Lebenslauf

Dr. Sven Deutschmann

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BERUFLICHE ERFAHRUNG

01/2018 - heute	Head of Global Analytical Sciences and Technology "Adventitious Agents Testing & Alternative Microbiological Methods" - Roche Global QC Global Accountability for all Adventitious Agents detection assays and all Alternative (Rapid) Microbiological Methods within Roche Global QC
07/2015 - 12/2017	Head of Biological Quality Control - Roche Diagnostics GmbH Responsibilities: Head of Biological Quality Control with responsibility for the biological quality control in the biotechnological production of the Pharma Division of Roche (Pharma Biotechnologie Produktion & Entwicklung / Pharmaceutical Biotech Production & Development) • micro- and cell biological In-Process-Control-testing (IPC-testing) of fermentation and downstream-processing samples • micro- and cell biological release testing of raw materials for the biotechnological production of active pharmaceutical ingredients (APIs) and test-kits of the Diagnostic Division • environmental monitoring • monitoring of cleaning processes and cleaning validation Experience: • experience in microbiology: microbiological analysis in pharmaceutical production (product-related testing and testing for environmental monitoring) • experience in cell biology: bioassays (such as testing for cytotoxicity, testing for growth promoting properties, potency assays, testing for non-cultivable mycoplasmas, …), fermentation of cell cultures (insect cell lines, hybridoma cell lines, rodent cell lines, …) • experience in molecular biology: PCR, sequencing • experience in biochemistry: biochemical testing of environmental monitoring samples
04/2014 - 12/2017	Head of Global Method Management and Technology "PCR/NAT & RMM" - Roche / Genentech Biologics Operational Unit Global Accountability for all Nucleic Acid Technology-based assays and all Rapid Microbiological Methods within Global Commercial Manufacturing of the Biologics Operational Unit.
08/2005 - 07/2015	Director Quality Control - Roche Diagnostics GmbH Responsibilities: Director Quality Control with responsibility for the micro- and cell biological quality control in the biotechnological production of the Pharma Division of Roche (Pharma Biotechnologie Produktion & Entwicklung / Pharmaceutical Biotech Production & Development) • micro- and cell biological In-Process-Control-testing (IPC-testing) of fermentation and downstream-processing samples • micro- and cell biological release testing of

	- raw materials for the biotechnological production of active pharmaceutical ingredients (APIs) - test-kits of the Diagnostic Division Experience: • experience in microbiology - microbiological analysis in pharmaceutical production (product-related testing and testing for environmental monitoring) • experience in cell biology - bioassays (such as testing for cytotoxicity, testing for growth promoting properties, potency assays, testing for non-cultivable mycoplasmas, …) - fermentation of cell cultures (insect cell lines, hybridoma cell lines, rodent cell lines, …) • experience in molecular biology - PCR, sequencing • experience in biochemistry - biochemical testing of environmental monitoring samples
01/2012 - 03/2014	Head of Global Method Management and Technology "PCR / NAT" - Roche / Genentech Biologics Operational Unit Global responsibility for all Nucleic Acid Technology-based assays within global Commercial Manufacturing of the Biologics OU.
09/2001 - 07/2005	Director Quality Control - Roche Diagnostics GmbH Responsibilities: Director Quality Control with responsibility for the micro- and cell biological quality control in the biotechnological production of the Pharma division of Roche • micro- and cell biological IPC-testing of fermentation and downstream-processing samples • micro- and cell biological release testing of - raw materials for the biotechnological production of APIs - test-kits of the diagnostic division • environmental monitoring • monitoring of cleaning processes and cleaning validation
01/1996 - 08/2001	Manager Quality Control - Roche Diagnostics GmbH Responsibilities: Manager Quality Control with responsibility for the micro- and cell biological quality control in the biotechnological production of the Pharma division of Roche • micro- and cell biological IPC-testing of fermentation and downstream-processing samples • micro- and cell biological release testing of - raw materials for the biotechnological production of APIs - test-kits of the diagnostic division • environmental monitoring
1995	Gesellschaft für Biotechnologische Forschung mbH - Gesellschaft für Biotechnologische Forschung mbH Grant of the German Federal Ministry of Research and Technology (program: “Förderung der Talentsicherung für die Innovation”): Delegation for the calendar year 1995 as provisional Manager for the micro- and cell biological quality control in the biotechnological production of the Pharma Division of Boehringer Mannheim GmbH, site Penzberg (since 1999 the company name Boehringer Mannheim GmbH has been changed and officially registered as Roche Diagnostics GmbH).

