Curriculum Vitae – KAI KIEFER

PERSONAL:
Dipl.-Ing. (BA) Technische Informatik
Joseph-Haydn Strasse 26b
D – 65812 Bad Soden

kai.kiefer@me.com
+49.151.226.57576

OBJECTIVES

Challenges, Software & IT Services
Regulated Businesses / Life Sciences
Working in International Environment

KEY COMPETENCIES

- Management of International Teams and Projects Implementing Global IT Solutions in Regulated Environments, since 2001 (PMI, GAMP, SoX)
- Management of Global IT Services and System Operations, since 2001 (ITIL), in Regulated Environments (FDA, EMEA, BfArM) since 2005
- Working in International Environments, since 1995
- Excellent Understanding of Quality and Compliance Processes in Life Science (API, Pharmaceutical & Medical Devices)
- Strong Experiences in Managing Implementations & Rollouts of Quality Management Processes and Compliance Solutions at Enterprise Level, since 2006
  - Several global TRACKWISE Implementations, since 2005 (CAPA, Deviations, Change, Complaints, Adverse Event Reporting, eMDR, Supplier Quality, Audit & Risk Management)
  - Several global DOCUMENTUM Implementations, since 2005 (SOP/ Procedures, Quality Records, Master Batch Records, Non-GxP Documentation, eROOM)
  - Several Reporting Solutions, since 2001 (SAP BW, Crystal Reports, QLIKVIEW Reporting, Trending & Management Reporting)
- ARIBA Purchasing/Invoicing Solutions Implementations (Indirect Procurement, Contract Management, Tender/Quotation Management, Reverse Auctions) from 1999–2004

HISTORY

Manager, IT Center of Excellence ECM & Quality Solutions
GAMBRO Renal Products, Medical Devices
March 2009 – today
- Responsible for IT Applications and Platforms, 2 Teams, 6 people located in Sweden and Hechingen,
  - Global Quality Management Solution Platform, used worldwide for Post Market Surveillance, CAPA and Audit Management. 700 users
  - 12 Enterprise Content Management Platforms used worldwide for Collaboration, Publishing, Doc Control, Labeling, Contract Management, 1500 users
  - Global eLearning Service, used worldwide with 2500 users
  - IT Solutions supporting Clinical Trails
- Technologies:
  DOCUMENTUM, TRACKWISE, QLIKVIEW, eROOM, SHAREPOINT, JAVA, .NET, XML, AS2 Messaging, MSSQL, MICROSOFT SERVERS

Curriculum Vitae – KAI KIEFER

- Achievements:
  - Established Center of Excellence for Content Management and Quality Solutions, aligned Cooperate IT and Quality and Business Functions, transitioned technical solutions to Center of Excellences, build up team and services for support and projects
  - Defined an overall Quality/IT Alignment Strategy, established Enterprise Architecture, Process and Technology Landscape. Established overall Program Road Map, Management of Implementation and Roll-outs of First Phase Projects.
  - Implemented full cycle Post Surveillance Solution (Complaints, Field Actions, Adverse Event Reporting, Management Product Review)
  - Established Global IT standards for Software Validation, System Operation and Change Control (based on GAMP5 and ITIL v3)
  - Supported Quality Organization during various FDA Inspections as System Owner
  - Given Public Speeches on Quality Management and Document Management

IT Manager for Global Document and Quality Management Solutions

Sanofi Aventis, Pharmaceutical Industry

March 2005 – February 2009

- Responsible for several IS Applications and Platforms, 10+ projects/year, 2 Project Teams, 15+ people located in Frankfurt and Paris, yearly Budget >5M$
  - Global Document Management Platforms for controlled Documents and non-controlled Documents , 6000+ trained users, used with in 25 Sites, globally 40.000 signatures/month, integration with local ERP Systems
  - Global Quality Process Platform Processes: Supplier Audits, Risk Management, Deviation Management, eCAPA and Change Control) for currently 1500 users used in over 80 sites.
  - Automated Functional Testing, IS Change control, IS Incident Management, IS Release Management System

- Technologies:
  DOCUMENTUM 5 & 6, ADOBE, TRACKWISE, CRYSTAL REPORTS, SERENA DIMENSIONS, HP/MERCURY QUICKTEST,JAVA, HP-UX, WINDOWS 2003, ORACLE DB

