INTERACTIVE
Consulting Associates GmbH

Global Partner for Good Manufacturing Practice

Curriculum Vitae

Dr. Gerhard Franckowiak

Education

1965 – 1970	Study of Chemistry at Münster University, Germany, Diploma in Organic Chemistry on ”Structures of Ergochrome dyes from Ergot”
1970 – 1973	PhD in Organic Chemistry ”On the Total Synthesis of Ergochromes from Ergot” Prof. Dr. B. Franck, University of Münster
1973 – 1975	Post Doctorial Fellowship at Imperial College, London Prof. Dr. Sir Derek Barton Research Scholarship by DFG

Experiences

Since 2011	Appointed Inspector for WHO, Geneva
Since May 2004	Senior Associate of INTERACTIVE CONSULTING ASSOCIATES; Zug, CH Various activities in Europe and Asia in cGMP Consulting, Training, Auditing Numerous audits on customer request and as Third party Audits
2000 – 2004	Head of API production staff at BAYER AG, Wuppertal, Germany Deputy of Head of API production Responsible Person acc. German AMG for API production Responsible Person for narcotics
1992 – 2000	Head PM of multi purpose / launch plant (3 PM, 95 employees) at BAYER AG API Production for Clinc. Phase III, launch, and market on kg to tons scale Focuses: cGMP Compliance, Safety, ecological and costs relevance, Qualification, Validation, Documentation, Cleaning and Cleaning validation, Deviation / Investigation, CAPA, and change management Risk Management, Safety Techniques, Training Inspection by Authorities, Customer Audits, Self Inspections Projects: Implementation of new API production processes, and API prod. transfers Applications for production licences, planning of modern GMP-Equipment, Handling of Highly Active Ingredients, Aseptic API production Internat. Sourcing for API precursors and APIs (Europe and Asia) Implementation of production processes at customer’s sites
1986 – 1992	Department for API Process Development at BAYER AG, Wuppertal Management of Pilot Plants for Development Chemistry, (2 PM, 55 empl.) Development of API Syntheses under GMP and API Production for Research and Clinical demand Phase I to III, and for launch, Process Transfer, Design of Process Description documents Additionally management of a Chem. Dev. Laboratory (GLP, GMP) Lab scale synthesis for synthetic alternatives and for process development, Critical Parameters, Safety Data, Cleaning, Development Report

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Experiences, cont.

Dr. G. Franckowiak

1975 – 1986 Research Work at the “Scientific Chemical Laboratory” of
BAYER Pharma Research Centre at Wuppertal
Syntheses for new cardiovascular APIs
especially Ca-antagonistic and –agonistic Dihydropyridines

Additionally management of a kg-Lab for the API supply of Preclinical Research

45 patents and multiple publications

Special Fields

Management of pilot plant and launch plant under cGMP
- Management of personnel, education and training
- Safety affairs for production in collaboration with specialised technical support departments
- ecological aspects of waste, waste water and waste air

Process Development
- Process optimization on laboratory scale, evaluation of critical parameters
- Validation of new or changed processes
- Design of registration documents for APIs in a modular system
- Development of cleaning procedures
- Development Report

API Production, specially in Multi Purpose equipment
- Integration of Production, QC, QA as a “Production Team”
- Qualification of new or redesigned equipment,
- Process Validation and Revalidation: Record, Realization, Report
- Cleaning, specially of Multi Purpose equipment and Cleaning Validation
- Master Batch Record (contents, lay out) and routine Batch documentation
- Deviation management, CAPA, Risk Assessment
- Design and handling of equipment for Purified Water, Utilities for gases and solvents
- Handling of highly active ingredients, Microbiological monitoring
- Change Management, Process changes and transfers

Preparations and training for Inspections (external audits and self inspection)
- Revisions of documentation and presentations
- Preparation for plant staff, techniques and neighbouring areas

Projects for new investment and updating of old sites and equipment, as
- main parts like reactors, filters, centrifuges, piping, tanks, computerised systems
- Optimisation of process, equipment, and installation, specially for cleaning aspects
- Safety management for equipment and processes

GMP-conform warehouses and material management

Contact the authorities, Pharmaceutical and Technical authorities

Contact and auditing of customers

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