SHORT PROFILE

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Over 30 years of experience in the pharmaceutical industry
Self-employed since January 2015

Pharm | AdInterim provides a network of highly experienced expert personalities with a wide and long-standing professional experience in various areas and functions within the pharmaceutical industry – Medical Research, Medical Affairs, Marketing & Sales as well as Pharmacovigilance, Regulatory Affairs and Quality Assurance.

Flexibility in terms of what, where, when

- ✓ Assumption of circumscriptive projects, individual working packages or consultancy mandates within a specified timeframe
- ✓ Demand-oriented absorbing of peaks in workload and bottlenecks in internal resources
- ✓ Flexible services on-site, at locations of the customer´s cooperating partners or supporting remote activities from the offices in Wiesbaden
- ✓ Master agreements/Back up services for global and national review and approval processes of promotional and non-promotional material
- ✓ Substitution of qualified personnel during sick leave, annual leave, sabbaticals, pregnancy leave or planned absences
- ✓ Interim projects in case of vacancy or until a qualified successor/candidate for the replacement of key functions will be onboarded
- ✓ Consultancy mandates targeting organisational structures and management as well as "hands on" services with operational character
- ✓ Plus, in combination: Concept creation, implementation, supervision and adjustment
- ✓ Representing the customer in external appointments or meetings

Main areas of activities

- Interim Management for the pharmaceutical industry and biotech entrepreneurs in Medical Affairs (global and national projects in Medical Affairs, Pharmacovigilance, Regulatory Affairs, GCP-Quality Assurance)
- Consulting in business management and organisational consulting for biopharmaceutical industry in situations as: company take-over, re-structuring/re-organisation, implementing new business processes
- Integrated services for start-ups and new branches of international pharmaceutical companies
- Definition and analysis of interfaces and processes, interdisciplinary process optimisation and quality-oriented time and capacity analysis to enhance efficiency of teams and their workflows
- Development of approaches in case of capacity constraints; moderation, supervision, monitoring and subsequent improvement of implemented reassures and processes if required (in the spirit of TQM)
- Strategy development for newly implemented processes/structures to entry into force and have a lasting effect within the organisation (e.g., SOPs, review and approval processes, staff training, organisational structures (e.g. during re-organisations, merger, spin-off) or systems (e.g. global data bases, CRM systems, Regulatory Content Management Platforms)

CLIENTS

EXAMPLES OF SUCCESSFULLY MANAGED INTERIM PROJECTS

- Consulting in business management and organisational consulting for new branches of international pharmaceutical companies

- Global Regulatory Affairs Consultant for review and approval processes of international promotional and non-promotional materials in the therapeutic areas of neurology, rare diseases, haematology, gastroenterology, metabolic diseases, fertility

- Integrated services for the establishment and organisation of medical departments including preparation for competent authority inspections (pharmacovigilance, wholesale permission)

- Interim projects in Medical Affairs covering the therapeutic areas of haematology, dermato-oncology and neurology. Design, supervision, evaluation and communication of non-interventional studies and structured collection of real world data in cooperation with contract research organisations

- Acting as Interim "Information Officer" according § 74a German Drug Law (AMG) and § 56 Austrian Drug Law in national review and approval processes for promotional and non-promotional materials

- Regulatory Advertising and Promotion Consultant and Reviewer for global Consumer Health Care branch of pharmaceutical company

- Regulatory and Compliance Consultant for start-up biotech company in rare disease area

- Global Regulatory Advertising and Promotion Senior Advisor Rare Diseases, Haematology, Immunology, Neurology

PROFESSIONAL BACKGROUND

Management and leadership positions in pharmaceutical industry from 1987 to 2014

- **Sanofi Genzyme GmbH**, Neu-Isenburg; Medical Affairs Director GSA
- **Basilea Pharmaceutica Deutschland GmbH**, Munich; Medical Director
- **Mundipharma Research GmbH &Co. KG**, Limburg; Executive Director of European R&D Drug Safety and Pharmacovigilance
- **Allergopharma Joachim Ganzer KG**, Reinbek; Director of Clinical Research
- **FOURNIER Pharma GmbH**, Sulzbach (Saar); Associate Medical Director
- **G. POHL-BOSKAMP GmbH & Co.**, Hohenlockstedt; Head of Medical Department
- **Boehringer Ingelheim KG**, Ingelheim am Rhein; Director Project Monitoring Clinical Trials, Pneumology

Qualifications

- Commissioner of the graduated plan acc. § 63a German Drug Law
- Qualified Person Pharmacovigilance
- Information Officer acc. § 74a German and § 56 Austrian Drug Law