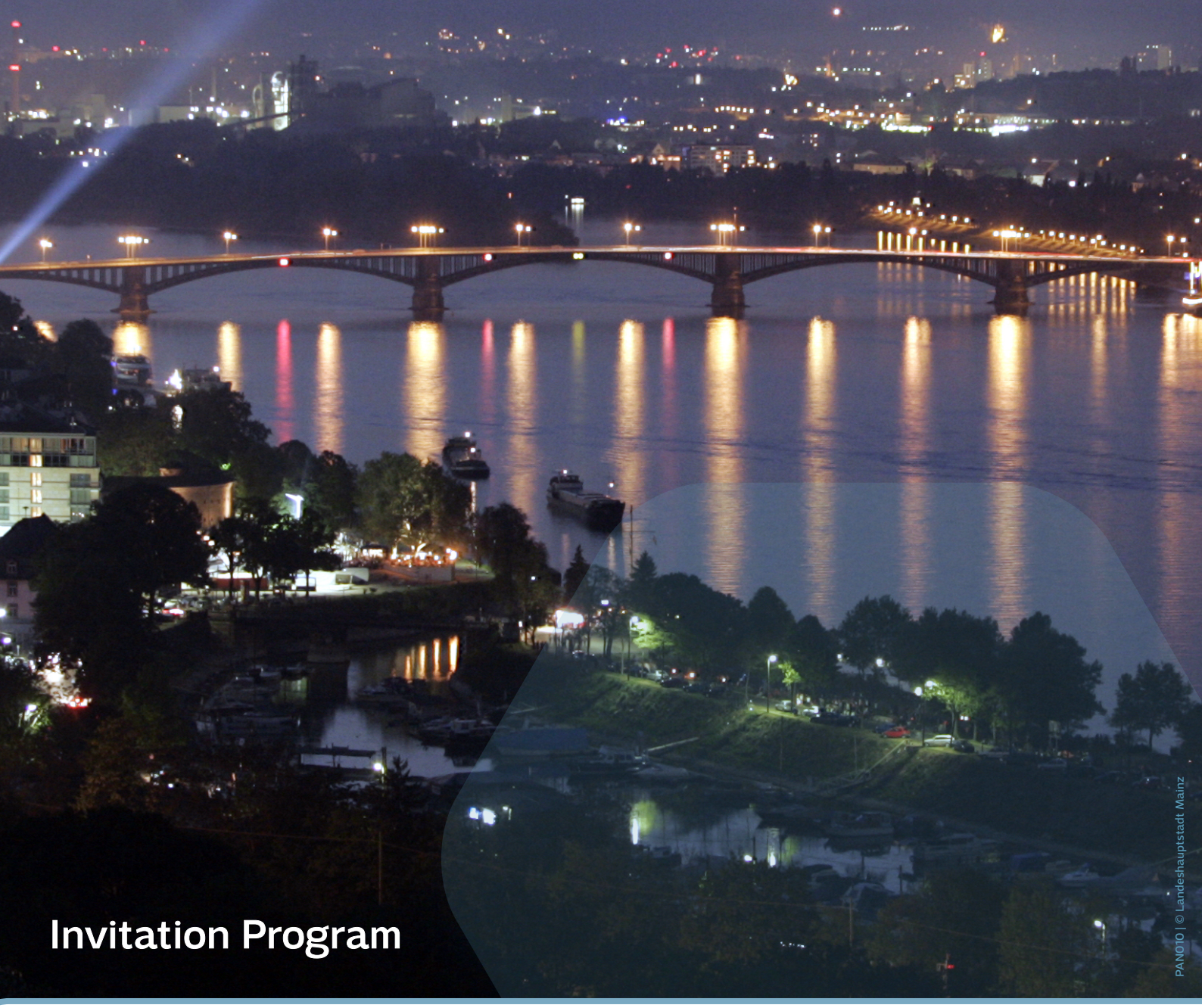
European QA Conference

19th–21st April 2023
Mainz, Germany

Quality - towards the next generation



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Invitation Program

European QA Conference

GQMA GERMAN QUALITY MANAGEMENT ASSOCIATION E.V.

