25. GQMA Jahres-tagung 2021

23.-24. Sept. 2021

Dorint
Kongresshotel
Düsseldorf-Neuss
Selikumer Str. 25
41460 Neuss

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GQMA
GERMAN QUALITY MANAGEMENT ASSOCIATION E.V.

Program Thursday 23 September 2021

	Conference Hall	Heine Hall	Cornelius Hall
9:00 – 9:15	**Opening address** **President Björn Niggemann**		
	GxP Session 1 **Chairperson: Björn Niggemann**, ELPRO-BUCHS AG, Buchs (Switzerland)		
9:15 – 9:45	**A Travel through time: 25 +1 yers from DGGF to GQMA** **Steffen König**, R&D Consulting/Training, Niederkirchen		
9:45 – 10:45	**Gawkers, Voyeurs or Sufferers?** **Peter C. Zimmermann**, Iskom-Institut, Neuss		
10:45 – 11:15	NETWORKING COFFEE BREAK		
	IT Session 1 **Chairperson:** **Dr. Ronald Schmidt**, Sanofi Aventis, Frankfurt	**GCP Session 1: QRM** **Chairperson:** **Dr. Karin Köhler-Hansner,** AH Clinical Trials Services GmbH, Niedernhausen	**GDP Session 1** **Chairperson:** **Dirk Johann Meyer,** ELPRO Messtechnik GmbH, Schorndorf
11:15 – 12:00	**EAGLES – The implementation and validation of a global cloud based GLP IT system** **Armin Sauer,** BASF, Limburgerhof	**„RBQM is the next RBM“** **Dr. Artem Andrianov,** Cyntegrity Germany Ltd., Hofheim am Taunus	**Audit and inspection preparation in GDP environment** **Björn Niggemann,** ELPRO-BUCHS AG, Buchs (Switzerland)
12:00 – 12:45	**OECD No. 17 – Application of GLP Principles to Computerised Systems – Inspection of selected examples** **Dr. Christian Schütz,** Landesamt für Umweltschutz Sachsen-Anhalt, Halle/Saale	**Quality Risk Management – Leveraging Modern Technologies for Moving from a Reactive to a Proactive Approach** **Robert Gärtner,** Veeva Systems, Frankfurt	**GDP inspection – A challenge from a practical point of view** **Werner Witten,** ACO Apotheken-Cooperation GmbH, Greven, **Dr. Ingo Schneider,** Castringius Rechtsanwälte und Notare, Bremen
12:45 – 14:00	LUNCH BREAK		
	GLP Session 1 **Chairperson:** **Frauke Hermann,** ICCR Rossdorf GmbH, Rossdorf	**GCP Session 2** **Chairperson:** **Dr. Karin Köhler-Hansner,** AH Clinical Trials Services GmbH, Niedernhausen	**GMP/GDP Session 1** **Chairperson:** **Dirk Johann Meyer,** ELPRO Messtechnik GmbH, Schorndorf
14:00 – 14:45	**OECD Advisory Document on GLP Data Integrity** **Dr. Ronald Schmidt,** Sanofi Aventis, Frankfurt	**Real-World Evidence data generation and the challenges for Quality Assurance** **Dr. Harald Ottinger,** Novartis, Basel (Switzerland)	**GDP and GMP Supervision Update in Germany** **Rico Schulze,** Sächsisches Staatsministerium für Soziales und Verbraucherschutz, Dresden
14:45 – 15:30	**Emerging Technologies in GLP** **Dr. Elisabeth Klenke,** Swissmedic, Bern (Switzerland)	**Panel Discussion GCP** **Dr. Artem Andrianov** **Robert Gärtner** **Dr. Harald Ottinger**	**The new WHO draft for a guidance on Good Storage and Distribution Practices (WHO Working document QAS/19.793, May 2019)** **Rico Schulze,** Sächsisches Staatsministerium für Soziales und Verbraucherschutz, Dresden
15:30 – 16:00	NETWORKING COFFEE BREAK		
	GLP Session 2 **Chairperson:** **Dr. Stefanie Becker,** DiQualis Deutschland GmbH, Saarbrücken/**Dr. Ulrich Schepers**	**GCP Session 3** **Chairperson:** **Dr. Ingo Rath,** CliPS-Clinical Project Services, Münster	**GMP/GDP Session 2** **Chairperson:** **Dr. Thomas Menne,** Charles River Laboratories Germany GmbH, Erkrath
16:00 – 16:45	**GLP Round Table Discussion (D/E)** **Participants:** **Dr. Cornelia Hunke** **Dr. Elisabeth Klenke** **Anja Prieß** **Dr. Christian Schütz**	**Audit Trail Review during Audits – Practical Aspects** **Aurélie Delaunay,** Merck, Lyon (France)	**Quality Metrics & Trends** **Dr. Wolfgang Schumacher,** SPC, Moehlin (Switzerland)
16:45 – 17:30	**GLP Round Table Discussion (D/E)** **Participants:** **Dr. Cornelia Hunke** **Dr. Elisabeth Klenke** **Anja Prieß** **Dr. Christian Schütz**	**SALSA, Statistical Assessment Layer for Site Audits: Support of Site Audits with Statistical Methods** **Dr. Jörg Holzinger,** GXP Engaged Auditing Services GmbH, München	**GMP/GDP Round Table** **Rico Schulze** **Dr. Wolgang Schumacher** **Dr. Ingo Schneider**

