

James Greene

Birthdate: 1964



PERSONAL PROFILE

An information systems consultant with more than 25 years of international experience in Life Science industries. Certified in several project management methodologies, auditing of Quality Management Systems and Computerized Systems Validation. I am a project and program management practitioner, a validation and compliance consultant, a business analyst, a team leader, coach and mentor, a teacher and an author.

CAREER OBJECTIVE

A role that integrates my varied interests and experience, where I can continue to learn while helping others to achieve their full potential.

PROFESSIONAL EXPERIENCE

10/2015 – present

Significon AG, 55130 Mainz, Germany

significon.de

Senior Manager / Partner

- > Senior Manager for the Business Areas Computerized Systems Validation and Compliance, Quality Management and Project Management.
- > Validation Manager for the operational GxP Change Request Management (ChaRM) process, based on SAP Solution Manager.
- > Validation Manager for various projects: SAP Solution Manager 7.2 green field implementation; Retirement of a legacy Change Control system; Validation of a bulk data entry/upload tool; Qualification of an Application Portal.
- > Consulting/Workshops: System Retirement; Qualification of an IaaS infrastructure; PM Methods in a GxP-relevant Environment.
- > Webinars (in German): IT Project Management in a GxP Environment (2016); System Retirement (2017), Documentation of SAP Roles (2017)

07/2014 – 09/2015

Rescop GmbH, 79379 Müllheim (Baden), Germany

rescop.com

Director Business Development & Operations, Germany; Managing Director of Rescop GmbH

- > FDA Audit Preparation for a medical device manufacturer (Switzerland / Germany / United Kingdom)
- > Compliance analysis for a GxP-relevant software provider
- > Service Management Request Fulfilment Process design and review for a global chemicals manufacturer

02/2013 to 06/2014

D-ploy (Schweiz) GmbH, Kaiseraugst, Switzerland

d-ploy.ch

Senior Project & Program Manager

- > Program Manager in IT Infrastructure for a series of carve-out (corporate divestiture) programs (Fine Chemicals industry)
- > Team Leader with 7 direct and 2 indirect reports
- > Account Manager, responsible for > 1.5 mio CHF annual turnover

79418 Schliengen
Germany

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04/2012 to 01/2013

DHC Dr. Herterich & Consultants GmbH,
Bülach, Switzerland and Saarbrücken, Germany

dhc-gmbh.com

Senior Manager

- > Program Manager, IT Infrastructure Integration (corporate merger) (Fine Chemicals industry)
- > Presentation and Webinar on Validation of Cloud-Based Systems

09/2008 to 03/2012

Arcondis AG, Reinach, Switzerland

arcondis.com

Manager, Computer Systems Validation

- > Program Manager for IT Infrastructure technology transition program (Fine Chemicals industry)
- > Validation Responsible for a Cloud-Based system delivery project
- > CSV- and GxP Audits for various customers

07/2006 to 08/2008

ims Health / M&H Informatics, Allschwil, Switzerland

Senior Consultant

- > Project Manager in Clinical Development IT, implementing new features in the (GxP-relevant, validated) Clinical Trial Management System
- > Project Manager leading the on-site migration of end-user devices with CSV-compliant documentation (integration following a corporate acquisition)

07/2004 to 06/2006

redtoo AG a.k.a. **caatoosee AG**, Reinach, Switzerland

redtoo.com

Senior Consultant

- > Project Manager in the PKI organization of a global pharmaceuticals company

02/2000 to 06/2004

innobit AG, Basel, Switzerland

innobit.ch

Senior Consultant / Managing Director

- > Responsible for Consulting, Project & Quality Management, Software Package Engineering and Training.
- > Lead a team of up to 12 direct reports and responsible for > 2.5 mio CHF annual turnover.

07/1996 to 04/2002, 07/2014 – 10/2014

James Greene Informatics Consulting
Lörrach, Germany / Schliengen, Germany

informatics-consulting.de

Owner

- > Interim management services.
- > Development of various shareware and freeware tools, personal and company websites and bespoke software.

07/1992 – 01/2000 – F. Hoffmann-La Roche AG, Basel, Switzerland

03/1990 – 06/1992 – Hoffmann-La Roche AG, Grenzach-Wyhlen, Germany

06/1986 – 01/1990 – EEsos, Inc, Westlake Village, California, USA

EDUCATION

1987 Bachelor of Science, Computer Science
California Lutheran University, Thousand Oaks, Calif., USA

CERTIFICATES

2018 telc Deutsch B1 (German language certificate)
2015 Quality Management Systems Auditor (QMA-TÜV, ISO 9001:2015)
2013 PRINCE 2 Foundations
2012 Foundations for Information Security Management Systems
2011 Quality Management Systems Representative (QMB-TÜV)
2009 Project Management Professional (PMP®) (*not renewed in 2018*)
2005 Computerized Systems Validation Representative
(CSV-Beauftragter)