AUSBILDUNG

1994	Dr. rer. nat. - Technische Universität Braunschweig Biologie, Promotion
1991	Diplom - Technische Universität Braunschweig Biologie

LEHR- UND VORTRAGSTÄTIGKEIT

10/2012 - heute	MCI Management Center Innsbruck Biopharmazeutische Entwicklung und Produktion: Biologische Qualitätskontrolle
1997 - 07/2013	German Chamber of Commerce and Industry, CCI (Industrie- und Handelskammer, IHK) teaching unit “Microbiology” as part of a professional education with the intended career “Biotechnologist”

SONSTIGES

11/2019 - heute	Chair of the Expert Group 1 "Biological Methods and Statistical Analysis” of the European Pharmacopoeia Commission (responsible for all Biological Tests – see Ph. Eur.-Chapters 2.6.x – and all General Texts on Microbiology – see Ph. Eur.-Chapters 5.1.X)
2016 - heute	Lecturer in training courses / seminars in the context of pharmaceutical microbiology: Three lectures – „Prüfung auf Bakterien-Endotoxine (LAL-Test)“ (“Bacterial Endotoxins Test (LAL-Assay)”), „OOS bei der Endotoxinbestimmung“ (“OOS-Results in Bacterial Endotoxins testing”) and „Moderne mikrobiologische Methoden und das papierlose Labor“ (“Modern microbiological methods and paperless lab”) – as part of the training course „Der Mikrobiologie Compliance Manager“ (Compliance Manager „Microbiology”) of Concept Heidelberg (2016, 2018 and 2019, each)
2016 - heute	Lecturer in training courses / seminars in the context of pharmaceutical microbiology: Four lectures – “Sterility Test”, “Rapid Microbiological Methods”, "Investigation of Out-of-Specification-Results" and "Paperless Laboratory" – and a workshop on “Rapid Microbiological Methods” as part of the training course „Modern Microbiological Laboratory Practice” of the European Compliance Academy (2016)
11/2015 - heute	Member of the Parenteral Drug Association (PDA) “Post Approval Change Implementation for Biologics and Pharmaceutical Drugs”
2013 - heute	Member of the Expert Group 1 "Biological Methods and Statistical Analysis” of the European Pharmacopoeia Commission (responsible for all Biological Tests – see Ph. Eur.-Chapters 2.6.x – and all General Texts on Microbiology – see Ph. Eur.-Chapters 5.1.X)
2011 - heute	Chairman of the Working Party “Mycoplasmas” of the European Pharmacopoeia Commission (Ph. Eur.-Chapter 2.6.7 “Mycoplasmas”)
2011 - heute	Member of the Parenteral Drug Association (PDA) “Bioburden and Biofilm Management Task Force”
2011 - heute	Member of the Working Party “Modern Microbiological Methods” of the European Pharmacopoeia Commission (Ph. Eur.-Chapter 5.1.6 “Alternative methods for Control of Microbiological Quality”)
2011 - heute	Member of the Working Party “Mycoplasmas” of the European Pharmacopoeia Commission (Ph. Eur.-Chapter 2.6.7 “Mycoplasmas”)
2011 - heute	Member of the Parenteral Drug Association (PDA) “Bioburden and Biofilm Task Force”

