BAGGERMAN
FARMA CONSULT BV

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Baggerman Farma Consult

Baggerman Farma Consult is a consultancy serving the health-care industry with a staff of 7 highly-experienced consultants. The company can now count pharmaceutical companies, medical device manufacturers and healthcare organizations, both in the Netherlands and many other (non-)European countries, among its clientele.

Services offered include project management and consultancy geared to:

- DESIGN AND IMPLEMENTATION OF QUALITY SYSTEMS
- REGULATORY AFFAIRS OF DRUGS, MEDICAL DEVICES AND COSMETICS
- STRATEGY AND DEVELOPMENT

introducing bfc

- **STRATEGY AND DEVELOPMENT**

BAGGERMAN FARMA CONSULT has been involved in a number of strategic and developmental projects in the healthcare industry including feasibility studies of manufacturing or distribution facilities, market-analysis of health care products, scenario analysis for hospital pharmacies, definition studies of information systems, as well as mergers and acquisitions of SME's. Likewise, support has been given to product development projects of drugs, medical devices, automated distribution systems and healthcare telematic devices.

BAGGERMAN FARMA CONSULT has, since the start of its activities, produced or distributed a number of early developmental reports on emerging health-care issues such as home-care, mail-order pharmacy, pharmaco-economics, home care telematics, and automated distribution in hospital pharmacy. Through its combined experience, gained in numerous projects, the company has an overall-look at strategic issues and developmental dilemmas, including technological, operational, regulatory and marketing aspects.

- **DESIGN AND IMPLEMENTATION OF QUALITY SYSTEMS**

BAGGERMAN FARMA CONSULT has wide experience in the design and implementation of quality systems. These include EU-GMP/GLP systems in pharmaceutical and medical device production facilities, ISO/EN-13485 systems in medical device companies, EU-GDP systems in distribution facilities as well as quality systems for home care facilities and hospital pharmacies. The company is thoroughly familiar with all kinds of products relevant to these sectors, such as pharmaceuticals, medical devices, biopharmaceuticals, homeopathics, blood products, radiopharmaceuticals, veterinary drugs and cosmetics.

BAGGERMAN FARMA CONSULT has also been involved on a regular basis in a number of related projects including (re)design and construction of production or distribution facilities, business-management analysis of production units, licensing of facilities, outsourcing programs, employee training programs and validation programs.

- **REGULATORY AFFAIRS OF DRUGS, MEDICAL DEVICES AND COSMETICS**

BAGGERMAN FARMA CONSULT has been involved in the regulatory procedures for a wide variety of drugs and medical devices and is fully acquainted with the EU Directives involved. The company is responsible for the regulatory matters, including product license maintenance, of a significant number of European companies in the Netherlands and is also regularly involved in European centralized procedures, mutual recognition procedures or decentralized procedures. Similarly it has been involved in the CE marking procedures for various types of medical devices as well as safety evaluations of cosmetics.

BAGGERMAN FARMA CONSULT is also familiar with all the documentation required for the regulatory processes, including nonclinical, clinical and quality overviews or technical files. Other areas of the company's expertise are clinical trial applications and reimbursement procedures for pharmaceuticals as well as vigilance programs for drugs or medical devices.

the consultants

dr Kees Baggerman

Kees Baggerman, founder of Baggerman Farma Consult, began his career with a short period as an industrial pharmacist. He then went on to work as a hospital pharmacist until 1987. In 1986 he obtained his Ph.D. degree at Leyden University for his thesis related to pharmaceutical technology. He then started his pioneering work as an independent consultant in the field of pharmaceutical production and regulatory affairs. Since then he supported numerous companies with all kinds of regulatory and quality issues, got involved in a wide variety of developmental projects, ran various projects in over 30 hospital pharmacies, served for many years as an evaluation expert in various EU research programs, acted as secretary of a federation of pharmaceutical SME's for over 10 years, and published over 30 articles and reports on various pharmaceutical issues and developments.

