Curriculum Vitae

Dr. Bernd C. Schade

Overall: 28 years experience in Quality Assurance, Quality Control and Technical Operations of Pharmaceutical Production of Formulations and Active Pharmaceutical Ingredients.
In-depth experience

- in the function of main spokesperson of the site for Authority Inspections (over 20 inspections),
- in performing GMP inspections (over 100) and providing GMP training,
- in GMP training

Received 'Kontrollleiter' (former Qualified Person) status in 1985

2005 to 2008

Responsible for GMP-Compliance of the Bayer Production Site Wuppertal, the major production site for APIs for Bayer. Responsibilities include establishing and harmonization of global Bayer Corporate Policies and Directives and Site Standard Operating Procedures, Self-Inspection-System for the Site, Change-Management Support, heading the Site- Quality-Committee with the Site Management, GMP compliant handling of major deviations/CAPAs and coordination of the on site training. Prepare, accompany and follow up of official government inspections (Germany, USA/FDA and from other countries) as well as customer inspections in all Bayer API sites.
In addition membership of the global Bayer Corporate Compliance Inspectors team; in this function performance of Corporate GMP Self Inspections and GMP evaluations in Bayer subsidiaries world wide as well as key suppliers and contract manufacturers in EU, US, and Asia for the global Bayer Corporate Compliance organization.
Provide GMP-Training to technical managers of Bayer sites worldwide for Bayer QA.

1995 to 2005

Global responsibility within Corporate Compliance Bayer Pharma Leverkusen (all Bayer prescription drugs) for the coordination of all Bayer API audits, planning, execution, report establishing and follow up by Bayer auditors.
Prepare and accompany all Governmental and Customer Inspections in all Bayer API sites world wide.
Perform Self Inspections and key Supplier Inspections for all areas of pharmaceutical production like tablet -, semi solid -, parenteral- and API – production.
Provide GMP-Training to managers and to the leading Top-Management of Bayer Pharmaceutical Operations. Provide Training for the inspectors team of global Bayer Corporate Compliance
Establishing and harmonization of global Bayer GMP – Policies and Directives.

1992 to 1995

Global Responsibility for QA of pharmaceutical Over-The-Counter products and consumer products within the headquarter of Technical Operations in the Bayer Division for Consumer Products. The product ranges were in OTC tablets, ointments and semi solids and Consumer Products like sun care ointments and semi solids, artificial sweetener solid and liquid, insect repellents.
Establishing and harmonizing of GMP-Guidelines for technical operations, coordinate and perform Self-Inspections world wide, establish and coordinate the recall system, survey major deviations.

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1989 to 1992

Director QA/QC at Miles/Elkhart, USA, Consumer Division, a subsidiary of Bayer Pharma Business Unit. Directing all respective functions like release of all materials, release testing, raw material testing, In-Process-Control testing, documentation, change management, validation, qualification, deviations. The QA/QC department had 70 people, the turnover was 30 tons of tablets per day in house and in addition contract manufactured ointments, liquids and aerosols.
Release testing and stability testing of the outsourced ointments, liquids and aerosols was done in house.
For product development for all formulations the department performed the respective analytical development, stability and stress testing for solid, liquid, semi solid and aerosol formulations.
We established the first paperless Laboratory within the world wide Bayer Organization in 1990.

1985 to 1989

Global responsibility of QA for the Business Group Self-Medication for Bayer in Leverkusen. OTC Products were solids, semi solids, liquids.

1980 to 1985

Joined Bayer. Analytical Development, stability testing and testing for formulation research in the Business Group Pharma in Leverkusen

Education: Diploma and PhD in Chemistry and Biochemistry at the Universities of Frankfurt, Konstanz and Regensburg

Languages: German and English fluent; Spanish little;

Accomplishments:

The first paperless Laboratory within the Bayer world wide organization in 1990

The first robotic in a QC lab within the Bayer world wide organization 1991. It performed 150 analyses per day.

Shortened the release time to max. 3 working days for a production scale of about 30 batches per day.