2010 - heute	Lecturer in training courses / seminars in the context of pharmaceutical microbiology: Three lectures – “Sterility Test”, “Rapid Microbiological Methods” and "Investigation of Out-of-Specification-Results" – and a workshop on “Rapid Microbiological Methods” as part of the training course „Microbiological Best Laboratory Practice” of the European Compliance Academy (2011, 2012, 2013, 2014 and 2015, each)
2010 - heute	Member of the German Pharmacopoeia Commission (Deutsche Arzneibuch-Kommission)
2009 - heute	Member of the Central Commission for Biological Safety (CCBS) Note: The CCBS is a brains trust of the Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) for the scientific evaluation of molecular, health, and ecological data during the notification process according to the Genetic Engineering Act (Gentechnikgesetz). In all notification procedures, the BVL asks for an opinion of the Central Commission for Biological Safety (CCBS), which hosts experts in the field of bacteriology, virology, plant breeding, medicine and ecology, as well as industrial and environmental safety
2008 - heute	Member of the Working Party “Bacterial Endotoxins Test” of the European Pharmacopoeia Commission (Ph. Eur.-Chapter 2.6.14 “Bacterial Endotoxins” and 5.1.10 “Guidelines for using the Test for Bacterial Endotoxins”)
2008 - heute	Chairman of the “Pharmaceutical Microbiology"Working Group” (Working Group of European Pharmaceutical Microbiologists) of the European Compliance Academy Foundation
2007 - heute	Member of the Microbiology Expert Group (Ausschuss Mikrobiologie) of the German Pharmacopoeia Commission (Deutsche Arzneibuch-Kommission)
2007 - heute	Member of the Parenteral Drug Association (PDA) “Mycoplasma Task Force”
2006 - heute	Lecturer in training courses / seminars in the context of pharmaceutical microbiology: Three lectures – „Nährmedienherstellung, kontrolle und lagerung“ (“Manufacturing of Microbiological Growth Media, Media Quality Control and Media Storage”), „OOS und Change Control Prozedere“ (“OOS and Change Control Procedure”) and „Probenahme, -transport und -lagerung“ (“Sampling, Sample Transport and Storage”) – as part of the training course „Qualitätssicherung im mikrobiologischen Labor“ (“QA in the Microbiological Laboratory”) of Concept Heidelberg (2006, 2007, 2008, 2009, 2010 and 2011, each)
2006 - heute	Member of the Working Party “Monocyte Activation Test” of the European Pharmacopoeia Commission (Ph. Eur.-Chapter 3.6.30 “Monocyte Activation Test”)
2006 - heute	Member of the Working Party “Alternative Pyrogentests” (“Alternative Pyrogene Testing”) of the German Pharmacopoeia Commission (Deutsche Arzneibuch-Kommission)
1980 - heute	Skiing Instructor of the German Skiing Instructor Association (Deutscher Skilehrerverband - DSLV)
02/2002 - 12/2015	Responsible project leader acc. German Genetic Engineering Act (Gentechnikgesetz, GenTG) for a building of Pharmaceutical Biotech Production and Development of Roche Diagostics GmbH, site Penzberg (since February 2002)
08/1997 - 12/2014	Responsible person acc. german IfSG (Infektionsschutzgesetz; formerly known as Federal Law on Epidemic Control) and TierSeuchErrVO (Tierseuchenerregerverordnung) for buildings of Pharmaceutical Biotech Production and Development of Roche Diagostics GmbH, site Penzberg (since August 1997).

2011	Lecturer in the training course in acc. to the Genetic Engineering Act (GenTSV §15 Abs.2, no.3): "Safety Technology for Genetic Facilities and Laboratories" Ausbilder im Rahmen der Fortbildungsveranstaltung nach Gentechnik-Sicherheitsverordnung (GenTSV) §15, Abs. 2, Nr. 3 zum Thema "Sicherheitsmaßnahmen für gentechnische Anlagen"
2009 - 2010	Lecturer in training courses / seminars in the context of pharmaceutical microbiology: Two lectures – "Sterility Test" and "Rapid Microbiological Methods" – and a workshop on "Rapid Microbiological Methods" as part of the training course „Microbiological Best Laboratory Practice" of the European Compliance Academy (2009 and 2010, each)
2007	Lecturer in training courses / seminars in the context of pharmaceutical microbiology: Two lectures – „Testing and Release of Cell Banks" and „Mycoplasma Detection and Removal" – as part of the training course „Microbiological Safety for Biopharmaceuticals" of the European Compliance Academy (2007)
2007	Lecturer in training courses / seminars in the context of pharmaceutical microbiology: Two lectures – „Herstellung, Kontrolle und Lagerung von Nährmedien" („Production, Quality Control and Storage of Media") and „Mikrobiologische Schnellmethoden" („Rapid Microbiological Methods") – as part of the training course „Neue Herausforderungen in der Mikrobiologie" („New Challenges in Microbiology") of the International Quality & Productivity Center (2007)
2004 - 2005	Lecturer in training courses / seminars in the context of pharmaceutical microbiology: Two lectures – „Sterility Tests: Test Validation" and „Detection of Endotoxins / Pyrogens: Method Description & Validation of the Bacterial Endotoxins Test" – as part of the training course „Validation of Microbiological Test Procedures" of the European Compliance Academy

