

## Curriculum vitae for Per H. Damgaard (PhD)



Owner and founder of GMP4Pharma, established in 2010. A certified partner of Key2Compliance.

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### Personal Data

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Born: 21. November, 1967

Marital status: Married to Jette Finkas. 2 children.

### Education

1995	<p><b>Royal Veterinary and Agricultural University Copenhagen, Denmark</b></p> <p><b>Doctor of Philosophy (PhD)</b></p> <p>Thesis: "Environmental aspects of the bacterial insect pathogen <i>Bacillus thuringiensis</i>"</p>
1991	<p><b>Royal Veterinary and Agricultural University Copenhagen, Denmark</b></p> <p><b>Master of Science</b></p> <p>Thesis: "Sollys inaktivering af <i>Bacillus thuringiensis</i> delta-endotoksin"</p>

<b>Employment, Company, Position, and Responsibilities</b>	
2013 - 2022	<p><b>Novo Nordisk A/S, Inspection Office</b></p> <p><b>Vice President</b>            Planning, executing and follow-up on authority GMP/GDP inspections from worldwide authorities (e.g. DKMA, FDA, China, Russia, Brazil) as well as Notified Bodies (ISO13485, MDD/MDR, MDSAP)</p> <p>Main responsibilities:</p> <ul style="list-style-type: none"> <li>• Acting as bridge between authority and site of inspection in planning of inspections</li> <li>• Corporate host during inspections from authorities</li> <li>• Planning and hosting FDA PAI/PLI inspections</li> <li>• Follow-up on findings from authorities, ensuring consistency in responses and commitments.</li> <li>• Responsible for selection and implementation of new Notified Body according to MDR as well as certification audits according to MDR/MDSAP for new products incl. both physical as well as Software as Medical Devices.</li> </ul>
2006 - 2013	<p><b>Novo Nordisk A/S, Internal/External Audits</b></p> <p><b>Director (Senior Lead Auditor)</b>            Performing GMP audits of manufacturing and QC departments both internally at Novo Nordisk A/S as well at CMO's.</p> <p>Main responsibilities:</p> <ul style="list-style-type: none"> <li>• Planning, executing and follow-up on audits within GMP/GDP</li> <li>• Have performed 100+ audits with a totaling 1.000+ on-site hours</li> </ul>
2005 - 2006	<p><b>Novo Nordisk A/S, QC Finished Products</b></p> <p><b>Director</b>            Responsible for 75 employees, covering control and release of raw materials and aseptic finished pharmaceutical formulation within microbiology, chemical and physical testing.</p> <p>Main responsibilities:</p> <ul style="list-style-type: none"> <li>• Managing the department as well as 3 associate managers</li> <li>• Release of products according to specifications</li> <li>• Validation of analytical methods</li> <li>• Trouble shooting in aseptic filling department e.g. EM excursions etc.</li> </ul>

2002 - 2005	<p><b>Novo Nordisk A/S, Internal/External Audits</b></p> <p><b>Lead Auditor</b> Performing GMP audits of manufacturing and QC departments both internally at Novo Nordisk A/S as well at CMO's.</p> <p>Main responsibilities:</p> <ul style="list-style-type: none"> <li>• Planning, executing and follow-up on audits within GMP/GDP</li> <li>• Have performed 100+ audits with a totaling 1.000+ on-site hours</li> </ul>
2001 - 2002	<p><b>Novo Nordisk A/S, QA Fermentation and Recovery</b></p> <p><b>Department Manager</b> Responsible for building a QA department responsible for releasing of intermediate API (Biotech).</p> <p>Main responsibilities:</p> <ul style="list-style-type: none"> <li>• Setting up a department with 3 associate managers responsible for ensuring GMP compliance of the world largest insulin API manufacturing facility</li> <li>• Building a framework for GMP compliance, knowledge and awareness in the organization</li> </ul>
1998 - 2001	<p><b>Novo Nordisk A/S, Department of Microbiology</b></p> <p><b>Department Manager</b> Building a department from 9 employees to 40+ consisting of both academics and technicians responsible for all types of microbiological analysis of a biotech API from fermentation, recovery and purification.</p> <p>Main responsibilities:</p> <ul style="list-style-type: none"> <li>• Managing the department with a 400% increase in personal</li> <li>• Implementing and validating all types of microbiological methods</li> <li>• Implementing a ISO9001 QMS and receiving certification</li> </ul>
1997 - 1998	<p><b>Novo Nordisk A/S, Department of Microbiology</b></p> <p><b>Cell Bank Microbiologist</b> Testing and release of cells banks from use in commercial manufacturing and Investigational Medicinal Products</p> <p>Main responsibilities:</p> <ul style="list-style-type: none"> <li>• Validating new methods for cell bank testing</li> </ul>

