Executive CV Gunhild Klarskov Kristiansen, Ph.D.

P: +45 2851 4413 *Haspegårdsvej 27*
E: gklar@cmcvalueadvisory.com *DK-2880 Bagsværd*
IN: https://www.linkedin.com/in/gunhild-kristiansen/

Key position in focus:

- Project portfolio manager
- CMC/DP/Analytical coordinator
- Due Diligence of CDMO/CRO
- Business development facilitator
- Interim capacity as project manager, coordinator or scientist

Within research, development, manufacturing of pharmaceutical drug products

Professional skills

Experience

- GMP & non-GMP Biopharma: +25Y
- CMO/CRO: +7Y
- Experienced analytical coordinator
- Trained project leader
- Consultant in regulatory documentation & test scheduling

Analytical Techniques

- Development of analytical and biophysical methodologies
- SEC, IEC, RPC, HIC, NPC methods
- Elucidation by LC-MS & MS/MS
- Quality by Design
- Maximizing output by design

Clients

- Direct customer experience
- Client consultancy
- Analytical reporting for Filing
- Presentation and meeting discussion of findings
- Preparation of contracts scoped at analytical aspects

Substances

- Proteins & peptides
- Glycoproteins & glycopeptides
- Antibodies
- Glycans
- Product stability

Personal skills

Strengths

- Senior competence
- High level communication
- Ability to understand and manage details
- Business minded
- Holistic approach

Motivators

- Passion
- Engaging collegues
- Bridging between office and laboratory
- Mutual respect
- Balanced ratio of ”Engine room”
- High performance teams

Contribution to new job position

- High level intergrity
- Scientific curiosity
- Learning culture
- Initiator

Retarders

- Micro management
- Unfocused strategies
- ”Ivory towers”

”Directors cut” of the CV on the following pages

CURRICULUM VITAE

NAME: Gunhild Klarskov Kristiansen
NATIONALITY: Danish
PERSONAL FACTA: Married, two children, 22 and 20 years
ADRESS: Haspegårdsvej 27, DK-2880 Bagsværd
MOBIL: +45 28514413
EMAIL: gklar@cmcvalueadvisory.com

EDUCATION: Ph.D., Analytical Chemistry, University of Southern Denmark and Danish Meat Research Institute,1993,
Cand. Scient., Molecular biology/ Chemistry, University of Southern Denmark,1990.

CURRENT JOB: Senior Advisor at and owner of CMC Value Advisory

Professional experience:

Year	Employment	Job function
2019-	Founder and owner of CMC Value Advisory	Project management Business Development Interim Capacity
2011-2019	Analytical Development, AGC Biologics	Principal Scientist Project management Regulatory client consultant
2009-2011	Protein Characterisation, Biopharm, Novo Nordisk A/S	Research Scientist
2007-2008	Biopharm Research unit, Novo Nordisk A/S	Research Scientist
2000-2007	Development Novo Nordisk A/S	Research Scientist Team Leader
1994-2000	Development Novo Nordisk A/S	Research Scientist Analytical Coordinator
1993-1994	Danish Meat Research Institute	Scientist
1990-93	Danish Meat Research Institute	PhD. student

Professional profile:

Scientific competence	
Analytical & technical skills	• Hands-on experience and development of HPLC /UPLC (SEC, RPC, HIC, NP & IEC) methods for purity profiling of protein based pharmaceutical drugs in early or late product development phase • Collection and stabilisation of LC peaks for characterisation • Solid phase extractions of blood and tissue for LC and LCMS analyses of trace amounts of antibiotics, growth promotors and ochratoxin Software: Microsoft Office (Word, Powerpoint, Excel, Project), SAS JMP (statistics), Sharepoint, WebEx Waters Empower for LC and BiopharmaLynX & MassLynX fo MS Thermos Chromeleon for LC and Excalibur and BiopharmaFinder for MS Protein Metrix´ Intact, Byonics, Byologics and Byomap for MS Wyatts Dynamics for SLS & DLS.
Biophysical & structural	• Expert operator level of HPLC/UPLC (SEC, RPC & IEC), Static and Dynamic Light Scattering, LC-MS and MS/MS

