



SIGNIFICON

Management & Consulting



CONSULTANT PROFILE

James Greene

PERSONEL SUMMARY

QUALIFICATION LEVEL	Program Manager
DATE OF BIRTH	September 1964
LANGUAGES	English (native language), German (fluent)
INDUSTRIES	Pharmaceuticals, Medical Devices, Fine Chemicals, Local Governments High-Frequency Electrical Engineering, Not-for-Profit Organizations
EXPERIENCE SUMMARY	<ul style="list-style-type: none">• Manager with more than 25 years of international experience in Life Science industries• Certified in several project management methodologies, auditing of quality management systems, information security management systems and computerized systems validation.• Project and program management practitioner, validation and compliance consultant, business analyst, team leader, coach and mentor, teacher and author.

CORE SKILLS

- Project and Program Management (PMI, PRINCE2, Lean Sigma, ...)
- CSV
 - Validation Strategies, Policies and Guidelines
 - Computerized Systems Compliance and Validation per GAMP 5
 - GxP-Compliance Check, IT Security Check, Supplier Audit for GxP-relevant systems
 - Retrospective validation
 - FDA Inspection preparation
 - Design, documentation and implementation of logistic processes for the handover of qualification documentation as part of a global network outsourcing activity.
- IT Service Management (ISO/IEC 20000, ITIL)
- IT System Landscape
- Quality Management Systems / DIN EN ISO 9001:2008 and 9001:2015 (QM-Auditor)
- Information Security Management Systems
- Systems Development
 - Requirements analysis and Requirements Engineering
 - SDLC of GxP-relevant applications and computerized systems
- Technical Migrations (Platform- or Operating System migrations)
- Adult Education

TECHNICAL SKILLS & METHODS

	Process Level	System Level	Technical Level
Systems	<ul style="list-style-type: none"> • Quality Management • IT Service Management (In-house / Outsourced / Cloud) • Information Security Management • Validation & Compliance Management 	<ul style="list-style-type: none"> • Microsoft Windows, MacOS • Microsoft Office tools • Database Management Systems • SharePoint 	<ul style="list-style-type: none"> • C, C++ • Pascal • BASIC • PHP • SQL • HTML/CSS
Methods	<ul style="list-style-type: none"> • Process Management: ITIL / ISO 20000 fundamentals; Service Catalogue, Service Reporting, SLR, SLAs, OLAs, Process documentation, SOPs, TOPs, Working Instructions; Process Audits • Project Management: PMI PMBoK® Guide, PRINCE 2, Lean Sigma, GDPM, Customer-specific methodologies (Crystal, ICE, ...) • Performance Measurement: IT Strategies: SWOT Analysis, Architectures, IT Controlling: BSC, KPIs, Benchmarking, TCO calculation • Compliance Management: Regulatory guidelines for GxP (FDA 21 CFR, EU Annex 11), GAMP 5, Software Testing and Quality Management, Risk analysis and –management (FMEA, ZHA, GAMP); Risk Management Systems (e.g. ISO 31000) • Systems Development: Analysis and Creativity: Brainstorming, Mind Mapping, Methodologies: V-Model (CSV), Agile Methods, Requirements Engineering: Use Case Analysis (UML), Testing: Strategies, Planning and Execution, Traceability 		

SOFT SKILLS

- Issue and problem solving skills
- Excellent communication, presentation skills and customer oriented attitude
- Good team player & strong team orientation
- Excellent leadership qualities

EXTRACT PREVIOUS POSITIONS

Senior Project & Program Manager, D-Ploy (Schweiz) GmbH
Competence Centre Manager CSV, Dr. Herterich and Consultants GmbH
Manager CSV, Arcondis AG, Reinach, Switzerland
Project Manager, F. Hoffmann-La Roche AG, Basel

EDUCATION

1987 Bachelor of Science, Computer Science, California Lutheran University

CERTIFICATES

2015	Quality Management Systems Auditor (TÜV-QMA)
2013	PRINCE 2 Foundations
2012	Foundations for Information Security Management Systems
2011	Quality Management Systems Representative (TÜV-QMB)
2009	Project Management Professional (PMP®)
2005	Computerized Systems Validation Representative (CSV-Beauftragter)

EXTRACT OF PROJECTS

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Date	2015
Customer	Chemicals and active substances
Branch	Chemical Industry
Project Subject	GxP compliant IT Landscape
Role	Senior Consultant
Tasks	Consulting concerning the GxP requirements and the setup of GxP compliant IT Service Management Processes

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Date	2015
Customer	Pharmaceutical Manufacturer
Branch	Pharmaceutical Industry
Project Subject	Cloud based Pharmacovigilance System
Role	Auditor / Senior Consultant
Tasks	Support of supplier evaluation, contract and auditing

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Date	2015
Customer	ISPE GAMP D-A-CH
Branch	--
Project Subject	SIG Cloud Computing
Role	Member
Tasks	Member of the GAMP D-A-CH Cloud Computing Special Interest Group. The SIG has already published a position paper on IaaS technology validation, and a paper on PaaS validation has just been submitted for review. Future topics for the SIG include auditing guidance for PaaS providers and support for E-signatures in Cloud-based systems.