	<ul style="list-style-type: none"> <li>• Testing and release of new <i>Saccharomyces cerevisiae</i> cell banks for insulin, insulin analogues, GLP-1 API</li> <li>• Inoculation of fermentation batches</li> </ul>
1996 - 1997	<p><b>Novartis A/S (Ciba-Geigy), Registration and Development</b></p> <p><b>Registration Associate</b> Writing summaries for the approval of pesticides for agricultural use.</p>
1994 - 1996	<p><b>Royal Veterinary and Agricultural University, Department of Entomology</b></p> <p><b>Associate Research Professor</b> Research responsible in the area of <i>Bacillus thuringiensis</i> and inspect pathology. Managing one technician.</p> <p>Main responsibilities:</p> <ul style="list-style-type: none"> <li>• Planning and executing research</li> <li>• Writing scientific publications</li> <li>• Funding application</li> </ul>
1991 - 1994	<p><b>Royal Veterinary and Agricultural University, Department of Entomology</b></p> <p><b>PhD student</b> Research responsible in the area of <i>Bacillus thuringiensis</i> and inspect pathology. Managing one technician.</p>

<b>External presentations</b>		
<b>Year(s)</b>	<b>Course</b>	<b>Company</b>
2008 -	<p>Developing tailor made GMP courses to:</p> <ul style="list-style-type: none"> <li>Agilent, Air Liquid, ALK Abello, AJ Vaccines, AlfaNordic, Ascendis, Bavarian Nordic, Berendsen Tekstiler, Chr. Hansen, Clauson-Kaas, CMC-Biotech, DB Lab, Ferring, Ferrosan Medical Devices, Glenco Ventilation, Genau and More, GN Hearing, HB Medical, LEO Pharma, Lift-Up, Lundbeck, Neurodan, Neurosearch, Novo Nordisk, Pharmacosmos, Scantago, Schenider, SmartPractice (Mekos), SSI, World Courier</li> </ul> <p>Open courses in Denmark, Japan and China:</p> <ul style="list-style-type: none"> <li>Basic GMP</li> <li>GMP for QC technicians</li> <li>GMP Up-dates</li> <li>GMP for QC</li> <li>GMP for Management</li> <li>EMA &amp; PIC/S Inspections: What To Expect And How To Prepare</li> <li>EU GMP – News and updates</li> </ul>	Key2Compliance, Sweden and Concept Heidelberg/European Compliance Academy, Germany

<b>Educational training taken by Per H. Damgaard</b>
<b>Title and Company</b>
<p><i>Auditing</i></p> <ul style="list-style-type: none"> <li>ISO 13485:2016 Clause by Clause Training Course, BSI (2020)</li> <li>ISO 13485 Lead Auditor, the Knowledge Academy (2020)</li> <li>MDR Auditing – Training of Internal Auditors in Relation to MDR, MEDICO Industrien (2020)</li> </ul>

- Training of internal auditors in relation to country specific requirements within the MDSAP program (2020)
- GMP Compliance and Auditing Sterile Pharmaceuticals, Pharmaceutical Compliance Associates (2003)
- ICH Q7A Auditor Training Course, ECA
- Compliance with the Medical Device Directive 93/42/EEC (MDD)
- QMI 40-hour ISO 9001:2000 QMS Lead Auditor Training Course, QMI/CSA, USA (2002)
- GMP compliance auditing, Pharmaceutical Compliance Associates (1999)

