

Curriculum Vitae

Dr. Volker Schulze

Summary of Education, Experience and Representation

EDUCATION

- March 1960 **Completion of High School, (Athaneum, Stade, North Germany) with the German "Abitur" (University Admission Qualifications)**
- 1960 - 1962 **Pre-University practical training in pharmacy in a public pharmacy**
- 1952 - 1965 **First degree** taken in pharmacy at the University of Kiel, Germany, with approval as "State Registered Pharmacist"
- 1965 - 1969 **Doctorial studies** under Prof. O.E. Schulz, University of Kiel with final grade "Magna cum laude"
- March 1969 **Military service** as Qualified Pharmacist

EXPERIENCE

- From August 2002 **Senior associate at INTERACTIVE CONSULTING Assoc. GmbH**, Wuppertal, specialising in consulting in Quality Control and Registration activities for the pharmaceutical industry including release procedures according to EU requirements.
- 1995 - 2001 **Qualified Person for the Pharmaceutical Division of BAYER AG.** Main activities have been the assessment of the compliance of all bulk drugs and finished drugs products manufactured by BAYER AG for compliance with the legal requirements before release including assessment of manufacturing conditions, deviations, and test results
- 1991 - 1995 **Head of the Release Control Dept in the Quality Control Dept of Pharmaceutical Division of BAYER AG.** Main activities were the establishment and direction of a group of experienced QC personnel to meet the requirements of the EU Directive of 1991 on the assessment before packaging of bulk drug products.
- 1975 - 1991 **Founding Member** of the Pharmaceutical Division **Auditing Board**, which had the responsibility for **auditing** pharmaceutical plants **for compliance with GMP**
- 1975 - 1991 **Head of the QC laboratory control group for pharmaceutical starting materials** in the QC Department of the **Pharmaceutical Division** of Bayer AG, responsible for the analysis and release of pharmaceutical starting materials including the validation of the analytical methods where required.
- 1969 - 1975 Joined the newly established **Analytical and Quality Control Department of the Pharmaceutical Division** of Bayer AG as laboratory manager responsible for the analysis of bulk pharmaceutical drugs before packaging

OTHER RESPONSIBILITIES

- As laboratory manager: Development of chromatographic test procedures such as TLC, GC and HPLC for pharmaceutical active ingredients and excipients
- Preparation and approval of specifications and test procedures for the registration of pharmaceutical starting materials with local and international drug agencies, (Registration documents)
- Investigations into customer complaints and direction of the necessary laboratory testing when this was called for
- Installation and maintenance of a GMP system meeting both EU and FDA requirements in the laboratories under his control

POSITIONS HELD

- Member since 1985 of the **“COMMISSION 10 B”**, of the European Pharmacopoeia Commission for the Establishment of Monographs in the EP for Active Pharmaceutical Ingredients (APIs)..
- Member since 1980 of the **Commission "Pharmaceutical Chemistry"** of the Deutsche Arzneibuch Kommission, (German Pharmacopoeia).