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Position: **Senior Process Clean Utilities Engineer, Project Manager
& Good Engineering Practice (GEP) advisor.**

Languages: **French, English, Dutch**

SUMMARY

Since 1994, I have worked in different functions in the pharmaceutical engineering business as Project Engineer, Process Engineer, Clean Utilities Engineer, Engineering Manager and Project Manager. The missions I worked on concerned different facilities types : vaccines, aseptic liquids, blood fractionation, biotech labs, oral solid dosage forms and radiopharmacy.

These functions have been performed along the full life cycle of a project : feasibility study, conceptual design, basic design, detailed design, procurement, construction management, FAT, SAT, commissioning, installation qualification and operational qualification.

With the experience accumulated during my carrier in different engineering offices, I also advice companies that performs engineering activities (design and/or construction of equipment & facilities), with regards to Good Engineering Practices based on GEP ISPE guidelines.

MAIN SKILLS

→ As Project Manager

Management of the scope, cost, time, quality, resources, communication, risk and procurement through different techniques : stakeholder management, PEP, WBS, risk register, S-curves, communication plan, change management, quality plan, TIC,...

→ As Clean Utilities/Pharma/Process Engineer

- **Clean Utilities Systems**

Production and distribution systems for Pure Steam, Purified Water, Water for Injection, Sterile Compressed Air, pharmaceutical gases, liquid nitrogen, process piping.

- **CIP/SIP systems**

Experience in various CIP/SIP systems (fixed and mobile tanks) with different levels of automation (manual, semi-automatic, fully automatic)

- **Effluent decontamination**

Experience in project with effluent decontamination systems (batch and continuous) within biosafety facilities up to level 3

- **Washing Machines**

Experience in pharmaceutical washing machines in various facilities.

- **Autoclaves**

Sterilization and decontamination autoclaves in different pharmaceutical processes.

- **Oral Solid Dosage (OSD)**

Powder material handling systems, weighing systems, mixing systems, sieving, granulation systems, tableting machines, primary/secondary packaging machine, continuous systems, vacuum transfer systems,...

→ **As GEP Advisor**

As GEP advisor, I provide the following services :

- Company audit & assessment with regards to Good Engineering Practices & organizational maturity.
- Definition of GEP scope for the company.
- Strategy definition in alignment with the company goals.
- Proposal of GEP implementation timeline.
- Setup of internal GEP projects.
- Trainings linked to GEP implementation

EDUCATION

1994-96 : Master in Pharmaceutical Engineering and Industrial Technology.

- Catholic University of Louvain. School of Pharmacy.
- Thesis : Automatic systems for the weighing of big quantities of powders in the pharmaceutical industry dedicated to oral dosage forms (ODF).

1987-93 : Electronic Engineer.

- Catholic University of Louvain. Applied Science Faculty.
- Thesis (92-93) performed in the electro-technology & instrumentation department :
 - Design of a signal acquisition software for mathematical data treatment.
 - Construction of a selective follower analog/digital converter (12 bits).

EMPLOYERS & FUNCTIONS

2015 – till now : **Freelance and owner at ATP Engineering.**

2013 – 2015 : **NNE PHARMAPLAN** – Project Manager and Clean Utilities Engineer

2001 - 2013 : **SNC-LAVALIN** – Project Manager and Process/Clean Utilities Engineer.
 1997 - 2001 : **ICCE S.A.** – Engineering Manager, Project Manager.
 1994 - 1997 : **ELVECO-msj S.A.** - Project engineer.

PROJECT EXPERIENCE (MAIN PROJECTS)

- **New vaccine facilities – GSK RD423 projects (building W31)**
Site Country: Belgium
Customer Headquarter: Belgium
Clean Utilities team leader
 Detailed design for various utilities production & distribution : WFI, pure steam, process compressed air, nitrogen, NaOH, liquid nitrogen, industrial sewers.
GLAXOSMITHKLINE BIOLOGICALS, 2021-2022

- **Facility Engineer – Univercells.**
Site Country: Belgium - Jumet
Customer Headquarter: Belgium
Facility engineer within Univercells project team for the new COVID19 Vaccine production facility design & construction.
 Multi-disciplinary follow-up and coordination of the engineering offices in charge of the design of the new facilities. Alignment & coordination with the internal project team of Univercells.
UNIVERCELLS, 2020-2021

- **GEP (Good Engineering Practices) strategy setup – Univercells.**
Site Country: Belgium - Nivelles
Customer Headquarter: Belgium
GEP Expert within Univercells QA Department.
 Audit of the company and gap assessment with regards to ISPE GEP Guidelines. Setup of a GEP development strategy within the engineering activities. Support to internal engineering staff and setup of engineering standards & procedures. Training organization & internal coaching.
UNIVERCELLS, 2019-2020

