Project descriptions

van Opstal Consulting

Projects

Project descriptions

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QA Manager NMVO

Customer: Stichting NMVO
Period: 2018 - 2021
Location: Den Haag
Project Type: QA / Validation
Project Function: QA Manager
Auditor

Description of activities

The Netherlands Medicine Verification Organisation (NMVO) is implementing the National Medicine Verification System (NMVS) to support the FMD regulations in the Netherlands based on a new Quality Management system.
In this project I am responsible implement and maintain the QMS and manage the validated state of the NMVS approved by the local and European authorities. Together with other European QA Managers joined acceptance test are performed for each new release.
The supplier of the NMVS is managed through audit, where I am selected as lead auditor representing the European countries using the system.

IT Supplier Audit

Customer: SANQUIN Plasma Products,
Period: 2021
Location: Amsterdam
Project Type: Audits
Project Function: Auditor
Description of activities

The SANQUIN Plasma Products organisation is being separated from the “Bloedbank” organisation. This implies that the IT Infrastructure will also be separated and new service providers are being contracted.

My role in this project is to audit 2 of the service providers on GMP aspects to the IT systems and infrastructure.

ERP validation

Customer: KEPRO,
Period: 2020 - 2021
Location: Deventer
Project Type: Validation
Project Function: CSV Consultant
Description of activities

KEPRO is an organisation producing and suppling veterinarian medicines. KEPRO has implemented an EXACT ERP and Warehouse Management System. My role in this project is to supervise the validation of the ERP system.

Project descriptions

DCS upgrade validation

Customer: Patheon Biologics,
Period: 2020 - 2021
Location: Groningen
Project Type: Validation
Project Function: CSV Consultant
Description of activities

Patheon Biologics has applied a DeltaV DCS system controlling several Bioreactors for production of human medicines. Since Patheon is extending the production, the DeltaV system is migrated into a high availability virtual environment. My role in this project is to validate the system during the migrating in cooperation with the supplier Emerson.

Maintaining the validated state

Customer: V.E.S
Period: 2020
Location: The Netherlands
Project Type: Validation
Project Function: CSV Lead Auditor
Description of activities

Several Parallel Importers of medicines, united in the V.E.S. are using a Melior system to implement the FMD regulations (serialisation). In this project we audited the supplier en maintain the validated state of the FMD system for the V.E.S. members at updates of this cloud based system.

Data Integrity Audit

Customer: SAHZ,
Period: 2018
Location: Haarlem
Project Type: Audits
Project Function: Auditor
Description of activities

SAHZ is a hospital Pharmacy that produces personalised medicines. In this project the awareness of their employees regarding Data Integrity aspects was investigated. The available computerised system were scanned to verify the compliancy to Data Integrity regulations. A report was created about the actual status and proposed improvements.

Project descriptions

ERP validation project

Customer: Focus Care
Period: 2020 -2021
Location: Zaandam
Project Type: Validation
Project Function: Validation lead

Description of activities

A market authorization Holder (MAH) has implemented an AFAS ERP system.

In this project I am responsible for the validation of the system.

FMD and EPR validation for a Parallel importer

Customer: Fisher Farma
Period: 2018
Location: Lelystad
Project Type: Validation
Project Function: Validation lead lead

Description of activities

A parallel importer is implementing an ERP and an serialisation system.

In this project I am responsible for the validation system.

Serialisation project

Customer: Focus Care
Period: 2018
Location: Zaandam
Project Type: Validation
Project Function: Validation lead

Description of activities

A market authorization Holder (MAH) is implementation a Tracelink serialisation system..

In this project I am responsible for the validation of the system and the definition and implementation of a System Life Cycle procedure.

Project descriptions

Greenfield project

Customer: Produlab Pharma
Period: 2017 - 2021
Location: Raamsdoncksveer
Project Type: Automation
Project Function: Automation lead
Computer Validation

Description of activities

The existing factory for veterinary products is extended with a new building.

In this project I am responsible for the IT and automation of the new factory based on ISA-95 and ISA-88 standards. The first part of the facility is operational. We realized a paperless environment in the clean rooms with full traceability of material, people and equipment.

ERP Validation

Customer: Pluripharm
Period: 2017 - 2018
Location: Alkmaar
Project Type: Validation
Project Function: SME Computer Validation

Description of activities

Pluripharm is migrating a homemade ERP and WMS system to a new JDE system.

In this project I am responsible for the validation of the system. The system is implemented with an Agile project approach.

System Life Cycle implementation

Customer: Pluripharm
Period: 2017 - 2018
Location: Alkmaar
Project Type: Validation
Project Function: SME Computer Validation

Description of activities

Pluripharm is implementing a validation approach for the complete Pluripharm group.

In this role I am implementing a System Life Cycle approach for all business units in the Pluripharm group. This starts with defining a lean approach based on GAMP 5 standards, training of stakeholders, creating system inventory, validation of new systems and remediation of existing systems that have to comply to CF, GDS, GMP and GDP regulations

Validation of Document handling system

Customer: RIVM
Period: 2017 - 2018
Location: Bilthoven
Project Type: Validation
Project Function: SME Computer Validation

Description of activities

RIVM is implementing an Document handling solution in the organization, where several departments store GxP critical data and documents. The system is implemented with an Agile project approach.