#### *GxP*

- Combination Products, ECA Academy (2021)
- Annex 1 – The Revised Draft, ECA (2020)
- Data Integrity & Chromatography: A Data Governance Approach, Green Mountain Quality Assurance (2020)
- New EU GMP Annex 1 draft 2020, Key2Compliance (2020)
- GMP Updates, IFF (2017)
- Data Integrity Assurance, Green Mountain Quality Assurance (2015)
- Advanced Data Integrity / Train-the-Trainer, Green Mountain Quality Assurance (2015)
- cGMP Interpretation and Application, Pharmaceutical Compliance Associates (2015)
- Process Validation – What the future holds, IFF (2011)
- ICH Q7A Compliance for APIs Manufactured by Cell Culture/Fermentation, ECA
- The Pharmaceutical Laboratory Manager, ECA
- Validation of autoclaves, NN (2003)
- Value adding audits, DIEU (2003)
- Validation of spreadsheets, NN (2003)
- Computer validation, NN (2002)
- Introduction to GCP, Leo Pharma (2001)
- Active Pharmaceutical Ingredients manufacturing, Pharmacon (2001)
- Investigating OOS Test Results, NN (1999)
- Deviation handling, FDA´s API Draft guidance, NN (1999)
- Batch Record Review and Investigations, Pharmaceutical Compliance Associates (1998)
- cGMP Interpretation and Application, Pharmaceutical Compliance Associates (1998)

<p><i>LEAN/Performance Management</i></p> <ul style="list-style-type: none"> <li>• Lean in Service &amp; Administration, DRF Academy (2005)</li> </ul>
<p><i>Management</i></p> <ul style="list-style-type: none"> <li>• Strategic Business Leadership, NN (<i>Winning Team</i>) (2001)</li> <li>• Supply Managers Academy, NN</li> <li>• Labor law for managers, NN</li> <li>• Commercial negotiations techniques, Rommerdahl Udvikling og Anvendelse (2001)</li> <li>• Work environment course for department managers (1999)</li> <li>• Management and Leadership, Holbæk Tekniske Skole (1998)</li> <li>• Management Developments, NN (1998)</li> </ul>
<p><i>Others</i></p> <ul style="list-style-type: none"> <li>• MHRA GMP &amp; GDP Symposium, MHRA (2014)</li> <li>• MHRA GMP &amp; GDP Symposium, MHRA (2013)</li> <li>• PDA/FDA Joint Regulatory Conference, PDA (2012)</li> <li>• PDA/FDA Joint Regulatory Conference, PDA (2011)</li> <li>• PDA/EMA Conference, PDA (2011)</li> <li>• PDA/FDA Joint Regulatory Conference, PDA (2010)</li> <li>• PAT in Microbial QC, European Compliance Academy (2006)</li> <li>• Pharmaceutical Process Academy (Module 1, 2 and Project), NN (2005)</li> <li>• ISPE Nordic Annual Conference, ISPE (2016)</li> <li>• ISPE Biotech Conference – with focus on regulatory issues &amp; possibilities, ISPE</li> <li>• GMP Series Microbiology Laboratory Equipment Validation, American Society for Microbiology, Los Angeles, USA (2000)</li> <li>• Validation Principles for Microbiological Methods and Manufacturing Controls, American Society for Microbiology, Los Angeles, USA (2000)</li> <li>• Clean Room Technology, Centre for Professional Advancement, New Jersey, USA (1998)</li> </ul>

<p>List of publications</p>
<p><b>Peer Review</b></p> <ul style="list-style-type: none"> <li>- Damgaard, P.H. (1991): Sunlight inactivation of the <math>\delta</math>-endotoxin from <i>Bacillus thuringiensis</i> var. <i>kurstaki</i> (In Danish). MSc. thesis, pp. 133. Section of Zoology, RVAU.</li> <li>- Damgaard, P.H. (1993): Colonization potential of <i>Bacillus thuringiensis</i> on barley roots. Report, pp. 52. Section of Microbiology, RVAU.</li> </ul>

