

CURRICULUM VITAE

Inger Mollerup

Experience

2018

Independent Consultant, Inger Mollerup Regulatory Consulting. Experienced in:

- Regulatory strategies and plans: Building robust regulatory strategies and plans, facing regulatory reality, interpreting Agency feed-back, navigating the regulatory landscape and optimising Agency negotiations.
- Supporting international global harmonisation by training and presentation on ICH guidelines, first and foremost ICH E17 and ICH Q5E.
- Biosimilars: has actively contributed to regulatory guidelines and pathways for biosimilars, has in-depth understanding and experience of the scientific basics for biosimilar guidelines. Experienced in applying this in advocacy as relevant and in understanding how biosimilar guidelines are applied in the real world.
- Support of international convergence on biosimilar regulations by training both industry and regulatory authorities on biosimilar regulations and scientific basis for data requirements

2017 - 2018

Senior Regulatory Consultant, Regulatory Affairs, Novo Nordisk A/S

- Drives development of strategies for regulatory advocacy. Conducts training on biosimilars both within Novo Nordisk and at international conferences or training courses. Supports key affiliates in the efforts to enhance interactions and engagement with their health authority.

2015 - 2016

Head of Region Pacific CMR (Clinical, Medical and Regulatory), Novo Nordisk

- Coordinated and led aspects of drug development in Region Pacific: Canada, Japan/Korea and Australia

2014 - 2015

Corporate Vice President, RA Insight, Novo Nordisk A/S

- Project management and regulatory responsibility for conducting and reporting the interim analysis for the Cardiovascular Outcomes Trial DEVOTE, to support US FDA regulatory approval of Novo Nordisk's next generation insulins, Tresiba® and Ryzodeg®. To maintain the integrity of the ongoing trial while the interim analysis was conducted, submitted, and acted upon by the FDA, and also until completion of the full trial, only a small team working in seclusion was unblinded to the interim results.

2009 - 2014

Corporate Vice President, Regulatory Affairs, Novo Nordisk A/S

- Regulatory oversight and responsibility for the insulin degludec franchise including CMC, nonclinical and clinical areas leading to marketing authorisations in EU, US, Japan and a number of additional countries. Has in this capacity overseen a number of license application and approval projects with multiple agency consultations and interactions in several regions of the world including USA (incl. Advisory Committee preparations), EU, Japan, China, Canada, India, Latin America and Southeast Asia.

2004 - 2009

Vice President, Regulatory Affairs, Novo Nordisk A/S

- Regulatory oversight and responsibility for new products including CMC, nonclinical and clinical areas. Products covered included both coagulation factors and insulins.

Responsibilities included ensuring approvals of Clinical Trial Applications and developing regulatory strategies targeting global regulatory approvals.

2003 ó 2004

Project Vice President, NovoSeven Support, Novo Nordisk A/S

- Leads global development and life cycle management efforts for NovoSeven encompassing line extensions, 2nd generation processes, optimisation of product profitability
- Responsibility covers development, documentation, regulatory approval and implementation

2000 ó 2002

Vice President, Protein Process Development, Novo Nordisk A/S

- Leads functional area of Protein Process Development (6 departments, 130 people) encompassing cell culture and downstream processes, analytical development and virology. Major projects in this period: rFVIIa, Insulin analogues, Glucagon Like Peptides
- Responsible for development, documentation, scale-up, process validation and transfer of processes to production
- Responsible for state-of-the-art biologics GMP pilot plants including manufacture of drug substance for clinical supplies
- Built strong leadership team and trained 4 new dept. managers
- Established 2 new departments to ensure the performance as the area grew
- Developed short and long term strategies for technology development within cell culture and downstream process development. More than 3 new initiatives started in this field with industry and university partners.

