Pierre FRAUMAN

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About me

GDP and GMP specialist with 7 years experience in the pharmaceutical industry in various areas including compliance, validation, change control, project management, regulatory affairs and audit, and acting in turn as a team leader, autonomously and as a team member.

I am a result oriented, out of the box thinker who can take responsibility and enjoys working hand in hand with stakeholders and management with the goal of achieving extraordinary results.

Fluent in French and English, good level of Dutch.

Experience

@ Rescop, International

July 2015 – Present: GxP consultant in the Rescop international team. Various projects including validation management, GDP gap assessment and training, all aiming to help pharmaceutical and logistics companies to comply with GMP and GDP regulations.

Project: Validation management at H Essers: several warehouses dedicated to pharmaceutical activities were not validated. I was responsible for defining a new validation approach, writing the validation documents, creating procedures and templates and coaching the quality team.

Project: GDP gap assessment at Dishman (Netherlands). Dishman had a newly appointed supply chain responsible and requested a one day training to Good Distribution Practices (GDP) and a gap assessment on the current practices regarding GDP. I developed and gave a GDP training and performed a gap assessment and reviewed related CAPA.

Project: Deviation backlog Smith and Nephew (Curaçao). Smith & Nephew had a backlog of deviations and CAPAs. These had to be brought back to a

sustainable level, as per FDA commitment, in order to be able to restart production. Pierre was responsible for performing key investigations.

@ GSK Vaccines, Wavre

February 2011 – Present: Validation and change control manager, GSK Vaccines, Planning & Logistics department

Validation manager: owner of the continuous validation plan; organize validation activities internally and with subcontractors; manage contracts with subcontractors; write/approve protocols and reports, and execute validations; topics include: storage room, transport, clean room (grade C/D), computer related systems.
Risk analysis: perform risk assessments related to change controls, validation (cleaning, environmental monitoring, cold chain), documentation (gap analysis vs cGMP, Eudralex and CFR21) and processes.
Change control local system owner: manages all change control related activities within the department, from impact analysis (phase 0) to change control documentation, and regulatory actions (annual reports,…).
Manage deviations and CAPA: responsible for deviations and CAPA related to validation and change control, manage major CAPA (with impact on change control) for the department.
Project Management: planning management of all the projects in the department.
Regulatory Affairs: write submission files related to change control, answer to Q&A and fronter at regulatory inspections (FDA, AFMPS, China, Japan, Brazil, Korea, …), on the following topics: cold chain, transport, cold chain validation, validation, change control, and specific CAPA and deviations.
Audits: organize and participate to internal audits (validation, change control, maintenance, computer related systems) and subcontractor audits regarding good distributions practices (EU GDP)
Documentation: write SOP and give training on validation of storage room (cold and ambient) at GSK Belgium, validation of cold truck for transport at GSK Belgium, change control management in the department Planning & Logistics
Team management: small team **(**up to 3 employees)

July 2009 – February 2011: Core file project - Project of improvement of technical documentation - Responsible for managing technical documents, knowledge management - Inspection readiness (FDA and AFMP) and writing of change control and validation documentation

@ Bosch, Tienen

2007 – 2009: Process Development Engineer, working as consultant for Altran. Development of a new windshield wipers production line from product design to the ramp-up after start of production.

@ Aalto University, Helsinki, Finland

2005 – 2006: Research on electromechanics and lead a research project (supervise 2 students) - Publication in IEEE Transactions on Magnetics

Languages

French: *Mother tongue*	**English**: *Fluent*	**Dutch** : *Good*
Finnish : *Basic*	Malagasy : *Basic*	

Education

2005: Master Degree of Electro-mechanical Engineer received with the highest possible grade (La Plus Grande Distinction) from ULB.
- 2004-2005 Erasmus in Aalto University (Helsinki, Finland)
- 2003-2004: Erasmus Belgica in VUB

Hobbies & Interests

Music is a universal language. I like to listen to all types of music. I also play the violin in an orchestra.

I occasionally do sports: running, swimming, football and floorball, and dance.

Active member of several European students associations: ESN (Erasmus Student Network) and BEST (Board of European Students of Technology), I am a citizen of the world, always happy to meet new people and discover new places.