- Damgaard, P.H. (1995): Diarrhoeal enterotoxin production by strains of *Bacillus thuringiensis* isolated from commercial *Bacillus thuringiensis*-based insecticides. *FEMS Immunology and Medical Microbiology*, 12, 254-249.
- Damgaard, P.H. (1996): Environmental aspects of the bacterial insect pathogen *Bacillus thuringiensis*. Ph.D. thesis, pp. 63. Section of Zoology, RVAU.
- Damgaard, P.H. (2000): Natural occurrence and dispersal of *Bacillus thuringiensis* in the environment. In J.F. Charles (ed), *Entomopathogenic bacteria: From laboratory to field application*. Kluwer Academic Publication.
- Damgaard, P.H., Abdel-Hameed, A., Eilenberg, J., Smits, P.H. (1998): Natural occurrence of *Bacillus thuringiensis* on grass foliage. *World Journal of Microbiology & Biotechnology*, 14, 239-242.
- Damgaard, P.H., Eilenberg, J., Harding, S. (1994): Environmental assessment of the use of *Bacillus thuringiensis* in Polish forestry. Report, pp. 13. Danish Environmental Protection Agency.
- Damgaard, P.H., Eilenberg, J., Harding, S. (1994): *Bacillus thuringiensis*: In forestry in Denmark and Poland (In Danish). *Skoven*, 10: 11-15.
- Damgaard, P.H., Granum, P.E., Bresciani, J., Torregrossa, M.V., Eilenberg, J., Valentino, L.. (1997): Characterization of *Bacillus thuringiensis* isolated from infections in burn wounds. *FEMS Immunology and Medical Microbiology*, 18: 47-53.
- Damgaard, P.H., Hansen, B.M., Pedersen, J.C., Eilenberg, J. (1997) Natural occurrence of *Bacillus thuringiensis* on cabbage foliage and in insects associated with cabbage crops. *Journal of Applied Bacteriology*, 82: 253-258.
- Damgaard, P.H., Jacobsen, C.S., Sørensen, J. (1996): Development and application of a primer set for specific detection of *Bacillus thuringiensis* and *Bacillus cereus* in soil using magnetic capture-hybridization and PCR amplification. *Systematic and Applied Microbiology*, 19: 436-441.
- Damgaard, P.H., Larsen, H.D., Hansen, B.M., Bresciani, J., Jørgensen, K. (1996): Enterotoxin producing strains of *Bacillus thuringiensis* isolated from food. *Letters in Applied Microbiology*, 23: 146-150.
- Damgaard, P.H., Smits, P.H., Hansen, B.M., Pedersen, J.C., Eilenberg, J. (1994): Natural occurrence of *Bacillus thuringiensis* on cauliflower and grass foliage. *IOBC/WPRS Bulletin*, 17: 262-265.
- Damgaard, P.H., Malinowski, H., Glowacka, B., Eilenberg, J. (1995): Degradation of *Bacillus thuringiensis* serovar kurstaki after aerial application to a Polish pine stand. *IOBC/WPRS/EPRS Bulletin*, 19: 61-66.
- Eilenberg, J., Damgaard, P.H. (1996): Interactions between *Bacillus thuringiensis* and a pine forest environment. *Integrated Management of Forest Lymantriidae, Proceedings*, 83-91.
- Eilenberg, J., Damgaard, P.H., Bresciani, J., Singh, M., Larson, R. (1994): Fungal, bacterial and protozoan pathogens on *Delia radicum* and *Delia floralis*. *IOBC/WPRS Bulletin*, 17: 27-



30.

- Eilenberg, J., Damgaard, P.H., Thomsen, L. (1998): Activity of *Bacillus thuringiensis* strains against *Pieris brassicae*. Bekæmpelsesmiddelforskning fra Miljøstyrelsen, Report nr. 43. Danish Environmental Protection Agency.
- Hansen, B.M., Damgaard, P.H., Eilenberg, J., Pedersen, J.C. (1996): *Bacillus thuringiensis* - Ecology and environmental effects of its use for microbial pest control. Report, pp. 126. Danish Environmental Protection Agency.
- Hansen, B.M., Damgaard, P.H., Eilenberg, J., Pedersen, J.C. (1998): Molecular and classical characterisation of *Bacillus thuringiensis* isolated from leaves and insects. *Journal of Invertebrate Pathology*, 71: 106-114.
- Pedersen, J.C., Damgaard, P.H., Eilenberg, E., Hansen, B.M. (1995): Dispersal of *Bacillus thuringiensis* var. *kurstaki* in an experimental cabbage field. *Canadian Journal of Microbiology*, 41: 118-125.
- Strandgaard, S, Tarp, P., Damgaard, P.H. (1995): Project evaluation mission to Lithuania on forest pest management and control. Report, pp. 17. Danish Environmental Protection Agency.
- Strandgaard, S, Tarp, P., Damgaard, P.H. (1995): Project evaluation mission to Belarus on forest pest management and control. Report, pp. 19. Danish Environmental Protection Agency.
- Thomsen, L., Damgaard, P.H., Eilenberg, J. (1995): Screening of selected *Bacillus thuringiensis* strains against *Agrotis segetum* larvae. IOBC/WPRS Bulletin.

