



GEERT VANDENBOSSCHE

FOUNDER, OWNER,
COMPLIANT & EFFICIENT SOLUTIONS BV

ABOUT ME



C&E Solutions BV pioneers compliant and efficient aseptic processing solutions for pharmaceutical companies, spanning startups to established firms.

With 35+ years of experience, we specialize in Annex-1 compliance and advanced techniques like e.g. Radio Ligand Therapy.

Our expertise ensures GMP and regulatory adherence while optimizing efficiency.

From startups establishing protocols and process design to established firms refining processes, we deliver tailored solutions for operational excellence. Through meticulous attention to detail, we empower clients to overcome challenges.

Work experience summary:

- 4 Y Startup upgrade & integration
- 6 Y Global Quality roles
- 16 Y Site Leadership team
- 4 Y Site Engineering/MS&T
- 5 Y R&D

CONTACTS



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WORK EXPERIENCE



2019

2024

Global Head MST and Engineering Advanced Accelerator Applications (Integration Startup to Novartis RLT)

AAA/Novartis RLT

Integration of acquired startup into Novartis systems: Creation of validation department and deployment of Technology Transfer process (MS&T). Creation of global engineering department. Process/equipment re-design, efficiency improvement, COGs reduction, upscale and GMP (Annex-1) upgrade. Knowhow transfer to Novartis RLT: MS&T, Engineering, IT/OT and TRD (Development). Design rollout of global semi- and fully automated equipment (US, Spain, Italy, China, Japan). Development of patient ready dose (Prefilled Syringes/Cartridges).

2017

2019

Global Head Novartis Technical Operations QA Strategic Initiatives/Global DI Lead

Novartis Pharma

Global Novartis data integrity project for all Novartis facilities, contract manufacturers, (NBS) Novartis Business Services, country organizations and development. Novartis Aseptic Processing Improvement Project for (28) manufacturing sites and new acquisitions (NAP-CIP, anticipating on Annex-1 updates). Working groups within PDA and ISPE for Annex-1 review, redrafting and workshops.

2016

2017

Global Head Quality BTDM Drug Product

Novartis Pharma

Quality oversight biological drug product sites Novartis Pharma (Austria and Switzerland).

2014

2016

Global Head Quality Sterile and Special Technologies

Sandoz International;

Quality oversight in six Sandoz manufacturing sites (Germany, Slovenia, Austria and Canada). Remediation of Sandoz aseptic sites: 2 Warning Letters lifted. Within 6 months: creation and completion of all priority items in the global CAPA plan on aseptic operations in 28 Novartis sites (80% risk reduction).

2011

2014

Plant Manager

ALCON BELGIUM

Management Custom Paks®, Viscoelastics and Ointment department Warehouse and production automation (3 m\$; 3Y pay back). Prefilled syringe filling line (9 m\$; 3Y pay back).

SKILLS



Equipment & Process Design

Aseptic Processing (Annex-1)

Radio Ligand Therapy (RLT)

Coaching & upscale at Startups

Remediation & Crisis Management

Inspection readiness and back-office support

Corporate Management

LANGUAGES



Dutch

English

2010
2011

QA Director/Site restructuring lead

Alcon Barcelona

Selection of QA director, site re-organization and integration of QA with manufacturing and regulatory affairs.

2001

2010

Quality Assurance / Regulatory Affairs Manager

ALCON BELGIUM

Responsible for Regulatory affairs, QC and QA. Qualification of ERP/MES system. Analytical method remediation and upgrade European (CTD) regulatory files (Spain, France and Belgium). Lean lab (rhythm wheel) and release reliability improvement above 99%.

1998

2001

Plant Systems Manager

ALCON BELGIUM

Previous role, including maintenance/engineering, automation, safety and environmental affairs. Engineering of dispensing area, ointment area, automation masterplan for equipment utilities, ...

1994

1998

Manufacturing Systems Manager

ALCON BELGIUM

Engineering, validation, calibration, technology transfer, training, compliance, clinical supplies, manufacturing support (MST).

1993

1994

Free-lance Industrial Pharmacist (Consultant)

Formulation, engineering, validation, lab certification (BelCert), VHP monitoring with H2O2 measuring device.

EDUCATION



1993

Ph. D. Doctor in Pharmaceutical Sciences Greatest distinction

UNIVERSITY OF GHENT

1987

Master Degree in Pharmaceutical Science Greatest distinction

UNIVERSITY OF GHENT

1982

Secondary Education

St. Lievenscollege | Ghent

1999

"International Manufacturing Program" INSEAD,

INSEAD | Fontainebleau

1997

"The effective Manager"

De Vlerick School voor Management | Ghent