V.S.A.N

SENIOR PROJECT MANAGER & ENGINEERING, CQV/CSV, QA CONSULTANT
26 YEARS OF EXPERIENCE

Summary

Subject Matter Expert in Life Sciences and he developed a proper offer on large scale Engineering/CQV/**Quality project management.** Vincent Stockman has **extensive experience (26 years)** across multiple technologies and industries both from the manufacturing and engineering services perspective, gives Vincent a unique insight into the requirements and constraints that regulatory bodies place on our customers.
His deep practical appreciation of regulatory expectation and industry guidance, coupled with his at-tools expertise positions him well to advise both customer and implementation teams on the most effective use of effort to deliver and maintain a compliant suite of systems, which meet business needs.
His expertise spans full-facility delivery, and his experience in developing and delivering CQV & CSV & **QA projects** spans from early implementation of Regulations through to modern best practices

Most recently, his involvement has included **QA Lead** verification/follow-up for:

- Galderma, Lausanne: **Senior GMP/GDP QA Lead** with responsibility to deliver**, in accordance with the worldwide regulations,** qualified ERP & CRM software (M3 & iScala) **in support of multi sites/clients' worldwide interactions. Project Quality Governance Documentation (Plan, Risk Strategy, Procedures), Risks Assessment, CSV Documentation (URS, RTM, Validation Plan) verification, CSV Verification Phases (DQ, IQ, UAT's, OQ, PQ) Execution & Reports including VSR verification, procedures implementation worldwide follow-up and Mock-up inspection on Spain & Portugal site.**

- SOPHiA Genetics, Saint-Sulpice & Geneva: **Senior CQV/CSV/QA Work stream Leader** with responsibility to deliver, a qualified cloud-based ERP & CRM software (Dynamics 365) **in support of multi sites/clients' worldwide interactions. Project Quality Governance Documentation (Plan, Risk Strategy, Procedures), Risks Assessment, CSV Documentation (URS, RTM, Validation Plan) verification, CSV Verification Phases (DQ, IQ, UAT's, OQ, PQ) Execution & Reports including VSR verification, procedures implementation worldwide follow-up.**

- GEHC, Ireland: **Generation of a global Quality Governance Model**, with a view to **maximum portability across multiple jurisdictions, and levels of regulation** in support of a multi-site BioPark rollout strategy. (Plan, Planning, Risk Strategy, Procedures), **Verification of all documentation** design and installation/operational/performance and process verification for novel single-use-technology multi-tenant facility in Cork. Construction & **CQV/QA Management** for GEP/GMP Utilities and processes systems (cost control, project reporting, change management…) and **CQV/QA Verification Phases** (URS, RTM, DQ, IV, FV, IOQ, PQ)

Skills

- Basic, detailed design Building & Equipment Engineering, cost control, equipment investment plan
- Revamping, Technical Transfer, Sterilization, Process Equipment Management
- API/Vaccines/Drug products, Medical Devices
- R&D, Manufacturing, Packaging, Serialization, UID, Distribution, Shipping, Cold Chain,
- Commissioning, Qualification, Validation, Electronic Documentation (URS, DQ, FAT, SAT, IQ, OQ, PQ, PV, CSV/Data integrity, CV, VP, TM, DR)
- **QA, QMS, CAPA, Deviation, Change, Internal/External Audit, Training, Risk Analysis (PFMEA, FMECA, APR, AMDEC…), Due diligence report, AQL and Default Library**
- Autoclaves, Freeze dryers, Depyrogenation tunnel…
- HPLC, GC, spectrophotometers… Laboratory Equipment
- Buildings, Cleanroom, Laminar Flow, Safety Cabinet… Building & Utilities Equipment
- Purification lines, Reactors, Peptides synthesizers,
- Granulators, Compressors, Coater, Filling, Cappers, Cartoners, Printers, Case packers, … Process Equipment
- Equipment Serialization Specific, Automatic inspection, ERP, MES, EMS…
- Automation, Electricity & Mechanics
- **21 CFR Parts 11, 210, 211 & 820**
- **Eudralex**
- **ICH Q5, Q7, Q8, Q9, Q10 (Q1-Q11 + Cross-cutting Topics)**
- **ISO 9000, 9001, 11607, 13485, 14644, 15378, 17025, 19011 & 60601**
- **GAMP5, ASTM E-2500**
- **cGMP, GMP, CMDR, EN, GDP, GLP, GCP, MDD, MDR & IVDR …**
- **FDA, Swiss medic, DGPSA, CMDR, EMA, MHLW, ANVISA, JMHLW (PMDA)…**
- EHS
- Trackwise, SAP, MS Office, MS Project, M3, Oracle, POMS, Documentum

