CURRICULUM VITAE

Erik Hesse

ADDRESS

TheraGenesis GmbH
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EDUCATION

Graduate Studies, Physiology – 1975-1978
Rutgers University -New Brunswick, New Jersey

B.Sc. (Biology/Chemistry) - 1974
Ramapo College of New Jersey - Mahwah, New Jersey

EXPERIENCE

1995 to Present
TheraGenesis GmbH
Stutensee, Germany
Managing Director

Establishment and management of a strategic clinical and regulatory consultancy and service company in Germany. Demonstrable expertise in the conceptualisation and realisation of clinical development programs and regulatory strategies in the European Union for pharmaceuticals, biologics and medical devices.

1990 to 1995
PHARMACO LSR GmbH (currently PPDI)
Karlsruhe, Germany
Managing Director

Responsible for the direction of concurrent multi-center clinical research studies for pharmaceuticals and medical devices by overseeing project development and planning, supervising the training of staff, directing all project management functions and performing on-going evaluations of study progress and profitability. Provision of clinical and regulatory consultancy support to clients. Administrative responsibilities for Phase II-IV operations within Pharmaco LSR GmbH's geographical areas of responsibilities. Development of clinical research expertise and capabilities and management of programs in Germany, Austria, Switzerland, Italy, Poland and the Netherlands.

1989 to 1990
PharmaKinetics Laboratories GmbH / MedResearch GmbH
Karlsruhe, Germany
General Manager

Established operations and managed European clinical trials for Phase II through IV clinical trials and product registration support services.

1986 to 1989
BOEHRINGER MANNHEIM GmbH
Mannheim, Germany
Director, Clinical Studies Management

Established, trained and developed an international clinical studies monitoring and quality assurance department. Coordinated the activities of some 35 clinical research associates and supportive persons. Twelve projects were in clinical development in the following indications: hypertension, congestive heart

failure, angina pectoris, peripheral vascular disease, renal insufficiency, pulmonary disease, diabetes mellitus, hyperlipidemia, rheumatoid arthritis and cancer. Further responsibilities included the international harmonization of study monitoring standard operation procedures, case report forms, and management information systems; and the logistical coordination of final clinical study reports.

1983 to 1986
ALLERGAN PHARMACEUTICALS, INC.
Irvine, California
Manager, European and Middle Eastern Clinical Research

Recruited, trained, motivated and managed clinical investigators for ophthalmic drug and optometric studies in Germany, Austria, France, Italy, United Kingdom, Scandinavia and Israel. Supervised clinical trial activities of some 185 European ophthalmologist investigators studying 2,500 subjects for Phase I through III and market support studies.

1983
ALLERGAN PHARMACEUTICALS, INC.
Irvine, California
Manager, Clinical Research Services and Administration

Managed a staff of seven regionally based clinical research associates and support personnel responsible for monitoring activities in the U.S.A. and Canada. Developed and implemented standard operating procedures for the clinical research department.

1981 to 1983
ALLERGAN PHARMACEUTICALS, INC.
Irvine, California
Senior Regional Clinical Research Associate

Investigator recruitment and monitoring of ophthalmologic, optometric, and dermatologic studies conducted in the northeastern quadrant of the U.S.A. and Eastern half of Canada. Local monitoring of FDA activities and hearings of commercial, scientific, or regulatory importance to Allergan.

1979 to 1981
IVES LABORATORIES, INC.
New York, New York
Clinical Research Associate

Monitoring of clinical studies directed toward the development of Sectal (acebutolol) for the treatment of hypertension, angina pectoris, and cardiac arrhythmias. Management responsibilities included liaison functions with clinical sub-contractors, e.g. for ambulatory ECG (Holter) recordings; and supervision of the nationwide distribution and accountability of investigational supplies.

1977 to 1979
JANSSEN PHARMACEUTICALS, INC.
New Brunswick, New Jersey
Clinical Research Assistant

Investigator recruitment, monitoring and analysis of clinical studies of the cardiovascular drugs: Clinum (lidoflazine) and Remivox (lorcainide) for the treatment of angina pectoris and ventricular arrhythmias, respectively. Monitoring and analysis support for miconazole, loperamide, etomidate, domperidone and levamisole clinical projects.

