis) the entire pharmaceutical sector of an Eastern European country was re-structured. In parallel six selected enterprises were directly supported in their turnaround management. Within the framework of a further project, a national Drug Regulatory Authority was established and then implemented into the national legal system. A Federal Drug Regulatory Authority was completely restructured, and its operations and organizational structure optimized. A GMP Training Centre and a Centre of Excellence (for the regional pharmaceutical industry and the authorities) were established. International (Donor) organisations (UNCTAD/WTO, ITC, EU, World Bank) and drug regulatory authorities were supported in implementing International standards, like GCP, GMP/GDP, GLP, business organisation and management

- **Clinical research:** Complete managing/organizing clinical studies (placement of studies, handling of the local regulatory/legislative issues, support in obtaining a marketing authorization/registration for medicinal and medical products, consulting on marketing and product placement).

Monitoring and auditing of clinical studies in particular in Central- and Eastern Europe according to GCP, GLP and GPP. Providing training courses in GCP, GLP and Management. Preparing and maintaining of all of the required study documentation. Reporting and Medical writing

- **Management consulting in the healthcare sector:** Optimizing R & D projects of research-based pharmaceutical companies, evaluation of marketing strategies for non-block busters of different therapeutic classes. Cost Containment Programme for a leading pharmaceutical wholesaler/distributor with special emphasis on warehousing/storing and distribution channels. Management for a limited period of time in a go-vernmental body to assure the proper implementation of recommenda-tions generated during the course of a restructuring project. Consulting of Biotech start-ups in Germany and Switzerland (business-, financial-, and marketing plans)

- **Consulting:** Supporting M & A projects of pharmaceutical companies from Ukraine, Switzerland and Germany by reviewing their respective product portfolios, marketing concepts and analysis of competitors (benchmarking) during the due diligence process. Preparing for the en-tering into the Japanese and South Korean markets for an European CRO. Developing a close-loop concept for the reduction of product devel-opment times for a pharmaceutical producer

- **Development and application of instrumental quantitative ana-lytical methods:** Developing analytical methods for the quantitative de-termination of xenobiotics in biological fluids in the course of clinical studies, toxicological and forensic evaluations and in environmental ana-lytics

Publications

- More than 75 scientific publications and presentations: publications of clinical trials, quantitative determination of xenobiotics in biological fluids (drugs, metabolites), R & D Management, Restructuring, Pharmaceutical marketing

Professional experience

Since March 2003

Management Consultant in the Healthcare/Life Sciences sector (self-employed), in particular consulting on GLP, GCP and defined areas of GMP/GDP. Complete managing (placing, monitoring, auditing, etc.) of clinical studies in particular in Central- and Eastern Europe. Project Man-ager in projects sponsored by the EU- or other Donor organisations. Business development, support of Biotech start-ups in Germany and Switzerland (*Ukraine, Russia, Poland, Czech Republic, Hungary, Jordan*)

2007	Ministry of Health of the Republic of Slovenia, Project manager, support in implementing GCP, joint inspections of selected clinical sites (<i>Slovenia</i>)
2007	Pharmaceutical manufacturer, Consultant, Preparing for a FDA GMP in-spection (<i>Belgium</i>)
2006	UNCTAD/WTO (ITC, International Trade Center), Project manager, as-sessment of service providers in clinical research in Russia and Ukraine (<i>Switzerland</i>)
Since 2006	STCU (Science and Technology Centre of Ukraine), Assessing R & D pro-jects in the life sciences sector (<i>Ukraine</i>)

2004/2006	Euro-Jordanian action for the development of enterprise (EJADA), Project manager, Audits for GCP and GLP compliance, establishing a Centre of Excellence for the regional pharma firms and health authorities (<i>Jordan</i>)
1999 – 2007	Project-Manager of Tacis projects in the pharmaceutical sector in Ukraine, Moldova, Jordan and Slovenia on behalf of the European Com-mission (<i>Ukraine, Moldova, Jordan, Slovenia</i>)
1995 - 1999	Bristol-Myers Squibb Corp., Pharmaceutical Research Institute, Clinical Pharmacology, Brussels, Belgium, Clinical Research Manager, Managing phase I and early phase II clinical studies in Europe (<i>Belgium</i>)
1991 - 1995	German Federal Health Authority (Bundesgesundheitsamt; BGA), Berlin, Consultant to the Managing Director of the Drugs Institute, Berlin, Reor-ganized Administration and working procedures ("Internal Planning and Controlling") (<i>Germany</i>)
1991	Roland Berger & Partner, International Management Consultants, Munich, Developed product-strategies for pharmaceutical companies, German-Federal Trust (created for the purpose of transferring former East Ger-man properties to private investors = "Treuhandanstalt", Berlin): Re-viewed, analyzed, validated and evaluated business plans of pharmaceu-tical/chemical companies (<i>Germany</i>)
1989 - 1991	LAB Gesellschaft fur pharmakologische Untersuchungen mbH & Co, Neu-Ulm, Assistant to the CEO, Head, "Management Consulting Division", Es-tablished new fields of business, developed the company's business in Japan and South Korea (<i>Japan, South Korea</i>)
1987 - 1988	ggu-Gesellschaft fur Gesundheits- und Umweltforschung mbH, Frank-furt/M., Managing partner, Established and profiled a high-tech company (<i>Germany</i>)
1985 - 1987	Kali-Chemie/Solvay Pharma GmbH, Hannover, Section leader "Pharma-cokinetics", Headed a group of 12 scientists/assistants, initiated and monitored clinical trials (mainly human pharmacokinetic studies), founded an Analytical Department (<i>Germany</i>)

1981 - 1985	LAB Gesellschaft fur pharmakologische Untersuchungen mbH & Co., Neu-Ulm, Associate Director R & D, Developed new fields of business, managed clinical trials worldwide (Germany)
1978 - 1981	Berlin Crime Investigation Force, Berlin, Head, "Special Toxicological Investigations Branch", Founded laboratories for (forensic) drug analysis by special instrumental analysis (Germany)
1976 - 1978	German Sports University, Cologne, Research assistant, Federal Commission for Doping Control, Participated in a programme on the analysis of doping agents (anabolic steroids) (Germany)
Education	
1976	Post-doc fellow, Dr. Carl-Duisberg-Foundation, University of Zurich, Institute of Legal Medicine, Switzerland, Applied new analytical (GLC/MS) techniques during the course of biotransformation studies
1974 - 1976	Scholarship holder, German Bishops Conference "Cusanuswerk", Received a Ph.D. (Dr.rer.nat.), under supervision of Prof. S. Goenechea, Institute of Legal Medicine, University of Bonn, on "Biotransformation of the psychostimulant Pemoline in man"
1974	Diploma (Dipl. Biol.) and State examination, Pharmaceutical Biology, Pharmaceutical Institute, University of Bonn, under the supervision of Prof. K.-W. Glombitza, on "Triterpenesapogenins in Phytolacca acinosa Roxb.
1969 - 1974	Studied Biology, Chemistry, and Oecothrophology, at the Rheinische-Friedrich-Wilhelms-Universitat, Bonn, Germany
1966 - 1969	High school, Neuwied

Certification:

I certify that the information contained herein is correct and accurate.