

TONY MOORCROFT

Tel: 860 753 0179

Commissioning and Qualification Program Development and Leadership

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Address: 6363 Zoellners Place, Hamilton, OH 45011, USA

Updated October 30th, 2011

CAPABILITIES INCLUDE

<u>Design Management</u>					
URS Development	Engineering Reviews	Design Qualification	Value Engineering		
<u>Construction Engineering</u>					
FATs	Receipt Verification	Construction QC	Installation Verification	Walkdowns	ETOPs
<u>Commissioning and Qualification</u>					
SATs	Start-up & Debug	Calibration	Operational Verification	IQ/OQ/PQ	
<u>Operation and Maintenance Planning</u>					
System Ownership Transfer	PM Data Acquisition	Job Plans	CAPA		

SUMMARY

Brings to the table a blended strategy based on ASTM E 2500-07 (Specification, Design and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment) and the ISPE Commissioning and Qualification Baseline Guide.

Held Commissioning and Qualification (C&Q) (CQV) leadership positions on large Pharmaceutical and Biopharmaceutical capital projects in Europe, USA, Caribbean and Far East for Pfizer, Centocor, Merck, Amgen and Amylin.

Played a primary role in the development of Amgen's corporate Commissioning and Qualification program and supported program implementation as the Subject Matter Expert on 10 capital projects spread over 6 Amgen sites.

Has a solid HVAC, BMS and mechanical design foundation acquired by serving on projects for Tanvec (now known as Bovis LL Pharmaceuticals) and Jacobs Engineering.

Continues with ease to network across functional groups building project team alliances and finding solutions to integrate workflows to realize effective and efficient project execution.

Positioning Tony Moorcroft on your capital project as the Commissioning and Qualification (C&Q) Leader will significantly contribute to project success.

EMPLOYMENT HISTORY

Jul 2009 to date	C&Q Consultant – Commissioning & Qualification Technology, LLC
Apr 2008 to Jul 2009	Associate Director Corporate Engineering – Amylin Inc
Jan 2004 to Feb 2008	Corporate Engineering, Principal Engineer – Amgen Inc
Dec 2000 to Dec 2003	Director of Tassgold on contract – Merck & Co., Inc
April 1997 to Dec 2000	Senior Validation Specialist – Jacobs Engineering
Jul 1989 to April 1997	Snr. Mech Design Engineer – Tanvec (now known as Bovis LL Pharmaceuticals)
Jul 1984 to Jul 1989	Mech Design Engineer – Tanvec (now known as Bovis LL Pharmaceuticals)

COLLEGE EDUCATION

Southbank University, London, UK	Higher National Certificate in Environmental Engineering
Guildford College of Technology, Guildford Surrey, UK	B Tech in Engineering
Alton College, Alton Hampshire, UK	CGLI Part 1 General Engineering

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SANOFI PASTEUR – Jul 2009 to Date – C&Q Technology Consultant

January 2010 to date (Swiftwater site PA) contracted as the C&Q Execution Lead for the B37 Retrofit Project – refurbishment of the manufacturing wing of the Webster building comprising new and existing equipment

- Developed and implemented execution strategies aligned with the Project C&Q Plan and SOPs
- Providing C&Q timelines and sequence inputs to the project schedule
- Defined and sourced resources required to execute C&Q project activities
- Developed and executed commissioning and qualification protocols
- Progress monitoring and reporting to project/site leadership
- Administrator of facility equipment decommissioning and recommissioning scope
- Administrator of area/system transfer of care custody and control

July 2009 to December 2009 (Acambis site MA) contracted to provide commissioning & qualification services for various projects.

AMYLIN – Apr 2008 to Jul 2009 – Associate Director Corporate Engineering

Assigned to Ohio USA to provide construction and commissioning team management of capital projects including bulk manufacturing, packaging and pilot plant suites together with warehousing and office accommodation (circa US\$250MM).

- Management oversight of capital project construction and commissioning teams.
- Liaison officer assuring seamless coordination between site operations and the project delivery team
- Coordination of care custody and control transfer of areas and systems to Operations
- Administrator of client work requests and change management
- Developer of educational tools, practices, procedures and templates to improve capital project delivery efficiency and cross departmental alliances.