VERÖFFENTLICHUNGEN IN FACHZEITSCHRIFTEN (PEER REVIEWED)

Deutschmann, S. M., Kaverman, H. and Knack, Y. (2010)
Validation of a NAT-based Mycoplasma Assay according European Pharmacopoiea, Biologicals 38, 238-248

Iding, K; Büntemeyer, F; Gudermann, F; Deutschmann, S. M.; Kionka, C. and Lehmann, J. (2001)
An Automatic System for the Assessment of Complex Medium Additives under Cultivation Conditions. Biotech. Bioeng., Vol. 73, Nr. 6, 442 448

Deutschmann, S. M. and Jäger, V. (1994)
Optimization of the Growth Conditions of Sf21 Insect Cells for High Density Perfusion Culture in Stirred Tank Bioreactors. Enzyme and Microb. Technol., 16, 506 512

VERÖFFENTLICHUNGEN IN FACHZEITSCHRIFTEN (EDITORIAL REVIEWED)

Sven Deutschmann, S. M., Reich, J. (2020) "General Chapter on Recombinant Factor C Test Adopted by the European Pharmacopoeia Commission". European Pharmaceutical Review, Issue 1, 2020

Deutschmann, S. M. and Traviglia, S. (2019, in press) "One Voice of Quality PAC Categorization Using ICH Q9, Q10 & Q12 Concepts: Rapid Microbial Detection with an Automated Colony Counter", PDA Inc.

Deutschmann, S. M., Laures, A., Newby, P., and Guest, M. (2019) "The Microbiology Modernisation Cross-industry Consortium". CLEANROOM TECHNOLOGY, HPCi Media Ltd.

Missed Opportunities for Adventitious Agents Testing, PDA Letter, Vol. LII, Issue 4, April 2016, 26, ff

LEHRBÜCHER

Asarnow, D.; Brorson, K. A.; Burgenson, A. L.; Chizhikov, V.; Coleman, T. A., Deutschmann, S. M.; Haemmerle, T. E.; Marian, M. Z.; Michaels, B.; Potts, B. J.; Romero-Arroyo, C. E.; Reddy, P.; Souza, K. S.; Takle, G.; Tiraby, M. and Windsor, H. M. (2010) “Alternative Methods for Mycoplasma Testing”. Parenteral Drug Association, Inc., Bethesda, ISBN 978-0-939459-31-5

Spanien: Sierra Nevada (trekking guide), 2009 (2nd edition), Conrad Stein Verlag, Welver

Ausrüstungsführer Teil I (equipment manual, Part I), 2009 (2nd edition), Conrad Stein Verlag, Welver (Coauthor)

Deutschland: Der Rennsteig, (trekking guide), 2008 (2nd edition), Conrad Stein Verlag, Welver

Griechenland: Trans Kreta – E4, (trekking guide), 2005, Conrad Stein Verlag, Welver

Frankreich: Alpenüberschreitung GR 5, (trekking guide), 2001, Conrad Stein Verlag, Welver

Ausrüstungsführer Teil II (equipment manual, Part II), 2001, Conrad Stein Verlag, Welver (Coauthor)

KAPITEL IN FACHBÜCHERN

Anisetti, V.; Mittelmann, M.; Adley, C.; Amin, P.; Arigo, J.; Baseman, H.; Bevel, J. P.; Clontz, L.; Deutschmann, S. M.; Devine, R. A.; Fornalik, M.; Hughes, P.; Lolas, A.; Melhem, R.; Noverini, P.; Pasmore, M.; Soli, T. C.; Sturman, P.; Survana, K.; Tsang, T.; Verghese, G.; Wagner, C. M. (2015) “Bioburden and Biofilm Management in Pharmaceutical Manufacturing Operations”. Parenteral Drug Association, Inc., Bethesda, ISBN 978-0-93-945976-6