Education

- 1994 Master's degree in **Automation** - ISICHt
- 2001 Master's degree in **Electromechanical engineering** - HES – IESTE

Industries

- Pharmaceutical
- Biotechnologies
- Medical Devices
- Blood
- Healthcare
- Food and Dietary Complements

Accomplishment

AMARIS 2018 – 2020 [25 Months]

Lead PM & ENGINEERING, CQV/CSV, **QA,** QC, GDP consultant, Technical Advisor Life Sciences and Offer Manager:

- **cGMP/Regulatory Affairs, Implementation** & Client Support consultancy with particular focus upon enabling manufacturing organisations to execute and maintain maximum control of & benefit from risk-based self-execution & contract-execution capital project models. For sustaining operations context, services include the provision of equivalent **PQMS and ISO-13485 Quality Management Systems support, & auditing & Audit Readiness.**
- **Lead** Engineering, GMP & CQV/CSV **& QA** & QC & **GDP Consultant**.
- Consultant for **Customer QMS policy** & Project Planning activities.
- **Internal & Supplier Auditor.**
- **Senior "Regulations inspections" Auditor.**
- **GMP, CQV, Trainer**
- Leader of Life Sciences Technical Committee and Life Sciences Technical Advisor
- Technical Audit Readiness and Guidance in Engineering & Testing (T.A.R.G.E.T.) Offer Manager

Merz Anteis – Aesthetics HA fillers 2020 – 2020 [3 Months]

Process Performance Development Engineer:

- Documentation generation for introduction of a new plastic syringe.
- Deliverables/responsibilities include:
  - **Project process development Documentation (equipment spare- parts, procurement documentation, Risk, Strategy, Procedures, Project Reports)**.
  - **CQV/CSV (URS, RTM, Validation Plan, IQ, OQ, PQ, PPQ)**.

Merck – Biotech Development Centre 2019 – 2020 [3 Months]

CQV Manager BPC Project:

- CQV Manager with responsibility to deliver the strategy to have the new BPC building qualified for end 2021.
- Deliverables/responsibilities include:
  - **Project Governance Documentation** (Man loader & Planning, Plan, Risk, Strategy, Procedures).
  - **Risks Assessment**.
  - CQV/CSV Documentation (URS, RTM, Validation Plan) generation.
  - CQV/CSV Verification Phases (DQ, IQ, UAT's, OQ, PQ, PPQ) Execution & Reports including VSR verification

Galderma - Nestlé Skin Health 2019 – 2019 [9 Months]

Senior GMP/GDP QA International Affiliates & Manufacturing NEXT project Leader:

- **Senior GMP/GDP QA Lead** with responsibility to deliver, **in accordance with the worldwide regulations**, qualified ERP & CRM software (M3 & iScala) in support of multi sites/clients' worldwide interactions.
- Deliverables/responsibilities include:
  - **Project Quality Governance Documentation (Plan, Risk Strategy, Procedures)**
  - **Risks Assessment**
  - **CSV Documentation (URS, RTM, Validation Plan) verification**
  - **CSV Verification Phases (DQ, IQ, UAT's, OQ, PQ) Execution & Reports including VSR verification**
  - **Procedures implementation follow-up**
  - **Mock-up inspection on Spain & Portugal site**

SOPHiA Genetics 2018 – 2019 [6 Months]

Senior CQV/CSV/QA Work stream Leader:

- Senior CSV & QA Lead with responsibility to deliver a qualified cloud-based ERP & CRM (MS Dynamics 365 with Azure) in support of multi sites/clients' worldwide interactions.
- Deliverables/responsibilities include:
  - **Governance Quality & Verification Documentation (Plan, Planning, Risk Strategy, Procedures)**
  - **Risks Assessment**
  - **CSV Documentation (URS, RTM, DQ, IQ, UAT's, OQ, PQ) generation & verification**
  - **CSV Verification Phases (DQ, IQ, UAT's, OQ, PQ) Execution & Reports including VSR & verification**
  - **Procedures implementation follow-up**

SysComm Project Management Ltd 2017 – 2018 [1 year]

Project Manager & Senior CQV/**QA** Lead:

- **cGMP/Regulatory Affairs, Implementation & Client Support consultancy with particular focus upon enabling manufacturing organisations to execute and maintain maximum control of & benefit from risk-based self-execution & contract-execution capital project models. For sustaining operations context, services include the provision of equivalent PQMS and ISO-13485 Quality Management Systems support, & auditing & Audit Readiness**.
- Senior Engineering, **QA** & CQV Consultant.
- **Consultant for Customer QMS policy & Project Planning activities.**
- **Internal & Supplier Auditor.**
- **Senior "Regulations inspections" Auditor.**
- **GMP, CQV, Trainer**

Allergan 2017 – 2018 [1 year]

Project Manager and Senior CQV Lead:

- Senior CQV Lead with responsibility to deliver a qualified facility in support of a new Stopper Processor. Deliverables/responsibilities include:
- Governance Documentation (**Planning**, Risk Strategy, Procedures).
- **Design Management for GEP/GMP Systems**.
- CQV Documentation (**URS**, RTM, DQ, IV, FV, **IOQ**, PQ) **generation**.
- **Construction & CQV Management for GEP/GMP Utilities and processes systems (cost control, project reporting, change management…)**
- **CQV Verification Phases** (DQ, IV, FV, **IOQ,** PQ) **Execution & Reports**

General Electric Healthcare (GEHC) BioPark 2017 – 2018 [1 year]

Project Manager and CQV/QA Lead with QMS Implementation Support:
Responsible for the following activities, and deliverables:

- **Generation of a global Quality Governance Model,** with a view to maximum portability **across multiple jurisdictions, and levels of regulation** in support of a multi-site BioPark rollout strategy. (Plan, Planning, Risk Strategy, Procedures).
- **GxP Design Management & Verification.**
- CQV Documentation (URS, RTM, DQ, IV, FV, IOQ, PQ).
- **Review & Approval of Design Basis.**
- **Approval of project-specific Review Procedure.**
- Development and leadership of Risk-Based GMP Assessment of proposed Facility, with focus on Open vs Closed processing.
- GMP Design Review Report.
- **Construction & CQV Management for GEP/GMP Utilities and processes systems (cost control, project reporting, change management…)**

Biogen (Oxford International) 2016 – 2017 [1 year]

Senior Engineering & Validation Consultant:

- Principal engineer Assembly, Label and Pack. For the Global Engineering department, manage the technical aspects of the ALP equipment and production rooms. Financial tables that will contribute to the data required for the project management. Based on the product/process all duties were conducted in compliance with current Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and regulatory requirements as defined by applicable standards i.e. 21 CFR 11/210/211.
- Serialization, Packaging/Distribution process improvements, Engineering, Commissioning, Qualification and Validation. Risk Analysis, PFMEA, Due diligence report, TOR Management.

Teoxane 2015 – 2016 [1 year]

Validation Manager:

- Validation Senior Manager. Define and set strategies for all validation and qualification activities associated with the introduction of products to FDA. Validation plans, protocols and reports that will contribute to the data required for regulatory submissions. Based on the product/process to be launched all duties were conducted in compliance with current Good Manufacturing Practice (GMP) Good Distribution Practice (GDP) and regulatory requirements as defined by applicable standards i.e. ISO13485, 21 CFR 600 and 820. Preparation of documentations for submission to the F.D.A. With QA department, realization of supplier's audits.
- Audits, PFMEA, Risk Analysis, CAPA, Change Management, Process Improvements, Serialization/UID, Engineering, Sterilization, Commissioning, Qualification and Validation.