1990 ó 2000

Manager, Protein Purification, Novo Nordisk A/S

- Leads Protein Purification department (45 staff: 15 scientists, 29 laboratory and engineering technicians, 1 administrative) responsible for downstream process development and documentation for new recombinant therapeutic proteins
- Manufacture of clinical supplies, scale-up and transfer of processes to manufacturing.
- Established state-of-the-art biologics GMP pilot plants comprising both traditional separation methods and high pressure reverse phase process chromatography.
- Downstream processes for a number of therapeutic proteins developed (e.g. rFVIIa, rlyso-plasminogen, rFVIII, rTPO, insulin analogues, GLP1, FFR-rFVIIa, rThrombin).
- Downstream process for rFVIIa transferred to production followed by ongoing optimisation
- Developed and coached staff to a variety of new positions such as project managers, department managers, principal scientists
- Responsible for numerous university and industry research contracts in different areas of separation sciences.
- Developed analytical HPLC method separating subforms of rFVIIa (single-chain, activated FVII and degradation products)

1989 ó 1990

Research scientist, Novo Nordisk A/S

- Developed preparative and analytical HPLC methods for recombinant hGH and various peptides.

1987 ó 1989

Research scientist, Preparative HPLC Laboratory, Novo Industri A/S

- Development and optimisation of preparative reverse phase HPLC methods for purification of insulin from pancreas or of recombinant origin.
- Development of methods for the evaluation of the effect of pore size on the separation efficiency of a given protein.

1976 ó 1987

Research scientist, Insulin Laboratory, Novo Industri A/S

- Responsible for development of recovery process for insulin precursor expressed in yeast.
- Heading process team responsible for developing downstream processes for recombinant glucagon in yeast.
- Ongoing optimisation of extraction and purification methods for insulin extracted from bovine and porcine pancreas. Yield increase of >25% realised, level of purity increased.
- Development of RP-HPLC methods for in-process quantification of insulin in impure process extracts as a substitute for isotope dilution analysis.

Education

1976

M.S. Chemical Engineering, Technical University of Denmark:

Additional education

Professional courses on Regulatory Affairs, cGMP, Biopharmaceutical facility design, technical regulatory requirements for biopharmaceuticals, separation sciences, project management and leadership skills (separate list available).

International Committees

- EuropaBio, member of Biosimilar task force from 2006 - 2012
- EBE (European Biopharmaceutical Enterprises), member of Biosimilar Task Force from 2004-2017
Chair of Biosimilar Task Force from 2010-2011
- Expert member in EFPIA Quality ad hoc group 2007-2008
 - Participated in ICH discussions on Q8-Q11 as scientific expert on biologics
- University College London, Biochemical Engineering Advisory Board from 2002-2005
- IUPAC Committee of Biotechnology: Titular member for Denmark 2000-2002
- Recovery of Biological Products Board: Member from 1996, chair from 1999-2001.
- EFB Working Party Downstream Processing: co-chair from 1999-2002
- Dyax Corp. Scientific Advisory Board 1998 - 2000

International Scientific Community

International recognition (industry and academia) in biotech product development:

- Organised the premier conference within downstream processing, Recovery of Biological Products IX, 1999 and 2006
- Experienced chair of scientific and workshop sessions at top level scientific conferences
- Frequently invited to speak at top level scientific and regulatory conferences
- Multiple scientific papers in international peer reviewed journals
- Multiple posters presented at scientific meetings

Oral presentations, Scientific Panels and other scientific presentations

- Regulatory Considerations, Complex and Synthetic Peptides. DIA Biosimilar Conference, October 2018 in London
- Drug safety assessment for biosimilars: Annual SFDA Conference, September 2018 in Riyadh
- The trend of global clinical trials - Implications of ICH E17: 18th World Congress on Basic and Clinical Pharmacology, July 2018 in Kyoto
- ICH E17 Multiregional Clinical Trials Implementation: Industry Considerations. DIA ICH Day, May 2018 in Beijing
- Considerations of Biosimilar Interchangeability: Naming, Labelling, and Establishment of Reference List, DIA China May 2018 in Beijing