Jäger, V.; Grabenhorst, E.; Kobold, A.; Deutschmann, S. M. and Conradt, H. S. (1992) “High Density Perfusion Culture of Insect Cells for the Production of Recombinant Proteins.” Vlak, J. M.; Schlaeger, E. J. and Bernard A. R. (eds.), "Baculovirus and Recombinant Protein Production Processes", Editiones Roche, Basel, 274 - 284

BEITRAG IN KONFERENZBAND (PEER REVIEWED)

Jäger, V.; Kobold, A.; Köhne, C.; Deutschmann, S. M.; Grabenhorst, E.; Karger, C. and Conradt, H. S. (1994) “High Density Insect Cell Culture for the Production of Recombinant Proteins with the Baculovirus Expression System”. In: Spier, R. E.; Griffiths, B. and Berthold, W. (eds.), "Animal Cell Technology: Products for Today, Prospects for Tomorrow", Butterworth Heinemann, Oxford, 207 - 211

Deutschmann, S. M.; Valley, U.; Jäger, V. and Wagner, R. (1994) “Cell Cycle Analysis as a Tool for Control and Regulation of Mammalian Cell Cultures in Bioreactors”. In: Spier, R. E.; Griffiths, B. and Berthold, W. (eds.), "Animal Cell Technology: Products for Today, Prospects for Tomorrow", Butterworth Heinemann, Oxford, 354 - 356

Deutschmann, S. M. and Jäger, V. (1992) “Production and Product Integrity of Recombinant HIV 1 gag Particies (p55) with the Baculovirus Expression System”. In: Murakami, H.; Shirahata, S. and Tachibana, H. (eds.), "Animal Cell Technology: Basic & Applied Aspects", Kluwer Acad. Pub., Dordrecht, 425 - 430

Deutschmann, S. M. and Jäger, V. (1990) “High Density Suspension Culture of Insect Cells in a Stirred Bioreactor”. In: Sasaki, R. and Ikura, K. (eds.), "Animal Cell Culture and Production of Biologicals”, Kluwer Acad. Pub., Dordrecht, 151 - 158

PRÄSENTATION EINES ARTIKELS AUF EINER KONFERENZ, WORKSHOP, SEMINAR

Deutschmann, S. M. (2020) “Validation and Implementation of an Automated Colony Counter for Product Testing in Biopharmaceutical Manufacturing”. PharmaLab 2020 Virtual Conference, November 2020

Deutschmann, S. M. (2020) “A Systematic Approach to Modern Microbiological Methods". PharmaLab 2020 Virtual Conference, November 2020.

Deutschmann, S. M. (2020) “Validation and Global Implementation of an Alternative Sterility Test”. 2020 PDA Rapid Microbiological Methods Workshop, Virtual Conference, October 2020.

Deutschmann, S. M. (2020) “Validation and Implementation of an Automated Colony Counter for Product Testing in Biopharmaceutical Manufacturing”. CASSS CMC Strategy Forum Fall 2020, Virtual Conference, Oktober 2020.

Deutschmann, S. M. (2020) “Automated Technology Platform for real-time PCR-based Adventitious Agent Detection”. ISPE 2020 Biopharmaceutical Manufacturing Virtual Conference, 2020.

Deutschmann, S. M. (2020) “Experiences in Pharmaceutical Quality Control Using the rFC-Based Bacterial Endotoxins Test” ECA GMP-Webinar/Panel Discussion “rFC – Bacterial Endotoxin Testing using Recombinant Assays”.

Deutschmann, S. M. (2019) “On-Line, Real-Time Bioburden Monitoring of Water Systems”. PharmaLab 2019 Conference, Neuss, Germany.

Deutschmann, S. M. (2019) “Validation and Global Implementation of PCR-based Alternative Mycoplasma Detection Assays”. 2019 PDA Rapid Microbiological Methods Workshop, Rockville, MD, USA.