In this project I am guiding the validation of the systems.

Serialisation

Customer: Teva
Period: 2015 - 2017
Location: Haarlem
Project Type: Validation
Project Function: SME Computer Validation

Description of activities

Teva is implementing an OptelVision serialisation solution in the packaging department.

In this project I am responsible for the IT integration and the validation of the systems.

Remediation and new validation approach

Customer: Teva
Period: 2015 - 2017
Location: Haarlem
Project Type: Project Management, Validation
Project Function: Project Manager

Description of activities

For Teva a large number of systems have gaps in the validation files. The remediation team is working on closing these gaps.

In this project I am responsible for leading the remediation team. After optimizing the approach of remediation and setting the standards for risk assessments and templates a new system validation approach will be created. The goal is to set a lean validation standard following a system lifecycle approach for all systems and all departments in Teva Pharmachemie Haarlem.

ERP and MES implementation

Customer: Ophtec
Period: 2014 - 2015
Location: Groningen
Project Type: Project Management, Validation
Project Function: Project Manager

Description of activities

A company is implementing an ERP system together with a MES system to automate the production if contact lens implants.

In this project I am responsible for the project management and validation of the systems with a lean and risk based approach, using Prince©2 and GAMP©5 guidelines.

Business Information Manager

Customer: Astellas
Period: 2015
Location: Meppel
Project Type: Consulting
Project Function: Business Information Manager

Description of activities

In the role as Business Information Manager I am defining strategies, plans and requirements for IT and automation projects for the production facilities.

IT Infrastructure

Customer: Astellas
Period: 2014 - 2015
Location: Meppel
Project Type: Validation
Project Function: Validation Manager

Description of activities

To support GMP critical application a new IT infrastructure was created in the Pharmaceutical plant using virtual servers (VMware).

In this project I am responsible for the validation of the infrastructure with a lean and risk based approach.

Warehouse Management

Customer: Medcor
Period: 2014 - 2015
Location: Lelystad
Project Type: Project Management
Project Function: Project Manager

Description of activities

For a life science company in Lelystad ERP system is extended with warehouse management system.

In this project I am responsible for the project management, design and validation of the system.

Learning Management System

Customer: Astellas
Period: 2013 - 2014
Location: Europe
Project Type: Validation
Project Function: Validation Manager

Description of activities

Within the European division a Learning Management System (LMS) is implemented using the Plateau (SuccessFactors / SAP) software. With the LMS training of employees is registered.

In this project I am responsible for the validation of the system during the European roll-out of the system.

ERP validation

Customer: Medcor
Period: 2014
Location: Lelystad
Project Type: Validation
Project Function: Validation Manager

Description of activities

For a life science company in Lelystad a retrospective validation of the GMP critical part of the Exact system is performed, including qualification of the related IT Infrastructure.

In this project I am responsible for the validation of the system. The system validation was successful verified during an IGZ inspection

Aseptic Capacity Expansion

Customer: Abbott
Period: 2012 - 2013
Location: Netherlands; Zwolle
Project Type: Validation
Project Function: Validation Manager, Auditor

Description of activities

Within the Nutrition production plant in Zwolle a new production and packing line is implemented to produce medical liquid food products.

In this project I am assisting internal and external (international) suppliers to perform the automation of the equipment according to GAMP guidelines. In the project several suppliers have been audited by me. In a number of formal tests (FAT, SAT, IQ, OQ) I represented the QA department of Abbott.

Validation of production and laboratory equipment

Customer: Abbott
Period: 2012 - 2013
Location: Netherlands; Zwolle
Project Type: Validation
Project Function: Validation Manager

Description of activities

Within the Pharmaceutical production plant in Meppel production and laboratory equipment I installed or modified.

In these projects I was responsible for the risk-based validation of this equipment.

Document Management System

Customer:	Astellas
Period:	2012 - 2013
Location:	Netherlands; Meppel
Project Type:	Validation
Project Function:	Validation Manager

Description of activities

Within the Pharmaceutical production plant in Meppel a Global Document Management System was introduced.

In this project I am responsible for the validation of the roll-out of the system in the European organisation.

Laboratory Information Management System

Customer:	Astellas
Period:	2012 - 2013
Location:	Netherlands; Meppel
Project Type:	Validation
Project Function:	Validation Manager

Description of activities

Within the Pharmaceutical production plant in Meppel a Laboratory Information Management System (LIMS) and an Empower system is updated to a more recent version.

In this project I am responsible for the validation of the system during the project phase. For the operational phase an approach is developed to keep the system in a validated state.

Vendor audits

Customer: Several companies
Period: 2012 - 2013
Location: International
Project Type: Audits
Project Function: Lead auditor

Description of activities

For a number of companies in Food and Pharmaceutical industries automation and IT suppliers have been audited against GMP regulations.

In this contracts I was lead auditor and worked together with the supplier to correct the issues that came out of the audit.