SEGCIB

SOFAQ FRENCH QUALITY ASSURANCE SOCIETY

Invitation Program 19th April 2023

	Stream 1 | Kongress Saal
8:30 – 8:45	**Opening address – GQMA** President Björn Niggemann
8:45 – 9:30	**Keynote Address** Story telling Dani Nieth, Zurich, Switzerland
9:30 – 10:15	**Keynote Address** Impact of the war in Ukraine on patients and environment for clinical trials Dr. Iana Maltseva, GCP Inspection Department, State Expert Center of the Ministry of Health of Ukraine (SEC)
10:15 – 10:45	Networking Coffee Break

	Stream 1 | Kongress Saal	Stream 2 | Gutenberg A	Stream 3 | Gutenberg B	Stream 4 | Gutenberg C
	Session IT I Chair: Dr. Thomas Menne	**Session GCP I** Chair: Dr. Ingo Rath	**Session GLP I** Chair: Frauke Hermann	**Session Animal Health I** Chair: Marci Murphy
10:45 – 11:30	How to establish a corporate GxP compliant esign tool? Alexander Kunz, Merck Healthcare KGaA, Germany	QMS beyond QA compliance – QA oversight & governance in the GCP environment Dr. Harald Ottinger, Novartis Pharma AG Switzerland	Challenges of Medical Devices Testing in Rodents and Farm Animals in a University GLP Setup Dr. med. vet. Flurina Clement Frey, Musculoskeletal Research Unit (MSRU) Zurich, Switzerland	QA in VICH GCP clinical field studies in accordance with Regulation 2019/6 Dr. Claudia Schneider, KLIFOVET GmbH, Germany
11:30 – 12:15	Survival of the Fittest – A Darwinistic Take on the Evolution of Quality Fabrizio Maniglio, Sparta Systems, Switzerland	The signature chaos in (electronic) Trial Master Files Dr. Marc Brooks, Elderbrook consulting GmbH, Switzerland	Realise the Power of Data Visualization for Auditing Richard Crossland, Labcorp Drug Development, UK	Getting "dirty" with Animal Health GLP audits Núria Elisenda Puigoriol, Zoetis Spain S.L., Spain
12:15 – 13:30	Networking Lunch Break			

Invitation Program 19th April 2023

	Stream 1 | Kongress Saal	Stream 2 | Gutenberg A	Stream 3 | Gutenberg B	Stream 4 | Gutenberg C
	Session IT / Cloud Chair: Dr. Ronald Schmidt	**Session GMP I** Chair: Dr. Thomas Menne	**Session PV I** Chair: Dr. Grit Lynch	**Session GxP / Quality I** Chair: Dr. med. Markus Hahn
13:30 – 14:15	Cloud and GLP/GxP-Compliance – Curse or blessing? Dr. Cornelia Hunke, DiQualis, Germany	Phase-Appropriate-Quality System: How to keep flexibility in R&D manufacturing whilst ensuring supply of safe clinical material? Anke Liewald, SANOFI, Germany	PV Inspections Dr. Nicole Seibel, MAIN5, Germany	Next generation: how to make Quality work in a remote and distributed setting Dr. Marina Kemmerer, Otsuka, Germany
14:15 – 15:00	A GLP Archive in the Cloud – BASF's Experience to reach Compliance Dr. Frank Schieweck, BASF, Germany	GMP Biobanking in 21 Century Dr. Vincent v. Walcke-Wulffen, BioKryo GmbH, Germany	Learnings & Challenges of Remote Pharmacovigilance (PV) Inspections Maria Calvo, Ferrer Internacional, S.A., Spain	Training Approaches for the Workforce 4.0 – Breaking Down Barriers between Procedures and GxP Training Iain Searle, Veeva UK
15:00 – 15:30	Networking Coffee Break			
	Session IT / Validation I Chair: Robert Geiger	**Session GCP II** Chair: Dr. Ingo Rath	**Session Archive** Chair: Dr. Laurent Bouillot	**Session Animal Health II** Chair: Nùria E. Puigoriol
15:30 – 16:15	An introduction to the new ISPE GAMP ® 5 2nd Edition and Computer System Assurance Frank Henrichmann & Oliver Herrmann, Q-Finity, Germany	Challenges and Future Visions - Novel Trial Designs in Early Drug Development Dr. Angela Bischoff, Arensia Exploratory Medicine GmbH, Germany	When paper fish eat GxP archives – case study for updating IPM (pest control and archive compliance) Dr. Benjamin Bader, Z.A.S. Zentral Archiv Service GmbH / Rhenus, Germany	Recent experiences with veterinary clinical supplies' import into EU Dr. Klaus Hellmann, KLIFOVET GmbH, Germany
16:15 – 17:00	Validation and modern IT – challenge or chance? Dr. Dmitrij Lisak, Thescon GmbH, Germany	Requirements for ‚clinical trial assays' (MDCG 2022-10) Dr. Karl Kleine, Simply Quality, Germany	Archiving: present and upcoming challenges Anne Florence Hachet, Palm'Data, France	Veterinary GCP Sponsor Site Inspection in France – sharing experiences and lessons learned Dr. Katharina Töpfer, Boehringer Ingelheim Vetmedica GmbH, Germany

Immediately afterwards, all delegates are invited to our one-hour welcome reception in the exhibition area.