- **Revamping – Aseptic filling facilities – Pfizer.**
Site Country: Belgium - Puurs
Customer Headquarter: US
Utilities Project Engineer within the Pfizer Engineering Department.
 Basic & detailed design for new and existing facilities. Clean and black utilities design systems : production and distribution systems for industrial steam, chilled water, compressed air, softened water, purified water, water for injection, clean steam.
PFIZER, 2018-2019

- **Revamping – Vaccine facilities – GSK WN358 projects (building W27)**
Site Country: Belgium
Customer Headquarter: Belgium
Clean Utilities team leader
 Basic & detailed design for the revamping of existing facilities and the new washing center facilities : WFI loop, pure steam network, NaOH network, process compressed air network, parts washers.
GLAXOSMITHKLINE BIOLOGICALS, 2017-2019

- **Revamping – Vaccine facilities – GSK WN280 & WN300 projects (building W17)**
Site Country: Belgium
Customer Headquarter: Belgium
Clean Utilities team leader

Site supervision, commissioning for the revamping and upgrade of WFI loop, pure steam network, NaOH network, process compressed air network, autoclave bioseal, washing machines, CO2 and N2 networks, mobile COP station, sewers.

GLAXOSMITHKLINE BIOLOGICALS, 2016-2017

- **Revamping – Plasma fractionation facilities – Plasma Industries (former CAF-DCF)**
Site Country: Belgium
Customer Headquarter: The Netherlands
Project Engineer
Revamping and upgrade of the existing chemical storage and distribution systems (NaOH, CH3COOH, HCl).
PLASMA INDUSTRIES, 2016
- **New Facilities – Plasma fractionation facilities – Plasma Industries (former CAF-DCF)**
Site Country: Belgium
Customer Headquarter: The Netherlands
Clean Utilities team leader
Follow-up of basic design for the production & distribution systems for the pharmaceutical clean utilities : Softened water, Purified Water, Pure steam, Water for Injection, sterile compressed air, ethanol. Follow-up of basic design for the CIP system and effluent treatment systems.
PLASMA INDUSTRIES, 2016
- **Revamping – Plasma fractionation facilities – Plasma Industries (former CAF-DCF)**
Site Country: Belgium
Customer Headquarter: The Netherlands
Project Engineer
Engineering and design for new powder weighing and vacuum dispensing systems.
PLASMA INDUSTRIES, 2015
- **New Facilities – Plasma fractionation facilities – LFB 2020**
Site Country: France
Customer Headquarter: France
Clean Utilities team leader
Basic design of the production & distribution systems for the pharmaceutical fluids : Softened water, Purified Water, Pure steam, Water for Injection, sterile compressed air.
LFB, 2015
- **Revamping – HVAC units - Eurogentec**
Site Country: Belgium
Customer Headquarter: Japan
Project Manager
Basic design & detailed design for the revamping of the existing HVAC units.
EUROGENTEC, 2014
- **New Facilities - Plasma protein (AAT) purification process facility – GLASSIA – Baxter Bioscience.**
Site Country: Belgium
Customer Headquarter: United States
Clean Utilities team leader
Basic design, detailed design, procurement, construction management, commissioning & qualification of the production & distribution systems for the pharmaceutical fluids : Purified Water, Water for Injection, sterile compressed air.
BAXTER BIOSCIENCE, 2011-2013
- **Revamping - Polio Vaccine production line – Netherlands Vaccine Institute (NVI)**
Site Country: Netherlands

Customer Headquarter: Netherlands

Process team leader

Revamping of process equipments and clean utilities systems. Detailed design, procurement, construction management, commissioning & qualification.

Netherlands Vaccine Institute (NVI), 2010-2011

- **New facilities - GMP Pilot plant**

Site Country: Belgium

Customer Headquarter: Belgium

Project Manager

Detailed design, construction management, commissioning of the new GMP pilot plant facilities for the new R&D nutrition activities.

BAXTER NUTRITION, 2008-2009

- **New facilities – Biotech – Cardio3 Bioscience.**

Site Country: Belgium

Customer Headquarter: Belgium

Project Manager

Basic design and detailed engineering study for new laboratory dedicated to clinical trials (phase 2). New production facilities for the differentiation of stem cells into heart cells for heart tissue reconstruction.

CARDIO3 BIOSCIENCE, 2008-2009

- **New facility - Vaccine production facilities - ST03 – GSK BIOLOGICALS**

Site Country: France

Customer Headquarter: Belgium

Clean utilities team leader.

Site construction management. Distribution networks : water for injection, purified water, pure steam, process compressed air, liquid & gaseous nitrogen, caustic soda. Process equipments : washing machines, CIP/SIP for mobile vessels, sterilisation autoclaves.

GLAXOSMITHKLINE BIOLOGICALS, 2007

- **New facility - Vaccine production facilities - WN168 – GSK BIOLOGICALS**

Site Country: Belgium

Customer Headquarter: Belgium

Technical Coordinator

Technical coordination of the whole engineer team (10 people) for the detailed engineering of new vaccine production facilities.

