

European QA Conference

19th–21st April 2023

Mainz, Germany

Quality - towards the next generation

Program



Welcome

Welcome to the European QA Conference 2023 Mainz, Germany

Dear delegates and friends,

On behalf of GQMA, SOFAQ and SEGCIB, I am delighted to invite you to the European QA Conference 2023 taking place in Mainz, Germany, from Wednesday 19 April to Friday 21 April 2023.

With our slogan “Quality – towards the next generation” we would like to express our enthusiasm to move forward especially in these demanding times. The COVID-19 Pandemic showed us again the high value of personal interaction, which is fundamental for an easy exchange of knowledge as well as bringing quality to the next level. We are happy to offer an opportunity for Quality Managers networking and meeting friends without sharing a computer interface.

The scientific program will include a wide range of sessions with excellent and professional speakers. Our business partners will show their state of the art at our great exhibition area. Furthermore, the discussions during our round table sessions will help us to illuminate the context of our topics. During the Conference Reception on Wednesday 19 April and the great Dinner Evening on Thursday 20 April, you might get in touch with acquaintances and newcomers. Our conference app will guide you through the venue with the possibility to create your own schedule while receiving the latest news and being able to connect with other delegates, sponsors and speakers.

The upcoming European QA Conference will take place in Mainz, a vibrant University City, but also rich in tradition, attractive for its location in a wine region and next to the river Rhein and last but not least very close to Frankfurt Airport.

The city thus sets the ideal stage to revitalize the European QA Community and provides an inspiring atmosphere for the European QA Conference 2023.

Take your chance to be part of an open exchange across Europe with thriving transfer of expertise in a professional network. Do not miss the possibility to learn with and from others while strengthen your national and international contacts!

It is my great pleasure to welcome you onsite, trusting that you will find your participation a rewarding and enjoyable experience!

Björn Niggemann
President GQMA



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 tba

12:15 – 13:30

Networking Lunch Break



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: Marci Murphy
15:30 – 16:15	An introduction to the new ISPE GAMP @ 5 2nd Edition and Computer System Assurance Frank Henrichmann, 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.



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			



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 Elisenda Puigoriol, 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	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	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			

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.



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		



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

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General Information

Scientific Organiser



GERMAN QUALITY MANAGEMENT
ASSOCIATION E.V.

Panoramastraße 1, 10178 Berlin
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in cooperation with



Conference & Industry Organisation

EUROKONGRESS

Congress + Event + Exhibition Management

EUROKONGRESS GmbH

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Conference Venue

Rheingoldhalle Mainz
Rheinstraße 66
55116 Mainz

Conference language

The lectures will be held in English.
There will be no simultaneous translation available.



Registration

The congress registration is only possible online via our [registration page](#).

Registration Fees

Category	Early Bird Rates until 7th February 2023	Standard Rates from 8th February 2023 on
Member GQMA RQA SOFAQ SEGCIB	982,00 Euro (incl. 19% German VAT)	1.130,00 Euro (incl. 19% German VAT)
Non-Member	1.285,00 Euro (incl. 19% German VAT)	1.428,00 Euro (incl. 19% German VAT)

The Registration for the congress includes your name badge, access to the Conference App with networking possibilities, access to all scientific sessions, access to the industry exhibition, and all personal congress documents, coffee breaks and lunches, invitation to the Welcome Reception, invitation to the Gala Dinner as well as your certificate of attendance.

Our Partner DGPharMed holds its annual congress from 18th to 19th April 2023 at the Hilton Hotel Mainz. Therefore we offer a 10% discount for everyone who is member of both societies (GQMA & DGPharMed).

Conference App

The conference web app completely enhances your conference experience by providing a comprehensive overview on everything you need for a successful visit of the European QA Conference in Mainz.

Create your personal account with password protection to create your own conference schedule, receive the latest news and connect with other delegates, speakers and sponsors. Open the web app via this URL, which is loaded in the browser of your smartphone or laptop: www.euqa2023.com

Welcome Reception

The Welcome Reception will take place in the industry exhibition area on Wednesday, 19th April 2023.



Gala Dinner

The Gala Dinner will take place in the congress hall on Thursday, 20th April 2023 with Pre-Dinner Drinks at 19:15h followed by dinner at 19:45h. After dinner, dance the night away until midnight. The cost of the dinner is included in the registration fee.

Additional tickets for the Gala Dinner can be purchased for € 125 during the registration process.

COVID-19 Regulations

The conference will apply to all necessary COVID-19 regulations valid at the time of the conference.

Cancellation

Cancellations have to be submitted in writing to: euqa@eurokongress.de.

Cancellations received until 22nd February 2023 incur a cancellation fee of 113 € incl. 19% German VAT. From this date onwards, registration fee reimbursements are no longer possible unless the organiser is provided with a named replacement who will take on the registration.

Photography and Recordings

All presentations and lectures are intellectual property of the authors and thus no audio or video shall be recorded or broadcasted at any time by the delegates.

Program Changes

Any last minute changes due to functional, private or organisational reasons will be announced in the conference app. The event organiser accepts no liability for any additional costs caused by a change of program. The Program is subject to change.

Contact

If you face any questions or problems regarding the registration process, we will be happy to help you:

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