



## Curriculum Vitae

### Personal information **Ib Alstrup**

#### Work experience

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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

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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

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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 –