Deutschmann, S. M. (2019) “European Pharmacopoeia Chapter 5.1.6 - Alternative Methods for Control of Microbiological Quality”. 2019 PDA Rapid Microbiological Methods Workshop, Rockville, MD, USA.

Deutschmann, S. M. and Paul, M. (2019) “Rapid Sterility Testing with BacTAlert and CELSIS” BPOG-EMA/EDQM-f2f-Meeting, Rome, Italy.

Deutschmann, S. M. and Stacey Traviglia, S. (2019) “PAC Example Managed Only In The PQS: Automated Colony Counter”. PDA "Post-Approval-Change"-Workshop, Rockville, MD, USA.

Deutschmann, S. M. (2019) "Automated Colony Counter: An Alternative Method or NOT?". Joint Workshop of the Paul-Ehrlich-Institut and the European Compliance Academy on Alternative Microbiological Methods. Langen, Germany.

Deutschmann, S. M. (2019) "Alternative Microbiological Methods Implementation Roadmap - Current Status @ AstraZeneca, GlaxoSmithKline, Johnson&Johnson, MSD, Sanofi Pasteur and Roche". Joint Workshop of the Paul-Ehrlich-Institut and the European Compliance Academy on Alternative Microbiological Methods. Langen, Germany.

Deutschmann, S. M. (2018) „Microbial Control Strategy for Biopharmaceutical Manufacturing”. European GMP Conference: Bioburden – Regulatory Expectations and Practical Experience, Berlin, Germany.

Deutschmann, S. M. (2018) „Assessment of Bioburden Excursions in Non-Sterile Biologics Manufacturing Processes”. European GMP Conference: Bioburden – Regulatory Expectations and Practical Experience, Berlin, Germany.

Deutschmann, S. M. (2018) "Die QK in der Zukunft: Herausforderungen an ein globales QK-Netzwerk". EU/FDA GMP Compliance Trends 2020-Conference, Heidelberg, Germany

Deutschmann, S. M. (2018) „Key Note - Alternative Microbiological Methods: AstraZeneca's, GlaxoSmithKline's, Johnson&Johnson's and Roche's Global Implementation Roadmap". PharmaLab Congress 2018, Neuss, Germany.

Deutschmann, S. M. (2017) „Key Note: Challenges for QC Network”. PharmaLab Congress 2017, Düsseldorf/Neuss, Germany.

Deutschmann, S. M. (2017) "PCR-based Adventitious Agents Testing". International Microbiology Symposium 2017, EDQM, Strasbourg, France.

Deutschmann, S. M. (2017) "Online Bioburden Monitoring of Water Systems – Feasibility Studies". International Microbiology Symposium 2017, EDQM, Strasbourg, France.

Deutschmann, S. M. "Paperless Laboratory". 10th European Microbiology Conference (organized by the European Compliance Academy), Prague, Czech Republic.

Deutschmann, S. M. (2017) "Challenges for QC Network" (Key Note), PharmaLab 2017 (organized by the European Complinace Academy), Neuss, Germany.

„Advances in Adventitious Agents Control Strategies“. 2016 PDA Annual Meeting “Achieving Manufacturing Excellence: Current Trends and Future Technologies in Bioprocessing”, San Antonio, TX, USA.

„Detection of P. acnes in Biotech Processes“. 9th European Microbiology Conference (organized by the European Compliance Academy), Barcelona, Spain.

Deutschmann, S. M. (2015) „Handling of OOL/OOS Results in Biopharmaceutical Manufacturing“. 8th European Microbiology Conference – Microbiological OOS/OOL Pre-Conference Workshop (organized by the European Compliance Academy), Prague, Czech Republic.

Deutschmann, S. M. (2014) „Microbial Control Strategy for Biopharmaceutical Manufacturing“. 5th European Microbiology Conference (organized by the European Compliance Academy), Prague, Czech Republic.

Deutschmann, S. M. (2014) „User’s Perspective on the WHO IS in Validations“. PDA Europe Conference, Berlin, Germany.

Deutschmann, S. M. (2014) „Microbiological Quality Control of Biopharmaceuticals“. GMP Compliance for Vaccines and Biologics – The Bio Production Forum (organized by the European Compliance Academy), Dessau, Germany.