Invitation Program 20th April 2023

	Stream 1 | Kongress Saal	Stream 2 | Gutenberg A	Stream 3 | Gutenberg B	Stream 4 | Gutenberg C
	Session GLP / OECD Chair: Catherine Liang	**Session GCP III** Chair: Dr. Karin Köhler-Hansner	**Session GMP II** Chair: Laurent Bouillot	**Session GDP** Chair: Dirk Johann Meyer
9:00 – 9:45	Why and how to apply OECD GLP for a monitoring authority? Thomas Lucotte, Agence nationale de sécurité du médicament et des produits de santé, France	Culture of Quality – by Design and in Practice Sameera Ibrahim, Bristol Myers Squibb, UK	HPAPI (Highly Potent Active Pharmaceutical Ingredients) Handling from Lab Bench to Pilot Plant within Chemical Development (case studies) Dr. Thomas Adam, Bayer, Germany	GDP towards the next generation: 10 years on – Global Regulatory Updates and post-Covid trends in GDP - Michael Fleischer, Roche Pharma AG, Germany
9:45 – 10:30	Draft OECD Advisory Document No.17. Supplement No. 1: GLP and Cloud Computing Martijn Baeten, Sciensano, Belgium	General considerations for clinical studies (ICH E8) – The Renovation of Good Clinical Practice – A Framework to Support Implementation (guidance on the QbD principle and "fit for purpose" approach) Dr. Marion Pillwein on behalf of TransCelerate, Bristol Myers Squibb, Switzerland	The Qualified Person (QP) – How to meet current and upcoming needs for IMPs? Dr. Bettina Pahlen, Quality x Pharma Consulting GmbH, Germany	Temperature Mapping and Storage Qualification Marisa Remsing, ELPRO Messtechnik GmbH, Germany
10:30 – 11:00	Networking Coffee Break			
	Session GLP / IT Chair: Andreas Henrichs	**Session GCP IV** Chair: Alain Piton	**Session Medical Devices I** Chair: Ingrid Ramon	**Session GxP / Quality II** Chair: Dr. Grit Lynch
11:00 – 11:45	Advisory Document Nr 22 of the Working Party on Good Laboratory Practice on Data Integrity What's new, what's old and what's required some questions and some answers? Marek Ubraniak, Bureau for Chemical Substances, Poland	Advanced Therapy Medicinal Products (ATMPs): A Long Patient Journey Dr. Laura Castagnaro, IRCCS Ospedale San Raffele / SR-Tiget, Italy	MDR – new requirements in the field of clinical research Dr. med. Markus Hahn, ARTIMED Medical Consulting GmbH, Germany	Quality Culture – three steps to success Dr. Jörg Neumann, Jörg Neumann Beratung, Germany
11:45 – 12:30	Introduction of an ERP system in a consulting company „on the fly" – practical lessons for GxP compliance Alexander Billasch & Dr. Timo Kretzschmar, Innosolve Consulting Service & Engineering GesmbH, Austria	Just Like Home Project Margherita Levi, Fondazione Telethon, Italy	Digital Health Applications (DIGA) Dr. med. Kai Markus, VYSYO GmbH, Germany	Training to build a quality culture Magnus Jahnsson, Key2Compliance AB, Sweden
12:30 – 14:00	Networking Lunch Break			

Invitation Program 20th April 2023

	Stream 1 | Kongress Saal	Stream 2 | Gutenberg A	Stream 3 | Gutenberg B	Stream 4 | Gutenberg C
	Session GLP II Chair: Anne-Florence Hachet	**Session GCP V** Chair: Dr. Karin Köhler-Hansner	**Session Medical Devices II** Chair: Dr. med. Markus Hahn	**Session Animal Health III** Chair: Marci Murphy
14:00 – 14:45	**Lessons Learned from Inspections on External Archiving of GLP Data – An Inspector's Perspective** Dr. Tobias Jacobi, Ministerium für Klimaschutz, Umwelt, Energie und Mobilität, Germany	**The revision of ICH-E6 on Good Clinical Practice including new approaches for QA/QC of clinical trials** Gabriele Schwarz, Federal Institute for Drugs and Medical Devices (BfArM), Germany	**Overview of IVDR including implementation and challenges in achieving compliance** Harinder Korhonen, LabQuality Oy, Finland	**Animal Health Veterinary Products Quality Q&A** Marci Murphy, MSD Animal Health R&D, Germany Dr. Klaus Hellmann, KLIFOVET GmbH, Germany Dr. Claudia Schneider, KLIFOVET GmbH, Germany Dr. Katharina Töpfer, Boehringer Ingelheim Vetmedica GmbH, Germany Núria Elisanda Puirigiol, Zoetis Spain S.L., Spain
14:45 – 15:30	**Keeping GLP compliance in (electronic) archiving and archive transfers** Dr. Benjamin Bader, Z.A.S. Zentral Archiv Service GmbH / Rhenus, Germany	**Up-to-date standards for the use of computerised systems, electronic data acquisition tools and data processing in clinical trials** Lisbeth Bregnhøj, The Danish Medicines Agency, Denmark	**IVDR-LDTs – What is needed for compliance to IVDR?** Dr. Karl Kleine, Simply Quality, Germany	
15:30 – 16:00	Networking Coffee Break			
	Session Roundtable GLP Chair: Catherine Liang / Dr. Ronald Schmidt	**Session Roundtable GCP** Chair: Dr. Karin Köhler-Hansner / Dr. Jörg Holzinger		
16:00 – 16:45	Dr. Tobias Jacobi, Ministerium für Klimaschutz, Umwelt, Energie und Mobilität, Germany Dr. Eva Rached, Swissmedic, Switzerland Dr. Christian Strüh, Bundesinstitut für Risikobewertung, Germany Thomas Lucotte, Agence nationale de sécurité du médicament et des produits de santé, France Martijn Baeten, Sciensano, Belgium Idoya Calvo Alonso, Health Department of the Government of Navarra, Spain Dr. Holger Uhde, Roche, Switzerland Marek Ubraniak, Bureau for Chemical Substances, Poland	Dr. Iana Maltseva, GCP Inspection Department, Ukraine Lisbeth Bregnhøj, The Danish Medicines Agency, Denmark Gabriele Schwarz, Federal Institute for Drugs and Medical Devices (BfArM), Germany Stephanie Croft, World Health Organisation (WHO), Switzerland		
16:45 – 17:30				

