

# James Greene



79418 Schliengen  
Germany



## PERSONAL PROFILE

I am a senior CSV manager and business systems expert with more than 30 years of international experience in Life Science and manufacturing 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 systems consultant, a team leader, a coach, mentor, teacher, author and musician.

## CAREER OBJECTIVE

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

## PROFESSIONAL EXPERIENCE

11/2020 – present

**INNIO Jenbacher GmbH & Co OG**, 6200 Jenbach, Austria [innio.com](http://innio.com)

### Group IT, Head of IT PMO

- ▶ Member of the Group IT Leadership team, reporting to the Group CIO.
- ▶ Head of Group IT **Project Management Office**: Continuous improvement of project delivery performance and project portfolio management.
- ▶ Ad Interim responsible for IT **Communications** (09/2022 – present) and IT **Finance Controlling** (10/2022 – 04/2023).
- ▶ Preparing the ISO 27001 Certification for Group IT (2022 – 2023).
- ▶ Responsible for the configuration and deployment of **ServiceNow** ITBM/SPM (Strategic Portfolio Management) and IRM (Integrated Enterprise Risk Management) across the INNIO Group.
- ▶ **Training**: Prepared and presented a series of Project Management training sessions (German/English) organized by the INNIO Quality Assurance dept. (Project Cost Management, Project Risk Management, CtQ/Requirements Engineering, and Project Management with ServiceNow SPM).
- ▶ Responsible for “Talent Development” projects in Group IT in cooperation with INNIO HR (2021, 2022)

10/2015 – 10/2020

**Significon AG**, 55130 Mainz, Germany

[significon.de](http://significon.de)

### Senior Manager / Partner

- ▶ Senior Manager for Computerized Systems Validation and Compliance, Quality Management and Project Management.
- ▶ **Validation Manager** for the implementation and operation of various business applications and services, including **SAP Solution Manager 7.2** (ChaRM, Test Management and Solution Documentation), **ServiceNow** as a global IT Service Management tool, and **Veeva QualityDocs** as a Document Management System, and **UiPath** for Robotic Process Automation.
- ▶ Consulting, Workshops and Publications: 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).

# James Greene

07/2014 – 09/2015

**Rescop GmbH**, 79379 Müllheim (Baden), Germany

[rescop.com](http://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)

02/2013 to 06/2014

**D-Ploy GmbH**, Kaiseraugst, Switzerland

[d-ploy.ch](http://d-ploy.ch)

**Senior Manager / Key Account Manager**

- ▶ Program Manager, IT Infrastructure Integration (corporate divestitures)
- ▶ Key Account Manager / Team Lead responsible > CHF 1.5 Mio. turnover.

07/2014 to 10/2014 and 07/1996 to 04/2002

**James Greene Informatics Consulting**

[informatics-consulting.de](http://informatics-consulting.de)

Lörrach, Germany / Schliengen, Germany

**Owner**

2008 – present (once annually)

**Concept Heidelberg**, 69123 Heidelberg

**Trainer, [CV 20 – GAMP 5 2nd Edition – praktisch angewendet](#)**

04/2012 – 01/2013

DHC Dr. Herterich & Consultants GmbH,  
Bülach, Switzerland and Saarbrücken, Germany  
(Senior Manager)

09/2008 – 03/2012

Arcondis AG, Reinach, Switzerland  
(Manager. Computer Systems Validation)

07/2006 – 08/2008

ims Health, Allschwil, Switzerland  
(Senior Consultant)

07/2004 – 06/2006

redtoo AG a.k.a. caatoosee AG, Reinach, Switzerland  
(Senior Consultant)

02/2000 – 06/2004

innobit AG, Basel, Switzerland  
(Senior Consultant / Managing Director)

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** (Project management methodology)

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)

## SKILLS

- ▶ **Computerized Systems Validation** and Infrastructure Qualification per US FDA cGMP (current Good Manufacturing Practices) / QSR (Quality Systems Regulations) and 21 CFR (Code of Federal Regulations); EudraLex Volume 4, Annex 11 & 15
  - Risk Management, ISO 31000, FMEA, Ishikawa and 5-Why Root-Cause Analysis
  - Change Request Management
- ▶ **IT Project and Program Management** (IT business application implementation, upgrade and retirement; IT infrastructure renewal, data centre consolidation, global end-user device upgrades; Mergers, acquisitions and divestitures (organizational and technical),
  - Generic Project Management Methodologies: PMI PMBoK® Guide, Prince2, Lean SixSigma, GAMP® 5, V-Model, Agile Methods (e.g., Scrum)
  - Company-specific PM Methodologies: Novartis ICE, Boehringer Ingelheim LeVA (Lean Validation Approach) and Hybrid-Agile LeVA.
  - ServiceNow SPM (Strategic Portfolio Management)
- ▶ **IT Service Management** (Change Request & Change Control Management, Test Management, Document Management, Service Request Management, Incident and Problem Management, etc.)
  - ISO 20000 / ITIL IT Service Management
  - ISO EN 27001 Information Security Management Systems, PROTECT
  - DevOps
- ▶ Business Analysis, Business Process Design, Management Consulting, Requirements Analysis and Modelling, Communications, Training
- ▶ ISO EN 9001:2015 Quality Management Systems (Auditor)
- ▶ Published author (English & German) of technical/professional articles.'

**References** available upon request.

## BACKGROUND INFORMATION

- ▶ Address: 79418 Schliengen, Germany
- ▶ Email: [james.greene@outlook.com](mailto:james.greene@outlook.com)
  
- ▶ Date of Birth: 1964
- ▶ Birthplace: Los Angeles, California, USA
- ▶ Citizenship: German / EU (naturalized 04/2019)
- ▶ Languages: English (mother language),  
German (fluent, B1-certificate)
  
- ▶ LinkedIn: <https://www.linkedin.com/in/jamesgreene/>

*References / Copies available on request*

**Greene, James, [Executive Editor]. 2006.** *PM@CH - The Swiss Project Management Journal*. Switzerland: PMI Switzerland Chapter, December 2006. No. 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.** Projekttrisikomanagement in der Life-Science-Industrie. (German) *Management komplexer IT-Projekte*, Symposion 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.

**Greene, James; Kappis, Paul. 2020.** System- und Prozessstilllegung in der Pharmaindustrie. *TechnoPharm* 10, Nr. 4, ECV – Editio Cantor Verlag, D-Aulendorf,

pp. 216-223 (German). ISSN 2191-8341.