Curriculum Vitae – postgraduate training.

Name:	**Lone Cleveland Andersen**
Birth:	15 September 1962
Nationality:	Danish
Education/year:	M.Sc. Pharm., 1993
Education inst.:	The Danish Pharmaceutical University, Copenhagen
CV updated:	23-MAR-2022

Postgraduate training/ courses/ seminars

2022:

- Webinar; Current Inspection Trends, ECA Heidelberg

2021:

- Dataintegrity – IT & GMP course, Pharmakon, 1 day
- QP annual Forum, ECA Heidelberg, 2 days online seminar
- GDP-practical challenges, Pharmakon, 1 day
- Seminar: How to develop competences in QA and for QP/dQP, WEB seminar arranged by the QP network and PharmaDanmark
- GMP update with Karen Ginsbury, GMP course arranged by IFF Copenhagen, 1 day
- The QP dilemmas, WEB seminar and workshop with the DKMA, arranged by the QP network and PharmaDanmark

2020:

- The QA role, Pharmakon, 1 day in August
- Webinar July 2020: Manufacture of Oral Solid Dosage Forms, ECA Heidelberg, 1 day

Other planned courses in Q1-Q2 2020 cancelled due to the Corona Pandemic:

- *QP; Qualified Person – GMP update, challenges and dilemmas, Pharmakon, 2 days*
- *Process validation, Pharmakon, 2 days*
- *Quality Oversight, Pharmakon, 1 day*

2019:

- GDP 2 – The Quality Management System, Pharmakon, 1 day
- GMP updates, The Danish Pharmaceutical Industrial Association, Copenhagen, 1 day
- GMP for Cannabis; what you need to know, ECA Heidelberg, Heidelberg, 1 day
- GMP: Readiness for IT inspections, Pharmakon, Hillerød, 1 day
- GVP: Pharmacovigilance – an introduction, Pharmakon, Hillerød, 2 days

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2018:

- GxP: Lifecycle Management of Processes, The Danish Pharmaceutical Industrial Association, Copenhagen, 1 day
- GDP with focus on performing temperature mapping of transport vehicles, The Danish Pharmaceutical Industrial Association, Copenhagen, 1 day
- GMP Updates, The Danish Pharmaceutical Industrial Association, Copenhagen, 1 day
- GCP: Clinical Trials with human medicinal products an introduction
- GCP workshop; Clinical Trial Support, The Danish Pharmaceutical Industrial Association, Copenhagen, 0.5 day
- GDP seminar: How to qualify/approve GDP supplies, transporters, vendors, The Danish Pharmaceutical Industrial Association, Copenhagen, 0.5 day
- GDP: Temperature Controlled Storage and Transportation of Pharmaceuticals, inclusive cold chain, ECA Heidelberg, Copenhagen, 3 days
- GMP: Environmental monitoring of classified areas, Pharmakon, Hillerød, 1 day
- GMP: New Eudralex Annex 1 – Manufacturer of Sterile Medicinal Products, The Danish Pharmaceutical Industrial Association, Copenhagen, 1 day
- GDP: Good Supply Chain Practices, The Danish Pharmaceutical Industrial Association, Copenhagen, 1 day
- GMP seminar: Interpretation of new Eudralex Annex 1 incl. experience with environmental monitoring, The Danish Industrial Pharmaceutical Association, Copenhagen, 0.5 day

2017:

- GDP Conference with focus at transportation incl. visit at the Permissible Centre at Frankfurt Airport, ECA Heidelberg, Frankfurt, 2 days
- GMP Seminar; All the basics of filtration, The Danish Pharmaceutical Industrial Association, Copenhagen, 0.5 day
- GMP Seminar: Outsourcing of API manufacturing and audit of CMO's, The Pharmaceutical Industrial Association, Copenhagen, 0.5 day
- GCP Seminar: Introduction to Clinical Trial Regulation No. 536/2014, Clinical Trial Supply, The Danish Pharmaceutical Industrial Association, Copenhagen, 0.5 day

2016:

- GMP Quality Reviews, ECA Heidelberg, Copenhagen, 2 days
- GDP for Management, Pharmakon, Hillerød, 1 day
- GMP Data Integrity course, The Pharmaceutical Industrial Association, Copenhagen, 1 day
- GMP Seminar: QP requirements and interpretation of EudraLex Annex 16, The Danish Pharmaceutical Industrial Association, Copenhagen, 0.5 day

- GMP Seminar: Serialisation , The Danish Pharmaceutical Industrial Association, Copenhagen, 0.5 day

2015:

