

Anne B. Tolstrup, Ph.D.

Owner of AbtBioConsult ApS

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Profile

Anne B. Tolstrup, Ph.D., is an experienced biopharmaceutical industry professional with more than 25 years of involvement in the areas of biologics cell line and process development, MCB/WCB manufacturing and qualification, scale-up, process validation including process performance qualification (PPQ), clinical and commercial GMP manufacturing, genetics analyses, gene therapy including viral vectors technology. She has extensive experience working with regulatory agencies, including FDA, EMA, and national agencies in Europe, both with respect to IND and BLA filings. Since she founded her consultancy company AbtBioConsult ApS Anne has supported more than 50 clients from 13 different countries with various aspects of biologics CMC development, including pre-clinical and clinical CMC development, clinical and commercial GMP manufacturing, strategic support, CDMO collaborations, regulatory filings, and technical due diligences for investment banks and pharma companies. She also serves as Expert Witness.

Experience

AbtBioConsult ApS, Hillerød, Denmark 2018-present

CEO/Founder

Global consulting in bioprocesses with special expertise in cell line development and upstream process development and manufacturing for early/late stage and commercial biological products. Very experienced both with pre-clinical and late-stage CMC development of Biologics, PPQ, audits and regulatory module 3 submissions (clinical and market applications) as well as CDMO selection and management. Experienced with strategic organizational changes for biopharma companies entering the Biologics arena and with technical due diligence of Biologics assets and companies.

BioProcess Technology Consultants/BPTG BDO, Boston, MA, USA 2018-2019

Senior Consultant and Managing Director

Cell line development and manufacturing process consultant in the areas of bioprocess CMC development and manufacturing for early/late stage and commercial products. Technical due diligence and strategic support of companies entering the biologics field.

Biogen, Manufacturing Sciences, Hillerød, Denmark 2015-2018

Sr. Manager Process Management (2016-2018)
Sr. Manager Cell Culture (2015-2016)

Scientific ownership of Large Scale (15.000 L) GMP Drug Substance Manufacturing processes (USP and DSP) for late-stage clinical and commercial manufacturing. Products included Novel Biologics Entities (NBEs) and biosimilars. Responsibilities included Tech transfer, Scale-up, Next-generation technology implementation, PPQ execution, global partners collaboration, investigations, audits including PAIs.

Boehringer Ingelheim, Biberach an der Riß, Germany 2011-2015

Director Cell Culture NBE/Biosimilars (2014-2015)
Director Cell Culture CMB (2013-2015)
Head of Cell Culture II (2011-2013)

Covering >50 internal and external biologics programs: mAbs/bispecifics/biosimilars. Accountable for Expression Vectors, Genetic Testing, Cell Line Development, Media Development, Upstream Process Development, Harvest, Tox Material and Tech Transfer to GMP. Line management of ~110 people.

Symphogen, Ballerup, Denmark 2003-2011

Director, Antibody Expression

Cell line and upstream process development for manufacturing of recombinant antibody mixtures. Design of regulatory strategy for approval of antibody mixtures in close contact with FDA/EMA

Inoxell, Horsholm, Denmark 2001-2003

Director Molecular and Cellular Biology

Intracellular target discovery based on retroviral peptide library screenings in mammalian cells

Pharmexa (former M&E Biotech), Horsholm, Denmark 1997-2001

Project Manager

Responsible for the CellScreen drug discovery program based on retroviral peptide libraries.