Quotient 2014 [1 year]

Project & Validation Manager:

- Validation Senior Manager. Quotient: Blood analysis solution (full anti-bodies and antigens analysis) with dedicated analysis equipment. For the global QA&RA department: Define and set strategies for all validation and qualification activities associated with the introduction of the new product through design/development, technical transfer, manufacturing and licensure. Acting as the primary interface between the Validation department, Assay/Product Development team and all manufacturing partners, I was ensuring that during all phases of product development, focus is given to delivery of a robust validation plan ensuring success at each of the identified phases. Based on the product/process to be launched all duties were conducted in compliance with current Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and regulatory requirements as defined by applicable standards i.e. ISO13485, 21 CFR 600 and 820. Preparation of documentations for submission to the F.D.A. With QA department, realization of all supplier's audits (10 done in UK, Netherlands, Germany, Italia, Japan, Switzerland…).
- Development of the Manufacturing Electronic System for the new site (Delta V) linked to an Electronic Batch Record.
- Audits, Risk Analysis, PFMEA, Commissioning, Qualification, Validation, CAPA, Change Management, Engineering Development of the manufacturing and analytical equipment, Storage and Distribution. Revamping of the production area.

Aston Life Sciences 2012 – 2013 [1 year]

Senior QA Validation Consultant:

- QA Validation Senior Consultant. For Philip Morris International, on Modified Risk Tabaco Products new FDA regulations: Commissioning, Qualification and validation of all equipment and processes to put in conformity to the regulations. Preparation of documentations for submission to the F.D.A. Engineering design and drawing of the first factory for the client with the follow up of the new line installation (area, HVAC, black piping, clean piping, steam, purified water, …)
- Work closely with New Product team, quality to establish and document the master validation plan in conformance with the system design specification. Plans, coordinates and executes design verification testing to directly support the master validation plan. Participates with the New Product team to establish and review the design or process FMEA. Routinely provides assurance guidance and direction to engineers.
- Work closely with the QA and Regulatory teams to develop, update and implement the new QMS. Realization of supplier's audits (3 done Netherlands, Germany and Italia).
- Packaging of electronic smoking device and new kind of cigarette (it's the IQ actually on the market) with really high-speed manufacturing/packaging, Engineering Development and Validation. Elaboration plan for the Manufacturing Electronic System (Delta V) linked with a Electronic Batch Record (Master Control)

Zimmer Surgical 2012 [1 year]

Senior Project Validation Engineer:

- Product Development Validation Engineer Senior. Process and Validation Evaluation, update of the working area, study of global and local SOPs, update of working method with the team in place and update of all concerned SOPs and batch record. Commissioning, Qualification and validation of all equipment and processes to put in conformity to the regulations as defined by applicable standards i.e. ISO13485, 21 CFR 600 and 820. Preparation of documentations for submission to the F.D.A. Revamping of the production area (workplace, HVAC, equipment,) follow up and supervision of contractor's installation.
- Work closely with product development team, quality to establish and document the master validation plan in conformance with the system design specification and electrical testing principles. Plans, coordinates and executes design verification testing to directly support the master validation plan. Participates with the product development team to establish and review the design or process FMEA. Routinely provides assurance guidance and direction to product development engineers.
- Work closely with the QA and Regulatory teams to develop, update and implement the new QMS, PFMEA, Risk Analysis, CAPA, Change Management, and Deviation Management.

VS Consult Services 2001 – 2012 [11 years]

Owner, Managing Director, Principal Trainer and Principal Project Manager & Validation Engineer Senior

- Specialized in project management in both engineering and validation, VS Consult Services provided specific advices in the design and the improvement of production areas, premises & equipment (OEE) ; improvement of material and personnel flows in compliance with the regulations (cGMP, GMP, ISO, ...), and an experienced support for commissioning, qualification, process validation, cleaning validation, computerized system validation & cold chain management, ...
- VS Consult services offered to its clients its expertise in Quality Assurance. Our team of experienced consultants provided the most relevant support and solutions in the management of your quality systems adapted to your needs. Among other services we offered our help and assistance in:
    - Execution of external companies' audits (supplier, subcontractor…) or internal audits
    - Preparation for and follow-up of regulatory audits (Customer, MOH…)
    - Writing and updating of quality documents
    - Writing of technical and quality agreements with your customers and your suppliers
    - Updating and implementation of different QA processes (change control, CAPA, deviation, complaints, …)
    - Implementation of follow-up and monitoring tools for your different quality processes
    - Implementation and follow-up of continuous quality improvement plan

