



Curriculum Vitae

Personal information **Ib Alstrup**

Work experience

1. Employer: Danish Medicines Agency
 - Start date: 012017
 - End date:
 - Position: Medicines Inspector, GxP IT
 - Activities: Inspecting GLP, GCP, GMP, GDP and GVP (all GxP) regulated companies within computer system validation, data integrity and IT security
 - Country: Denmark
2. Employer: Novo Nordisk A/S
 - Start date: 062015
 - End date: 092016
 - Position: Principal Specialist, Computer Systems Validation and Auditing
 - Activities: Principal Specialist in Computer Systems Validation and Auditing of GLP and GCP contract research organisations
 - Country: Denmark
3. Employer: Novo Nordisk A/S
 - Start date: 052010
 - End date: 062015
 - Position: Principal Specialist, Lead Auditor
 - Activities: Principal Specialist and full_time Lead Auditor for audits of suppliers of GxP critical software, equipment and services
 - Country: Denmark
4. Employer: Novo Nordisk A/S
 - Start date: 062006
 - End date: 052010
 - Position: Senior Supplier Quality Assessor, Lead Auditor
 - Activities: QA and Lead Auditor for purchasing of GxP critical products and services
 - Country: Denmark
5. Employer: Novo Nordisk A/S
 - Start date: 022002
 - End date: 062006
 - Position: Senior Quality Assessor
 - Activities: IT QA for GxP critical corporate IT systems
 - Country: Denmark
6. Employer: LM Ericsson A/S
 - Start date: 021999
 - End date: 012002
 - Position: Organisational Quality Manager, Lead Auditor and CMMI Assessor
 - Activities: Quality responsible, process responsible, lead auditor and CMMI assessor for design centre (150 employees) for telecommunications software
 - Country: Denmark
7. Employer: LM Ericsson A/S
 - Start date: 051997
 - End date: 021999
 - Position: Project Quality Engineer
 - Activities: Quality Assurance and Audit of telecommunications software projects
 - Country: Denmark
8. Employer: LM Ericsson A/S
 - Start date: 031991
 - End date: 051997
 - Position: System Designer and Tester
 - Activities: Development and test of telekommunikations software
 - Country: Denmark
9. Employer: Philips Components Research
 - Start date: 061989
 - End date: 021991
 - Position: Product Yield Engineer
 - Activities: Development of test software for test and release of SRAM
 - Country: Netherlands

Education and training

1. Subject: Enlitic
 - Start date: 2019
 - End date: 2019
 - Qualification: Course (1 day): AI
 - Organisation: Implementation and qualification of artificial intelligence (AI) and machine learning (ML) systems
 - Country: United States
2. Subject: Insafe
 - Start date: 2017
 - End date: 2017