- Achievements:
  - Build up Support and Project teams, developed and implemented mid-term and long-range project and budget plans
  - Coordinated and managed Roll-out Program with over 30 Sub projects, managed several Data Centre Migrations (3), and migration several major(5+) and minor(10+) Software releases and Upgrades, Managed Migration and Integration of several existing solutions into global platforms
  - Ensured Development and Support Process being audible and conform with internal Quality Standards, defended operations against internal and external audits, Optimized internal Processes according to industry best practices (ITIL, GAMP, TQM, PMBOK) Actively driven relationships with Software Vendor and Sanofi-Aventis Industrial Affairs

Curriculum Vitae – KAI KIEFER

HISTORY

- o Implemented Integrated version, build & release management Solution
- o Implemented Support Delivery Process Solution
- o Developed several automated Functional Testing Programs

IT Manager – Global Support e-Procurement Solution
Sanofi Aventis, Pharmaceutical Industry
December 2001 – February 2005

- Responsible for operation and support of an Global e-Procurement Platform
   20.000 users, integrated with 18 SAP system in 24 countries, Team with 10+ people located in France, US and Germany
  ARIBA BUYER & SOURCING, TIBCO, SAP, JAVA, HP-UX, ORACLE, CFT
- Achievements:
  - o Build up and established a global 24h Support organization
  - o Managed established SLAs and managed Services Delivery according to agreements and KPIs (based on ITIL Framework)
  - o Coordinated and managed several Go-Lives and Migration Activities
  - o Setup up and implemented Quality Improvements and Efficiency Programs
  - o Organized and performed Workshops for technical ARIBA SOURCING
  - o Actively driven Supplier Relationship

Senior Consultant, B2B Buy Side Technology
Deloitte Consulting, Management Consulting Industry
January 2001 – November 2001

- Support Global Purchasing in Supplier Integration Process to eProcurement Platform (ARIBA BUYER) Netherlands
- Lead Internal Education Program and Sales Awareness Activities
- Performed Software Cost Estimation for Banking Software

Consultant, e-Procurement Solutions
Hewlett Packard, Information Technology and Services Industry
June 1999 – December 2000

- Support Sales & Marketing Activities for TOP 100 HP European Clients (ARIBA)
- Conduct Presentations, Public Speeches and Workshops
- Developed and Maintained a global eCatalog Publishing Application
- 2 month support Internal Roll-out Activities and Supplier Adoption Projects (Palo Alto / CA)
- 3 month intense ARIBA Train the Trainer Program in Sunnyvale, CA

Sales Engineer – Electronic Test & Measurement Products
Hewlett Packard, Electrical/Electronic Manufacturing Industry
October 1995 – May 1999

- Consulting customers on using Electronic Test & Measurement Tools (D/A/CH)
- Support Fairs, Presentations and Road shows (D/A/CH)
- In-house Telesales activities (Germany)
- 2 months stay in Mountain View, CA for T&M University

Curriculum Vitae – KAI KIEFER

HISTORY

Seed Student
Hewlett Packard, Electrical/Electronic Manufacturing Industry
October 1992 – September 1995
- 2 months stay in Colorado Springs / CO, during Senior Project

EDUCATION

1992 – 1995 Berufsakademie Stuttgart, Computer Science
- Dissertation: "Embedded Debugging Concept for a Siemens Micro Controller Family", Grade 1.0

1994 Staatl.–geprüft. Mathematisch Technischer Assistent

1992 Werner–Siemens Schule,Stuttgart,
      Allgemeine Hochschulreife, Grade Average 1.9

1992 Staatl.–geprüft. Technischer Assistent Nachrichten Technik
1989 Fachschule Reife – Berufsfeld: METAL, Award
1987 Hauptschulabschluss , Award

QUALIFICATIONS

Languages:
- German – mother tongue
- English – fluent
- French – intermediate

Skill Trainings
- CERTIFIED COMPUTER VALIDATION MANAGER
- ITIL Infrastructure in Regulated Environments
- IT–Service Management with ITIL
- HP Strategic Visioning, HP Effective Presentation, HP Effective Sales
- HP Test & Measurement Sales Engineer

Technology Trainings
- ARIBA BUYER Train the Trainer Certificate
- DOCUMENTUM Compliance Manager 5
- TRACKWISE Configuration & Utilities
- ARIBA BUYER 7.0 Customization
- SERENA DIMENSION CM 10 Administration and Configuration
- HP QUICKTEST PROFESSIONAL Basic and Advanced
- QLIKVIEW Developer

PRIVATE INTERESTS

Sports
- Swim/Bike/Run & Triathlon
- Volleyball
- WindSurfing

Music
- Guitar (Blues/Pop)
- Piano