1974 to 1977
ORTHO PHARMACEUTICALS, INC.
Raritan, New Jersey
Research Assistant

Development of pharmacologic models used by the cardiovascular pharmacology group including the autonomic dog, acutely hypertensive dog, chronic hypertensive dog, and hemodynamic dog. These tests were used to screen and characterize potential anti-hypertensive agents.

PROFESSIONAL ORGANIZATIONS

Member, ACRP Foundation Board of Trustees, Association of Clinical Research Professionals, 2001-2002.

Chairman (Association Board of Trustees), Association of Clinical Research Professionals, 2000. (Board membership 1997 – 2001).

Member, European Clinical Investigator Certification Committee, Association of Clinical Research Professionals, 2000 to 2008.

Member, European Clinical Research Coordinator (CRC) Certification Committee, Association of Clinical Research Professionals, 1999 to 2008.

Recipient, 1999 *European President's Special Award* "In Appreciation of Extraordinary Dedication to the Association of Clinical Research Professionals in Europe"

Recipient, 1997 *North American President's Award* "In Appreciation for Outstanding Service" to the Association of Clinical Research Professionals for the establishment of a european affiliate society.

President, Association of Clinical Research Professionals - Europe, 1997 to 1998. (European Regional Council Membership 1996 – 2000).

Member, European Clinical Research Associate (CRA) Certification Committee, Association of Clinical Research Professionals, 1997 to 2008.

Officer, European Operating Committee, Regulatory Affairs Professional Society, 1993 to 1998.

Chairman, European Development Committee, Association of Clinical Research Professionals, 1994 to 1997.

Certified Clinical Research Associate (Europe) awarded by the Association of Clinical Research Professionals, 1. November 1997.

Certified Clinical Research Associate (USA) awarded by the Association of Clinical Research Professionals, 18. May 1997.

Extraordinary member, Deutsche Gesellschaft für Pharmazeutische Medizin e.V., DGPharmMed (German Society for Pharmaceutical Medicine), 1989 to present.

Member, European Drug Program Planning Committee, Regulatory Affairs Professional Society, 1990 to 1993.

Trustee, Board of Directors, Associates of Clinical Pharmacology, 1983 to 1984.

Chairman, Program and Planning Committee for 1983 Annual Meeting, San Diego, California, Associates of Clinical Pharmacology.

Member, Association of Clinical Research Professionals, Regulatory Affairs Professional Society, Deutsche Gesellschaft für Pharmazeutische Medizin e.V.

PUBLICATIONS/PRESENTATIONS

Hesse, E.U.: „Efficient Strategies for Clinical Development of Medical Devices in the USA and Europe" at 3rd ACRP Israeli National Conference, Jerusalem, 29 May 2006.

Hesse, U.: "CRA Certification and Training" at 1. Norddeutsches Symposium für Medizinische Dokumentation und Pflegeberufe, Hamburg, 19-20 October 2000.

Hesse, U. (Moderator), Chalmers, S., Kehne, K.: "Clinical Trials in Europe" at Regulatory Affairs Professional Society Annual Conference, Vienna, 7-10 May 2000.

Hesse, U., Bannenberg, J.: "Can European clinical trials expedite US device development efforts and FDA approval processes?" at Medical Alley Conference, Minneapolis, 17 November 1999.

Hesse, U. (Moderator), Lightfoot, G., Tassignon, J.-P.: "Future Trends in Clinical Research" at Association of Clinical Research Professionals Annual Conference, Brussels, 25-28 November 1998.

Hesse, U. (Moderator), Robert, M.: "The EU GCP Directive – Accelerating the Drug Development Process" at Association of Clinical Research Professionals Annual Conference, Brussels, 25-28 November 1998.

Hesse, U., von Martius, K.: "Medical Device Clinical Trials in Germany" at German Society of Physicians in the Pharmaceutical Industry (FÄPI), Frankfurt, 15 June 1998.

Hesse, U. (Moderator), Lekschas, J., Robinson, A., Bell, R.: "Electronic Marketing Dossiers: Current Status and Experience in Europe and the USA." at Regulatory Affairs Professional Society European Conference & Exibition, Cannes, France, 27-30 April 1997.