characterisation	• Development of peptide mapping and elucidation by LC-MS/MS for identity and characterisation purposes • Development of methods for and analysis of released glycans and sialic acids • Use and interpret level of results from Differential Scanning Calorimetry, near/far Circular Dichroism, fluorescence, Analytic Ultra Centrifugation, N-terminal sequencing, Isoelectric Focusing, bioactivity assays, Capillary Electrophoresis and general electrophoresis methods.
Formulation and stability of proteins	• Liquid and freeze-dried for i.v, or i.s. of drugs for pre-clinical and phase 1 studies • Per-oral delivery systems for protein • Sustained release, (external collaborations) for pre-clinical studies • Design, perform and report data from forced degradation and stability studies.
Modification	Design of specific digestions site for changes/opening of the tertiary structure to improve the bioactivity of hGH.
Project leadership	
Analytical/ CMC coordinator	• Experience as analytical and drug product coordinator for both early and late development state projects. • Leading transfer team for a project moving from research/external collaborators to development and further to QC • Experienced in coordination of insourcing/outsourcing and cross-functional use of analytical tasks • Direct customer experience in CMO/CRO relations. • CMO/CRO in-side experience as employee
Organisation & structure	
Team leader	Pioneer in use of teams in Novo Nordisk development area.
LEAN, Quality & Regulatory affairs	Participation in Quality Development Planning for defining analytical and characterization packages aligned with product development level, setting DS and DP specifications and establishment of Reference Material (clin. Ph I/II), identification of CQAs, Risk mapping and proposal of control strategies Setting up LC-MS and MS/MS lab and workflows at AGC Biologics for Intact Mass analysis and peptide mapping for product identity and characterization of collected peaks from release LC assays • Qualifying instrument and workflows for result generation to be reported in e.g. NDA/BLA filings Writing input-reports and directly in quality chapters (Characterization and analysis related) in IND/IMPD/MAA/BLA/NDA applications Qualification of equipment according to SOPs; Protocol and report writing: URS, IQ, OQ and PQ Kaizen, PDCA-organized task, value stream mapping, identify, VoC (voice of the customer), organize and implement changes etc. GSP, GDP and GMP in daily work.

Personal skills	English fluently in both spoken and written, German, good both spoken and reading, fair skills in writing, Norwegian and Swedish, fair both spoken and reading Good to engage and motivate others, good to take initiatives, have a flexible attitude. Thrive and grow in a demanding environment with many simultaneous tasks and tight deadlines Life philosophy: Goals are better met in collaboration and by diligence and industry For every challenge there may be more than one solution.

Patents and publications:

Patent issued:

1 US 9,080,200 B2: Andersen M.D.; Kristiansen G.K.; Svane P.C.; Horlyck L.; Schroder M. (Issued: Jul. 14, 2015): "Method of quality control testing a Factor XIII containing sample"

2 EP200907351638(filing date: 2009-Apr-20) / US 12,937,884 (filing date: 2009-Apr-20): Brader, M., Falck, T., Kristiansen, G.K., Novo Nordisk A/S, (2008): "Dry Transglutaminase Composition"

3 DK9300132-A; DK173302-B: Kristiansen G K, Andersen J R, Slagteriernes Forskningsinstitut (1994): "Investigating slaughtered carcasses for detection of unacceptable sulphonamide content - involves automated process of analysis using mass spectrometric method."