Program Friday 24 September 2021

	Conference Hall	Heine Hall	Cornelius Hall
	IT Session 2 **Chairperson:** **Dr. Ronald Schmidt,** Sanofi Aventis, Frankfurt	**GxP Session 2** **Chairperson:** **Andreas Henrichs,** Sanofi Aventis, Frankfurt	**MP Session 1** **Chairperson:** **Dr. Markus Hahn,** Artimed Medical Consulting GmbH, Kassel
9:00 – 9:45	**Practical Aspects of Data Integrity based on computerised systems in heterogeneous GxP Environments** **Dr. Timo Kretzschmar,** Biomedizinische Forschung & Bio-Produkte AG, Wien (Austria)	**Remote Audits – Are we ready for the future?** **Dr. Bianca Scholz,** SCHOLZ Pharma GmbH, Bensheim Remote	**Challenges in the Quality Assurance of Medical Devices on the Market – Experiences from Blood Glucose Monitoring System Evaluations** **Dr. Guido Freckmann,** Institut für Diabetes-Technologie, Ulm
9:45 – 10:30	**Data Integrity: Transition from paper to cloud** **Marius Witt,** DiQualis GmbH, Therwil (Switzerland)	**Sample Archiving and Biobanking under GxP Conditions** **Dr. Benjamin Bader,** Z.A.S. Zentral Archiv Service GmbH, Neubrandenburg	**MDR & MPDG: What will change in the clinical investigation of medical devices in Germany?** **Dr. Ulf Schriever,** BfArM, Bonn (Remote)
10:30 – 11:00	NETWORKING COFFEE BREAK		
	IT Session 3 **Chairperson:** **Dr. Benjamin Bader,** Z.A.S. Zentral Archiv Service GmbH, Neubrandenburg	**GLP Session 3** **Chairperson:** **Jürgen Neuss,** Bayer AG, Frankfurt	**PV/GCP Session** **Chairperson:** **Dr. Andreas Horstmann,** Strathmann AG & Co KG, Hamburg
11:00 – 11:45	**Ensuring IT Compliance while using Cloud Applications in the regulated GxP environment** **Dr. Dmitrij Lisak,** Thescon GmbH, Coesfeld	**GLP at an Academic Research Institution from the perspective of a former inspector** **Dr. Isabella Berger,** IMC University of Applied Sciences Krems, Austria	**Pharmacovigilance Intelligence Surveillance – Considerations for an End-to-End (E2E) Process to assure Regulatory Compliance on a global scale** **Dr. Heike von Treichel & Alexander Tryba,** Merck Healthcare KGaA/Main5, Darmstadt/ Frankfurt
11:45 – 12:30	**Challenges in the Validation of GxP-relevant Artificial Intelligence platforms and Systems** **Marcus Schwabedissen,** Q-FINITY, Dillingen	**Method validation for neutralizing antibody assays according to GxP requirements** **Anastasia Schesler,** Sanofi Aventis, Frankfurt	**Implementation of Quality Tolerance Limits in clinical trials** **Marcin Makowski,** GSK, München
12:30 – 13:30	LUNCH BREAK		
	GxP Session 3 **Chairperson: Björn Niggemann,** ELPRO-BUCHS AG, Buchs (Switzerland)		
13:30 – 14:15	**Auditing a big player of corporate cloud service providers** **Dr. Ronald Schmidt,** Sanofi Aventis, Frankfurt		
14:15 – 15:00	**Contracts in GxP enviroment – A masterpiece in daily work practices** **Dr. Ingo Schneider,** Castringius Rechtsanwälte und Notare, Bremen		
15:00 – 15:15	**Closing Remarks** **Björn Niggemann**		
15:15 – 15:30	SHORT BREAK		
15:30 – 16:30	**GQMA Member`s Meeting** **Björn Niggemann** and **GQMA Presidium**		