Hesse, U.: "European Good Clinical Practice Directive." The Monitor, Vol. 11, Nr. 4, Winter 1997.

Hesse, U. (Moderator): "German Health Care Reform Initiatives: Current Status and Future Perspectives." at Regulatory Affairs Professional Society Meeting, Bonn, Germany, November 1996.

Hesse, U.: "Clinical Studies on Pharmaceuticals - Germany." at Clinical Studies on Pharmaceuticals: Regulatory Procedures - Present & Future, An IBC International Conference, London, England, October 1996.

Hesse, U.: "Technology and The Regulatory Affairs Professional." RAPS Focus, May 1996.

Hesse, U.: "Clinical Trials and Ethics Committees in Germany." RAPS News, December 1995.

Hesse, U. (Moderator), Garcia-Alonso, F., Berdaï, D., Tamarro, V., McCarthy, C.:"European Clinical Trial Approval Process." at Regulatory Affairs Professional Society European Conference & Exibition, Barcelona, Spain, 7-9 May 1995.

Hesse, U.: "The Development and Implementation of Good Clinical Practices." Conference on the Promotion of Epidemiological Research, Sponsored by the Polish Ministry of Health and Social Welfare and Pharmaco LSR GmbH, Krakow, Poland, 23-25 May 1994.

Hesse, U., Hardardt, J.L. (Moderator), Jacobs, D.M. & Shaible, T.F.: "From Biotech to Pharmaceutical: European Community vs. United States." at Associates of Clinical Pharmacology Annual Meeting, San Antonio, Texas, 23-26 March 1994.

Hesse, U. & Edwards, M.W.: "Foundation Training for the Regulatory Affairs Professional: Drug Clinical Trials." Regulatory Affairs Professional Society Workshop, Leuven, Belgium, 18-19 June 1992.

Hesse, U.: "Role of SOPs in Document Generation for GCP." Good Clinical Practice in Europe: The Key Issues Arising From the EEC GCP Guideline and Their Impact on Clinical Research in Europe, at Drug Information Association Conference, Madrid, Spain, 1990.

Hesse, U.: "Good Clinical Practices in the Federal Republic of Germany." J Clin Res Drug Dev, 3(2):129-146, 1989.

"Development of the Protocol, Case Report Form, and Monitoring of Clinical Studies" in Multinational Registration of Drugs - Planning - Problems - Principles, Neu-Ulmer Gespräche 1983. (Ed: Kuemmerle, H.P., Jaeger, H., and Feistle, K.), 1983.

Hesse, U.: "Prazosin as an Alpha-Blocker: A Hemodynamic Approach." at FASEB Meetings, Atlantic City, New Jersey, 1978.

Hesse, U.: "Adrenergic Receptor Supersensitivity Following Propranolol Withdrawal." at FASEB Meetings, Atlantic City, New Jersey, 1978.

Ram, N., Hesse, U., and Heilman, R.D.: "The Effects of Propranolol HCl in Hippocampal-Lesioned Rats." Arch Int Pharmacodyn, 229:138-43, 1977.

Ram, N., Bauer, E.W., Hesse, U., and Heilman, R.D.: "Cardiovascular Effects of 5-Hydroxpropranol (ORF 12592) in Dogs." Arch Int Pharmacodyn, 228(1): 118-125, 1977.

Ram, N., and Hesse, U.: "Modificiation of Digitalis Induced Arryhthmias by Central Adrenergic Neuron Exclusion." The Pharmacologist, 18(2):168, 1976.

Hesse, U.: "Cardiovascular Effects of 5-Hydroxypropranolol (ORF 12592) in Dogs." at FASEB Meetings, Anaheim, California, 1976; Federation Proceedings, 35: 696, 1976.

CLINICAL RESEARCH EXPERIENCE (Since 1990)

An Observational Study of the Performance and Safety of a Left Atrial Appendage Exclusion System

A Pilot Randomised Controlled Trial of the Use of an Autologous Cell Harvesting Device for Venous Leg Ulcers

A randomized, double-blind, placebo-controlled trial of an iron-chelation drug in patients with pantothenate kinase-associated neurodegeneration (PKAN).