drs Lies Neisingh

Lies Neisingh specialized as an industrial pharmacist at Montpellier University (F). She then held a position in the R&D Department of AKZO Organon before moving on to become Head of QA/QC of Chefaro International. In 1987 she set up her own succesful agency providing GMP courses for pharmaceutical companies. She joined Baggerman Farma Consult in 1992 and has since implemented several GMP projects as well as (European) regulatory projects, in addition continuing her educational activities. Within BFC she specialized in regulatory affairs and managed several MRP-procedures as well as acting as RA-manager on an interim basis in three major Dutch pharmaceutical companies. She has also for 8 years participated in the consultative body of the Dutch pharmaceutical industry and the MEB.

drs Wout Jan Louwaars

Wout Jan Louwaars, graduated as a pharmacist from the University of Utrecht in 1978. He began his career as an industrial pharmacist at the Central Military Pharmacy, before moving on to Chefaro International holding the position of Head of R&D and later Head of QA/QC. In 1996 he joined Baggerman Farma Consult and has since worked on projects aimed at the implementation of GMP/GDP, FDA/GcLP and ISO 9000/13485 for various pharmaceutical, chemical and medical device companies. He has also been responsible for a number of (European) regulatory projects for drugs, blood products and medical devices. He has been acting Qualified Person for a number of (bio)pharmaceutical companies in recent years.

drs Jens-Erik Vaessen

Jens-Erik Vaessen was engaged in a research project at the Analytical Department of Novo-Nordisk Denmark while being a pharmacy student at the University of Groningen. After his graduation in 1999 he started as a community pharmacist for a short period of time and then moved on to a phytopharmaceutical company. In 2000 he joined Baggerman Farma Consult and since he held various positions on regulatory affairs departments and in manufacturing plants as production pharmacist or Qualified Person. Other projects included the development and implementation of various quality systems (GDP, GMP) in several companies (food, cosmetics, pharmaceuticals). He also has been engaged in complex compliance projects in the area of the Code of Conduct for Pharmaceutical Advertising (CGR).

drs Chantal Ruijl-Vandierendonck

Chantal Ruijl-Vandierendonck completed her pharmacy study in 1991. She has worked for many years as an auditor in the Quality Assurance department of a Clinical Research Organization (CRO) and got very familiar with GCP, GMP, GDP and EN 540 systems. At the same time she was responsible for the storage and packaging of investigational medicinal products. She joined Baggerman Farma Consult in 2002 and acts as responsible pharmacist (QP) for several pharmaceutical distributors and packers. She also worked on projects regarding design and implementation of quality systems (GDP and GMP) as well as executing clinical research projects and various regulatory projects.

drs Harald Kistemaker

Harald Kistemaker studied pharmacy at the University of Utrecht. After a short period in hospital pharmacy he entered into 10 years of experience in the pharmaceutical industry, starting as an industrial pharmacist at the International Dispensary Association. In 2000 he became QA manager at TEVA Pharmaceutical Industries and later on worked for Sandoz as Head of QA & RA. During these years he became very familiar with GMP, GDP and GcLP as well as auditing these quality systems at all kinds of (non-)European manufacturers. In 2005 he joined Baggerman Farma Consult and currently acts as a Qualified Person for several pharmaceutical companies while holding RA-responsibility for others. He also is involved in releasing and auditing of investigational medicinal products imported from 3rd countries.

drs Ivan Utama

Ivan Utama studied bio-pharmaceutical sciences at Leyden University, graduating in 2000. He subsequently specialized in analytical biosciences performing research for a couple of years on the development of analytical techniques for the characterization of lipoproteins in plasma. In 2005 he switched to another discipline and joined Baggerman Farma Consult. Since then, his main focus has been on regulatory affairs and he has managed several extensive projects in major pharmaceutical companies, including a European parenteral manufacturing site as well as a leading OTC-company in Belgium.