GLAXOSMITHKLINE BIOLOGICALS, 2006-2007

- **New Facility - NEW QC LABORATORIES - WN128 – GSK BIOLOGICALS.**

Site Country: Belgium

Customer Headquarter: Belgium

Process Team Leader

Basic design, detailed engineering and construction supervision of the pharmaceutical processes for BL1, BL2 & BL3 laboratories. Systems : purified water, water for injection, pure steam, pharmaceutical gasses, liquid nitrogen, autoclaves, distillers, pure steam generators, batch and continuous, washing machines, CIP/SIP systems, cleanroom monitoring.

GLAXOSMITHKLINE BIOLOGICALS, 2003-2006

- **New facility – Laboratories – JRC-IRMM**

Site Country: Belgium

Customer Headquarter: Belgium

Project Manager

Design & construction of a BL3 laboratory for production of GMO references : basic design, detailed

engineering, construction supervision, commissioning, qualification and pharmaceutical validation.
EUROPEAN COMMUNITY (IRMM)

- **Revamping - Vaccine scaling-up unit – GSK Biologicals.**

Site Country: Belgium

Customer Headquarter: Belgium

Process Engineer (clean utilities)

Clean utilities : purified water, water for injection, pure steam, effluent neutralisation. Studies supervision, construction supervision, commissioning and pharmaceutical qualifications assistance to the pharmaceutical validation.

GLAXOSMITHKLINE BIOLOGICALS, 2000-2002

- **New facility – Biotech - Henogen**

Site Country: Belgium

Customer Headquarter: Belgium

Project Engineer

Balancing of an HVAC networks for laboratories dedicated to gene therapy (BL2 & BL3).

Study, installation, start-up and commissioning of a centralised monitoring system of the gene therapy laboratories.

HENOGEN S.A., 1999-2000

- **New facility – OSD - Sanovel**

Site Country: Turkey

Customer Headquarter: Turkey

Project Engineer

Feasibility study for new production & packaging facilities of oral dosage forms, study of the logistic link between production facilities and automated warehouse for storage of raw materials, intermediate and finished products.

SANOVEL, 1999-2000

- **New facilities - Radio-pharmacy – Université de Liège (Cyclotron)**

Site Country: Belgium

Customer Headquarter: Belgium

Project Manager

Feasibility study, detailed engineering, site supervision & commissioning of a new production department of radiopharmaceutical products (Fluor 18) for positron emission tomography (PET scan).

CYCLOTRON RESEARCH CENTER - UNIVERSITY OF LIEGE, 1999-2000

- **New facility - Biotech facility – Hopital du Sart-Tilman**

Site Country: Belgium

Customer Headquarter: Belgium

Project Manager

Feasibility study, detailed engineering, site supervision & commissioning of a new Cellular, molecular & gene therapy unit (BL2 & BL2+).

HOPITAL UNIVERSITAIRE DU SART-TILMAN, 1999-2000

- **New facilities - Biotech facilities – Erasme Hospital**

Site Country: Belgium

Customer Headquarter: Belgium

Project Manager

Detailed engineering and commissioning of a centralised environment monitoring system (SCADA) of a new cellular, molecular & gene therapy unit (BSL2 & BSL3).

ERASME HOSPITAL, 1999-2000

- **Audit - BSL4 R&D lab revamping - Vector**
Site Country: Russian Federation
Customer Headquarter: Russian Federation
Project Engineer
 Participation to an audit of the American Department of Defence (DoD) for the civilian reconversion of a bacteriological weapon production center in Siberia.
VECTOR, 1999-ongoing

- **Revamping - Insuline production line - Belmedpreparaty**
Site Country: Belarus
Customer Headquarter: Belarus
Project Manager
 Turnkey project : Basic Design, detailed engineering, construction management, commissioning & qualification of revamped facilities dedicated to the downstream part (filling, coding, sterilization, visual inspection, labeling and blistering) of an insulin vial production line.
BELMEDPREPARATY, 1997-1998

- **New facilities – OSD - Pliva**
Site Country: Croatia
Customer Headquarter: Croatia
Project Engineer
 Feasibility study and detailed Engineering of a automated material handling systems (AGV's & stacker cranes,...) for a new facility dedicated to OSD.
PLIVA, 1996-1997

- **New facility – OSD - KRKA**
Site Country: Slovenia
Customer Headquarter: Slovenia
Project Engineer
 Feasibility study & detailed engineering of an automated weighing system for OSD production facilities.
KRKA, 1995-1996

- **New facilities – OSD – Sanico N.V.**
Site Country: Belgium
Customer Headquarter: Belgium
Project Engineer
 Feasibility study & detailed engineering for a fully automated oral solid dosage production facilities (generic).
SANICO N.V., 1994-1995