Michel HUC
Age : 49
21, chemin de la Favasse
31140 Aucamville
☎+ 33 (0)561 239 349
+ 33 (0)622 086 156
michel.huc@aspe-conseil.eu

PROFESSIONAL ACTIVITIES

Since 2007 — **Founder and General Manager** — Aspe Conseil
R/D and Regulatory Affairs consulting agency — Toulouse

Medicinal products for human use

More than 40 CTD dossiers module 3 “quality” and 2.3 QOS writing (allopathic, phytotherapic and homeopathic products)

Quality expert in more than 40 CTD dossier

More than 10 CTD dossiers modules 2.4 and 2.6 “preclinical” writing (bibliographical applications)

More than 10 CTD dossiers modules 2.5 and 2.7 “clinical” writing (bibliographical applications)

More than 10 MA variations (module 3) drafting

More than 10 PIL user test

Quality documentation audit (5 audits), including CAPA’s SOP assessment

Parallel distribution and import of proprietary medicinal products dossiers writing

Representation of clients with health authorities (meeting and conference): ANSM, CEPS

More than 10 training sessions in GMP/GDP

Medical devices

More than 10 CE marking dossiers writing (class I to III), including risk analysis (ISO 14971), Essential Requirements compliance evaluation, preclinical (ISO 10993) and clinical (ISO 14155, Meddev’s guidelines) reports

QMS implementation (ISO 13485) in 3 companies

QA supervision in 3 companies: QA managers coaching including QMS management (processes, documentation, deviations, complaints, CAPA’s, training of the staff)

Audit (internal and suppliers) (ISO 13485)

Clients assistance during notified bodies audit

Training in MD regulation (directive 93/42/EC) and risk analysis (ISO 14971): 5 training sessions

Food supplements

More than 30 dossiers audit and writing (directives 2002/46/EC and 1924/2006/EC)

Notification to national authorities

Training in food supplements regulation (directives 2002/46/EC and 1924/2006/EC) : 6 training sessions

Cosmetics

Dossiers audit and writing (directive 1223/2009/EC)

Notification to national authorities

Training in GMP (ISO 22716): 2 training sessions

2001-2006	**General manager** **Head pharmacist (Qualified Person)** **Operations and project manager** ***Industry*** **:** 250 employees, 2 plants, 11 M€ budget, 100 millions units manufactured ***Purchasing*** **:** 7 employees, 14 M€ budget ***France & international supply chain*** **:** 400 employees, 24 subsidiaries, 65 M€ turnover ***Industrial and IT project*** **:** 9 employees, 8 M€ investment, 3,5 M€ IT project (SAP R/3) ***R&D*** **:** 13 employees, 2,9 M€ budget ***Regulatory affairs & quality assurance*** **:** 13 employees, 2 M€ budget	Laboratoires Dolisos Groupe Pierre Fabre Toulouse
1998-2001	***Organisation & project manager France & international*** Head pharmacist assistant	Laboratoires Dolisos Groupe Pierre Fabre Toulouse
1995-1998	***Industrial manager*** 80 employees, 2 plants Head pharmacist	Laboratoires Pierre Fabre Cahors
1991-1995	***Plant manager*** 40 employees Head pharmacist	Laboratoires Pierre Fabre Aignan
1989-1991	Quality control manager	Laboratoires Pierre Fabre Aignan
1988 12 months	Trainee Analytical chemistry methods development	Laboratoires MSD Riom
1986 6 months	Trainee Analytical chemistry methods development	Laboratoires Sanofi Montpellier

EDUCATION AND TRAINING

1981	A-level (Baccalaureate C, Academy of Montpellier, France)
1986	Pharmacy doctor (School of Pharmacy, Montpellier University)
1987	Postgraduate diploma in industrial pharmacy (DESS of Pharmaceutical industry)
1994	ICG Business management diploma (IFG Toulouse)
2011/ 2012	ISO 9001 (2 days)
	Certificate of QMS Auditor (ISO 9001) / IRCA (5 days)
	Medical devices European regulation (93/42/EEC and 90/385/EEC) (1 day)
	Medical devices QMS (ISO 13485) (2 days)
	Medical devices risk management (ISO 14971) (2 days)
	Medical devices: ethylene oxide sterilisation (1.5 days)
	Medical devices: irradiation sterilisation (1.5 days)
2013	Medical devices: steam sterilisation (1 day)

LANGUAGES

French: mother tongue

English: fluent speaking, written (I write all dossiers in English)