Evaluation of a Cold Plasma Technology as a Method for Surgical Incision Closure following Caesarian Section.

Gelatin Sponge Application in Venous Insufficiency Treatment Study.

Evaluation of a Second Generation High Definition and Narrow Band Imaging Colonoscopy System for the Detection and Characterization of Colorectal Adenomas – A European Multi-Center Study.

A Prospective Randomized Study of Endovascular Treatment (Liberation Procedure) of Chronic Cerebrospinal Venous Insufficiency in Patients with Multiple Sclerosis.

In-Tunnel European PFO Trial: A Prospective, Multi-Center Study to Evaluate the Safety and Performance of a PFO Closure System.

ASA Plavix Feasibility Study with a Left Atrial Appendage Closure Technology.

Continued Access PROTECT AF Registry - CAP Registry - US IDE PIVOTAL Clinical Study.

Pilot Study to Evaluate the Safety and Performance of an Orbital Atherectomy System in Treating *De Novo* Coronary Lesions.

A Study of the Effect of a Percutaneous ArterioVenous Fistula System (System A) on Excercise Capacity and Quality of Life in Patients with Chronic Obstructive Pulmonary Disease (COPD).

A Study of the Effect of a Percutaneous ArterioVenous Fistula System (System B) on Excercise Capacity and Quality of Life in Patients with Chronic Obstructive Pulmonary Disease (COPD).

A Feasibility Study of Temporary Bronchial Epicardial Stimulation for Cardiac Pacing Application.

Evaluation of Safety and Feasibility of a Cryotherapy Device for office-based Ultrasound-guided Treatment of Breast Fibroadenoma.

APOLO - Accessing Peripheral Occluded LessiOns – Prospective, Feasibility, Non-Randomized Clinical Study.

A Prospective, Unmasked, Cross-Over Evaluation of an Intraocular Stent in Patients with Primary Open-Angle Glaucoma.

A Prospective, Unmasked, Randomized Evaluation of an Intraocular Stent Versus Two Ocular Hypotensive Agents in Patients with Primary Open-Angle Glaucoma.

A Multi-Center Study of a Urethral Sling for the Treatment of Male Urinary Incontinence.

Study of a Trabecular Microstent in Subjects with Open Angle Glaucoma.

Multicenter European Study to Evaluate the Performance and Safety of an Anterior Chamber Implant in Glaucoma Patients.

Phase IV Clinical Experience Study to Evaluate a wound-healing device in the Treatment of Recalcitrant Wounds.

Post-Marketing, Multicenter Study to evaluate a Single Dose of a Wound-Healing Product Every Other Day in the Treatment of Venous and Arterio-Venous Wounds.

Multicenter European Study to Evaluate the Performance and Safety of a Hypothermia Induction System in The Minimization of Neurological Deficit in Patients following Cardiac Arrest and Resusitation.

Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation (PROTECT AF) – A US IDE Pivotal Clinical Study.

Evaluation of The Safety and Performance of a Left Ventricular Assist Device In Patients Requiring Hemodynamic Support.

A Clinical Study to Evaluate the Safety and Efficacy of a Cardiac Cryoablation System for the Treatment of Paroxysmal Atrial Fibrillation.

A Multi-Center Study of a Urethral Sling for the Treatment of Female Urinary Incontinence.

A Multi-Center Study of an Ultrasound Catheter System and Pharmacologic Lysis in Thrombotic Stroke.

Online Localization of the Position of the Prostate and Possible Repositioning in Intensity Modulated Radiotherapy Supported by Pictures (IGRT) of the Prostate using an Implanted Radio Transmitter.

A Multicenter, Randomized, Placebo-controlled, Double-blind, Phase 2 Study to Evaluate the Efficacy and Safety of a Pharmaceutical Administered for 12 Weeks in HIV-infected Patients With HIV-associated Visceral Obesity.

A Multi-Center Study of an Implantable Left Atrial Appendage Filter System for the Prevention of Ischemic Stroke.

A Multicenter, Randomised, Controlled Therapy Study to Evaluate Heroin Administration and Psychotherapeutic Support in Opiate Addicted Patients.

Multicenter, Non-Randomised, Prospective, Feasibility and Safety Clinical Study of an Embolic Protection Device During Transluminal Intervention in the Coronary Vessels.

