Curriculum Vitae

Dr. Norman C. Franklin

Education

1957 - 1960	**B.Sc.** (Honours Degree) in Chemistry at the University of Nottingham, England,
1960 - 1963	**Ph.D. in physical organic chemistry** , specialising in the applications of NMR to problems of stereo chemistry also at the University of Nottingham
1963 - 1966.	**Post-Doctoral Fellowship** at the Dept. of Pharmaceutical Chemistry, University of Tübingen, Germany, with research into the use of NMR of distinguish the different isomers of substituted cyclohexyl compounds such as menthols as well as menthylamines, resulting in about 20 publications.

Experience

Since Jan 2004	Principle Associate of **INTERACTIVE CONSULTING Associates Switzerland,** following fusion with Paul Scherer and Partners
Jan 1998 - Dec 2003	**Independent consultant** and **Managing Director** of **INTERACTIVE CONSULTING Associates**, a company specialising in GMP for the pharmaceutical and chemical industry and specifically Quality Management Systems for Active Pharmaceutical Ingredients and their Intermediates. Main business has been **conducting internal audits** of pharmaceutical and active pharmaceutical ingredient (API) manufacturers, including **audits in Germany, Switzerland, France, Italy, Finland, India and China** and **training in GMP** of staff of such companies. Training has been carried out **in Germany, Switzerland, France, Holland, Portugal, Macau and Latvia.** Other major business includes advising development departments on compliance with GMP during the development of new Drug substances and drug products, and preparing DMF for new APIs.
1992 - 1997	**Head of GMP and Documentation** in the Technical Operations Department of the **Pharmaceutical Division of Bayer AG** in Leverkusen, Germany, responsible for the establishment and maintenance of appropriate GMP systems in all world wide manufacturing plants of the division. This to be accomplished by **consultation** in the plants themselves, **training** of their staff, and **auditing** plants **for compliance with GMP**. Simultaneously responsible for "Qualification and Validation systems" at the production sites in Germany. Also responsible for "**Registration Documentation**" describing production processes, in-process controls and validation, etc. Also responsible for "**Change Management**", with responsibility for administration and management of the system for approval of all process changes affecting APIs and drug products. During this period responsible for auditing the GMP Status of suppliers of APIs in China, Japan, Italy, and other contractors in Indonesia, Thailand, Morocco, USA, etc

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Experience, cont.

1993 - retirement	All FDA inspections for Active Pharmaceutical Ingredients carried out at the BAYER AG manufacturing site for APIs in Wuppertal including three Pre-Approval Inspections resulted in **NO Form 483** ever being issued.
1989 - 1992	**Head of Quality Assurance of the Self Medication Division** of Bayer AG in Leverkusen, Germany, responsible for the establishment and auditing of quality assurance systems in factories of this division throughout the world, **particualrly effervescent tablet manufacture.** During this time also responsible for **setting up GMP systems** at active ingredient suppliers in Spain and Japan **including writing Drug Master Files** for such companies.
1987 - 1989	**Head of Quality Assurance of the Agrochemical Division** of Bayer AG in Leverkusen, Germany, responsible for the control and release of raw materials and active ingredients for pesticides
1984- 1987	**Head of Quality Assurance of the Diagnostic Division** of Bayer at Elkhart in the USA, responsible for the control and release of solid and liquid diagnostic products including all the electronic instruments manufactured by the Diagnostic Division. **During this time experience of several FDA inspections.**
1975 - 1984	Responsible for **developing and operating the GMP of the Pharmaceutical Division of BAYER AG according to FDA GMP** Guidelines, including responsibility for developing the system of Qualification and Validation of manufacturing process. This system was inspected by the FDA in October 1980 for 2 weeks in connection with an NDA for an aseptically produced drug product. **No defects were found** and approval was given in 11 months. Responsible for organising and **conducting Foreign Audits** of all Bayer pharmaceutical manufacturing plants through the world. In addition to **auditing** nearly all Bayer AG **active ingredient and drug product plants** in Germany, audits were conducted on the plants in Japan, Indonesia, South Africa, Venezuela, Columbia, Spain, etc
1972 - 1975	Laboratory manager responsible for **Analytical Development and Quality Control of bulk penicillins in the Pharmaceutical Division of BAYER AG**.
1969 - 1971	Laboratory manager responsible for **Development of formualtions and Process Scale-up of ELANCO fungicides and herbicides at Lilly Research Centre, Windlesham, Surrey, England, (Managing Director Dr. Mel Perlmann).**
1966 - 1969	Laboratory manager responsible for **NMR, IR and Physical Methods Development including Chromatographic separations, (GC and TLC) of new synthetic substances at Lilly Research Centre, Windlesham, Surrey, England, (Managing Director Dr. Mel Perlmann).**

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Representation

1998 - 1999	**LEADER** of the European Industries delegation to the ICH Q 7 Expert Working Group (EWG) of the **International Conference on Harmonisation (ICH)** on **GMPs for Active Pharmaceutical Ingredients (APIs).** **NOTE** This work resulted in the publication of the **ICH Guide on GMP for APIs** which was adopted in Europe in July 2001 and by the FDA on Sept 25, 2001.
1997 - 1998	Representative of **E**uropean **F**ederation of **P**harmaceutical **I**ndustries (**EFPIA**), on the **TABD**, - the **T**rans **A**tlantic **B**usiness **D**ialogue - which is the business meeting between the USA and the EU to provide the support for the Mutual Recognition Agreements between the USA and the EU
1995 - 1998	Member of the **EFPIA** "**Mutual Recognition Committee**" which prepared the European industry views on the GMP Mutual Recognition Agreement between the EU and the FDA and briefed the negotiators on the acceptable and non-acceptable points of this agreement.
1995 - 1996	**EFPIA** representative and **Chairman of the EFPIA / CEFIC Working Group** which drew up the joint **EFPIA / CEFIC Guidelines on GMP for Active Ingredient Manufacturers**, published in August 1996
1995 - 1997	Chairman of the **EFPIA Working Group on "GMPs for Active Ingredients"** which drew up the original EFPIA GMP Guideline for API manufacturers.
1993 - 1997	Founding member of the German VFA (Association of Research based Pharmaceutical Manufacturers) **GMP / QA Group** which provides evaluation and comments on proposed laws and regulations affecting pharmaceutical manufacture such as GMP or the PIC Guidelines.
1993 - 1996	Representative of the German pharmaceutical industry on the **International Standards (ISO) Committee** drawing up an ISO Standard on the Aseptic Manufacture of Healthcare products (i.e. Pharmaceuticals and Diagnostics), ISO Standard 13408.
1987 - 1989	Representative of Bayer AG on **CIPAC**, the **C**onfederation of **I**nternational **P**esticides **A**nalytical **C**ommittees, responsible for the development of internationally accepted analytical procedures for pesticides developed by Bayer
1982 - 1983	Representative of the German chemical and pharmaceutical industry at the **OECD** in Paris on the **introduction of GLP** in the toxicological testing of chemicals and pharmaceuticals.

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