AMGEN – Jan 2004 to Feb 2008 – Principal Engineer

(Jan 2006 to Feb 2008) Assigned to Puerto Rico to cross functionally support, guide and assist all capital projects implementing Amgen's integrated Commissioning & Qualification (C&Q) program – (circa US\$1,200MM).

- Promote an integrated project delivery culture and guide to site groups on meeting the expectations of the C&Q program.
- Improve established site/project execution strategies by enhancing existing cross functional work streams.
- Feed the C&Q Core Team with new principles and concepts realized out of project execution, needs of project teams and industry trends.
- Assist Project Teams to report C&Q Progress.
- Continually improve the Amgen corporate C&Q program policies, practices and procedures.

(Jan 2004 to Dec 2005) Assigned to Rhode Island USA to manage the renovation of laboratory and manufacturing suites together with the construction of a new process development building (circa US\$250MM).

- Coordination and management of the design/construction teams, vendors and specialist service provider.
- Management of the construction quality documentation, commissioning execution and turnover strategies.
- Provider of technical support into to Quality and Validation departments.

Member of Amgen's corporate Commissioning and Qualification Core Team tasked with providing the company C&Q strategy, policies, best practices and procedures together with training materials.

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MERCK (Under Contract) – Dec 2000 to Dec 2003 – Commissioning & Qualification Coordinator

Assigned to Singapore to support the design, construction, commissioning and qualification of Merck's pharmaceutical facility in Singapore (circa US\$ 500MM).

- Commissioning and qualification strategic planning, rollout and alignment of project procedures and templates to meet Quality Unit GMP/GDP expectation.
- Management oversight of construction QC, commissioning and qualification teams.
- Review of executed IQ/OQ Protocols ensuring compliance with procedures and the assisting in the technical closure of discrepancies not requiring re-tests.
- Liaison officer between the Quality Assurance Department and Construction Team providing technical interpretation in both directions
- Preparation of Purified Water OQ Protocol and Room Environmental PQ Protocols.
- Management of preventative maintenance engineering data acquisition and electronic entry into end user Maximo preventative maintenance system.

JACOBS ENGINEERING – April 1997 to Dec 2000 – Senior Validation Specialist

Lead Validation Engineer responsible for process equipment/utilities IQ/OQ for Merck Sharp and Dohme's Pavia Project II Manufacturing Facility in Italy.

Senior Validation Engineer responsible for the validation of Centocor's Biotechnology Pharmaceutical Plant in the Netherlands. Responsibilities also included the design of the new facility HVAC Systems and on site technical expertise to resolve HVAC commissioning issues.

TANVEC (now known as Bovis LL) – Jul 1989 to April 1997 – Senior Mechanical Design Engineer

Validation Engineer, Lead Mechanical Design Engineer, and site based Project Engineer for Pfizer's Pharmaceutical Sciences Building 510 in Sandwich UK.

Lead Mechanical Design Engineer for the design of S.A.I.P.H's Pharmaceutical Production Facility Tunisia.

Lead Mechanical Design Engineer and site based Project Engineer for Laporte Industries, Wallis Laboratories, England.

Lead Mechanical Design Engineer and site based Project Engineer for a Clean / Aseptic processing suite for Cyanamid Iberica in Madrid Spain.

Lead Mechanical Design Engineer for the design of a set of tropical environment suites for ICI, England.

Lead Mechanical Engineer assisting in the design of a clean / aseptic processing suite for Cyanamid UK.

Lead Mechanical Engineer designing front-end HVAC concept schematics for a local consultant to develop together with the detailed design of a purified water and water for injection system for a set of clean room suites for Kahira Pharmaceuticals, Egypt.

TANVEC (now known as Bovis LL) – Jul 1984 to Jul 1989 Mechanical Design Engineer

Mechanical Design Engineer for the front-end design and cost engineering for a pharmaceutical production facility for Apothekernes Laboratorium, Norway.