- Drug/Device Combination Products, Pharmakon, Hillerød, 1 day
- GMP: Aseptic & Terminally Sterilized production, Risk Management, The Danish Pharmaceutical Industrial Association, Copenhagen, 1day
- GMP updates, The Pharmaceutical Industrial Association, Copenhagen, 1 day
- GMP: The role of QP, The Pharmaceutical Industrial Association, Copenhagen, 1 day

2014:

- GDP new EU guidance – latest updates, Pharmakon, Hillerød, 1 day
- GMP Quality Risk Management, Pharmakon, Hillerød, 1 day

2013:

- GMP/GDP Global Supply Chains, PIC/S seminar, Ottawa, 3 days.
- GMP: Validation of computer systems, ECA Heidelberg, Barcelona, 2 days
- GMP: Understanding Pharmaceutical Sterilization, Compliance & Validations Services Ltd., Amsterdam, 3 days.
- GDP: Training and interpretation of new EU GDP guideline, The Danish Health and Medicines Authority, Copenhagen, 1 day
- GDP new EU guidance – latest updates, Pharmakon, Hillerød, 1 day
- GMP: Quality by Design and Analytical Methods, The Danish Health and Medicines Authority, Copenhagen, 1 day
- Professional GMP seminars, various GMP themes and update, The Danish Health and Medicines Authority, Copenhagen, 5 days
- Professional seminar in Blood Legislation and interpretation, The Danish Health and Medicines Authority, Copenhagen, 1 day
- EU GMP, Annex 11; inspection of computer systems, internal course, The Danish Health and Medicines Authority, Copenhagen, 1 day

2012:

- GMP meets GCP, ECA Heidelberg, Copenhagen, 2 days
- GMP for Excipients, ECA Heidelberg, Copenhagen, 2 days
- GMP: Cleaning and Cleaning Validation course, Compliance & Validations Services Ltd., Amsterdam, 3 days
- Professional GMP seminars, various GMP themes and updates, The Danish Health and Medicines Authority, Copenhagen, 5 days
- GMP: Internal course in fraud, The Danish Health and Medicines Authority, Copenhagen, 1 day
- GVP: 2012 EU Pharmacovigilance Training Course, Copenhagen, 3 days

- Professional seminar in Blood Legislation and interpretation, The Danish Health and Medicines Authority, Copenhagen, 1 day

2011:

- GMP: Biotechnology, ECA Heidelberg, Berlin, 2 days
- GMP: Environmental Monitoring, ECA Heidelberg, Copenhagen, 2 days
- GVP: Pharmacovigilance Inspectors Work Group (PhV IWG) Training Course, Antwerp, 3 days
- Professional GMP seminars, various GMP themes and update, The Danish Medicines Agency, Copenhagen, 4 days
- GVP: Professional Pharmacovigilance seminars, The Danish Medicines Agency, Copenhagen, 2 days
- GMP: Seminar: Filters, use, clean ability and validation, Millipore, Copenhagen, 1 day
- GMP: Conference for Medicines inspectors, The Danish Medicines Agency, Copenhagen, 1 day
- Professional GMP seminars, various GMP themes and update, The Danish Health and Medicines Authority, Copenhagen, 5 days
- Professional seminar in Blood Legislation and interpretation, The Danish Health and Medicines Authority, Copenhagen, 1 day

2010:

- Professional GMP seminars, various GMP themes and update, The Danish Medicines Agency, Copenhagen, 4 days
- GMP: Freeze drying - equipment and processes, Scantago, Copenhagen, 1 day
- ISO: DANAK assessor course in DS/EN ISO 17025 Laboratory Standard, DANAK, 3 days
- ISO auditor training, The Danish Medicines Agency, Copenhagen, 1 day
- Internal IT course; pilot-training in Diamant IT system pilot, , The Danish Medicines Agency, Copenhagen, 1 day
- User training course in Diamant IT system, The Danish Medicines Agency, Copenhagen, 1 day
- GVP: Pharmacovigilance IWG meeting at the EMA London, 1 day
- GVP IT course: Pharmacovigilance database Eudravigilance, EMA London, 1 day
- Use and management of GoPro IT system, The Danish Medicines Agency, Copenhagen, 0.5 day
- Professional GMP seminars, various GMP themes and update, The Danish Medicines Agency, Copenhagen, 5 days
- Professional seminar in Blood Legislation and interpretation, The Danish Medicines Agency, Copenhagen, 1 day

2009:

- GMP: Design Space & PAT, DTU ChemiTech, Copenhagen, 2 days
- GVP: Pharmacovigilance – introduction course, Pharmakon, Hillerød, 1 day
- GVP: QA in Pharmacovigilance Post-marketing & Clinical Trials, Pharmakon, Hillerød, 2 days
- GVP: Pharmacovigilance course, The Danish Medicines Agency, Copenhagen, 1 day
- Serology, practical training course, Næstved Blood bank, Zeeland Region, 2 days

