Curriculum Vitae

Bart Truijen

■ Professional Profile

In 1990 I got a **pharmacist's degree** and that very same year I started my professional career. Today, I can look back already on more than 25 years of experience as an industrial pharmacist with more than 60 pharmaceutical and food companies.

■ Personally

Nationality:	Belgian	
Year of birth:	21-06-1967	
Family:	2 children, Ferre (3/01/2000) and Lise (18/09/2001)	
Languages:	Dutch:	Mother tongue
	English:	Good
	French:	Moderate
	German:	Moderate
	Spanish:	Basic knowledge
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Period:	Type of education:	Name of school:	Degree:
1980 – 1983	Secondary education Latin – mathematics	St-Lievenscollege Antwerp	n.a.
1984 – 1985	Secondary education Latin – science	St-Lievenscollege Antwerp	n.a.
1985 – 1986	1st candidature Pharmacist	RUCA	with distinction
1986 – 1987	2nd candidature Pharmacist	RUCA	Bachelor of pharmacy with sufficiency
1987 – 1988	1st trial Pharmacy	UIA	with distinction
1988 – 1989	2nd trial Pharmacy	UIA	with sufficiency
1989 – 1990	3rd trial Pharmacy	UIA	**Master of pharmacy** with distinction

Thesis:	"The immunomodular properties of Viscum album (pharmacognosy)."
Special honors:	* Certificate of an **industrial pharmacist** (nr. 1394) since '92. * Recognition as **person in charge for pharmaceutical information** (nr. 600 / see KB of 7/4/'95 concerning the information and publicity for human use).
Seminars/courses:	* Project management (10/1997) * Quality improvement (SWOT-analysis, root quadrants etc...) (4/1998) * Validation course: GxP regulations, Validation Life Cycle and computer system validation (12/2002) * Record management training (Janssen Pharmaceutica) (5/2003) * Electronic signatures accountability training (Janssen Pharmaceutica) (5/2003) * Computerised system documentation training (Janssen Pharmaceutica) (5/2003) * Part 11 awareness training (Janssen Pharmaceutica) (5/2003) * Computer Systems Validation training (Janssen Pharmaceutica) (5/2003) ...

Company Name:	**Pharma & Food Consult**
Period:	5/2005 – Now
Company Profile:	Pharma & Food Consult is a consulting company that provides advice and services to pharmaceutical and food companies.
Function within the company:	Manager / Industrial pharmacist. Freelance consultant.

Activities:	**Scientific information:**
	
	▪ Writing of scientific information for doctors and pharmacists: compendia, flyers, mailings, advertisement etc…
	▪ Information for the public regarding medicines, food supplements and food advice (e.g. on behalf of magazines)
	▪ Writing texts of leaflets, packing and labels
	
	Registration:
	
	▪ Notification files of food supplements
	▪ Registration dossiers:
	  - SPC (summary of product characteristics)
	  - Leaflets
	  - expert reports
	  - collection and interpretation of toxicological, pharmacological and clinical studies
	
	Legislation:
	Follow up of all legislation concerning food supplements, cosmetics and medicines and for Belgium, the Netherlands and for Europe as an entity.
	
	Research & development:
	
	Development of new products
	
	Other services:
	▪ Answering medical and farmaceutical questions
	▪ Quality Assurance (QA) activities
	▪ Validation of computer systems
	▪ Software Quality Management
	  (Quality Manual for software companies with procedures, guidelines and templates)
	  …

Company Name:	**Pharma Consulting & Industries (PC&I), Eede (The Netherlands)**
Period:	4/2004 – 4/2005
Company Profile:	PC&I is a pharmaceutical company, specialized in phytotherapy and nutritherapy. Own GMP-production, but also active in the pharmaceutical industry as a consulting company.
Function within the company:	**Function:** industrial pharmacist **Scientific information:** ▪ Responsible for scientific information to doctors and pharmacists (compendia, flyers, mailings, advertisement etc…) ▪ Information to the public ▪ Scientific information to the sales unit ▪ Scientific files of every product with recent studies ▪ Leaflets/boxes/labeling of every product ▪ Compendia with scientific information **Registration:** ▪ Notification files ▪ Registration coordination ▪ Writing of expert reports **Legislation:** Follow up of all legislation concerning food supplements, cosmetics and medicines and for Belgium, the Netherlands and Europe as an entity. **Research & development:** Development of new products

Company Name:	**Real Software**
Period:	Start: 3/2001 – 4/2004
Functions:	Validation consultant – Analyst - Coordinator

Year-Year:	12/2003 – 3/2004
Project Name:	**Baxter Distribution Center Europe (BDCE)**
Activities:	Validation assessment of the warehouse and distribution Information System Europe (WISE) comprising the following deliverables: ▪ Project Planning ▪ Criticality Analysis ▪ GDP Audit ▪ Assessment of procedures, methodologies and validation documents ▪ Validation Assessment Report

Year-Year:	11/2003 – 12/2003
Project Name:	**Inter contract**
Activities:	▪ Presentation of validation and quality ▪ Review of validation documents ▪ Professional flyer for commercial purposes ▪ Training of sales people on validation ▪ Writing of general validation documents (e.g. Validation Glossary) ▪ Advanced Microsoft Word training ▪ Unified Modeling Language (UML) training: useful for modelling large and complex systems and for business analysis ▪ Coordination of all activities of the Validation & Quality competence center