M&E Biotech Copenhagen, Denmark 1996-1997

Research Scientist

Development of retroviral peptide libraries

Molecular Biology, University of Aarhus, Denmark 1994-1996

Assistant professor

Lentiviral vectors and HIV functional studies

Education	**University of Aarhus, Aarhus, Denmark** ***Ph.D. Molecular and Cellular Biology*** The tryptophanyl-tRNA synthetase and the membrane protein p106. Characterization of two proteins regulated by interferons	1994
	University of Aarhus, Aarhus, Denmark ***M.S. Molecular Biology and Immunology*** Characterization of an interferon-α inducible membrane protein.	1992
Board and Scientific Advisor Roles	Member of the Danish National Industrial PhD Evaluation Committee	2010-2011
	Board member, BRIC Biotech Research & Innovation Center, University of Copenhagen, DK	2011-2015
	Scientific Advisor for "eCHO Systems" (EU program w/15 PhD grants)	2015-2019
	Committee member for Aftagerpanel for Molecular Biology and Molecular Medicine, Aarhus University, Denmark	2016-2018
	European Society for Advancement of Cell Technology (ESACT) Executive Committee (XC) Officer (Vice Chair)	2019-
	Danish National Biologics Facility, Industrial Advisory Board (chair)	2021-2023
	Danish Technical University (DTU) Bioengineering, Advisory Board Member	2022-
	DTU Board of Representatives	2024-
Professional Associations	Censor for Master and PhD students, Aarhus University and DTU	2005-
	Member of ESACT	2005-
	Adjunct Professorship at Systems Biology, DTU	2010-2015
	Teacher at ESACTs annual Animal Cell Technology Course, Llafranc, Spain	2011-
	ESACT 2017 Scientific Committee (SC) member and session chair, Lausanne, Switzerland	2015-2017
	ESACT2019 SC Chair and Organizing Committee (OC) member, 2019, Copenhagen, Denmark	2016-2019
	Member of American Chemical Society	2018-
	ESACT2022 SC member and session chair, 2022, Lisbon, Portugal	2019-2022
	Synapse (life science connect students' organization at Copenhagen University): Mentor	2020-2023
	ESACT2024 SC member and session chair Edinburgh, Scotland, UK	2022-2024
	Women in Life Science (WiLD) member	2022-
	Medicon Valley Alliance (MVA) member	2023-
	WiLD mentoring program: Mentor	2023-2025

Conferences Oral Presentations and Chair Roles Teachings

Product Quality session chair, 17th PEACe conference, Sept 14-18, 2025, Montreal, Canada

Cell and Gene Therapy session chair, Cell Culture Engineering conference, 27April-01May 2025, Tucson, Arizona, USA

Bispecifics: Different Formats bring different Treatment Opportunities but also different CMC challenges. Invited speaker. Japanese Society for Animal Cell Technology, Nagoya, Japan, Nov 2023

Bispecifics: Different Formats bring different Treatment Opportunities – but also different CMC challenges. Oral presentation, PEACe conference, Sitges, Spain, Sep 2023

Combining cell line development with product quality, purification and bioprocess concerns. Master student yearly course teacher at DTU, 2022-

Udvikling og produktion af biologiske lægemidler – fra ide til patient. Presenter at UNF (Ungdommens Naturvidenskabelige Forening); Nov 13, 2020. Odder Gymnasium, Denmark and on-line.

Next-Generation Biomanufacturing Processes and the Use of Integrated Advanced Process Control Tools. Presented at The Bioprocessing Summit; Aug 13-17 2018. Boston, MA.

How to implement next generation high titer biologics manufacturing at a commercial scale. Presented at the ManuPharma conference, Nov 30-Dec 1 2016. Frankfurt, Germany

Biologics - What will pharma manufacturing processes, technologies and sites look like in 2030? Round-table chair at the ManuPharma conference, Nov 30-Dec 1 2016, Frankfurt, Germany

Taking advantage of bioinformatics and omics technology to optimize CHO host cell lines and bioprocesses for biopharmaceutical Production. Keynote speaker presentation at Japanese Association for Animal Cell Technology (JAACT), Nov 11-14, 2014, Kitakyushu, Japan

New Approaches to Expedite Cell Line Development – Use of FACS Sorting and a Single Round of Cloning. Presented at Cell Line Development and Engineering, Sept 8-10, 2014, Berkeley CA

Systems biotechnology driven development of CHO expression host cell lines and biopharmaceutical production processes. Presented at Cell Culture Engineering May 4-9, 2014, Quebec City, Canada

Impact of High-Throughput Screening on Cell Line Development and Product Quality. Presented at Cell Line Development and Engineering, June 6-8 2012, San Francisco, CA

Cell Culture World, speaker and panel session, 26-28 Feb 2012, Munich, Germany

Cost-Efficient and Consistent Single-Batch Manufacturing of Antibody Mixtures. Presented at Bioprocessing Summit, Aug 24-25, 2011, Boston, MA

Cost-efficient development of recombinant antibody mixtures by single-batch manufacturing. Presented at Recombinant Protein Production (RPP 6), Feb 16-19, 2011, Vienna, Austria

3rd Annual Proteins Congress, speaker, Berlin, 2010

Therapeutic Antibodies Europe, speaker, London, 2010

Second-generation platform based on random integration for single-batch production of recombinant human polyclonal antibody. Presented at Cell Line Development and Engineering, 1-5 March 2010, Prague, Czech Republic