- Our mission was to bring relevant solutions to the clients adapted to their needs. Our motto is flexibility, quality, availability and adaptability. The clients trusted us for the management of their engineering projects, their validation projects and their quality systems (QA). Construction quality as part of construction management for renovation of an API plant.
- The Management team provided trainings in Engineering, Validation, Qualification, Commissioning, and Q.A.:
    - Study and development of area and equipment with conception of documents for approvals ISO 9000, European rules and FDA.
    - Commissioning of area and equipment with conception of documents for approvals ISO 9000, European rules and FDA.
    - Qualification of area and equipment with conception of documents for approvals ISO 9000, European rules and FDA.
    - Validation of process and computerised system with conception of documents for approvals ISO 9000, European rules and FDA.
    - GMP, management of quality, with conception of documents for approvals ISO 9000, European rules and FDA.
    - Internal audit, customer audit, supplier audit, with conception of documents for approvals ISO 9000, European rules and FDA.
    - Preparation Audit for European pharmacopeia and FDA Regulation
- The management team also realised audits in preparation of the regulations' inspections: Medtronics (Fourmies FR), Diagast (Loos FR), GSK sites and subcontractors (France, Germany, USA, Canada, Italia, …), Synthexim (Calais FR), Besins Manufacturing (Drogenbos BE) and (Montrouge FR), Catalent (Brussels BE), Lundbeck and Elaiapharm (Sophia-Antipolis France) …

Project Manager & Senior Validation Engineer Baxter (Lessines, Belgium)

- For BDCE department, relabelling area study, update of the working area and introducing of a printing room (revamping, commissioning and validation), study of global and local SOPs, update of working method with the team in place and update of all concerned SOPs and batch record in compliance with current Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and regulatory requirements as defined by applicable standards i.e. ISO13485, 21 CFR 600 and 820.
- PFMEA, Risk Analysis, CAPA, Change Management, Process Improvements, Serialization, Engineering, Qualification and Validation.

Senior Cleaning Validation Consultant CAF-DCF (Brussel, Belgium)

- Strategy synchronization of the cleaning (validation and in routine) between all departments and the site in Holland, study of global and local SOPs, update of working method with the team in place, proposal of a new Cleaning strategy in compliance with current Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and regulatory requirements as defined by applicable standards i.e. ISO13485, 21 CFR 600 and 820. Study of sterilization methods, optimization and update of sterilization cycle depending on sterilizing materials (plasma and semi-finished products) and process steps.
- PFMEA, Risk Analysis, CAPA, Change Management, Process Improvements, Engineering, Sterilization, Qualification and Validation

Project Manager & Cold Chain Manager Consultant GSK (Wavre, Belgium)

- For Warehouse QA and GQA, Project Management of equipment and trailer's validation, study of global and local SOPs, update of working method with the team in place, Project Management of a new "Cold Chain" strategy with product impact study. Development of this strategy for the GSK Bio sites overall in the world with the global QA department. "Cold Chain" management, continuous lean of the process, the flow, validations, documentations. Taking part in the Global Cold Chain Management" for all sites, definition of Roadmap (local and global), RACI, Global SOP, ...
- Serialization, Distribution process improvements, Engineering, Qualification and Validation. Risk Analysis, PFMEA, Due diligence report, TOR and Cold Chain Management

Technical & Validation Project Director GSK (Wavre, Belgium)

- Pandemic Flu Manufacturing Strategy (H1N1) Technical and Validation Project Director for international production sites (US, UK, Canada, Germany...) and subcontractors. Coordination between all services and all sites on validation aspects and documentations. Audits of production sites and subcontractor's sites.
- Global Project Management, transfers, adaptations and coordination of technologies and process between all production's sites (GSK sites and subcontractors for filling, packaging and distribution)
- Engineering, Qualification and Validation, Audits, Risk Analysis, PFMEA, TOR and Cold Chain Management