Mechanical Design Engineer assisting in the design of a solids production facility for C.P. Pharmaceuticals, England.

Mechanical Design Engineer and site based Project Engineer responsible for the relocation and installation of secondary pharmaceutical process equipment and HVAC plant from Welling Garden City to Crawly for SmithKline Beecham.

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Client	Client Location	Facility Type	Scope Of Service
Sanofi Pasteur	USA PA	Pharmaceutical Manufacturing Facility	C&Q project services
Sanofi Pasteur	USA MA	Pharmaceutical Manufacturing Facility	Project C&Q programming, protocol development, site C&Q alignment
Amylin	USA OH	Biotech Manufacturing Facility	Project management oversight of construction and commissioning teams
Amgen	Puerto Rico	ALM Biotech Manufacturing Facility Expansions & site development	Oversight & enhancement of site integrated C&Q, workflows & corporate C&Q program development
Amgen	USA RI	ARI Site Renovations and Biotech Process Development Lab	HVAC, BMS, PCS, Mech design support, project engineering/management & commissioning
Merck	Singapore	Pharmaceutical Production Facility	Cross functional design/construction support, commissioning & IQ lead & OQ support
Merck	Italy	Pharmaceutical Production Facility	HVAC, BMS, process utilities & process system, IQ lead & OQ support
Centocor	Netherlands	Biotech Pharmaceutical Plant	HVAC & BMS design, construction support, commissioning & IQ/OQ qualification
Intel	Ireland	Warehouse to Micro Elec Cleanroom fit out	HVAC, mechanical & BMS design
S.Q.A.R.E Pharmaceuticals	Bangladesh	Solids Production Facility	HVAC, mechanical & BMS design & detailed design team support
Pfizer	England	Pharmaceutical Sciences Building	HVAC, mechanical & BMS design and construction, commissioning & validation support
S.A.I.P.H	Tunisia	Pharmaceutical Production Facility	HVAC, mechanical & BMS design and cost engineering
Laporte Industries / Wallis Labs	England	Solids Facility and Equipment Relocation	HVAC, mechanical & BMS design
Cyanamid Iberica	Spain	Cleanroom (Aseptic / Clean)	HVAC, mechanical & BMS design, project engineering construction support
I.C.I	England	Tropical Environment Facility	HVAC design
Cyanamid	England	Cleanroom (Aseptic / Clean)	HVAC, mechanical & BMS design
Kahira Pharmaceuticals	Egypt	Cleanroom (Aseptic / Clean)	HVAC, mechanical & BMS design, cost engineering & procurement support
Apothekernes Laboratorium	Norway	Pharmaceutical Production Facility	HVAC, BMS & Mech conceptual design and cost engineering.

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C P Pharmaceuticals	England	Solids Production Facility	HVAC, mechanical & BMS design
Pfizer	England	Research and Development Facility	HVAC conceptual design and cost engineering
Roussel Laboratories	England	Cleanroom (Aseptic / Clean)	HVAC, mechanical & BMS design
Smithkline Beecham	England	Solids Facility and Equipment Relocation	HVAC, mechanical & BMS design, project management/engineering & commissioning lead
William Ransom	England	Pharmaceutical Production Facility	HVAC, mechanical & BMS design
Smithkline Beecham	England	Pharmaceutical Production Facility	HVAC, mechanical & BMS design
Madeva	England	Cleanroom (Aseptic / Clean)	HVAC, mechanical & BMS design
Metek	Greece	Liquids Production Facility	HVAC, mechanical & BMS design
Penn Chemicals	Ireland	HVAC Modifications	HVAC & dust collection system design
Schering Plough	Belgium	Pharmaceutical Production Facility	HVAC, mechanical & BMS design
Souflon Pharmaceuticals	England	Cleanroom (Aseptic / Clean)	HVAC design
Upjohn	England	Cleanroom (Aseptic / Clean)	HVAC design
Welcome Foundation	England	Cleanroom (Aseptic / Clean)	HVAC, mechanical & BMS design
Welcome Foundation	England	Liquids Production Facility	HVAC, mechanical & BMS design