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Date	2015
Customer	Medical Device Manufacturer
Branch	Medical Devices
Project Subject	CSV / Audit Preparation
Role	Validation Lead
Tasks	VMP Inventory Review and CSV remedial activities In preparation for FDA inspections in several European locations, review the VMP system inventory, identify gaps and initiate remedial activities to close these before the inspection dates. Review the validation status of critical systems and perform retrospective validations of several systems (PLM, MDM and small Notes DBs) that had been changed or had not been validated previously. → CSV Status Review, Retrospective System Validation

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Date
Customer
Branch
Project Subject
Role
Tasks

2014
Swiss specialty chemicals
Chemicals
Request Fulfilment
Requirement Analyst
Process Design

Design and modelling of Service Request Fulfilment processes for a global chemicals company. Once defined, InfoSys implemented these processes in the Service-Now platform. Processes included hardware procurement, software configuration and access rights and permissions management.

→ ITSM, Process Design (Service Processes, Change Management)

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Date
Customer
Branch
Project Subject
Role
Tasks

2014
Software Manufacturer
Software
Compliance Audit
Auditor
CSV Compliance

GxP-compliance audit for a software manufacturer. Activities included development of a consolidated questionnaire, on-site interviews with the service managers and delivery of a detailed audit report and remediation plan.

→ GxP Compliance Audit, Software manufacturer

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Date
Customer
Branch
Project Subject
Role
Tasks

2012-2014
Swiss specialty chemicals
Chemicals
SPICE IT Separations
Program Manager
Program Management

Support the internal program manager with the initiation, planning, execution and controlling of a series of projects to separate the IT infrastructure and services following a corporate divestiture of several business units. The project areas include network connectivity / separation, data centre separation, interim service management and transfer of licenses and contracts, while ensuring that service management (incident, problem, change and request management) all continue to be provided to the user community during the transition.

→ IT Infrastructure Separation, Program Management, Change Management

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Date
Customer
Branch
Project Subject
Role
Tasks

2011-2012
Swiss specialty chemicals
Chemicals
S-C IT Integration
Program Manager
Program Management

Support the internal program manager with the initiation, planning, execution and controlling of a series of projects to integrate the IT infrastructure and services following a corporate acquisition. The project

areas include network connectivity, data centre consolidation, service management process integration, and global service desk integration.

→ IT Infrastructure, M&A, Program Management, Change Management

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Date
Customer
Branch
Project Subject
Role
Tasks

2011-2012
Pharmaceuticals Manufacturer
Pharmaceutical Industry
IHCP
CSV Manager
CSV Compliance

CSV manager for the development of a cloud (PaaS)-based application development. Responsibilities included preparing the Validation Plan, supporting the documentation of various specifications, creating and maintaining traceability, supporting the documentation of verification activities and creating the Validation Report.

→ CSV Compliance, Cloud-Computing, Quality Management, Change Management

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Date
Customer
Branch
Project Subject
Role
Tasks

2011
Medical Device Manufacturer
Medical Devices
Mock Audit
Auditor
CSV Compliance

GxP-compliance mock audit in the Corporate IT department. Activities included development of a consolidated questionnaire, on-site interviews with the service managers and presentation of the audit report to the CIO.

→ GxP/CSV Compliance Audit, Medical Devices

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Date
Customer
Branch
Project Subject
Role
Tasks

2010-2011
Swiss specialty chemicals
Chemicals
OurWorkspace
Program Manager
Program Management

Support the internal program manager with the initiation, planning, execution and controlling of a series of projects to prepare and implement a global migration from Lotus Domino to a Microsoft-based service, including the upgrade of roughly 13,000 clients to Office 2010 and later to Microsoft Windows 7.

→ IT Infrastructure, Migration, Program Management

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Date
Customer
Branch
Project Subject

2009-2010
Multinational pharmaceuticals
Pharmaceutical Industry
BPOS Migration

Role Tasks	Project Management Service Management Manage the planning (and development of the management system) of a global migration from Lotus Domino to Microsoft Exchange / Office Communications Server for a leading pharmaceuticals organization. → IT Infrastructure, Project Management
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Date Customer Branch Project Subject Role Tasks	2008 German Engineering Conglomerate, Healthcare Division Medical Devices C4S Supplier Audit Auditor Compliance Management GxP-readiness audit of a service provider for an application that is used to support a validated process. Activities included development of a consolidated question catalogue, on-site visits by the service manager, interviews with service providers and presentation of the audit report to top management. → GxP/CSV Compliance Audit, Medical Devices
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Date Customer Branch Project Subject Role Tasks	2008 – 2014 Concept Heidelberg Services GAMP 5 Training Course preparation and presentation Compliance Management Design, development and presentation of the “GAMP 5: praktisch angewendet” course for Concept Heidelberg. This course is presented annually – next in October 2015 in Mannheim, Germany. → GxP/GAMP/CSV Training
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Date Customer Branch Project Subject Role Tasks	2008 Multinational pharmaceuticals Pharmaceutical Industry QDocs Project Management, Process Definition, Coaching Compliance Management Development of processes and procedures for the collection, cataloguing, and shipping of qualification documents for the corporate network infrastructure as part of a global outsourcing initiative. → GxP Infrastructure Qualification, Project Management
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Date Customer Branch Project Subject Role Tasks	2007-2008 Multinational pharmaceuticals Pharmaceutical Industry LEAD Team leader, Procedure Development Team leader for a team of up to 10 technicians performing an in-place technical migration procedure with CSV-compliant documentation on

several hundred end-user workstations (Budget responsibility 250 KUSD).

→ GxP Infrastructure, Migration, Project Management

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Date
Customer
Branch
Project Subject
Role
Tasks

2006-2007

Multinational pharmaceuticals

Pharmaceutical Industry

ClinTCF

Project Management, Change Management

IT Service Management

Managing the development of a series of enhancements and new interfaces to the clinical trial management system of an international pharmaceuticals company, using both on- and offshore development resources (Budget responsibility 575 KUSD).

→ GxP-critical system, Project Management