Engineering Project Manager and QA Validation Consultant Besins Manufacturing (Drogenbos, Belgium)

- Upgrading of documentation, qualification (retrospective and prospective) and for engineering for FDA approvals (HVAC, mixers, production area, filling and packing lines syringes, blisters and bottle dispensers, QC laboratories, …).
- Project Manager of revamping of production areas and QC laboratories (project management from engineering to validation) and preparation and documentation of a new production site (office's, production, laboratories, logistic, …) project management from engineering to validation, follow-up and supervision of contractor's (area, black piping, clean piping (gas, steam and water), purified water, HVAC, clean steam, equipment, ...)
- Work closely with Engineering team and QA to establish and document the master validation plan in conformance with the system design specification. Plans, coordinates and executes design verification testing to directly support the master validation plan. Participates with the Engineering team to establish and review the design or process FMEA. Routinely provides assurance guidance and direction to product development engineers.
- Work closely with the QA and Regulatory teams to develop, update and implement the new QMS. Serialization, Manufacturing/Packaging/Distribution process improvements, Engineering, Qualification and Validation, Audits, Risk Analysis, PFMEA, Due diligence report, TOR Management.

Engineering Project Manager Phact Assist (Châtelet, Belgium)

- For new production areas (production, filling, packaging,) and laboratories (QC and IPC) in Gosselies. Follow-up and supervision of contractor's (area, black piping, clean piping (gas, steam and water), purified water, HVAC, clean steam, equipment, ...)

Project: Engineering Project Manager & QA Validation Consultant ICCE (Brussel, Belgium)

- Consultancy in Validation and revamping for several international projects: Study, revamping and validation of production line of milk, purified water, filling/packaging lines, freeze dryers, sterilizers, aseptic clean rooms, QC laboratories, (project management from engineering to validation with follow up of contractor's during construction) for several pharmaceutical's industries (Novartis Suisse, Candia France, Spimaco Saudi Arabia, GSK …).
- Distribution process improvements, Engineering, Commissioning, Qualification and Validation. Risk Analysis, PFMEA, Due diligence report, TOR and Cold Chain Management

Project: Engineering & QA Validation Consultant CMI (Brussel, Belgium)

- Consultancy in Validation and revamping for several national projects: Study, revamping and validation of production area … (project management from engineering to validation with follow up of contractor's during construction) for several pharmaceutical's industries (Janssens, GSK …).
- Distribution process improvements, Engineering, Commissioning, Qualification and Validation. Risk Analysis, PFMEA, Due diligence report, TOR and Cold Chain Management

UCB-Bioproducts 1994 – 2005 [11 years]

Head of Engineering Validation Department:

- Head of Engineering Validation Department for QA & RA Department.
- Development and Validation of W.F.I. Analysis.
- Development and Validation of Cleaning Validation.
- Development and Qualification of Equipment and Instruments Calibration.
- Engineering (project management from engineering to validation), installation, protocols' writing (commissioning, qualification, validation… and procedures of use and maintenance), tests realization and signature of certificate, cleaning and process validation.
- Study, optimization and update of sterilization cycles and depyrogenation cycles depending on materials.
- Development, setup and management of Cold Chain (storage, transfers, transports, …) and associated validations
- Development, study and revamping of QC Laboratories (cold rooms, benches, analytical equipment, material and personnel's flows,). Build up supervision for the three new buildings with contractor's supervision and follow up. (building, electricity, city water, black piping, clean piping (gas, steam and water) clean steam, HVAC, cooling system, …)
- Design, installation and validation of a peptide synthesiser (solid phase) with Delta V as Control system.
- Design, installation and validation of a tanks farm with Delta V as control system.
- Presentation of Engineering, Qualification, Validation, Calibration during 6 FDA audits.
- Audits, API Manufacturing/Packaging/Distribution process improvements, Engineering, Calibration, Qualification and Validation, Risk analysis, PFMEA, Change Management, CAPA, Due diligence report, Cold Chain Management and Shipping Validation.

Languages

English	Fluent
French	Mother tongue
Dutch	Fair