- Key Aspects of Biologicals vs Biosimilars: Production, Quality & Comparability Regulatory Pathway in EU: background; clinical data; product guidance; safety; approved products ABLE and BIO Biosimilars Bootcamp, New Delhi, December 2016
- Biosimilars in EU, regulations and experience: CFDA/CCPIE workshop, Beijing August 2014
- Key Aspects of Biologicals vs Biosimilars - Production, Quality & Comparability: ISPE Symposium on Biosimilars, Istanbul May 2014
- Comparability of biotherapeutic products following manufacturing process improvement: IFPMA/AIPM Conference on Biotherapeutic Medicines, Moscow May 2013
- EBE Policy statements and interchangeability aspects for Biosimilars: Presented on behalf of EBE at the Norwegian Pharmaceutical Industry Seminar in Oslo, December 2011
- Process Changes: Lessons Learned from Innovative and Biosimilar Products, DIA/FDLI Biosimilars Conference, Washington DC, June 2011
- Comparability Studies, Industry Experience, DIA US, June 2010
- Biosimilars ó Linking Quality, Nonclinical and Clinical Characteristics, DIA China, Nov 2009
- Biosimilars: Linking quality, non-clinical and clinical characteristics. Presented and participated in panel at the IABS/HC Workshop on Biologicals related to WHO draft guidance on Biosimilars, Ottawa 2009
- Process Changes and Biosimilars ó Chemical differences matter. Presented and participated in panel at Biosimilar Super Session at BIO International Convention, San Diego, June 2008
- Biosimilar Products, DIA Clinical Forum, Madrid 2007
- Biosimilar Products, EBE/PDA Conference on Biopharmaceutical Development and Manufacturing Challenges in the European Environment, June 2007
- Testified before the US Government Oversight and Reform Committee, Hearing On óSafe and Affordable Biotech Drugs ó The Need for a Generic Pathwayö, Washington DC, March 2007
- Presentation to WHO INN committee on naming of therapeutic proteins, November 2006
- Post Marketing Safety Surveillance Innovator and Biosimilar Products, IBC, Zürich June 2006
- Insulin, EMEA/DIA Workshop on Biosimilars, Paris December 2005
- Biosimilar products: Scientific considerations, IIR London June 2005
- FDA/DIA Scientific Workshop on Follow-on Protein Pharmaceuticals: Moderator in session on Biological Characterisation and Impurities, Washington DC, February 2005
- Comparability and Biosimilars, Science and Regulation, BioLogics Geneva May 2005
- Lessons Learned from manufacturing Biopharmaceuticals. Manufacturing Off-Patent Biologics, IBC, San Diego USA, March 2004
- Maintaining Product Characteristics of Biologics from Early Development to Market: NovoSeven. Presented at the 6th Interlaken Conference on Advances in Production of Biologics, Interlaken 2003 and at the Generic Biopharmaceutical Global Summit, Washington 2003
- Impact of Process Changes on Regulatory Strategy ó NovoSeven Examples. Presented at the IIR Conference on Registration of Biotechnology Products, Copenhagen 2003
- Characterisation of NovoSeven for Technical Transfer and Scale Up. Presented at the Biological Production Forum, Lyon 2003
- Downstream Processing: Implications of new technologies on Process Design. Presented at the EUFEPS conference on Optimising Biotech Medicines: Rational Development of Therapeutic Proteins, Berlin 2002
- Purification of Proteins for Therapeutic Use ó the Power of RPC. Presented at the 3rd HIC/RPC meeting, Athens 2001
- Improvements in Downstream Processing. Presented at IV European Biotechnology Symposium, Amsterdam 2000
- Maintaining Product Characteristics of Biologics from Early Development to Market. Presented at BioLOGIC 2000, Geneva, 2000
- Design and development of ligands for affinity purification of rFVIIa. Presented at Recovery of Biological Products IX, Whistler 1999.
- Recombinant Factor VII: Process Design and Product Purity. Presented at IBCø Biological Safety and Production, Boston 1999