Publications & presentations:

4 Kristiansen, G.K.: "Development and Different Uses of Peptide Mapping in the Pharmaceutical Industry", **Presentation** at ESAC 2018 held in Copenhagen, Denmark, Apr-2018

5 Hørlyck, L., Andersen, M.D., Kristiansen, G.K. and Faber J.H: "Strategies for characterization and control of a low-abundant conformational variant", **Poster** presented at WCBP held in Washington DC, USA, Jan-2013

6 Kristiansen, G.K., Hørlyck, L. and Andersen, M.D.: "Dissociation of the homodimer rFXIII molecule upon calcium induced activation and reassociation due to elimination of calcium", **Poster** presented at ISTH held in Kyoto, Japan, Jul-2011

7 Andersen, M.D., Hørlyck, L., Faber, J., Kristiansen, G.K., Kiehr, B. and Olson, E.H.N.: "The two different activated forms of FXIII, FXIIIa* and FXIIIa^{o} have similar structures, catalytic activity and substrate specificity", **Poster** presented at ISTH held in Kyoto, Japan, Jul-2011

8 Kristiansen, G.K. and Andersen, M.D.: "Reversible activation of cellular FXIII by calcium", **Jour. Biol. Chem**. Vol. 286, p. 9833, (2011).

9 Andersen M.D, Hørlyck, L., and Kristiansen, G.K.: Characterisation and measurement of the non-proteolytical activation of rFXIII (rFXIIIa°)", **Poster** presented at WFH held in Buenos Aires, Argentina, jul-2010

10 Kristiansen, G.K.: "Dynamic and Static Light Scattering: From light to size", **Presentation** given at the 5th Annual Biophysical PhD meeting, Holbæk, Denmark, Jun-2010

11 Kristiansen, G.K.; Hach, M.; Jars, M.U. and Bayne, S.: Verification of disulfide bridges and deamidation site in enzymatically digested biosynthetic proteins by online ESI-MS/MS. **Poster** presented at the ABRF'99, held in Durham, USA, Mar-1999

12 Kristiansen, G.K.; Langballe P.; Welinder, B. and Sørensen, H.H.: Degradation products of somatropin determined by RP-HPLC analyses: An in-house method on the Ph. Eur.: "Related Proteins" method. **Poster** presented at the 2nd Symposium on the analysis of WCBP held in San Francisco, USA, Jan-1998

13 Kristiansen, G.K. and Sørensen, H.H.: "Characterisation of iodated Methionines in Biosynthetic Human Growth Hormone". **Poster** presented at XIth International Conference on MPSA held in Annecy, France, Sep-1996

14 Kristiansen, G.K., Bojesen, G. and Brock, R.: "Comparisation of Flow injection/Thermospray MS/MS and LC/Thermospray MS/MS Methods for Detection of Sulfonamides in Meat and Blood. **Anal. Chem**. Vol 66, No. 19 (1994)

15 Ph.D. project: "Determination of residue in animal tissue and blood analysed by mass spectrometry". (1993)

16 Kristiansen, G.K., Bojesen, G., Andersen, J.R., Holmsberg, H. and van Poucke, L.: "Qualitative and quantitative determination of sulphonamides in biological matrices by LC MS/MS". **Poster** presented at 8. Nordiske Massespektrometri Konference held in Helsingør, DK, May-1992

17 Kristiansen, G.K. and Holmsberg, H.: "Qualitative and quantitative determination of sulphonamides in biological matrices by LC-MS/MS". **Poster** presented at 12th Int. MS Conference held in Amsterdam, Holland, Aug-1991

18 Kristiansen G.K. and Holmsberg, H.: "Qualitative and quantitative determination of residues in biological matrices by LC-MS/MS", **Presentation** held at FLAIR meeting in Copenhagen, Denmark, Jun-1991

19 Holmsberg H., Kristiansen, G.K. and Petersen, C.T.: "Quantification of ochratoxin A in animal matrices by HPLC". **Acta Vet. Scan**., suppl 1987, (1991)

20 Master: "Peptidsekvensbestemmelse ved "Fast Atom Bombardment" kombineret med kollisionsaktivering". (1990)