**Abstracts from symposia and conferences:**

- Damgaard, P.H., Eilenberg, J., Hansen, B.M., Pedersen, J.C. (1994): Naturally occurring *Bacillus thuringiensis* strains on foliage. First Nordic Workshop on *Bacillus thuringiensis*/-*Bacillus cereus*, Oslo, Norway.
- Damgaard, P.H., Glowcka, B., Eilenberg, J. (1995): Interactions between a natural and a sprayed population of *Bacillus thuringiensis* on pine needles. 28th Annual Meeting of Society for Invertebrate Pathology, Ithaca, USA.
- Damgaard, P.H., Hansen, B.M., Pedersen, J.C., Eilenberg, J. (1994): Naturally occurring *Bacillus thuringiensis* strains on foliage, in soil and in insects. II'nd International Conference on *Bacillus thuringiensis* & 27th Annual Meeting of Society for Invertebrate Pathology, Montpellier, France.
- Damgaard, P.H., Harding, S., Eilenberg, J. (1996): Natural occurrence of *Bacillus thuringiensis* on pine needles and its interaction with sprayed *B. thuringiensis* product. 29th Annual Meeting of Society for Invertebrate Pathology and 3rd International Colloquium on *Bacillus thuringiensis*, Cordoba, Spain.
- Damgaard, P.H., Jacobsen, C.S., Sørensen, J. (1994): Molecular detection of *Bacillus cereus* and *B. thuringiensis* by a unique DNA stretch. New Approaches in Microbial Ecology, Helsingør, Denmark.

- Damgaard, P.H., Malinowski, H., Glowacka, B., Eilenberg, J. (1995): Degradation of *Bacillus thuringiensis* serovar kurstaki after aerial application to a Polish pine stand. 5th European Meeting on Microbial Control of Pests, Poznan, Poland.
- Damgaard, P.H., Skovmand, O., Eilenberg, J. (1992): Protection of the  $\delta$ -endotoxin of *Bacillus thuringiensis* var kurstaki HD-1 against sunlight inactivation. 25th Annual Meeting of Society for Invertebrate Pathology, Heidelberg, Germany.
- Damgaard, P.H., Smits, P.H., Eilenberg, J., Pedersen, J.C. (1992): Study on the natural occurrence and population dynamics of *Bacillus thuringiensis*. 25th Annual Meeting of Society for Invertebrate Pathology, Heidelberg, Germany.
- Damgaard, P.H., Smits, P.H., Hansen, B.M., Pedersen, J.C., Eilenberg, J. (1993): Natural occurrence of *Bacillus thuringiensis* on cauliflower and grass foliage. 4th Meeting of the I.O.B.C. group on Insect Pathogens and Entomoparasitic Nematodes, Zürich, Switzerland.
- Eilenberg, J., Damgaard, P.H., Bresciani, J., Larson, R. (1992): Infection of adult cabbage root flies by a combination of fungal, protozoan and bacterial pathogens. 4th British Invertebrate Mycopathologist Meeting, Bath, England.
- Hansen, B.M., Damgaard, P.H., Eilenberg, J., Pedersen, J.C. (1994): Detection and classification of *Bacillus thuringiensis* by non-radioactive colony hybridization, southern hybridization and PCR. New Approaches in Microbial Ecology, Helsingør, Denmark.
- Hansen, B.M., Damgaard, P.H., Eilenberg, J., Pedersen, J.C. (1994): Molecular characterisation of *Bacillus thuringiensis* isolated from the Danish environment. 2nd International Conference on *Bacillus thuringiensis* & 27th Annual Meeting of Society for Invertebrate Pathology, Montpellier, France.
- Thomsen, L., Damgaard, P.H., Eilenberg, J. (1997): Screening of selected *Bacillus thuringiensis* strains against *Agrotis segetum* larvae. 6th European Meeting on Microbial Control of Pests, Copenhagen, Denmark.