- Analytical RPC for early process development of recombinant therapeutic proteins. Presented at ISPPP Vienna, 1998.
- The effect of process design on the bioprocess reproducibility for therapeutic protein production. Presented at the 3rd European Biotechnology Symposium, Glasgow 1998.
- rFVIIa: Process Changes after registration in the European Union. Presented at the ACS annual meeting, Boston, August 1998.
- Process RPC: A Workhorse in Protein Production. Presented at the δEuropean Forum - Advances in Industrial Downstream Processingö, Stuttgart 1998.
- Production of Recombinant Glucagon. Inger Mollerup et al. Presented at the 4th Interlaken Meeting on Production of Recombinant Proteins, Interlaken 1997.
- Insulin: A case of continuous development. Inger Mollerup et al. Presented at Recovery of Biological Products VIII, Tucson 1996.
- Chromatographic purification of glucagon. Inger Mollerup et al. Presented at ACS spring meeting, New Orleans 1996.
- The use of RP-HPLC for measuring activation and cleavage of rFVIIa during purification. Inger Mollerup et al. Presented at: Recovery of Biological Products VII, San Diego 1994.

Teaching and training:

2018	<u>APEC and CoRE Duke-NUS Medical School Graduate programme on Biotherapeutics and Biosimilars, Singapore (October)</u> Key learnings from existing guidelines governing the regulations of biosimilars. Defining and handling non-comparable biologics Challenges in industrialisation of biosimilars Extrapolation of therapeutic indications
2017	<u>The PKU APEC Regulatory Sciences Center of Excellence (CoE), Beijing (December)</u> ICH E17 and MRCT Planning: Considerations Related to ADRs and Managing Risk <u>APEC Biotherapeutics Workshop, Lima, Peru (November)</u> Q5E: How to do Comparability: Interpretation of the data, risk-based understanding of changes, acceptance criteria; Highlights on major guidelines (ICH, WHO, etc.) governing the regulation of biosimilar; Getting into clinical trials: Clinical trial methodology with specific emphasis on biosimilars (insulin case included)
2011-2014	<u>Copenhagen Business School (CBS) BioBusiness and Innovation Platform:</u> Introduction to Regulatory Affairs
2000-2005	<u>Pharmaceutical Process Academy (Novo Nordisk internal course)</u>
1999-2009	<u>Massachusetts Institute of technology (MIT): Advanced Downstream Processing</u>
2002-2006	<u>Copenhagen University, Master of Industrial Drug Dev.: Downstream Processing</u>
1987-1991	<u>Novo Nordisk internal course: Protein chromatography</u>

Conference chairmanships:

- WCBP 2000, 2003, 2004, 2005 and 2007: Workshop co-chair, chaired workshops on biosimilars in 2005 and 2007
- CMC Forum Europe, Programme Committee and frequent session chair, 2008 and onwards
- Recovery of Biological Products:
 - Phoenix 2006 Conference co-chair with Brian Kelley (Wyeth Biopharma) and Jorg Thommes (Biogen Idec).
 - Whistler 1999: Conference co-chair with Stuart Builder (Strategic Biodevelopment) and Charles Cooney (MIT).
 - Recovery of Biological Products X, Cancun 2001: Session co-chair with Ken Taksen (Pfizer): Scale up challenges for Recombinant Biotherapeutics
 - Recovery of Biological Products VIII, Tucson 1996: Session co-chair with Charles Gooch (Chiron): Primary separations/integrated product recovery

- Recovery of Biological Products VI, Interlaken 1992: Session co-chair with Bill Hancock (Genentech): Analytical session.
- IV European Biotechnology Symposium, Amsterdam 2000: Session chair
- European Forum - Advances in Industrial Downstream Processing, Stuttgart 1998.: Session chair.