4th Biotechnology and Molecular Biology, speaker, DK 2009

Development of third generation antibody therapeutics: Recombinant human polyclonal antibody products. Presented at the Animal Cell Technology Industrial Platform (ACTIP) meeting, Nov 17-18, 2008, Cambridge, UK

Optimizing Cell Culture Development, speaker, Boston, USA 2008

Drug Discovery Summit, Montreux, speaker, Switzerland, 2008

A cell banking strategy for recombinant polyclonal antibody manufacturing. Presented at Cell Line Development and Engineering, 3-7 March 2008, Prague, Czech Republic

One-pot production of recombinant human polyclonal antibody drug product. Presented at the 8th PEACE conference, 16-20 Sept 2007, Angra dos Reis, Brazil

Production of recombinant human polyclonal antibodies against Rhesus-D in CHO Flp-In cells. Presented at 3rd Recombinant Protein Production Meeting, 11-14 Nov 2004, Tavira, Portugal

Publications

Alexandra Schulz, Trent Munro, Anja Puklowski, Emma Slack, Anne B. Tolstrup* & Kerstin Otte* (*shared last author) (2026): Systematic review and data-driven insights into CHO cell engineering for next-generation antibody production. mAbs vol 18, 2026, NO. 1 https://doi.org/10.1080/19420862.2026.2615475

Anne B. Tolstrup, Steven I. Max, Denis Drapeau and Timothy S. Charlebois (2021): Cell Culture Process Validation including Cell Bank Qualification. Book chapter (37) in Handbook of Validation in Pharmaceutical Processes, 4th Edition, edited by James Agalloco, Phil DeSantis, Anthony Grilli, Anthony Pavell.

Anne B. Tolstrup (2019): ESACT 2019 conference report. BioTechniques, 22 Aug 2019.

Tastanova A, Schulz A, Folcher M, Tolstrup A, Puklowski A, Kaufmann H, Fussenegger M. (2016): Overexpression of YY1 increases the protein production in mammalian cells. J Biotechnol**. 219**:72-85.

Jennifer D. Könitzer, Markus M. Müller, German LeParc, Martin Pauers, Jan Bechmann, Patrick Schulz, Jochen Schaub, Barbara Enenkel, Tobias Hildebrand, Martin Hampel, Anne B. Tolstrup (2015): A global RNAseq-driven analysis of CHO host and production cell lines reveals distinct differential expression patterns of genes contributing to recombinant antibody glycosylation. Biotechnol J.;**10**(9):1412-23

Lore Florin, Søren K Rasmussen, Torben P Frandsen and Anne B. Tolstrup (2014): Manufacturing of complex protein products. Book chapter in Animal Cell Biotechnology (Wagner/Hauser, Eds., Gruyter)

Anja Puklowski, Till Wenger, Simone Schatz, Jennifer Koenitzer, Jochen Schaub, Barbara Enenkel, Anurag Khetan, Hitto Kaufmann, Anne B Tolstrup (2013): BI-HEX-GlymaxX cells enable efficient production of next generation biomolecules with enhanced ADCC activity. BMC Proc. **7** (Suppl 6): P63

Michaela Strotbek, Lore Florin, Jennifer Koenitzer, Anne Tolstrup, Hitto Kaufmann, Angelika Hausser, Monilola A. Olayioye (2013): Stable microRNA expression enhances therapeutic antibody productivity of Chinese hamster ovary cells. Metab Eng. **20**: 157-66.

Søren K. Rasmussen, Henrik Næsted, Christian Müller, Anne B. Tolstrup, Torben P. Frandsen (2012): Recombinant antibody mixtures: production strategies and cost considerations (Review). Arch Biochem Biophys. **526**(2): 159-45.

Søren K. Rasmussen, Lars S. Nielsen, Christian Müller, Thomas Bouquin, Nina T. Mønster, Frank Nygaard, Dietmar Weilguny, Torben P. Frandsen, Anne B. Tolstrup (2011): Recombinant antibody mixtures, optimization of cell line generation and single-batch manufacturing processes. BMC Proc. **5** (suppl 8): O2

Torben P. Frandsen, Henrik Næsted, Søren K. Rasmussen, Peter Hauptig, Finn C. Wiberg, Lone Kjær Rasmussen, Anne Marie Valentin Jensen, Pia Persson, Margareta Wikén, Anders Engström, Yun Jiang, Susan J. Thorpe, Cecilia Förberg, and Anne B. Tolstrup (2011): Consistent manufacturing and quality control of a highly complex recombinant polyclonal antibody product for human therapeutic use. Biotechnol Bioeng. **108**(9): 2171-81.

