

James Greene

Birthdate: September 1964



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PERSONAL PROFILE

I am an information systems quality expert with more than 30 years of international experience in Life Science industries, holding certifications in project management, auditing of Quality Management Systems and Computerized Systems Validation. I am a quality and compliance expert, a project and program management practitioner, a business analyst and consultant, a team leader, a coach, mentor, teacher and 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 Computerized Systems Validation and Compliance, Quality Management and Project Management.
- ▶ Validation Manager for the implementation of ServiceNow as a global IT Service Management tool.
- ▶ Quality and Compliance Manager for multiple business application and information systems.
- ▶ Operational Validation Manager for ChaRM processes using SAP Solution Manager (7.1 and 7.2).
- ▶ Validation Manager for various projects: SAP Solution Manager 7.2 green field implementation; Retirement of a legacy information system; Validation of Winshuttle Studio, SAP NetWeaver Portal, and ServiceNow as a global Incident/Change Mgmt./Request Fulfilment / CMDB system.
- ▶ 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); Paperless Validation Systems (2019).

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 and in the United Kingdom)
- ▶ Compliance analysis for a GxP-relevant software provider
- ▶ Service Management Request Fulfilment Process design and review for a global chemicals producer.

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

04/2012 to 01/2013

DHC Dr. Herterich & Consultants GmbH,

dhc-gmbh.com

Bülach, Switzerland and Saarbrücken, Germany

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

informatics-consulting.de

Lörrach, Germany / Schliengen, Germany

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
(International Project Manager)

03/1990 – 06/1992 – Hoffmann-La Roche AG, Grenzach-Wyhlen, Germany
(Systems Programmer / LAN Administrator)

06/1986 – 01/1990 – EEsof, Inc, Westlake Village, California, USA
(Systems Programmer)

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®) (05/2009 – 05/2018)**
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 Process Design, Management Consulting, Requirements Analysis and Modelling, Communications, Training
- ▶ Computerized Systems Validation, Infrastructure Qualification per US FDA cGMP / QSR and 21 CFR; EudraLex 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, Prince2, Lean SixSigma, Novartis ICE, GAMP® 5, V-Model, Boehringer Ingelheim LeVA, Agile Methods (e.g. Scrum)

PROFESSIONAL PUBLICATIONS (excerpt)

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; Reitz Alexander. 2017. Good Documentation Practices für SAP Rollen [Webinar]. (German) Significon AG, 24. Nov. 2017

Greene, James; Rombach, Niklas. 2019. Papierlose Validierung - Anforderungen und Lösungen [Webinar]. (German) Significon AG, 29. Mar. 2019

Greene, James, [Executive Editor]. 2018. *ASPECTS - The Official Newsletter of the Association of Software Professionals*. Association of Software Professionals, April 2018. Volume 29, Number 1.

— **2018.** The Key to Productivity. *ASPECTS*. Association of Software Professionals, April 2018, Vol. 29, 1, pp. 5-6.

— **2018.** You've got the Killer App...Now What? (Part 1)

ASPECTS. Association of Software Professionals, July 2018, Vol. 29, 2, pp. 4-5.

— **2018.** You've got the Killer App...Now What? (Part 2)

ASPECTS. Association of Software Professionals, October 2018, Vol. 29, 3, pp. 4-5.

— **2019.** You've got the Killer App...Now What? (Part 3)

ASPECTS. Association of Software Professionals, January 2019, Vol. 30, 1, pp. 4-5.

— **2019.** You've got the Killer App...Now What? (Part 4)

ASPECTS. Association of Software Professionals, April 2019, Vol. 30, 2, pp. 3-5.

— **2019.** You've got the Killer App...Now What? (Part 5)

ASPECTS. Association of Software Professionals, July 2019, Vol. 30, 3, pp. 5-8.

References / copies available on request.