Deutschmann, S. M. (2014) „Gefährliche GVO – Modernste (Hoch?)Sicherheitstechnik schützt Mensch, Tier und Umwelt“. Symposium des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit (BVL) „Herausforderung 2015: Neue Entwicklungen in der Gentechnik – Neue Ansätze für das behördliche Handeln“, Berlin, Germany.

Deutschmann, S. M. (2014) „Ph. Eur.-Changes on Endotoxin Testing”. PharmaLab Congress – Endotoxin & Pyrogen Testing (organized by the European Compliance Academy), Düsseldorf/Neuss, Germany.

Deutschmann, S. M. (2014) "Validation of a Fully-Automated PCR-Based Mycoplasma Detection Method". European Mycoplasma Testing Conference (organized by the European Compliance Academy), Heidelberg, Germany.

Deutschmann, S. M. (2014) “Roadmap to PCR-Based Adventitious Agents Testing”. 7th European Rapid Microbiology Methods Conference (organized by the European Compliance Academy), Heidelberg, Germany.

Deutschmann, S. M. (2014) „Successful MycoTOOL Application to FDA“. PDA Europe Conference, Berlin, Germany.

Deutschmann, S. M. (2013)
Mycoplasma PCR: Interactions with Agencies A Journey to Global Acceptance – Lessons Learned
European Mycoplasma Testing Conference (organized by the European Compliance Academy), Copenhagen, Denmark.

Deutschmann, S. M. (2013) Leptospira licerasiae A Novel Bacterial Contamination in Biopharmaceutical Manufacturing. Advanced Analytics for Therapeutic Proteins: From Research to Manufacturing. Monastery Irsee, Germany.

Deutschmann, S. M. (2013) Eine neue bakterielle Kontamination in der Zellkultur-Produktion: Leptospira licerasiae. (A Novel Bacterial Contamination in Cell Culture Manufacturing: Leptospira licerasiae). Mikrobiologie-Konferenz, Mannheim, Germany

Deutschmann, S. M. (2013) Aktuelle Entwicklungen beim Mycoplasmen-Test (Recent Developments Concerning Mycoplasma-Testing). Mikrobiologie-Konferenz, Mannheim, Germany

Deutschmann, S. M. and Kavermann, H. (2012) “Mycoplasma PCR – Agencies Acceptance and Expectations”. 4th European Microbiology Conference (organized by the European Compliance Academy), Frankfurt / M., Germany.

Deutschmann, S. M. and Steinle, A. (2012) „Papierloses Labor“ („Paperless Laboratory“). Aseptikon, Cologne, Germany

Deutschmann, S. M. (2012) “Mycoplasma PCR: FDA-Approval”. 5th European Rapid Microbiology Methods Conference (organized by the European Compliance Academy), Munich, Germany.

Deutschmann, S. M. (2012) “A Novel Bacterial Contamination in Biopharmaceutical Manufacturing: Leptospira licerasiae”. 5th European Rapid Microbiology Methods Conference (organized by the European Compliance Academy), Munich, Germany.

Deutschmann, S. M. (2011) “Qualification and Validation of an Automated Rapid Growth Based System for In-Process-Control and Water Testing”. 2011 PDA Annual Meeting, San Antonio, TX, USA.

Deutschmann, S. M. (2011) “WHO International Standard for Mycoplasma NAT”. European Mycoplasma Testing Conference (organized by the European Compliance Academy), Prague, Czech Republic.

Deutschmann, S. M. (2011) “NAT-based Mycoplasma Detection: Additional Approaches”. European Mycoplasma Testing Conference (organized by the European Compliance Academy), Prague, Czech Republic.

Deutschmann, S. M. (2011) “May Rapid Microbiological Methods Speed Up Process Development and Process Validation ?”. Vaccines and Biologics Conference (organized by the European Compliance Academy), Dessau, Germany.

Deutschmann, S. M. (2010) “The MycoTOOL Touchdown PCR Assay - The First Commercial NAT-Based Detection System Approved by Regulatory Authorities for Mycoplasma Biosafety Testing of Biological Products”. 2nd International Mycosafe Symposium, Vienna, Austria.