Christina R. Andersen, Lars S. Nielsen, Alexandra Baer, Anne B. Tolstrup and Dietmar Weilguny (2011): Efficient expression from one CMV enhancer controlling two core promoters. Mol Biotechnol. **48**(2):128-37.

Lars S. Nielsen, Alexandra Baer, Christian Müller, Kristian Gregersen, Nina Terp Münster, Søren K. Rasmussen, Dietmar Weilguny and Anne B. Tolstrup (2010): Single-batch production of recombinant human polyclonal antibodies. Mol Biotechnol **45**:257-66.

Søren K. Rasmussen, Lone K. Rasmussen, Dietmar Weilguny and Anne B. Tolstrup (2007): Manufacture of recombinant polyclonal antibodies. Biotechnology Letters, **29**(6):845-52.

Anne B. Tolstrup, Torben P. Frandsen and Søren Bregenholt (2006): Development of recombinant human polyclonal antibodies for the treatment of complex human diseases. Expert Opinion on Biological Therapy, **6**(9): 905-912.

Finn C. Wiberg, Søren K. Rasmussen, Torben P. Frandsen, Lone K. Rasmussen, Kaja Tengbjerg, Vincent W. Coljee, Jacqueline Sharon, Chiou-Ying Yang, Søren Bregenholt, Lars S. Nielsen, John S. Haurum, and Anne B. Tolstrup (2006): Production of target-specific recombinant human polyclonal antibodies in mammalian cells. Biotechnology and Bioengineering **94**(2):396-405.

Mark Howarth, A Williams, Anne B. Tolstrup, Tim Elliott (2004): Tapasin enhances MHC class I peptide presentation according to peptide half-life. Proc Natl Acad Sci U S A. **101**(32):11737-42.

Anne B. Tolstrup, Mogens Duch, Iben Dalum, Finn Skou Pedersen and Søren Mouritsen (2001): Functional screening of a retroviral peptide library for MHC class I presentation, Gene, **263**, 77-84.

Pedersen, F.S., Lund, A.H., Jespersen, T., Dalum, I., Tolstrup, A., Mouritsen, S., and Duch, M.: Retroviruses in animal cell biotechnology. Meeting report from China-EU Workshop: Applications of biotechnology to Health. 1997.

Anne B. Tolstrup, Anette Bejder, Jan Fleckner and Just Justesen (1995): Transcriptional regulation of the interferon-gamma inducible tryptophanyl-tRNA synthetase includes alternative splicing. J. Biol. Chem., **270**, 397-403.

Jan Fleckner, Pia M. Martensen, Anne B. Tolstrup, Niels O. Kjeldgaard and Just Justesen: Differential regulation of the human, interferon inducible tryptophanyl-tRNA synthetase by various cytokines in cell lines. Cytokine, **7**, 70-77.

Anne Tolstrup, Peter Hokland, Bendt Nielsen, Just Justesen and Marianne Hokland (1993): Expression and regulation of an interferon-alpha-inducible membrane protein p106 on human hematopoietic cells. J. Interferon Res. **13**, 433-441.

Jan Fleckner, Anne Tolstrup, Marianne Hokland and Just Justesen: Expression studies of the human interferon-induced tryptophanyl-tRNA synthetase (γ2) mRNA in various cell types. J. Interferon Res., sup. 1, 1992. s85.

Anne Tolstrup, Nick Hoogenrad, Marianne Hokland and Just Justesen: Characterization of an interferon-α inducible membranprotein, p106. J. Interferon Res., sup. 1, 1991. s158.

Patents

Anne B. Tolstrup, Lars S. Nielsen, Dietmar Weilguny, Christian Müller, Finn C. Wiberg, Jonas H. Graversen. Methods for manufacturing a polyclonal protein. Application WO 2009/129814

Anne B. Tolstrup, Johan Lantto, Finn C. Wiberg and Lars S. Nielsen: Methods for recombinant manufacturing of anti-RSV antibodies. Application WO 2009/030237