- Qualification: Conference (1 day): PV
 - Organisation: PV Conference
 - Country:
3. Subject: EMA GMP IWG
 - Start date: 2017
 - End date: 2017
 - Qualification: Course (3 days): GMDP
 - Organisation: GMDP
 - Country: United Kingdom
 4. Subject: ECA and Concept Heidelberg
 - Start date: 2017
 - End date: 2017
 - Qualification: Course (3 days): Data Integrity
 - Organisation: Data Integrity _ Requirements for a GMP_compliant Data Life Cycle
 - Country: Denmark
 5. Subject: Novo Nordisk internal (consultant advising FDA)
 - Start date: 2016
 - End date: 2016
 - Qualification: Course (2 days): CDISC's SEND
 - Organisation: Implementation of CDISC's SEND protocol
 - Country: Denmark
 6. Subject: Novo Nordisk internal (author of GAMP5)
 - Start date: 2015
 - End date: 2015
 - Qualification: Course (1 day): IT Compliance, Cloud Computing and Data Integrity
 - Organisation: IT Compliance, Cloud Computing and Data Integrity
 - Country: Denmark
 7. Subject: Novo Nordisk internal (ex_MHRA inspector)
 - Start date: 2015
 - End date: 2015
 - Qualification: Course (1 day): GLP Auditing
 - Organisation: GLP Auditing
 - Country: Denmark
 8. Subject: Novo Nordisk internal
 - Start date: 2015
 - End date: 2015
 - Qualification: Course (2 days): ISO 13485
 - Organisation: ISO 13485, MDD and CMDCAS, Key2Compliance
 - Country: Denmark
 9. Subject: ECA and Concept Heidelberg
 - Start date: 2014
 - End date: 2014
 - Qualification: Course (2 days): Cloud Computing
 - Organisation: Cloud Computing and Outsourcing in a GxP Environment
 - Country: Germany
 10. Subject: Novo Nordisk internal (by qualified body)
 - Start date: 2013
 - End date: 2013
 - Qualification: Course (2 days): Medical Device Directive
 - Organisation: Internal audit with focus on MDD requirements, exam passed
 - Country: Denmark
 11. Subject: Novo Nordisk internal (by notified body)
 - Start date: 2008
 - End date: 2008
 - Qualification: Course (2 days): ISO 13485
 - Organisation: ISO 13485, exam passed
 - Country: Denmark
 12. Subject: ISPE
 - Start date: 2008
 - End date: 2008
 - Qualification: Course (2 days): Launch of GAMP 5
 - Organisation: Launch of GAMP 5
 - Country: Denmark
 13. Subject: Learning Tree
 - Start date: 2007
 - End date: 2007
 - Qualification: Course (2 days): SW Quality Assurance
 - Organisation: SW Quality Assurance, exam passed
 - Country: Denmark
 14. Subject: HP
 - Start date: 2007
 - End date: 2007
 - Qualification: Course (3 days): ITIL Foundation
 - Organisation: ITIL Foundation, exam passed
 - Country: Denmark
 15. Subject: Novo Nordisk internal (by former FDA inspector)
 - Start date: 2006
 - End date: 2006
 - Qualification: Course (2 day): GMP Update
 - Organisation: GMP Update
 - Country: Denmark
 16. Subject: Novo Nordisk internal (by former FDA inspector)
 - Start date: 2005
 - End date: 2005
 - Qualification: Course (2 day): GMP Compliance Auditing
 - Organisation: GMP Compliance Auditing
 - Country: Denmark
 17. Subject: IRQA
 - Start date: 2003
 - End date: 2003
 - Qualification: Course (4 day): ISO 9001 Lead Auditor
 - Organisation: Tick_IT ISO 9001 Lead Auditor, exam passed
 - Country: United Kingdom
 18. Subject: Novo Nordisk internal (by former FDA inspector)
 - Start date: 2002
 - End date: 2002
 - Qualification: Course (2 day): cGMP Interpretation and Application
 - Organisation: cGMP Interpretation and Application

- Country: Denmark
- 19. Subject: ECA and Concept Heidelberg
 - Start date: 2002
 - End date: 2002
 - Qualification: Course (2 day): Computer Validation
 - Organisation: Computer Validation
 - Country: Germany
- 20. Subject: Aarhus University School of Engineering (Aarhus Teknikum)
 - Start date: 081983
 - End date: 011989
 - Qualification: BSc Electronic Engineering
 - Organisation: Computer Engineering, Medical Devices
 - Country: Denmark

Additional information

Publications –

Projects –

Memberships

Chairing subgroup under EMA GMP IWG revising EU GMP Annex 11. Member of the e_subgroup under EMA GCP IWG drafting various guidelines, including but not limited to the Guideline on Computerised Systems and Electronic Data in Clinical Trials. Member of the PIC/S subgroup revising the PIC/S Guideline on Data Integrity. Member and contributor to several OECD GLP subgroups on Data Integrity, Cloud Computing and Emerging Technologies (AI/ML).

Other Relevant Information –