

VAN ROY XAVIER,

Owner & Managing Director

Projexia SPRL

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PERSONNAL OBJETIVE:

Take full benefit of my 20+ years of experience in bio-pharma and my strong Laboratories Information Management System (LIMS) & e-analytics expertise to contribute to companies 's organization and process efficiency through optimal system integration, while focusing on quality assurance and compliance.

EXPERTISE:

- LABWARE LIMS Administration certification
- Project Management (Use of PMI Methodology)
- Computerize System Qualification (GAMP)
- Data & Knowledge management
- Process Thermal Hazard Evaluation (Stoessel's Methodology)
- Process Analytical Technologies
- Scaling-up from laboratory to industrial scale, according to cGMP rules

STRENGTHS:

- Customer and Result oriented, trough strong involvement into the business
- Strategic Thinking (Analytical mindset Creativity/Innovation)
- Listening
- Quick learner
- Interpersonal Skills
- Team Work Skills

PROFESSIONAL EXPERIENCE:

Projexia SPRL - Owner, Managing Director

LIMS Business Analyst, GSK Vaccines S.A.

2016

- Give support to the Business project leader and project manager in the context of New LIMS Foundations Project.
- Apply IT change management cycle respecting IT standards:
 - o Collect, understand and challenge business requirements;
 - Perform the informal testing of the application;
 - Define tests acceptance protocols;
 - Perform the validation phase of the application;
- Ensure support to the business with the use of the application :
 - Communicate and manage issues (IT tickets);
 - Ensure issues follow-up;
 - o Determine priority of resolution.
 - o Be the single point of contact between IT & BUS
 - Lead complex investigations
 - Ensure system is fit for purpose:
 - o Ensure validation state of the system
 - Take part to system future design
 - Manage initiatives (projects) aiming at improving system performance
 - Ensure system is aligned with business requirements
 - Ensure system meets the quality standards

LIMS Business Analyst, GSK Vaccines S.A.

2015

- Give support to the ROXIS Business project leader and project manager in the context of ROXIS remediation Project.
- Be the link between IT and Business.
- Align IT improvements with the Business reality.
- Align specific data reduction models and IT developments.
- Participate to Change Request Management.

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UCB S.A. - LIMS Business Analyst

Corporate QC Support

- As **Subject Matter Expert**, be the key contact between Business and IT Support Team:
 - Drive implementation & improvements of LIMS Process (Project Mgmt, Planing, quality & feasibility, cost...).
 - o Support Global Process Owner until solution implementation and maintain technically the system after Go Live.
 - Support Global & Local Key Users during Users Requirement Specification (URS) definition, validation phase (Operational Qualification (OQ)/ Performance Qualification (PQ)) and business implementation.
 - o Permanent Member of the LIMS Change Advisor Board.
- As Global Process Owner (LIMS Administration and LIMS-SAP interface), be a Global Business Representative:
 - o Collect and challenge requirement with a global approach.
 - o Review and approbation URS and ensure adhesion of local business.
 - o Participate to validation phase (OQ/PQ), and guarantee adequacy with URS.
 - o Challenge, after go live, new business requests and ensure the consistency of these.

UCB S.A. - GLIMS Amdin. Team Manager

2013

2014

Corporate Analytical Services

- Manage the global LIMS Team (6 direct reports + 4 dotted reports)
- Ensure successful administration of the Team through staff performance management and financial objectives.
- Drive implementation & improvements of e-Analytical tools (Project Mgmt, Planing, quality & feasibility, cost...)
- Provide robust and seamless system around e-Analytical tools (global SOP, Change Control, Development & Validation of interfaces with others systems)
- Work with QA to ensure compliance, RA to ensure high quality and timely submission documentation.

UCB S.A. - GLIMS Amdininistrator

2010-2012

Corporate Analytical Services

 Ensure the local development & implementation of any electronic Analytical tool and provide local support to the network as needed. (QC's and Analytical Development lab's for Braine (Belgium) and Slough (UK))

UCB S.A. - Associate Scientist

1995-2010

Chemical Process Development & Industrialization

- Development and industrialization of chemical process from lab scale to full scale validation.
- Act as specialist in high technology tools for chemical process understanding and optimization by the use of automated equipment and statistical tools

EDUCATION:

Bachelor's degree in Computer sciences

2000

Institut d'Enseignement de Promotion Sociale de la Communauté Française

Bachelor's degree in Chemistry (Specialization: Industrial chemistry)

1995

Institut Paul Lambin - Haute Ecole « Léonard de Vinci »

IT SKILLS:

- Windows 7
- LINUX (Ubuntu)
- Microsoft Office 2010
- Open Office
- SAP
- Programming (C/C++, Visual Basic & VBA)
- SQL and Data base Management
- Virtualization (VirtualBox)
- Infrastructure Architecture
- Deployment and Maintenance of CMS (Joomla / Wordpress)

LANGUES:

- French Mother tongue
- English Excellent knowledge

HOBBIES:

- Martial art (Tenshin Shoden Katori Shinto Ryu, Karate & Ju-jitsu)
- Fitness & RPM
- Table top role-playing games.
- Web mastering.
- Road cycling fan
- ASBL Administration