- GMP: Clean rooms, Dansk Standard, The Danish Medicines Agency, Copenhagen, 1 day
- HCV seminar blood tests, Danish Transplantation Association, Copenhagen, 0.5 day
- PIC/S seminar: Tissue, cells and blood components, Copenhagen, 4 days
- Professional GMP seminars, various GMP themes and update, The Danish Medicines Agency Copenhagen, 3 days
- Professional seminar in Blood Legislation and interpretation, The Danish Medicines Agency, Copenhagen, 1 day

2008:

- GMP: 3rd Annual Qualified Person Conference, ECA Heidelberg, Munich, 2 days
- Blood seminar: NAT test (blood test/method) by MD. Henrik Ullum, The Danish Medicines Agency, Copenhagen, 0.5 day
- Seminar: Falsifications and fraud, The Danish Medicines Agency, Copenhagen, 1 day
- RA: Regulatory approval of medicines, Pharmakon, Hillerød, 1 day
- GDP: PIC/s seminar; Good Distribution Practise, Krakow, 3 days
- GMP: Risk Management in Sterile Manufacturing, ECA Heidelberg, Copenhagen, 2 days
- GMP: Holm & Halby seminar re. monitoring of clean rooms, The Danish Medicines Agency, Copenhagen, 1 day
- Professional GMP seminars, various GMP themes and update, The Danish Medicines Agency, Copenhagen, 4 days

2007:

- GMP: 2nd Annual Qualified Person Conference, ECA Heidelberg, Berlin, 2 days
- GMP Seminar: Physical particles characterization, Particle Analytical, Copenhagen, 1 day
- GMP: Risk and Science based Manufacturing (Powder & tablets), ISPE Copenhagen, 1 day
- API requirements and legislation, The Danish Medicines Agency, Copenhagen, 1 day
- GMP: QP network meeting, Pharma Danmark, Copenhagen, 0.5 day
- Expectations and rules for employees at The Danish Medicines Agency, Copenhagen, 2 days
- Written communication in public services, The Danish Medicines Agency, Copenhagen, 1 day
- Doc2000, Internal IT course, The Danish Medicines Agency, Copenhagen, 1 day
- LOS Database, Internal IT course, The Danish Medicines Agency, Copenhagen, 1 day
- Introduction course for new employees, The Danish Medicines Agency, Copenhagen, 1 day
- The Quality Management System in the DMA; The Danish Medicines Agency, Copenhagen, 1 day
- Professional GMP seminars, various GMP themes and update, The Danish Medicines Agency, Copenhagen, 3 days

2006:

- GMP: Non-Conformities Handling, Novo Nordisk AS, Kalundborg, 1 day
- KREA leader; creative project mgt. tools, Krea Consult, Høje Taastrup, 2 days
- cLEAN; various LEAN tools allocated to Novo Nordisk AS, Bagsværd, 6 days

- Management: Advanced Power to Influence module 2; Personal leadership and development, Learn 2 Lead Korsør, 4 days

2005:

- Management: Supply Professionals Academy module 1-3, project management and business understanding, Novo Nordisk AS, Copenhagen 6 days
- cLEAN standards, Novo Nordisk AS, Bagsværd, 1 day
- GMP seminar: Handling alarms and interventions, Novo Nordisk AS, Bagsværd, 1 day
- GMP: Non-sterile Drug Products, GMP Compliance & Education, Copenhagen, 2 days

2004:

- Management: Unwritten rules of carrier, DIEU, Copenhagen, 2 days
- Seminar: Market Awareness French Culture, Novo Nordisk AS, Bagsværd, 1 day
- Seminar: Market Awareness Japanese Culture, Novo Nordisk AS, Bagsværd, 1 day
- Seminar: Market Awareness Brazilian Culture, Novo Nordisk AS, Bagsværd, 1 day
- Seminar: Market Awareness American Culture, Novo Nordisk AS, Bagsværd, 1 day
- ISOTrain Training Coordinator Course, Novo Nordisk AS, Bagsværd, 1 day

2003:

- Management: Advanced Power to Influence module 1; personal development, Learn 2 Lead Korsør, 4 days
- GMP in Global Support, module 2, Novo Nordisk AS, Bagsværd, 1 day
- IT course COCPIT; handling customer complaints, Novo Nordisk AS, Bagsværd, 1 day
- GMP: QBIQ UserAR2 database; handlings/use, Novo Nordisk AS, Bagsværd, 1 day
- GMP: Aseptic production, Novo Nordisk AS, Bagsværd, 1 day
- GMP seminar: Clean rooms qualifications, Novo Nordisk AS, Bagsværd, 1 day
- GMP compliance, ECA Heidelberg, Copenhagen, 2 days

2002:

- GMP: Internal practical training in Microbiology, Novo Nordisk AS, Bagsværd, 2 days
- ISO: Process orientation and mapping of business processes, Force Technology, Copenhagen, 2 days
- GMP: Environmental and social evaluation of Suppliers, Novo Nordisk AS, Bagsværd, 1 day
- GMP in Global Support, module 1, Novo Nordisk AS, Bagsværd, 1 day
- New ISO 9001:2000 standard, Force Technology, Copenhagen, 1 day
- ISO training and audit preparations, Novo Nordisk AS, Copenhagen, 1 day

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2001:

- GMP seminar: Millipore Filters, Novo Nordisk AS, Bagsværd, 1 day
- GMP: QMS Compliance with 21 CFR part 11, Pharmakon, Hillerød, 2 days
- GMP: Latest legislation/guidelines, inspection and enforcement trends for FDA's CFR Part 11 in pharmaceutical laboratories, Agilent Technologies, Copenhagen, 1 day
- Outlook 2000, Novo Nordisk AS, Bagsværd, 1 day
- Introduction to A2DB - non-conformity database, Novo Nordisk AS, Bagsværd, 1 day
- GMP: Contract Manufacturing, Pharmakon, Hillerød, 1 day
- Change Control, Novo Nordisk AS, Bagsværd, 1 day
- GMP: FDA and European GMP Compliance for cleanrooms and how the best to meet it, ECA Heidelberg, Copenhagen, 2 days

2000:

- ISO seminar: ISO 9000 Standard, Novo Nordisk , Copenhagen, 2 days
- GMP compliance for Biopharmaceuticals, API manufacturing, Novo Nordisk AS, Bagsværd, 2 days
- GMP: Active Pharmaceutical Ingredients, Daniel H. Gold, Novo Nordisk AS, Kalundborg, 1 day
- Introduction to Statistics, Novo Nordisk AS, Bagsværd, 2 days
- Presentation techniques, Novo Nordisk AS, Bagsværd, 1 day
- Introduction to DBEIS IT System, Novo Nordisk AS, Kalundborg, 1 day
- Fire Fighting, Novo Nordisk AS, Kalundborg, 0.5 day
- Effective communication and cooperation, Technology Institute, Copenhagen, 3 days
- GMP: Requirements for Physical and electronical documentation, Novo Nordisk AS, Bagsværd, 1 day

1999:

- Management: Workers rights Legislation, Management module no. 1 -5, Novo Nordisk AS, Kalundborg, 5 days
- GMP: Applied statistics for chemists, Novo Nordisk AS, Bagsværd, 2 days
- Project management, module 2, Novo Nordisk AS, Bagsværd, 5 days
- GMP: Statistics, Novo Nordisk AS, Bagsværd, 2 days

1998:

- GMP: Preparation and validation of sterile drugs, Pharmakon, Hillerød, 3 days
- GMP: HC*LIMS lab. System, Novo Nordisk AS, Bagsværd, 1 day
- Project management, Novo Nordic AS, Bagsværd, 4 days
- GMP: Cleaning Validation by Rebecca Brewer, Novo Nordisk AS, Bagsværd, 2 days

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1997:

- Certified Auditor/Lead Auditor examination, BSI Training Service, Copenhagen, 5 days
- Introduction to ISO 9000, Force Institute, Copenhagen, 2 days
- GMP: Preparation for FDA inspections, Novo Nordisk AS, Bagsværd, 2 days
- GMP: FDA Pre and Post- approval Inspections, Pharmakon, Hillerød, 2 days
- Report writing skills, advanced level, Novo Nordisk AS, Bagsværd, 3 days
- Internet from the pharmaceutical perspective, Pharmakon, Hillerød, 1 day

1996:

- GMP: Self-inspection and quality audits, Pharmakon, Hillerød, 2 days
- GMP: Change Control, Novo Nordisk AS, Bagsværd, 0.5 day
- Word Perfect Windows 5.2; Novo Nordisk AS, Bagsværd, 1 day

1995 (on maternal leave):

- GMP Compliance Auditing, Novo Nordisk AS, Bagsværd, 2 days
- GMP statistics, Novo Nordisk AS, Bagsværd, 1 day

1994:

- GMP: Quality improvements in Production, international Conference in London, 2 days
- High-level English, Novo Nordisk AS, Bagsværd, 1 day
- GMP: Batch Records Review and Investigation, Novo Nordisk As, Bagsværd, 2 days
- GMP and dissemination, Pharmakon, Hillerød, 3 days
- GMP: Quality understanding; Novo Nordisk AS, Bagsværd,1 day
- Understanding GMP, Novo Nordisk AS, Bagsværd, 2 days
- Introduction to new employees, Novo Nordisk AS, Bagsværd, 1 day