Deutschmann, S. M. (2010) “LIMS – Paperless Laboratory Solutions”. 3rd European Microbiology Conference (organized by the European Compliance Academy), Barcelona, Spain

Deutschmann, S. M. (2010) “ECA’s Survey to Ph. Eur Chapter 5.1.6”. 3rd European Rapid Microbiology Methods Conference (organized by the European Compliance Academy), Budapest, Hungary.

Deutschmann, S. M. (2010) “Evaluation of RMMs”. 3rd European Rapid Microbiology Methods Conference (organized by the European Compliance Academy), Budapest, Hungary.

Deutschmann, S. M. (2009) “EP-chapter 2.6.30 ‘Monocyte Activation Test'". Endotoxin and Pyrogen Testing Conference (organized by the European Compliance Academy), Berlin, Germany.

Deutschmann, S. M. (2009) “Adventitious Agents”. Pharma Mikrobiologie Konferenz, Berlin, Germany

Deutschmann, S. M. (2009) “Implementation of a Rapid, Non-Destructive Enumeration System”. 2nd European Rapid Microbiology Methods Conference (organized by the European Compliance Academy), Vienna, Austria.

Deutschmann, S. M. (2008) “Validation of a Mycoplasma PCR Assay acc. E. P. Chapter 2.6.7”. 2008 PDA Annual Meeting, Colorado Springs, Colorado, USA.

Deutschmann, S. M. (2008) “Cleaning Validation”. 1st European Microbiology Conference (organized by the European Compliance Academy), Berlin, Germany.

Deutschmann, S. M. (2008) “Validation of a Mycoplasma PCR Assay acc. E. P. Chapter 2.6.7”. FDA Workshop on Mycoplasma Testing, Gaithersburg, MD, USA.

Deutschmann, S. M. (2008) “Monocyte Activation Test”. PDA’s 3rd Annual Global Conference on Pharmaceutical Microbiology, Chicago, Illinois, USA.

Deutschmann, S. M. (2008) “Validation of a Mycoplasma PCR Assay acc. E. P. Chapter 2.6.7”. European Mycoplasma Testing Conference (organized by the European Compliance Academy), Berlin, Germany.

Deutschmann, S. M. (2009) “Validation of a Mycoplasma PCR Assay acc. E. P. Chapter 2.6.7”. PDA’s 3rd Workshop on Mycoplasmas, Berlin, Germany.

Deutschmann, S. M. (2007) “Nucleic Acid Copies : CFU-Ratio”. FDA / PDA “Mycoplasma Task Force”-Meeting, Bethesda, Maryland, USA.

Deutschmann, S. M. (2007) “Mycoplasma Testing acc. E. P. Chapter 2.6.7”. FDA / PDA “Mycoplasma Task Force”-Meeting, Las Vegas, Nevada, USA.

SONSTIGE PUBLIKATIONEN

Deutschmann, S. M., Mousumi Paul (Merck & Co., Inc.) and Ren-Yo Forng (Amgen) - Reviewers: Shebeer Shereefa (Abbvie), Lisa Yan (Amgen), Aditya Prasad (AstraZeneca), Bill Carpenter (Biogen), Chris Knutsen (Bristol Myers Squibb), Simon Urwyler (CSL Behring), Lisa A. Wysocki (GSK), James Hauschild (J&J), Ellen Brunbeck (Novo Nordisk), Ulrik Lytken-Schack (Novo Nordisk), Caroline Dreyer (Novo Nordisk), Thais Wilgren (Novo Nordisk), Marja Claasssen (MSD), Pieta Ijzerman-Boon (MSD), Jessica Long (MSD), Philip Villari (MSD), Lucile Plourde (Sanofi), Mark Kapeckas (Sanofi) and Dawood Dassu (BioPhorum Operations Group) (2020). „A framework for the evaluation, validation and implementation of alternative and rapid microbiological testing methods“. BPOG-homepage: https://www.biophorum.com/download/alternative-and-rapid-micro-methods-armm-a-framework-for-the-evaluation-validation-and-implementation-of-alternative-and-rapid-microbiological-testing-methods/

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