Company Name:	**Janssen Pharmaceutica, Beerse**
Period:	5/2003 – 10/2003
Project Name:	IVIVC, in vitro – in vivo correlation
Company Profile:	Janssen – Cilag is a leading research-based pharmaceutical company, with more than 19,000 employees worldwide and establishments in about 50 countries. The company markets prescription and over-the-counter medicines for a range of conditions in the areas of gastroenterology, fungal infections, women's health, haematology, mental health, neurology and pain relief.
Project Subject:	Application to develop an in vitro/in vivo correlation (IVIVC) for an extended release drug product. The system is a web-based application to predict the absorption profile in vivo and is used to avoid and substitute clinical tests. The application also permits formulation and manufacturing changes.
Function within the project:	Validation consultant. Validation activities: writing user requirements, functional specifications, test scenarios, risk analysis, GCP compliancy, validation plan, communication with the vendor for reporting bugs and improvement of the application, writing standard operating procedures (SOPs), write training presentations etc…

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Company Name:	**Internal project, Kontich**
Period:	3/2003 – 4/2003
Project Name:	PMWTA (Project Management Web Tracking Application).
Project Subject:	Application that uses a portal system for project managers to create and manage projects. A folder structure is automatically created on the basis of the chosen methodologies (PM and SDLC) and shared documents can easily be modified or managed.
Following standard components are used:	ASP, VBscript, Javascript, VB 6.0 and Visual Studio 6.0. Data storage with usage of Sharepoint Server Webstore or XML-files.
Function within the project:	Test engineer / Technical writer / Quality assurance

Company Name:	**AstraZeneca, Ukkel**
Period:	3/2001 – 2/2003
Project Name:	eCRF (electronic Case Report Forms)
Company Profile:	As one of the world's leading pharmaceutical companies, business of AstraZeneca is focused on providing innovative, effective medicines that make a real difference in important areas of healthcare.
Project Subject:	Electronic Case report forms (eCRFs) of 3 studies (One, Safe and Surf): clinical studies phase IIIb. Web Based Data Capture (WBDC).
Following standard components are used:	ASP, VBscript, Javascript, VB 6.0, Visual source safe, Test Track pro
Function within the project:	- Coordinator helpdesk - Test engineer - Technical writer - Programmer - Quality assurance - Validation activities: write user requirements, functional specifications, technical specifications, test scenarios, Release notes, SATS (system acceptance tests), change management documents (Problem reports etc…).

Company Name:	**VSM Belgium, Kontich**
Period:	2/1994 – 11/2000
Company Profile:	VSM is a pharmaceutical company, specialized in homeopathy and phytotherapy.
Function within the company:	**Function:** responsible industrial pharmacist **Delivery of pharmaceutical medicines:** • Responsible for the following documents in compliance with the current GMP and GDP-rules: standard operating procedures (SOPs), specifications, production protocols, site master plan, job descriptions etc… • Production planning. • Recruit, train and manage 8 persons. **Quality assurance:** **Function:** quality assurance manager • Responsible for assuring that manufacturing operations are performed in compliance with cGMPs and GDPs as well as with company standards. • Implementing and maintaining the quality system. • GMP and GDP compliance: execute inspections/audits. • Review batch records. • Verification and issuance of medicines. • Increase the quality consciousness of the employees. • Product complaint handling: analyze quality deviations and failures, take steps to prevent quality problems like new extra controls and process improvements. Follow-up on and close pending PACARs (Preventive and Corrective Action Requests). • Developing any needed procedures for quality assurance and improvement. • Change control management. • Assess the quality systems of contract manufacturers by performing on-site audits. **Quality control:** **Function:** quality control manager. **Registration:** **Function:** registration coordinator, e.g. contacts with pharmaceutical inspection. **Information:** **Function:** person in charge for scientific information for doctors and pharmacists.

Company Name:	**Pharmacie Daems (Diest)**
Period:	11/1993 – 1/1994
Function within the company:	Provisor pharmacist

Company Name:	**Dolisos**
Period:	9/1990 – 10/1993
Company Profile:	Dolisos is a pharmaceutical company, specialized in homeopathy and phytotherapy.
Function within the company:	Production manager, quality control manager and responsible person for scientific information to doctors and pharmacists.

■ ICT Knowledge

Operating systems:	Windows 98, windows 2000, Windows XP
Languages:	HTML, Visual Basic 6.0, VBscript, SQL, ASP 3.0, CSS, principles of JavaScript, (Introduction to) ASP.NET (using VB.NET).
Specific software & tools:	- Microsoft Word - Microsoft Excel - Microsoft Outlook - Microsoft Powerpoint - Microsoft Visio - Microsoft Visual Basic 6.0 - SQL Server 2000 - CuteFTP pro - Homesite 4.5 - Microsoft Visual SourceSafe 6.0 - Norton Systemworks - SQL server enterprise manager

■ Skills, personality and hobbies

Not mentioned skills: typing blindly and fluently **Personality/assets:** * Analytical attitude: analyzing the details and/or bugs * Go-getter * Critical * Sense of humor * Looking at the result * Communicative / deliberative * Exacting	**Hobbies:** * Sport: VTT (mountain biking), cycling, jogging, tennis and hiking * Making excursions with the family * Geocaching * Film * Cooking * Internet (several websites) * Reading articles about health and other concerns Etc…