Tonight's gala dinner begins at 19:15 with pre-dinner Drinks in our exhibition area followed by dinner at 19:45 in the conference hall. After dinner, dance the night away until midnight.

Invitation Program 21th April 2023

	Stream 1 | Gutenberg A	Stream 2 | Gutenberg B	Stream 3 | Gutenberg C
	Session GxP / Quality III Chair: Dr. Thomas Menne	**Session GCP VI** Chair: Dr. Jörg Holzinger	**Session IT II** Chair: Dr. Ronald Schmidt
9:00 – 9:45	**The Future of Auditing: Are We There yet?** Tülay Kahraman & Marc Cwikowski, WORLD OF AUDITING, Belgium	**Challenges and opportunities for decentralized, direct-to-patient studies** Dr. Clare Barnett & Elisabeth Finger, ZEG Berlin	**Learning Management Systems Implementation – Opportunities, Pitfalls and Lessons Learned** Alexander Tryba & Sabine Gölden, MAIN5 GmbH & Co KGaA, Germany
9:45 – 10:30	**Auditor's view on traceability and reliability of data collected under GxP in terms of risk management, validation of computerised systems, and data integrity** Dr. Timo Kretzschmar, Innosolve Consulting Service & Engineering GesmbH, Austria	**Experiences from GCP inspections conducted by the WHO** Stephanie Croft, World Health Organisation (WHO), Switzerland	**Building the Industry Cloud for Life Sciences – Why and How** Robert Gaertner, Veeva Systems, Germany
10:30 – 11:00	Networking Coffee Break		
	Session IT / Validation II Chair: Andreas Henrichs	**Session GLP III** Chair: Claudie Dromard	**Session PV II** Chair: Maria Calvo
11:00 – 11:45	**Computer Software Assurance – FDA Draft Guidance Is this a Step forward to a new Validation Approach?** Florian Fricke, DiQualis Schweiz GmbH, Switzerland	**Use of Artificial intelligence in the context of digital pathology, a GLP stand point** Alain Piton, ALP Quality Systems, France	**Data protection in the EU – what does it mean for pharmacovigilance data** Dr. Grit Lynch, Biotest AG, Germany
11:45 – 12:30	**Do the new guidelines for computer validation have a practical value on daily work or do they miss the target?** Dr. Wolfgang Schumacher, SPC-Schumacher Pharma Consult, Switzerland	**Mutually Acceptable? Maintaining Quality Across A Multi-National Harmonised CRO** Andrew Price, Charles River Laboratories, UK	**Pharmacovigilance – does it demand computerised systems to be validated and compliance to data integrity guidelines?** Dr. Timo Kretzschmar, Innosolve Consulting Service & Engineering GesmbH, Austria
12:30 – 13:30	Networking Lunch Break		

Invitation Program 21th April 2023

	Stream 1 | Gutenberg A
	Session Chair: Björn Niggemann
13:30 – 14:15	**The Psychology of Audit and Inspection** Dipl.-Psych. Peter C. Zimmermann, Iskom-Institut, Germany
14:15 – 14:30	**Closing Remarks – GQMA** Björn Niggemann
14:30 – 14:45	Short Break
14:45 – 16:00	**GQMA Member`s Meeting** Björn Niggemann and GQMA Presidium