VOLUNTEER ACTIVITIES

Association of Software Professionals (ASP)

2016 – present ASP Director (Member of the Board)

Tammazla Kampfkunstschule e.V., Müllheim (Baden)

2015 – present Director (Chairman since January 2017)

Volunteer Fire Fighter

2004 – 2012 Ramlinsburg / Wildenstein, Switzerland
PFC, SCBA-certified, Machinist, Pioneer, Fire Inspector
2013 – present Schliengen / Niedereggenen, Germany
SCBA-certified, Advisory Board Member 2014-present

PMI Switzerland Chapter

2001 – 2009 Board of Directors, VP Special Projects,
VP Communications, Chapter President (2007)
2001 – 2014 Webmaster pmi-switzerland.ch

SKILLS

- > Business Analysis, Business Consulting, Requirements Analysis and Modelling, Communications, Training
- > Computerized Systems Validation, Infrastructure Qualification per US FDA cGMP / QSR and 21 CFR; Eurdalex Volume 4, Annex 11 & 15
- > Published Author (English & German) of technical/professional articles
- > ISO EN 9001:2015 Quality Management Systems (Auditor)
- > ISO 20000, ITIL V3/2011, IT Service Management
- > ISO EN 27001 Information Security Management Systems, PROTECT
- > Risk Management, ISO 31000, FMEA, Ishikawa Root-Cause Analysis
- > Methodologies: PMI PMBoK® Guide, PRINCE 2, Lean SixSigma, Novartis ICE, GAMP® 5, V-Model, Boehringer Ingelheim LeVA, Agile SDLC Methods

PROFESSIONAL PUBLICATIONS

Greene, James, [Executive Editor]. 2006. *PM@CH - The Swiss Project Management Journal*. Switzerland: PMI Switzerland Chapter, December 2006. Number 1.

— **2007.** *PM@CH - The Swiss Project Management Review*. PMI Switzerland Chapter, Summer 2007. Number 2.

— **2008.** Spring 2008. Number 3.

— **2008/2009.** Winter 2008/2009. Number 4.

— **2009.** Summer 2009. Number 5.

— **2010.** Summer 2010. Number 6.

— **2011.** Spring 2011. Number 7.

— **2012.** Winter 2011/2012. Number 8.

— **2013.** Winter 2012/2013. Number 9.

Greene, James. 2008. System Retirement Planning. [ed.]

PMI Switzerland Chapter. *PM@CH - The Swiss Project Management Review*. Number 4, 2008, Vol. 4, 4, pp. 8-11. (English)

GAMP D-A-CH SIG ASDMM. 2009/2011. Alternative Software Development Models and Methods. (German). English translation by James Greene.

Pharmaceutical Engineering, Vol. 32, Nr 1, Jan/Feb 2012, pp. 17-24. ISSN 0273-8139

Greene, James und Häuptli, Patrick. 2010. Validierung von virtuellen Systemen. [ed.] Concept Heidelberg. *Computervalidierung im GxP-regulierten Umfeld*. 1st Edition 2010, Bd. Pharma Technologie Journal, pp. 143-154 (German) ISBN-13: 978-3-87193-412-4

Greene, James and Adamovsky, Stefan. 2012. Project Risk Management and a Risk-Based Approach to Testing. (English) *PM@CH - The Swiss Project Management Review*, Number 8, 2012, PMI Switzerland Chapter, pp. 9-19.

Greene, James und Adamovsky, Stefan. 2012. Projektrisikomanagement in der Life-Science-Industrie. (German) *Management komplexer IT-Projekte*, Symposium Publishing, Düsseldorf, 1. Auflage, 2012, pp. 271-292. ISBN-13: 978-3-86329-438-0

Greene, James. 2013. Program Management from the Perspective of a Project Manager. PMI Switzerland Chapter. *PM@CH* Number 9, pp. 16-19. (English)

Greene, James; Müller, Dr. Stephan; Zimara, Jessica. 2015. Cloud Computing: Ein Validierungsansatz für Cloud-Basierte Systeme. [ed.] Concept Heidelberg. *IT-Trends im GxP-Umfeld*. 1st Edition 2015, 2015, Bd. Pharma Technologie Journal, pp. 28-38 (German) ISBN-13: 978-3-87193-302-8

Greene, James. 2016. IT-Projekt-Management im GxP-regulierten Umfeld [Webinar]. (German) Significon AG, 28. Jan. 2016

Greene, James. 2017. System Retirement: Der Anfang vom Ende [Webinar]. (German) Significon AG, 27. Apr. 2017

Greene, James; Ludt, Béatrice; Reiz Alexander. 2017. Good Documentation Practices für SAP Rollen [Webinar]. (German) Significon AG, 24. Nov. 2017

Greene, James. 2018. The Key to Productivity. *ASPECTS*. April 2018, Vol. 29, 1, pp. 5-6.

References available on request.