

Name: **Mariann Østergaard Bomholt**
mbo@pharmakon.dk

Employment:

2008 - **Pharmakon (Danish College of Pharmacy Practice)**
Educational Consultant
Continuing education and training within GMP/GDP and subjects related to these areas in compliance with the authorities' requirement for training. Open courses at Pharmakon are held at different levels targeting academics, technicians or operators. Company-specific courses are developed in cooperation with the customer in order to adapt their needs.

Audit as an independent, external expert is performed for different companies in the pharmaceutical industry. Furthermore consultant for external commissioners, e.g. Quality audits and examination of quality systems.

2006 – 2008 **ALK Abello A/S**
Head of Quality Assurance Department.

2004 – 2006 **Unikem A/S**
Head of Quality Department (QA/QC) and Analytical Lab.
Qualified Person.

1997 – 2003 **Orion Pharma A/S**
Head of Quality Department.
Qualified Person.

1994 – 1997 **Danish Medicines Agency**
Medicines Inspector.
Inspections regarding GMP/GDP/GCP/GLP.

1994 – 2008 **External Consultant at Pharmakon**
EU-GMP regler – krav og fortolkninger.

1983 – 1994 **Bispebjerg Hospital Pharmacy**
Pharmacist in Quality Assurance Department and responsible for Microbiological Laboratory.
Head of Production Department for non sterile products.
Head of Quality Department and Qualified Person.

1982 **University of Pharmaceutical Sciences**
Institute of General Chemistry
Educational Assistant – Organic/Inorganic Chemistry.

Languages: **Danish:** Native.
English, Audit level: Speech, reading and writing.

Pharmakon a/s
Milnersvej 42
DK-3400 Hillerød
Danmark
Tel +45 4820 6000
Fax +45 4820 6060
www.pharmakon.dk
CVR nr 10038839

Education:

- 1995: Examinated Lead Auditor (DIEU).
- 1982: MSc (Pharm). Danish University of Pharmaceutical Sciences.
Dissertation: Institute of Pharmacy. Danish University of Pharmaceutical Sciences.
Internship: Albertslund Pharmacy, Denmark.
- 1973: Science high school graduate. Lyngby State School, Denmark.

Continuing education/Courses**GMP/GDP/GCP**

- Dansk EU-formandskab 2012 – hvad sker der på lægemiddelområdet. Pharmakon
- Råvarers kvalitet. Pharmakon
- FDA cGMP Interpretations and Applications. Orion Pharma Finland
- Site Master File. Pharmakon
- Afgangshåndtering. Pharmakon
- Fremstilling af Active Pharmaceutical Ingredients (API). Pharmakon
- Kvalitetsforbedring på Laboratoriet. Selvinspektion. ALK-Albello A/S med Pharmakon
- Medicines Inspectorate training week. Medicines Control Agency UK, Cheshire
- Applied Clinical Trials European Conference 1996. Düsseldorf
- GMP i blodbanker. Pharmakon
- Registrering af lægemidler. Pharmakon
- Fremstilling og validering af sterile lægemidler. Pharmakon
- Practical GCP Compliance Auditing. DIA kursus, London
- NLN Workshop, Stockholm, GCP-Inspection, Requirements, Strategies and Consequences

Communication and Pedagogical courses

- Internal pedagogical training programme, 12 modules - Pharmakon