Resume René van Opstal

Personal Details

Name	René van Opstal
Year of birth	1960
Nationality	Dutch
Function	Senior Consultant
Residence	Amersfoort, Netherlands
Start Carrier	1984

Profile

René is a very experienced and intelligent consultant in the field of process improvement, process automation, system selection and design. Beside that, due to his large experience in the execution of projects (from design, implementation and project management) he is capable of leading a large group of people in engineering teams or customer project teams.

For a large number of years he specialized in life science projects.

René is efficient and very effective, thinks fast and analytical.
René is an ISA trainer for ISA-95, ISA-88 and project management and teaches GAMP.

René founded an ISPE Community for Good Automation Manufacturing Practices and for Project Management for the life science industry in the Benelux and is board member of ISPE Netherlands

René is six sigma black belt and works with statistical software model to improve batch processes.
René is certified as PRINCE 2 Practitioner.
René is an experienced auditor for IT and automation suppliers

Overview of major projects

2021	MYTOMORROWS
	eQMS validation and SLC procedure development
2021	IMRES
	ERP and WMS validation
2021	MEDCOR PHARMACEUTICALS
	Validation support, procedure development
2020- 2021	KEPRO, DEVENTER
	ERP Validation
2020- 2021	SANQUIN PLASMA PRODUCTS, AMSTERDAM
	Supplier Audits
2020	V.E.S., NETHERLANDS
	Supplier Audit
	FMD validation
2020- 2021	PATHEON BIOLOGICS, GRONINGEN
	DCS Validation
2018, 2020 - 2021	FOCUS CARE, ZAANDAM
	FMD validation
	ERP Validation

Overview of major projects

2018	FISHER PHARMA, LELYSTAD
	ERP validation
	FMD validation
2018	SAHZ, HAARLEM
	Data Integrity Audit
2018	NMVO
	Create QMS / QA Manager
	Validate NMVS
	Supplier Audits
2017 - 2021	PRODULAB PHARMA, RAAMSDONKSVEER
	Automation greenfield factory
	Supplier audit
2017 - 2018	PLURIPHARM, ALKMAAR
	Validation of new ERP system
	Implementation of System Life Cycle
2016 -2020	RIVM, BILTHOVEN
	Validation guidance on ERP addition
	Validation Document management system
	Supplier audit
2015 -2018	TEVA PHARMACHEMIE, HAARLEM
	Introducing System Life Cycle, redefine validation approach
	Project Manager Remediation computerized systems
	Design & Validation of Serialisation system
	Setup integrated validation methodology
2014 - 2017	OPHTEC, GRONINGEN
	Project Manager for ERP and MES implementation and validation
2014 - 2015	MEDCOR, LELYSTAD
	Validation of ERP system Project and Validation manager for a Warehouse Management System
2010 – 2015	ASTELLAS, MEPPEL
	Validation Manager for: • Electronic Batch Record implementation (Werum), • LIMS and Empower systems • Document management system • Learning Management system • IT projects • Lab equipment • Production equipment Supplier Audits Business Information Manager
2012 - 2013	Abbott, Zwolle
	Validation Manager for a production and packaging line (liquid) Supplier audits

Overview of major projects

2010	NKM, VEENENDAAL
	Execute 2 Business Improvement projects based on Six Sigma
2007 - 2010	ORGANON, OSS
	Interim manager Automation department for a Biotechnology business Group. Project and validation manager for a number of automation and process improvement projects.
2007 - 2009	VOPAK, Rotterdam
	Member of steering committee for Terminal Master Automation Plan.
2006 - 2007	KRIJGER MOLENAARS, RENESSE
	Requirements definition of an MES integration according to ISA-95 for a flower factory.
2005 - 2006	AHOLD COFFEE COMPANY, ZAANDAM:
	Project Manager for the implementation of a number of optimization functions, like OEE.
2003 - 2005	SEVERAL LOCATIONS :
	Risk Assessment workshops, audits, validation training en advice on batch automation and validation, mainly for the pharmaceutical and food industry
2003	AKZO NOBEL DIOSYNTH, OSS
	Responsible for the design, implementation and validation of process control system for fermentation factory on a pharmaceutical site.
2002	CHEMAGIS, ISRAEL : ChemAgis is a pharmaceutical company that produces active steroids and other pharmaceutical products. Responsible for the design, realization and validation of the process control system.

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Education

1976-1984	Technical High school Information Technology

Training

2021	Introduction to Power BI
2020	ITIL Foundation
2019	Cloud Computing
2019	GMP-R
2017	SharePoint workflows
2017	Virtual IT Systems in a GxP environment (ECA)
2016	SAP Validation (ECA)
2015	Data Integrity (ECA)
2011	Prince 2 Practitioner
2009	Six Sigma Black Belt
2008	Six Sigma Green Belt
1993	Project Management
1993	Several system specific training
1990	Unix system Management, AT Computing
1987	Software Design
1988	Middle Management

Qualifications

Procedures & Regulations	GAMP, ISA-88, ISA 95, Risk Assessment, Validatie, 21 CFR part 11, Annex 11, HACCP, Six Sigma
System Knowledge	OSI PI, Invensys, DEC VAX, Yokogawa, Fischer & Porter / ABB, Modicon PLC, Siemens PLC / PCS7, Display Terminals, Intelligent Transmitters, Werum, Documentum, Empower, SQL-LIMS, Tracelink, NMVS, Wonderware, DeltaV, AFAS, MS Dynamics
Databases	MS-Access, DBase, FoxPro, Informix
Other tools	Word, Excel, Powerpoint MS Project, Minitab , MindManager, DevOps, MR4DevOps
SCADA	Unicell/FactoryLink, Wizcon, Fix/Dmacs, OSI PI
MES	RAPID, OSI PI, CSENSE, Werum PAS-X, OptelVision TrackSafe
Websites	Joomla, MS-Sharepoint
Validation	ECA Computer validation manager
Safety	VCA VOL

Resume René van Opstal

Languages	
Dutch	Native
English	Good
German	Good

Career overview		
2010 - now	Van Opstal Consulting	Owner & Consultant
2006 - 2010	Koning & Hartman	Business Unit Director & Consultant
1997 - 2006	AllMons Consulting	Owner, Consultant & General Manager
1994 - 1997	Miles GSM	Consultant & Business Unit Manager
1992 - 1994	ICT Process Automation	Consultant & Owner
1984 - 1992	Foxboro	Senior Application Engineer