An Open-Label Study to Evaluate the Performance and Safety of Device for the Continuous Monitoring of Intrapartum Fetal Oxygen Saturation and Fetal Heart Rate.

Extracorporeal Whole Body Hyperthermia in the Treatment of AIDS, Hepatis C and in Oncology.

A Prospective Evaluation of a Mechanical Anastomosis Device for Aortic Autologous Vein Grafts.

Cardiac Implant to Induce Ventricular Shape Change to Improve Myocardial Contraction Efficiency in Severe Congestive Heart Failure.

An Open-Label, Single Cross-Over Design Study to Determine the Clastogenic Potential of Two Iron Chelation Medications in Iron-Overloaded, Transfusion Dependent Thalasemia Patients.

Evaluation of a Transcatheter Atrial Septal Defect Occluder in the Treatment of Atrial Septal Defect and Persistent Foramen Ovalis: An International Closure Trial.

Treatment of Severe Ischemic Heart Disease with Transmyocardial Laser Revascularization: A Multinational Evaluation.

Treatment of Severe Ischemic Heart Disease with Percutaneous Transmyocardial Laser Revascularization: A Multinational Evaluation.

Safety and Efficacy of Two Therapy Regimens of Iron Chelation in the Treatment of Iron Overload in Thalassemia Patients.

Internal Mammary Artery Mobilisation Study using Robotic Endoscopic Technology.

European Trial Study for the Treatment of Stress Urinary Incontinence and Retention with a Urethral Insertable Valve.

Multicenter, Open-Label Study to Evaluate the Safety and Efficacy of an Oral Iron-Chelating Agent in the Treatment of Thalassemia.

A Randomized, Multicenter, Investigator-Blind Trial Comparing Oral Therapy with a new Antibiotic Drug and Augmentin for the Treatment of Complicated Infections of the Skin and Skin Structure.

A Randomized, Multicenter, Double-Blind, Multicenter Trial Comparing Oral Therapy with a new Antibiotic Drug and Oral Fluxclocacillin for the Treatment of Uncomplicated Infections of the Skin and Skin Structure.

A Prospective Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Group Sequential-Design, Multi-Center Study to Determine the Safety and Efficacy of Intravenously Administered Experimental Medication in Hospitalized Patients with Severe Traumatic Brain Injury.

A Study of the Patient-Activated Reservoir in the Intrathecal Delivery of Morphine Sulfate as Management of Pain due to Cancer and its Therapies.

A Double-Blind, Placebo-Controlled, Dose-Selection Study of a Controlled Release Muscarinic M3-Receptor Antagonist in Patients with Detrusor Instability or Hyperreflexia and Urge Incontinence.

Evaluation of the Efficacy and Tolerability of a Centrally Acting Agent Monotherapy in Epileptic Patients with Complex Partial Onset Seizures, Having Experienced Improved Seizure Control under Add-On Treatment; a 60-Week, Double-Blind, Multicentre, Responder-Selected Trial.

Multicenter, Placebo-Controlled, Randomized, Double-Blind Study of the Efficacy of an Antidepressive Agent in Hospitalized Patients with Major Depressive Episode Melancholic Type.

A Multicentre, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy of Osteoporosis Active Medication on the Prevention of Vertrebal Fractures and the Effect on Bone Mineral Density in Women with Postmenopausal Osteoporosis.

A Randomized, Double-Blind, Multinational Phase III Study Comparing the Safety and Efficacy of 2 Neuroleptics in the Treatment of Schizophrenia.

A Multinational, Controlled Phase II Study Comparing the Safety and Efficacy of Two Different Antibiotics in the Treatment of Acute Community Acquired Pneumococcal Pneumonia.

A Randomized Phase III Study of an Immunosupressive Agent Compared to Placebo on Time to Relapse after Autologous Bone Marrow Transplantation (ABMT) in Patients with Acute Myeloid Leukemia (AML).

A Placebo-Controlled, Parallel-Group, Dose-Ranging Pilot Study of Oral Phentolamine in Patients with Recent-Onset Impotence.