Learning Management System

Customer: Astellas
Period: November 2011, 2012
Location: Netherlands; Meppel
Project Type: Validation
Project Function: Validation Manager

Description of activities

Within the Pharmaceutical production plant in Meppel a Learning Management System (LMS) is implemented using the Plateau (SuccessFactors / SAP) software. With the LMS training of employees is registered.

In this project I am responsible for the validation of the system during the project phase. For the operational phase an approach is developed to keep the system in a validated state.

Infrastructure replacement

Customer: Astellas
Period: 2011 /2013
Location: Netherlands; Meppel
Project Type: Validation
Project Function: Validation Manager

Description of activities

Within the Pharmaceutical production plant in Meppel all client computers, servers and network equipment is replaced.

In this project I am responsible for the Qualification of the system and the critical (GMP) applications that were involved in the project phase. For the operational phase an approach is developed to keep the critical applications in a validated state by regulating patch management.

Vendor audits

Customer: Astellas
Period: 2011
Location: Netherlands; Meppel
Project Type: Audits
Project Function: Lead auditor

Description of activities

Due to the EU annex 11 pharmaceutical production companies are responsible for the quality of their suppliers. IT support services Astellas will be outsourced to an international IT Service provider.

In this contract I have been auditing different locations of the supplier as lead auditor and worked together with the supplier to correct the issues that came out of the audit.

Electronic Batch Record implementation

Customer: Astellas
Period: November 2010, 2011
Location: Netherlands; Meppel
Project Type: Validation
Project Function: Validation Manager

Description of activities

Within the Pharmaceutical production plan in Meppel an Electronic Batch Record system is implemented using the Werum PAS-X software. The EBR system is integrated with the SAP ERP system and a LIMS system.

In this project I am responsible for the validation of the system during the project phase. For the operational phase an approach is developed to keep the system in a validated state.

Business Improvement projects

Customer: NKM
Period: 2010, August - September
Location: Netherlands; Nieuwegein, Veenendaal
Project Type: Business re-engineering
Project Function: Business Consultant

Description of activities

Within the NKM organization 2 companies need a more efficient organization. Together with suppliers, customers and own personnel the business process are described. Based on the process descriptions and experience of involver persons, possible improvement are investigated and reported. Investigations are based on Lean and Six Sigma methods.

Improvements of > € 500.000 per year are discovered.

Involved customers are KPN and Ziggo. Business area for this project are Telecommunications.

Terminal Master Automation Plan

Customer: Vopak
Period: 2009
Location: Netherlands; Rotterdam
Project Type: Consultancy
Project Function: Consultant

Description of activities

Leader of a team to create a Master Terminal Automation Plan. Together with management and Operator a global plan was created how to control terminals for Vopak. This resulted in a blue-print for information flow and automation systems, taking care of regulation, business drivers and customer requirements for over 50 terminals all around the world.

Interim manager

Customer: Organon, Oss
Period: 2007 - 2010, may
Location: Netherlands; Oss
Project Type: Interim Management, Project Managment, Consultancy
Project Function: Manager, Project Manager

Description of activities

During this period several activities have been performed. An overview in random order:

Application Manager of a large DCS system (Invensys) until a new application manager was found and trained.

Setting up a application management department for a large scale bio-technology production facility. After some time the scope was enlarged to all bio-technology plants *7 in total). During this period a large information system (SharePoint) was set-up by me that contained an inventory of all automation systems for all factories, including all system documentation. Application Managers were trained in managing the applications in an efficient and consistent way, based on procedures. I was strategic and financial responsible for all automations systems in de Bio-tech division. I helped to optimize the project execution method and did setup a SharePoint to control all Biotech projects.

As a project manager several small and large MES and process control systems were specified , implemented or upgraded.

As a consultant I started several improvement projects, like Risk based verification, risk based change control and process improvement based on statistical information with CSENSE, SIPAT and several MES and reporting packages. And many other activities……..

Requirements definition of a MES system - flower factory

Customer: KRIJGER MOLENAARS
Period: 2006 - 2007
Location: Netherlands; Renesse
Project Type: Consultancy
Project Function: Consultant, Project Manager

Description of activities

Define the URS for a MES system for a flower factory. ISA-95 was used to structure the system. Together with the owners, managers and operators, the requirements were defined.

DCS for Organon

Customer: Organon
Period: 2001 - 2003
location: Netherlands; Oss
Project Type: Consultancy
Project Function: Consultant, Project Manager

Description of activities

Define the URS for a DCS to control a large fermentation factory. Together with all shareholder the requirements were defined and the automation approach was defined. As a project manager, the supplier for the DCS was selected. After the selection the supplier was controlled to ensure all requirements were met. Risk based approach for testing was introduced. Installation and commissioning of the system was part of the activity, until the factory was operational in 2003.

The system was fully validated and 21 CFR compliant.

DCS in Israel

Customer: Chemada
Period: 2002
location: Israel; Kibuts Nir Itzrak
Project Type: Consultancy
Project Function: Consultant, Project Manager

Description of activities

Helped a local Israeli company to deliver a DCS for a Pharmaceutical company. A lot of guidance and training was required to succeed in such a complicated country with a different culture.