Scientific papers:

- Hanne Theilgaard, Inger Mollerup, Ida Carøe Helmark, Lars Endahl, MSc, Shawn Hoskin, Anders Hvelplund, Lene Klixbüll Amby, Alan C. Moses, on behalf of the DEVOTE Study Group: Developing, Planning and Conducting an Interim Analysis: Lessons From the DEVOTE Cardiovascular Outcomes Trial (Trial Comparing Cardiovascular Safety of Insulin Degludec Versus Insulin Glargine in Patients With Type 2 Diabetes at High Risk of Cardiovascular Events). Therapeutic Innovation & Regulatory Science, 1-8, 2018.
- Mounho, B., Phillips, A., Holcombe, K., Grampp, G., Lubieniecki, T., Mollerup, I. and Jones, C.; Global Regulatory Standards for the Approval of Biosimilars. FDLI Journal, Vol 65, No 4, 819-837, 2010
- Hubbuch, J., Brixius, P., Lin, D., Mollerup, I., Kula, MR; The influence of homogenisation conditions on biomass-adsorbent. Biotechnology and Bioengineering (in press 2005)
- Brixius P, Mollerup I, Jensen OE, Halfar M, Thommes J, Kula MR.: Expanded bed adsorption as a primary recovery step for the isolation of the insulin precursor MI3 process development and scale up. Biotechnol Bioeng. 2005 Nov 21;93(1):14-20
- Staby, A., Johansen, I., Wahlstrøm, H. and Mollerup, I.: Comparison of Loading Capacities of Various Proteins and Peptides in Culture Medium and in Pure State. J. Chromatography (accepted for publ. 1998).
- Mollerup, I., Jensen, S.W., Larsen, P., Schou, O. and Snel, L.: Purification and Analysis of Insulin. Encyclopedia of Biotechnology (accepted for publ. 1998)
- Mollerup, I., Kornfelt, T., Oreskov, P. and Tøttrup, H.V: The Industrial Production of Glucagon. In Lefebvre: Glucagon III, Springer Verlag, 1996.
- Mollerup, I., Bayne, S., Halkjær, E., Jørgensen, T., Mandrup, G., Nicolaisen, E.M. and Thim, L: The Use of RP-HPLC for Measuring Activation and Cleavage of rFVIIa During Purification. Biotechnology and Bioengineering, Vol. 48 501-505 (1995).
- Nicolaisen, E.M., Thim, L., Jacobsen, J.K., Nielsen, P.F., Mollerup, I., Jørgensen, T., Hedner, U. FVIIa derivatives obtained by autolytic and controlled cathepsin G mediated cleavage. FEBS Lett. 317, 1993, 245-249
- Snel, L., Damgård, U. and Mollerup, I.: Chromatographia 24, 1987, 329 - 333

Selected Posters:

- Staby, A., Johansen, N., Wahlstrøm, H. and Mollerup, I.: Comparison of Column Capacities of Various Proteins in Culture Medium and in Pure State. Prep 98 and ISPPP 98.
- Christensen, J., Mollerup, I., Lowe, C.R., Sproule, K., Burton, S., Pearson, J. And Podgorski, T.: Identification of a triazine based synthetic ligand for the purification of Factor VIIa. ISPPP 98.
- Jørgensen, T.K., Mollerup, I. and Jacobsen, J.K.: Quantitation of Gla-domainless rFVIIa using weak Anion Exchange HPLC
- Jørgensen, T., Christensen J. and Mollerup I.: Control of the recombinant Factor VIIa autolysis reactions during the purification processes. Recovery of Biological Products VIII, Tucson 1996.
- Mollerup, I. Optimizing selectivity in RP-HPLC protein separation by temperature optimization. ISPPP Heidelberg 1994.
- Mollerup, I., Amsler, R., Jacobsen, K.T., Thim, L. and Toft, A.: Isolation, Purification and Proof of Identity of Glucagon Secreted from Yeast. "International Conference on Separations for Biotechnology", Reading 1987