Clinical Study of the Efficacy and Safety of Biosynthetic Human Growth Hormone in Children with Marked Short Stature without Growth Hormone Deficiency.

A Double-Blind, Phase III, Multinational Clinical Study to Evaluate the Safety and Efficacy of a Human Recombinant Cytokine Antagonist in the Treatment of Sepsis Syndrome.

A Randomized, Double-Blind, Phase III, Multinational Clinical Study to Evaluate the Safety and Efficacy of a Dopamine-Agonist Versus Placebo as Adjunctive Early Therapy of Levodopa in Parkinson's Disease.

A Phase III, Multicenter Single Blind Evaluation of the Efficacy of Low Dose Topical Retinoic Acid in an Optimised Delivery System Compared to Control Formualtions, in Patients with Acne Vulgaris.

Interstitial Chemotherapy for Malignant Glioma: A Randomized Clinical Trail of the Safety and Effectiveness of a Chemotherapeutic Device Placed at the Time of First Surgery.

Multicenter Evaluation of Safety and Effectiveness of a Urological Nerve Stimulation System for Treatment of Urinary Incontinence or Dysfunctional Voiding Patterns.

Multicenter Evaluation of Safety and Efficacy of a Bladder Stimulation System for Treatment of Neurogenic Bladder Secondary to Spinal Cord Injury with Paraplegia or Quadriplegia.

A Double-Blind, Multicenter Comparison of the Influence of a Combination of a Calcium Channel Blocking Agent and a Hypolipidaemic Agent As Well As of a Calcium Channel Blocking Agent Monotherapy or Respectively, an Hypolipidaemic agent Monotherapy, on Blood Pressure and Lipid Metabolism in Patients with Idiopathic Hypertension and Congenital, Primary Hypercholesterolemia.

Evaluation of the Effects on Growth, Acceptance and Tolerance of a Partially Hydrolyzed Iron-Enriched Cow's Milk Protein Formula and an Iron Enriched Cow's Milk Formula Fed to Term Infants from 14 - 120 Days of Life.

A Glucose Study in Insulin Independent (Noninsulin Dependent-Type II) Diabetes Mellitus. A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multi-Center Clinical Trial.

Use of an Ointment for Symptoms of Hemorrhoids.

REGULATORY AFFAIRS EXPERIENCE

Clinical Trial Notifications/Approvals:

Armenia	Medical Devices
Austria	Pharmaceuticals & Medical Devices
Belgium	Medical Devices

Bulgaria	Medical Devices
Canada	Pharmaceuticals & Medical Devices
Czech Republic	Medical Devices
Denmark	Medical Devices
Finland	Medical Devices
France	Medical Devices
Germany	Pharmaceuticals & Medical Devices
Greece	Pharmaceuticals & Medical Devices
Ireland	Medical Devices
Israel	Pharmaceuticals & Medical Devices
Italy	Pharmaceuticals & Medical Devices
Netherlands	Pharmaceuticals & Medical Devices
Norway	Medical Devices
Poland	Pharmaceuticals & Medical Devices
Portugal	Medical Devices
Spain	Medical Devices
Sweden	Medical Devices
Switzerland	Pharmaceuticals & Medical Devices
Turkey	Medical Devices
United Kingdom	Pharmaceuticals & Medical Devices
United States	Pharmaceuticals & Medical Devices

Marketing Authorization/Conformity Assessment Advisement & Submissions

Stem Cell Separation Device for Autologous Bone Marrow Transplantation
Autogenic Skin Transplant Product
Allogenic Bone Tissue Product
Autogenic Chondrocyte Transplant Product
Infusion Pump for Radioopaque Contrast Media
(2) Sulfonylurea Hypoglycaemic Agents
Active Implantable Neurostimulation Device
Implantable Medical Valve
Agent for the treatment of diabetic neuropathy
Hyperthermia probe for the treatment of BPH
A cutaneous/mucous membrane enhanced drug delivery formulation
Medical Laser for application in cardiology
Super-conducting QUantum Interference Device (SQUID) for measurement of body iron stores

Authorized Representative
Numerous USA-based medical device manufacturers with products in development and marketed pan-european portfolio of products. Full range of activities: product pre-market registrations, vigilance reporting, product recall coordination. Experience since 1995.